American Academy of Pediatrics
Institutional Review Board (AAP IRB)
NCT03177148
July 1, 2017

1. PROJECT TITLE

Population Effects of Motivational Interviewing on Pediatric Obesity in Primary Care (BMI2+)

2. PRINCIPAL INVESTIGATOR (PI)

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4. CO-PI(s), if applicable

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5. HUMAN SUBJECTS PROTECTION TRAINING REQUIREMENT

The AAP IRB encourages annual human subjects protection training but requires training every 3 years; this requirement must be satisfied prior to submitting the application for review.

Date and name of PI's most recent completion of human subjects training: 01/2017: Univ. Michigan PEERRS (See Attachment A)

Have all project investigators and key research staff received human subjects training within the last 3 years? ***Double click on the box to check.***

☒ Yes
☐ No

6. PROPOSED PROJECT DATES

Provide the estimated beginning and end dates of the project: July 1, 2017-May 31, 2021

7. FUNDING OR OTHER SUPPORT

Provide source(s) of funding: National Heart, Lung, and Blood Institute (NHLBI) – grant # 1R01HL128231-01A1

8. EXPEDITED REVIEW *(See last page of this form for the list of categories and their description).*

Are you requesting Expedited Review?

☒ Yes
☐ No

If Yes → Please check the categories for expedited review for which you are applying. *You may check more than one box.*

☐ **1** ☐ **2** ☐ **3** ☐ **4** ☒ **5** ☐ **6** ☒ **7** ☐ **8** ☐ **9**

Please note that our prior study – Brief Motivational Interviewing to Reduce Body Mass Index (BMI^2) (AAP IRB protocol # 07 RE 01) – was reviewed by the full IRB. We are requesting expedited review for our current study because it is an effectiveness trial, and our prior study was an efficacy trial that showed no adverse events. The current study is a minimal risk trial with monitoring by a Data Safety and Monitoring Board (DSMB).

9. LOCATION OF THE RESEARCH

List the specific site(s) at which the research will be conducted.

Location name(s), or description
18 pediatric primary care practices, all of which use Physician's Computer Company (PCC) as their Electronic Health Record vendor, throughout the United States. *We may have to recruit up to 25 practices to allow for replacement if a practice drops out before the clinician training sessions begin in fall 2017.*

10. HUMAN SUBJECTS

a. **Specify the participant population(s) to be included** (check all that apply):

☒ AAP members
☒ Children (< 18 years)
☐ Pregnant women
☒ Other, specify: Clinicians (non AAP members); office staff; parents of eligible children (Intervention arm only)

Although the primary outcome of interest is child body mass index (BMI), parents (consistent with our prior AAP IRB approved BMI^2 trial – IRB protocol # 07 RE 01) will receive the intervention. Therefore, parents – who have the lived experience of caring for the index child – are the active participants in this study. Children will never be contacted by the study team or asked to participate in any study procedures. They are included as research subjects solely for their medical record review.

b. **Provide the total number of participants (or number of participant records) for each category of human subjects** (e.g., AAP members, children, parents):

Subject Category	Total number to be studied (for each category)
Clinicians	18 - 36 (minimum of 1 and maximum of 2 clinicians per practice in each of 18 practices). *Due to attrition, we may have to consent up to 50 clinicians in up to 25 practices in order to secure the participation of 18-36.*
Office staff	At least 9 (minimum of 1 study coordinator in each of 9 Intervention Arm practices)
Parents of eligible children (Intervention arm only)	Up to 450 (~ 25 patients per clinician x up to 2 clinicians x 9 Intervention arm practices)
Children 3-8 years old	Up to 36,000* (calculated using numbers from our Electronic Health Record (EHR) vendor – Physician's Computer Company (PCC): 18 practices x ~2,000 active patients 3-8 years old who have had a well-child visit within the past 2 years) *We are unable to specify the exact number of children whose EHR and billing records will be extracted and utilized for analysis. We will learn the exact number of children a practice has after the data extraction has taken place. If the number of children is beyond our approved number of 36,000, we will submit an IRB amendment.

11. ABSTRACT

Briefly summarize the purpose and procedures of the proposed research (200 words or less).

In this cluster randomized effectiveness trial, pediatric primary care practices will be recruited from the American Academy of Pediatrics' national Pediatric Research in Office Settings (PROS) practice-based research network, as well as the client database of the Physician's Computer Company (PCC) – an Electronic Health Record (EHR) vendor. Up to 25 practices will be recruited in order to account for drop out and replacement, and achieve a final sample size of 18 practices. 9 practices will be randomized to the Intervention arm and 9 practices to Usual Care. Intervention arm practices will select 1-2 pediatric clinicians to receive in-person training in Motivational Interviewing (MI), behavioral therapy, billing and coding, and study procedures. Usual Care practices will select 1-2 pediatric clinicians to receive billing / coding and study protocol training only, via telephone and webinar; they will be offered in-person MI training at the close of the trial. Up to 450 parents of overweight or obese children (BMI $\geq$ 85th percentile for age and gender) between 3 and 8 years of age at baseline that are patients of participating Intervention arm clinicians will be enrolled. Over 24 months, these parents may receive up to 4 in-person, MI-based counseling sessions with a trained pediatric clinician and up to 6 telephone counseling sessions with an MI-trained Registered Dietician (RD). There will be no study-specific contact with parents or their children in Usual Care practices during the trial – they will continue to receive usual care. EHR and billing data for all 3-8 year old children within all participating practices (estimated to be approximately 36,000 children in total) will be extracted by PCC to permit determination of the effectiveness of the intervention versus usual care on change in BMI z-score among 3 groups: 1) all eligible children (n = up to 450 in the Intervention arm), 2) all eligible children whose parent actively participates in the trial (a subset of up to 450 eligible children in the Intervention arm), and 3) all 3-8 year old children in all participating practices (n = ~36,000).

12. LITERATURE REVIEW

Provide a brief review of the key literature, 2-3 paragraphs, with key references.

Nearly one-third (32%) of all US children are overweight or obese[1], with greater prevalence among children who are minority, lower income, or live in rural areas[1-4]. Most obese children remain so as adolescents and adults[5], facing health complications including diabetes, liver disease, asthma, heart disease, and cancer[6]. Childhood obesity is linked to lower health-related quality of life, behavior problems, depression, low self-esteem, and difficult peer relationships[7,8]. With some recent fluctuation, rates of overweight and obesity among all children remain 2-3 times higher than 30 years ago[1,9].

Expert guidelines for obesity treatment involve a four-stage approach. Stage 1 (prevention-plus) involves healthy eating and activity and can be implemented with brief counseling at routine primary care visits; Stage 2 (structured weight management) adds specific eating and activity goals and increased monitoring and can take place in primary care or specialty care settings; Stage 3 (comprehensive intervention) adds more frequent and structured visits with members of the multidisciplinary team (behavioral counselor, dietician, activity specialist) in a specialty care setting; and Stage 4 (tertiary treatment) adds options for medication, severe dietary restriction, or surgery[10].

Pediatric clinicians can play a crucial role in treating childhood obesity: as trusted professionals, they provide the majority of primary care to children in the US, routinely monitor growth, and have frequent contact with patients and their families[11-13]. Treatment efforts in pediatric primary care offer an important opportunity to address weight problems at an earlier age, and to monitor obesity-related behaviors and outcomes over time[14,15]. Recent reviews indicate that to date, there has been limited research on effective treatment interventions in primary care[16,17]. One recommended approach that builds on existing capacity of pediatric primary care and uses clinicians to deliver the intervention is Motivational Interviewing (MI) - a patient-centered clinical counseling style used by the pediatric clinician to facilitate behavioral change[18,19]. In fact, MI is a recommended approach to implement Stage 1 and Stage 2 of pediatric obesity treatment (see above)[10]. Despite this, few pediatric clinicians receive training in MI (though many have a strong interest in receiving additional training in this area), and many report feeling unprepared to use it and ineffective when they do use it to counsel their overweight or obese patients[20-22].

13. PROTOCOL

Please answer ALL the questions below using as much space as necessary to provide a clear, detailed description of your research protocol.

a. **Describe the purpose, major research questions and hypotheses of the proposed study.**

The proposed study builds upon our prior efficacy trial – *Brief Motivational Interviewing to Reduce Body Mass Index* (BMI^2): AAP IRB protocol # 07 RE 01 – which showed statistically and clinically significant reductions in BMI percentile in overweight and obese children 2-8 years old whose parents received the intervention versus usual care over 2 years. We now propose a randomized trial that compares the effectiveness of an enhanced version of the BMI^2 intervention – referred to as BMI^{2+} throughout this application – versus usual care in pediatric primary care practices across the US. Similar to BMI^2, the BMI^{2+} intervention involves training pediatric clinicians and registered dietitians (RD) in Motivational Interviewing (MI), and subsequent delivery of up to 10 MI-based counseling sessions to parents of overweight or obese youth, 3-8 years old at enrollment, over 2 years. Enhancements include:

- Provision of MI counseling by RDs centrally trained, supervised, and located in the University of Michigan Center for Health Communications Research
- Use of a study dashboard, which provides study clinicians, parents, RDs, and study team members at the University of Michigan a graphical user interface for securely accessing content
- Analyses of population level effects, in addition to effectiveness for study patients

Study Aims

1. Test the effectiveness of the BMI^{2+} intervention versus usual care on BMI z score over 2 years among children 3-8 years old who are patients of study clinicians trained in Motivational Interviewing

2. Test the effectiveness of the BMI^{2+} intervention versus usual care over 2 years among children 3-8 years old who are patients of study clinicians trained in Motivational Interviewing and whose parent actively participates in the intervention. *Active participation is defined as a parent receiving at least 1 MI counseling session from either a trained clinician or registered dietician.*

   Subaim 2a: Examine the effectiveness of the BMI^{2+} intervention versus usual care on BMI z score over 2 years according to intervention dose received.

3. Test the effectiveness of the BMI^{2+} intervention versus usual care on BMI z score over 2 years among the entire population of 3-8 year old children within participating practices.

We anticipate that at 2-year follow-up, children of parents that enroll and participate in the intervention, as well as the broader population of children of all eligible parents in Intervention arm practices, will show a net mean decrease in BMI z-score and BMI percentile compared to children in Usual Care arm practices.

b. **Describe the population, sample, and inclusion and exclusion criteria.**

	Inclusion criteria	**Exclusion criteria**
Practices	• Currently use Physician's Computer Company (PCC) as their Electronic Health Record (EHR) vendor	• Offer a comprehensive weight loss program or access to a RD at or through the practice • Unable or unwilling to send all participating study clinicians to in-person training • Unable or unwilling to identify and assign a study coordinator for the study
Clinicians (MDs, NPs, DOs, PAs)	• Have been employed by the practice for at least 1 year on or before July 1, 2017 • Work > half time (at least 6 sessions per week)	• ≥ 1 day of prior training in MI within the past 10 years • Prior participation in the AAP/PROS Healthy Lifestyles Pilot Study (HLS; AAP IRB protocol # 01SC01) or Brief Motivational Interviewing to Reduce Body Mass Index (BMI^2) Study (AAP IRB protocol # 07RE01)
Parents	• Parent or legal guardian of a child that meets the following criteria: o At least 3 but not yet 8 years of age on the date of the baseline data pull (estimated to occur in the summer or fall of 2017) o BMI for age and gender ≥ 85th percentile - documented at an office visit that occurred during the 12 months prior to the baseline data pull o Most recent well-child visit was with a participating study clinician during the 24 months prior to the baseline data pull *(does not apply to the population-level analysis that is specified in Aim 3 above)*	• Do not speak either English or Spanish • Parent or legal guardian of a child who has any of the following documented in their EHR: o Type I or Type II diabetes o Daily or chronic use of medications known to affect growth and mood / behavior (growth hormones, SSRIs, stimulants) o Use of atypical antipsychotics o A chronic, limiting, severe medical disorder, syndrome, or other condition (e.g., Downs syndrome, cerebral palsy)

c. **Describe the different procedures planned for this study. What are the procedures you will use to collect data? How will you carry them out, and how will participants be involved? What measurements will be performed?** *Please include separate information for each different procedure that you plan to use.*

We propose to conduct a trial that will compare parent receipt of the intervention versus usual care over 2 years on child health outcomes.

The two study arms are:

Usual Care	• Clinicians will complete surveys during enrollment and at the end of the intervention period • 1-2 pediatric clinicians per practice will be trained in study procedures, current obesity treatment guidelines, and obesity billing and coding via telephone and webinar • NO active enrollment of parents • Secure extraction of HIPAA limited Electronic Health Record (EHR) and billing data from practices for outcomes analyses (patient criteria and data elements appear in Attachment G.2) • At the end of the intervention period, 1-2 pediatric clinicians will be offered the in-person MI training and DVD materials
Intervention	• Clinicians will complete surveys during enrollment and at the end of the intervention period • 1-2 pediatric clinicians from each practice will receive 2.5 days of in-person MI and Behavior Therapy training (see below for description), two scored encounters with a standardized patient (with feedback using validated measures), and an interactive DVD MI booster training system focusing on pediatric obesity. • At least 1 office staff member in each practice will be designated as the study coordinator, and will be responsible for helping to facilitate study execution and communication with the research team. The study coordinator(s) will receive training in study procedures via telephone. • Active enrollment of up to 50 eligible parents per practice via clinicians or RDs • Clinicians will deliver up to 4 in-person, MI-based counseling sessions to enrolled parents over the course of 2 years. • RDs will deliver up to 6 telephone, MI-based counseling sessions to enrolled parents over the course of 2 years. • Parents will complete surveys after enrollment and at the end of the intervention period • Secure extraction of HIPAA limited Electronic Health Record (EHR) and billing data from practices for outcomes analyses (patient criteria and data elements appear in Attachment G.2). • Secure extraction of a fully identified contact file for parent recruitment purposes (patient criteria and data elements appear in Attachment G.2) • RD, clinician, parent, and Univ. of Michigan study team member access to a study dashboard that provides a graphical user interface (GUI) for accessing content that is securely stored on a server at the University of Michigan.

An IRB amendment will be submitted in summer 2017 that includes:

- **Spanish language versions of all parent materials (including those used for recruitment, consent, and HIPAA authorization), surveys, and parent-facing pages of the study dashboard.**
- **Procedures for and content of tailored text messages (to provide reinforcement between RD counseling calls, and for appointment reminders) for Intervention arm parents.**
- **Final versions of all study dashboard pages**.
- **Further detail regarding the optional quality improvement project for Maintenance of Certification (MOC) credit**

Below we outline the different procedures planned for the study after practice recruitment has been completed.

Please refer to Data Flow diagrams (Attachment G.1) and the Protection of Data grid (Attachment G.2) for further information about the steps below.

Please see *section 14, Participant Identification, Recruitment and Selection,* for recruitment details.

Step 1: Practice / clinician enrollment and consent

- PROS staff will send the Clinician Eligibility Survey (Attachment B) and Study Participation Form (Attachment C) to interested PCC clients by email, fax, and / or US mail / express courier (FedEx/UPS).

- After verifying that interested clinicians are eligible to participate based on their responses to the Clinician Eligibility Survey (Attachment B) and Study Participation Form (Attachment C), PROS staff will send an enrollment packet containing the Clinician Obesity Experience Survey (Attachment D), Clinician Consent Form (Attachment E), Individual Investigator Agreement (IIA-see below for a description), and PROS intake forms via email, fax, and / or US mail / express courier (FedEx/UPS) to clinicians. The PROS intake forms are standard PROS forms and are therefore not included as an attachment in this application. The IIA is an IRB pre-approved form and process, and also not included as an attachment in this application. Clinicians will be asked to complete and return all forms in the enrollment packet to PROS; all materials except the Data Use Agreement (DUA) and Data Transfer Agreement (DTA) - see below - must be received by PROS before the practice can be cleared for randomization.

    - PROS requires each participating clinician and study coordinator to complete the National Institutes of Health "*Protecting Human Research Subjects*" online course, and to provide their certification date and number on an AAP-endorsed Individual Investigator Agreement (IIA). The IIA must be completed before the practice can be randomized.

    - All RDs will complete the Michigan online Program for Education and Evaluation in Responsible Research and Scholarship (PEERS) prior to initiating patient contact.

- A Data Use Agreement (DUA) (Attachment F.2) between the AAP and each practice, as well as a Data Transfer Agreement (Attachment F.5) between the University of Michigan and each practice, will be included in the enrollment packet.

    - The DUA allows for the transfer of a HIPAA limited dataset at baseline, the end of the intervention period, and the end of the study as a whole from the EHR vendor – PCC (the "data transfer agent") – to the data coordinating center at The Children's Hospital of Philadelphia (see Attachment F.1)

    - The DTA is used in conjunction with parent HIPAA authorization to allow for the free exchange of study-related and clinical information between the practice and RDs / researchers at the University of Michigan during the study (see Attachment F.1)

The DUA and DTA will be signed by the authorized official on behalf of the practice, and returned to PROS. PROS will then send a copy of the DTA to staff at the University of Michigan. The DUA and DTA must be received by PROS before baseline data extraction can occur (see Step 3 below).

- Should any participating practices have their own local IRB, approval from those IRBs would also be obtained; procedures for this are in place as part of the PROS network.

Step 2: Practice randomization

- Once a practice completes enrollment, PROS staff will send Dr. Roger Vaughan (RStat) – the study biostatistician – or his designee a spreadsheet containing PROS practice ID and practice characteristics (including the estimated percentages of patients by race and ethnicity) as reported on the PROS intake form.

- Dr. Vaughan – blinded to practice name – will pair match practices based on estimated percentages of patients by race and ethnicity (as reported on the PROS intake form).

- Within pairs, one practice will be randomly assigned to the Usual Care arm and the other practice to the Intervention arm.

- Dr. Vaughan will securely transfer the spreadsheet, with assigned study arm included, to PROS staff.

- PROS will inform each participating clinician about their practice's assigned study arm.

Step 3: Baseline EHR and billing data collection

- PROS will send signed copies of the DUAs (Attachments F.2 and F.3) to PCC staff assigned to this project; this is done so that PCC has documentation that the practice has agreed to allow them to send practice EHR data to The Children's Hospital of Philadelphia.

- PROS staff will securely transfer a spreadsheet linking the name of each consented clinician with the name of their practice and that practice's assigned study arm to PCC.

- PCC will develop a query and conduct an initial data extraction for up to 25 practices (to allow for replacement if a practice drops out before the clinician training sessions begin in fall 2017, and achieve a final sample size of 18 practices).

    - PCC will extract a HIPAA limited dataset that contains all IRB approved EHR and billing data elements (listed in Attachment G.2, #5) for all children in all participating practices that are at least 3, but less than 8, years of age on the date of the baseline data pull, regardless of who their primary care provider is. PCC will extract data for the previous 24 months for all of these children.

    - PCC will prepare a separate file that links the IDs of each participating clinician with their practice's ID and study arm assignment. This will allow CHOP to identify clinicians that are participating in this study and link them with their practice's assigned study arm. This is needed so that CHOP can identify children whose parents are eligible for recruitment.

- Once the data are extracted but before sending to the data coordinating center at CHOP, PCC will perform a series of pre-transmission steps (defined in Attachment H.1) to ensure that the HIPAA limited dataset does not include any unauthorized protected health information (PHI).

- PCC will securely transfer the data to CHOP

- Within approximately one week of data transfer, Dr. Robert Grundmeier or his assigned designee at CHOP will review the data to confirm that only allowable PHI elements are included. If unauthorized data are included, the steps outlined in Attachment I.1 will be taken.

Step 4: Define cohort of patients whose parents are eligible to participate

- CHOP will clean all growth data using an established method[23], and subsequently note out of range, erroneous height and weight values.

- CHOP will then apply remaining inclusion and exclusion criteria (described in section 13b) to generate a list of children within each of the 18 practices whose parents are eligible to participate in the study. At the end of this process, each eligible child in all participating practices will be linked with a study clinician – **if a child did not have their most recent well-child visit with a study clinician, they are not eligible to participate (Intervention arm) or be a part of the comparison cohort (Usual Care arm). However, they would contribute data towards the population-level analysis in Study Aim # 3.**

Step 5: Refine cohort of patients whose parents are eligible to participate in the study (Intervention arm ONLY)

- CHOP will securely transfer to PCC a list of unique IDs for children in Intervention arm practices whose parents are eligible to participate in the study and whose clinician completed the in-person MI training (see Step 6). This list will contain patient study ID, clinician ID (corresponding to the clinician that CHOP assigns to that child in step 4), and practice ID. **Note that study IDs for children within Usual Care arm practices will NOT be sent back to PCC because families of these children <u>will NEVER be contacted</u>, although their EHR data will be used for outcomes analysis.**

- For each Intervention arm practice, PCC will add a "BMI2+ eligible flag" for each eligible child within the practice's EHR system. PCC will help each practice use that flag to generate a list of eligible patients with accompanying data, on the practice's server, that includes:
  - patient first and last name
  - date of birth
  - all major visit diagnoses
  - medical record number

- Participating clinicians in that practice will be asked to review the list of patients and make further exclusions within the list based on their clinical judgement within 2 weeks. During training (see Section 13c, step 6), clinicians will be instructed to exclude only those patients who may not benefit from the intervention, such as those with social circumstances that may not be captured by the EHR (e.g., homelessness, a recent death in the family, etc.).

- PCC will securely copy the list from each practice's server back to a PCC server at the end of the 2-week period.

- Using the lists of patients that have been reviewed by study clinicians, PCC will create a fully identified contact file that contains the following data elements for each child in Intervention arm practices whose parent is eligible to participate (removing parents of children excluded by clinicians in the previous bullet point):
  - patient study ID
  - patient first and last name

- patient age (in months)
- account id
- parent / guardian first and last name
- preferred contact method
- parent / guardian home and mobile phone numbers
- parent / guardian email address
- parent / guardian postal address
- patient primary language
- name and study ID for assigned study clinician (corresponds to the clinician that CHOP assigns to that child in Step 4)
- practice ID, name, address, and phone number

- Once the data are extracted but before sending it to the University of Michigan, PCC will perform a series of pre-transmission steps (defined in Attachment H.2) to ensure that the fully identified contact file does not include any unauthorized protected health information (PHI).

    - The Business Associate Agreement (BAA) between PCC and the University of Michigan allows for the transfer of patient contact information, without HIPAA authorization, for the purposes of study recruitment (see Attachment F.6)

- Within approximately one week of data transfer, Mr. Nowak will review the data to confirm that only allowable PHI elements are included. If unauthorized data are included, the steps outlined in Attachment I.2 will be taken.

Step 6: Training (Intervention arm)

- Study Coordinators (in participating practices)

Study coordinators will be trained in all study procedures via telephone

- Clinicians in participating practices and Registered Dieticians (RDs) at the University of Michigan

A core element of our intervention will be a 2.5 day, interactive, in-person training session for clinicians and RDs to enhance their confidence, skills, and clinical effectiveness for prevention and treatment of pediatric obesity. This training session offers 11 hours of face-to-face training in Motivational Interviewing (MI), 1 hour of face-to-face training in behavioral therapy, and additional training in billing and coding for pediatric obesity and the study protocol. Before parent recruitment can begin, all participating clinicians (n=1-2 per practice) and the study coordinator within a practice must complete study training.

All training sessions will be conducted by the PI (PI), with assistance from PROS and University of Michigan staff, plus outside experts. Ideally, clinicians and RDs will be trained simultaneously, at the same in-person training session. However, RDs may be trained separately at the University of Michigan, if this is logistically more feasible. Clinicians will select one of two identical training sessions to participate in; if they cannot participate in either one, they may be trained by the PI in existing sessions held elsewhere in the US.

Over 25 years, the PI has developed and refined a curriculum that includes a mix of didactic and experiential activities, teaching MI skills with real time constructive feedback. Core MI techniques include the use of reflective listening, allowing the client to interpret information, agenda setting, rolling with resistance, building discrepancy and eliciting self-motivational statements or "change talk." Rather than positioning MI as an entirely new counseling model for clinicians and RDs, we will show participants how to integrate this

approach into their current counseling "culture." For clinicians, we will demonstrate how to integrate the MI approach within the "culture" of anticipatory guidance whereas for RDs, this entails integrating MI within the "culture" of dietary therapy and nutrition education.

Each participant will have one standardized, role-played patient encounter that is videotaped during the training session, with scoring using the One Pass system. One Pass is a MI fidelity assessment and supervision tool; it requires raters to listen to a clinical encounter only once before providing feedback[24]. While preliminary feedback will be given immediately to the participant, they will also receive a consultative phone call from an MI trainer at the University of Michigan several weeks later, during which they will discuss their performance in greater detail.

A second standardized patient encounter with feedback from a University of Michigan MI trainer will occur over the phone, and be audiorecorded, approximately 6 months after completion of the in-person training session.

To enhance skill acquisition and reduce skill atrophy, we will provide each participant with a DVD to enhance their core skills of reflective listening, building motivation, and eliciting change talk. The DVD will demonstrate a range of full clinical scenarios relevant to the project using simulated patients. Examples demonstrating phone counseling will also be included for the RD segments. Although separate sections will be tailored for the clinicians and RDs, we will provide the same DVD to both so that they have the option of seeing encounters showing both clinicians and RDs.

A smaller portion of training time will focus on behavior therapy techniques specifically related to pediatric obesity, such as strategies to help parents make the changes they choose (versus prescribing particular changes). Key strategies will include tips for parents to set and implement gradual goals, and reinforce and manage their child's changes in behavior and the child's self-monitoring of their own behavior.

Remaining time in the training session will be used to review the study protocol (including obtaining verbal parent consent and HIPAA authorization, documentation of consent and HIPAA authorization in the EHR, scheduling / documentation of MI counseling visits, etc.). Participants will also receive training from experts on options for coding and billing for obesity-related services, and review current recommendations for obesity treatment in primary care.

<u>Maintenance of Certification (MOC) and Continuing Medical Education (CME) credit</u>
Clinicians in the Intervention arm will have the opportunity to earn MOC points and CME credits in several ways. All MOC and CME activities will be administered by the University of Michigan, and have already been reviewed and approved by the University of Michigan Medical School's Office of Continuous Professional Development. We will submit more detail about this QI project in a future amendment

1) For participating in the 2.5-day training workshop, clinicians can earn:
    - American Board of Pediatrics Part II MOC: 18.75 points
      AND
    - Live activity CME: 18.75 AMA PRA Category 1 CME credits

2) Clinicians can choose to complete an optional 18-month quality improvement project to earn:
    - American Board of Pediatrics Part IV MOC: 1 Performance in Practice activity or 25 points, depending on year of recertification
      AND
    - Performance Improvement CME: 30 AMA PRA Category 1 CME credits

Their performance on up to three Healthcare Effectiveness Data and Information Set (HEDIS) metrics related to the assessment and treatment of pediatric overweight and obesity will be determined by PCC during three time periods using existing constructs within the EHR system. At the end of each time period, PCC will generate clinician-specific feedback reports directly within the practice EHR (for those that chose to enroll in the optional QI study), and also securely transfer a copy of each report to the study team at the University of Michigan. Each clinician will then participate in a one on one telephone call with a study team member at the University of Michigan to review and discuss their results. During the call, the study team member will help the physician brainstorm about ways to improve performance.

MOC data will be kept separate from all research data, and will not be used for research analyses. Upon completion of the feedback calls, feedback reports and any notes from the feedback calls will be sent to the University of Michigan MOC office for management per MOC procedures, and will *not* be kept by the Michigan study team.

Opting in for voluntary MOC / CME is independent from, and not covered by, informed consent for the research study.

Step 7: Training (Usual Care arm)

Clinicians will be trained in all study procedures via phone and webinar. Intervention arm training sessions on coding and billing for obesity-related services, as well as review of current recommendations for obesity treatment in primary care, will be videotaped and made available to all Usual Care arm clinicians via an emailed YouTube link or a study dashboard link and passcode. For the latter, clinicians will be given access to a specific link via the dashboard interface that houses these videos (see Step 8 below for description of the dashboard graphical user interface (GUI); they will not be able to access any of the Intervention arm components of the study.

In-person training in Motivational Interviewing and Behavioral Therapy will be offered to participating clinicians in Usual Care arm practices <u>after</u> the intervention period has concluded. Training will be identical to sessions described above in Step 6, with the following exceptions: 1) the length of the training session will be reduced to 1.5 days since study protocol and billing / coding training will have been completed at the start of the trial (see above paragraph) and 2) there will be no standardized patient encounter with feedback over the phone 6 months after the MI training session.

<u>MOC and CME credit</u>
Clinicians in the Usual Care arm will have the opportunity to earn MOC points and CME credits as follows.

For participating in the 1.5-day training workshop, they can earn:

- American Board of Pediatrics Part II MOC: number of points to be determined
  AND
- Live activity CME: number of AMA PRA Category 1 CME credits to be determined

An IRB amendment will be submitted once the number of points and credits has been determined by the University of Michigan. Points for Usual Care arm training will differ from those available for Intervention arm training, due to the reduced length of the workshop.

Clinicians in the Usual Care arm will <u>not</u> have the option of completing the aforementioned 18-month quality improvement project to earn MOC Part IV or Performance Improvement CME credit, since there will not be enough time remaining in the study, after they complete in-person training, for such a project.

Step 8: Activate study dashboard

The study team at the University of Michigan has created a study dashboard. The dashboard is not a physical storage repository, but instead provides a graphical user interface (GUI) for users to access content that is securely stored on a server at the University of Michigan. Its primary function is to allow RDs located at the University of Michigan to schedule, track, deliver, and document their counseling calls with enrolled parents during the intervention period. It also provides users with access to study-related content as described in the table below.

Content	Use	Access	Storage	Covered by
Parent contact information	Research (recruitment and intervention delivery)	RD, Int. arm clinician, Univ. of Michigan study team members, parent	Secure server @ UMich	BAA
Baseline parent surveys	Research and clinical	RD, Int. arm clinician*, Univ. of Michigan study team members, parent	Secure server @ UMich	Consent; HIPAA Authorization *
Follow-up parent surveys	Research	Univ. of Michigan study team members, parent	Secure server @ UMich	Consent
>Clinical counseling notes overall and partitioned as: >Summary notes for clinician >Summary notes for parent	Research and clinical	RD, Univ. of Michigan study team members Above plus intervention arm clinicians All of above plus parent	Secure server @ UMich	DTA Consent; HIPAA Authorization
HIPAA limited dataset	Research	Univ. of Michigan study team members	Secure server @ UMich	DUA
Practice resources: coding and billing training videos	Study procedures	Clinicians and office staff in both study arms; Univ. of Michigan study team members, RDs	Secure server @Umich	N/A – not research data

**Intervention arm clinicians can see parent responses to survey questions, but only those that are directly relevant to MI counseling / clinical care. Parent responses to research-based questions will only be viewable by RDs and Univ. of Michigan study team members (see attachments K and L: baseline parent surveys)*

Access to specific clinical, research and study procedures content via the dashboard is restricted to up to five types of users: 1) RDs, 2) study clinicians in the Intervention arm, 3) participating parents in the Intervention arm, and 4) Univ. of Michigan study team members. User authentication is required, and each user can only access the specific content that they have permission to view (see table above). 5) Note that Usual Care arm clinicians, and office staff in both arms, may also be able to access content via the dashboard interface, but only for the purposes of viewing billing and coding training videos (see step 7 above).

We include data collection instruments with this submission for review and approval of content. The dashboard interface (including screen shots of user-specific pages) will be submitted, once finalized, via an IRB amendment.

Step 9: Parent recruitment and enrollment (Intervention arm only)

See steps 1-2b (*Parents: Intervention arm only*) in Section 14b for a complete description of this process.

Step 10a: MI counseling sessions delivered by Registered Dieticians (RD) (Intervention arm only)

RDs centrally trained, supervised, and located at the University of Michigan Center for Health Communications Research will deliver up to 6 MI-based telephone counseling sessions to enrolled parents over the course of 2 years. Each session will last approximately 30 minutes. All calls will be recorded to facilitate the provision of ongoing feedback by an MI supervisor to RDs about their MI skills.

- First MI counseling session (after consent and HIPAA authorization have been obtained – see sections 15 and 17)
    - At the start of the call, the RD will remind the parent that the call will be recorded and that summary notes from the call will be shared with their child's clinician
    - Approximately 3 days prior to the first scheduled telephone counseling session, an RD will email the parent a link to the baseline extended survey (Attachment L). Up to 5 reminder messages will be sent.
    - If a parent does not complete the baseline extended survey prior to the first counseling call, the RD will verbally administer the survey during that call.
    - The RD will work with the parent to schedule their next counseling call.
    - During or after the call, the RD will create Summary Notes for the parent and Physician Summary Notes for the clinician via the study dashboard.
    - The University of Michigan study team will send the RD Counseling Session Notes, RD-generated Physician Summary Notes, RD counseling session date, and patient first / last name to the study coordinator at their child's doctor's office by secure fax (fax machine located in limited access location). The study coordinator may upload these notes into the EHR so that the clinician can easily view them.

- Counseling calls #2-6
    - At the start of the call, the RD will remind the parent that the call will be recorded and that summary notes from the call will be shared with their child's clinician
    - The RD will review the content of the last session, discuss progress on previous goals, and ask parents what they want to focus on this time.
    - The RD will use the Counseling Guide (Attachment M) to guide their discussion with the parent, and the MI counseling that they provide. They will use the GoalCheck question to determine progress towards past goals, and the GoalArea question to help parents select one or more goals that they would like to address during that call. Each goal has a corresponding subset of questions which help elucidate current habits and behaviors within that area, readiness to change, confidence to change, and desired timeframe for initiating change.
    - The RD will work with the parent to schedule their next counseling call.
    - During or after the call, the RD will create Summary Notes for the parent and Physician Summary Notes for the clinician via the study dashboard.
    - The University of Michigan study team will send the RD Counseling Session Notes, RD-generated summary notes for the child's study clinician ['Physician Summary Notes'], RD counseling session date, and patient first / last name to the study coordinator at their child's

doctor's office by secure fax. The study coordinator may upload these notes into the EHR so that the clinician can easily view them.

Step 10b: MI counseling sessions delivered by study clinicians (Intervention arm only)

Clinicians will deliver up to 4 MI-based counseling sessions to enrolled parents over the course of 2 years. These sessions can be scheduled as stand-alone office visits, or occur within the context of other scheduled visits. It is up to the clinician and parent to decide when to schedule these visits. Each session will last approximately 15 minutes.

Step 10c: Parent withdrawal from the study (Intervention arm only)

Parents can withdraw from the study at any time. The parent can withdraw by informing the study clinician, the RD, or by contacting the PI – study Principal Investigator – directly. If a parent withdraws, his/her study-related counseling sessions with clinicians and RDs will end, he/she will no longer receive surveys, he/she will no longer have access to the study dashboard, and all contact information will be deleted. We will continue to securely store and analyze all data that the parent has provided up to the date of withdrawal, and will continue to extract their HIPAA limited data through the end of the study as a whole, as permitted in the Data Use Agreements (see Attachment F.1).

If a parent withdraws by informing the RD or contacting the PI, the University of Michigan study team will electronically transmit to PCC their child's study ID and practice ID. PCC will update a corresponding status flag in the EHR, and an automatic email notification will be sent to the practice study coordinator.

If a parent withdraws through the study clinician, the study coordinator will update the corresponding status flag in the EHR and inform the study team at the University of Michigan by sending the first and last names of the parent and their eligible child via secure fax (fax machine located in limited access location within the Center for Health Communications Research).

Step 11: EHR and billing data collection at the end of the intervention period, and linkage with parent survey responses, RD clinical counseling notes, and full contact information

- After the conclusion of the 2-year intervention period, PCC will extract a HIPAA limited dataset containing all IRB approved EHR and billing data elements for all children in all practices that were at least 3, but less than 8, years on the date of the baseline data pull. PCC will extract data for the previous 4 years (which includes the 2 years prior to the baseline data pull and the 2-year intervention period) for each child.

- Once the data are extracted but before sending it to the data coordinating center at CHOP, PCC will perform a series of pre-transmission steps (defined in Attachment H.1) to ensure that the HIPAA limited dataset does not include any unauthorized protected health information (PHI).

- Once Statistical Lead or his designee at CHOP receives an email from PCC that data is ready to transfer, he or his designee will send the designated PCC staff member a unique link to the CHOP secure file transfer website, along with information on how to upload data to the website.

- PCC will securely transfer the data to CHOP.

- Within approximately one week of data transfer, Dr, Grundmeier or his assigned designee will review the data to confirm that only allowable PHI elements are included. If unauthorized data are included, the steps outlined in Attachment I.1 will be taken.

- If no unauthorized PHI is included, the CHOP team will clean all growth data.

- CHOP will securely transfer the cleaned HIPAA limited dataset (containing all IRB approved EHR and billing data elements for all children in all practices that met eligibility criteria on the date of the baseline data pull) to the study team at the University of Michigan.

- The study team at the University of Michigan will merge the HIPAA limited datafile from CHOP (see above bullet point) with parent survey data, RD clinical counseling notes, and full contact information, via study ID.

- The study team at the University of Michigan will look for evidence of potential adverse events in the merged dataset, focusing on growth data and other obesity-related measures. Though highly unlikely, a potential adverse event could be detected AFTER the intervention period has ended if, for example, the only evidence of excessive weight loss is found within the EHR (note this is the first time that the study team at the University of Michigan has access to the EHR data). Note that parents who withdraw during the intervention period will not be included in this review because we will no longer have permission to re-identify their child's HIPAA limited dataset. *A description of adverse event detection and reporting DURING the trial is provided in section 20 of this application.*

- If there is any evidence of a potential adverse event within the dataset, the PI (study PI) will immediately contact the child's doctor, the AAP project manager, and the AAP IRB. Retaining full contact information received in Step 5 is therefore necessary in order to ensure the safety of our patient populations, and the study team's ability to identify the child and inform the clinician should a potential event be detected.

- After the study team at the University of Michigan has completed their review of the merged dataset and adverse events (if any) are appropriately addressed, they will:

    - Review all clinical counseling notes to scrub any potential identifying content: for example, [Johnny] would become [index child] or [father] or [brother] or [male relative/friend] or [boy] or [man]; Springer Park would become [park]; Lincoln school would become [school]; names of cities, streets, towns would become [city]; [street]; [town]. Any other geographic references will be similarly de-identified.
    - Delete all contact information received in Step 5 from the dataset and all servers at the University of Michigan.

- Mr. Nowak or his designee will sign an attestation letter (Attachment H.3) stating that all identifiers within clinical counseling notes and all contact information have been appropriately deleted, and send that letter to Dr. Wright at the AAP.

  Note that there is no way 1) any child in the Usual Care arm and 2) ineligible children in the Intervention arm can be re-identified, as the University of Michigan will never receive parent contact information for these individuals.

  It is extremely unlikely that children in the Intervention arm whose parents have opted out, refused to participate, not been contacted, or withdrawn from the study would be re-identified, as the University of Michigan will delete all contact information for these individuals before receiving the

HIPAA limited dataset from CHOP. At least monthly during the intervention period, Mr. Nowak or his designee at the University of Michigan will sign an attestation letter (Attachment H.4) stating that all such contact information has been appropriately deleted, and send that to Dr. Wright at the AAP.

Children in the Intervention arm whose parents have provided consent and HIPAA authorization to link their HIPAA limited medical data with their survey responses, full contact information, and RD clinical counseling notes will be re-identified. However, as described in Step 11 above, there is a limited period of time and a defined purpose for re-identification, after which all contact information will be deleted from datasets and study servers at the University of Michigan.

Step 12: EHR and billing data collection at the end of the study as a whole

- At the end of the study as a whole – estimated to occur approximately 1 year after the conclusion of the intervention period – PCC will extract a HIPAA limited dataset from all participating practices containing all IRB approved EHR and billing data elements for all children that were at least 3, but less than 8, years on the date of the baseline data pull. PCC will extract data for the previous 5 years (which includes the 2 years prior to baseline, the 2-year intervention period, and the approximately 1-year post-intervention) for each child.

- Once the data are extracted but before sending it to the data coordinating center at CHOP, PCC will perform a series of pre-transmission steps (defined in Attachment H.1) to ensure that the HIPAA limited dataset does not include any unauthorized protected health information (PHI).

- Once Statistical Lead or his designee at CHOP receives an email from PCC that data is ready to transfer, he or his designee will send the designated PCC staff member a unique link to the CHOP secure file transfer website, along with information on how to upload data to the website.

- PCC will securely transfer the data to CHOP.

- Within approximately one week of data transfer, Dr, Grundmeier or his assigned designee will review the data to confirm that only allowable PHI elements are included. If unauthorized data are included, the steps outlined in Attachment I.1 will be taken.

- If no unauthorized PHI is included, the CHOP team will clean all growth data.

- CHOP will securely transfer the cleaned HIPAA limited dataset (containing all IRB approved EHR and billing data elements for all children in all practices that were at least 3, but less than 8, years on the date of the baseline data pull) to the study team at the University of Michigan.

- The study team at the University of Michigan will create a full study analytic dataset by merging the HIPAA limited dataset from CHOP (see above bullet point) with parent survey responses and scrubbed RD clinical counseling notes [per Step 11] collected during the intervention period, via study ID. See section 16e, “final analytic dataset”, for a description of the content of this dataset, and how it will be stored.

- At the end of the study as a whole, the study team at the University of Michigan will send a fully deidentified version of the aforementioned analytic dataset – removing study ID and all dates – and send it to the AAP / PROS ongoing secondary analyses.

d. **What data will you collect? Please describe data collection for each phase, research strategy, tool, involved population etc. that you plan to use.** *Please include copies of all questionnaires, surveys, interview questions, etc. as appendices, and label each clearly so the IRB knows which questions, tool, etc. go with which research activity. If a draft of one of these documents is provided, it should be clearly labeled as such and a final version must be submitted before data collection begins.*

Data Source	From	Study Arm	When	Attachment
Clinician Eligibility Survey	Clinicians	Both	Study enrollment	B
Clinician Obesity Experience Survey	Clinicians	Both	Study enrollment & conclusion of intervention period	D
Standardized patient encounters	Clinicians	Both	During MI training sessions (both study arms), and approximately 6 months after MI training (Intervention arm only)	N/A
Standardized patient encounters	RDs	Intervention arm	During MI training sessions	N/A
EHR and billing data	PCC	Both	Baseline, conclusion of intervention period, end of study as a whole	G.2
Baseline Brief Survey	Parent	Intervention arm	Study enrollment	K
Baseline Extended Survey	Parent	Intervention arm	Study enrollment	L
RD Counseling Guide	Parent (completed by RD over the phone)	Intervention arm	During RD-delivered MI counseling sessions (#2-#6)	M
RD-parent telephone counseling sessions	RD and parent	Intervention arm	RD-delivered MI counseling sessions	N/A
Follow-up Survey	Parent	Intervention arm	Conclusion of intervention period	N

Clinicians

All clinicians will complete an eligibility survey (Attachment B) that captures information about their previous training in Motivational Interviewing, as well as their current work schedule [≤ half time (less than 6 sessions per week) vs > half time (at least 6 sessions per week)]. This survey will be distributed to clinicians by PROS staff immediately after they express interest in participating in the study. We will also survey all participating clinicians about their current practices for obesity treatment (Attachment D); we will do this twice – once at baseline and again after the 2-year intervention period concludes – to capture any changes in usual care. The baseline survey will be included in the enrollment packet (described above in Section 13c, Step 1), and the post-trial survey will be sent by PROS staff via email (as fillable PDFs), US mail/express courier (FedEx/UPS), and / or deployed using Qualtrics. We will incorporate items from the AAP Periodic Survey of Fellows that have been validated to assess clinician practices for obesity prevention and treatment in primary care.

As described above in Section 13c (steps 6 and 7), each clinician will have one standardized, role-played patient encounter that is videotaped during the MI training session. This encounter will be scored using the One Pass system. One Pass is a MI fidelity assessment and supervision tool; it requires raters to listen to a clinical encounter only once

before providing feedback. While preliminary feedback will be given immediately to the participant, they will also receive a consultative phone call from Shannon Considine - the MI supervisor at the University of Michigan – or her designee several weeks later, during which they will discuss their performance in greater detail. For clinicians in the Intervention arm only, a second standardized patient encounter with feedback from Ms. Considine will occur over the phone approximately 6 months after completion of the in-person training session.

RDs will also have one standardized, role-played patient encounter that is videotaped during the MI training session, with scoring using the One Pass system.

All RD-delivered counseling sessions with enrolled parents will be audiorecorded for training purposes. At least monthly, Ms. Considine or her designee will score these calls using the One Pass system described above; RDs will be able to view their own scores via the study dashboard interface.

EHR and Billing Data

See Attachment G.1 for a diagram of data flow at baseline, during the intervention period, and upon completion of the study as a whole.

Attachment G.2 lists the specific data elements that will be pulled at each time point

Procedures for EHR and billing data extraction are described above in Section 13c.

Parents

All participating parents (Intervention arm only) will be asked to complete two surveys at study baseline – 1) a brief survey (Attachment K) completed shortly after study enrollment that asks parents to grade how their child is doing with respect to different eating, screen time, and physical activity behaviors and 2) a longer survey (Attachment L) completed shortly before, or during, their first telephone counseling session with an RD that asks about their child's daily intake of fruits, vegetables, specific drinks, and snacks, participation in sports, use of TV, and video/computer games. Links to these surveys will be emailed to enrolled parents by the study team at the University of Michigan; parents log on to the study dashboard to complete these surveys. The surveys are designed to enable parents to explore and identify discrete behavior change goals that can be addressed by RDs during counseling sessions.

During all RD-delivered telephone counseling sessions (except the first one), RDs will use the Counseling Guide (Attachment M) to guide their discussion with the parent, and the MI counseling that they provide. They will use the "GoalCheck" question to determine progress towards past goals, and the "GoalArea" question to help parents select one or more goals that they would like to address during that call. Each goal has a corresponding subset of questions which help elucidate current habits and behaviors in that goal area, readiness to change, confidence that they can change, and when they will start implementing that change.

At the conclusion of the 2-year intervention period, parents in the Intervention arm will be asked to complete a Follow-up survey (Attachment N) that captures their feedback regarding the perceived impact of the intervention on their child's and family's lifestyle behaviors (including weight, eating, and physical activity), as well as their satisfaction with clinician and RD counseling sessions. Links to this survey will be emailed to parents by the study team at the University of Michigan. Note that study clinicians and RDs will never be able to see these survey responses from the follow-up survey.

e. **Describe other important information related to your protocol, if any.**

14. PARTICIPANT IDENTIFICATION, RECRUITMENT, & SELECTION

a. **Describe how potential participants will be identified (e.g., advertising, individuals known to investigator, record review, etc.). Explain how investigator(s) will gain access to this population, as applicable.**

Practices and clinicians

Potential practices and clinicians will be identified through two mechanisms that will be utilized simultaneously: 1) Physician's Computer Company (PCC) client database and 2) the well-established AAP Pediatric Research in Office Settings (PROS) research network.

Parents (Intervention Arm only)

Eligible parents will be identified after PCC extracts each practice's Electronic Health Record (EHR) and billing data at study baseline; securely transmits it to the data coordinating center at CHOP; CHOP cleans growth data, applies study inclusion and exclusion criteria, and determines the cohort of eligible parents within each participating practice; and study clinicians make further exclusions to the list of eligibles (see Section 13c, steps 3-5).

b. **Describe the recruitment process, including the setting in which recruitment will take place and who will conduct recruitment.** *Provide copies of proposed recruitment materials (e.g., ads, flyers, website postings, recruitment letters/emails, and oral/written scripts).*

Practices and clinicians

Recruitment through PCC

Step 1: Recruitment materials (Attachments O and P) will be sent to leadership at PCC.

Step 2: PCC staff will utilize their normal business channels, as well as direct conversations with practices as needed, to inform their clients of the study. Clients may receive information about the study at PCC-sponsored conferences; small gifts (including pens, water bottles, and thumb drives) may accompany this information.

Step 3: Clinicians interested in participating in the study will be instructed to contact PROS staff or let PCC know. PCC and / or PROS staff may follow-up with practices if they do not initiate contact.

Recruitment using PROS membership database

Step 1: PROS study staff will send recruitment materials (attachments B, C, O, and P) via email, fax, or US mail/express courier (FedEx/UPS) to the contact practitioner at each PROS practice that shows PCC as their EHR vendor in the PROS membership database. The contact practitioner at each PROS practice will be contacted up to 5 times; if no response is received, contact will be terminated and the practice will not be enrolled in the study.

We will utilize these two recruitment methods simultaneously, and it is therefore possible that some practices will receive recruitment information / materials from both PCC and PROS.

Parents (Intervention Arm only)

Step 1: Up to 50 parents per practice (Intervention arm only) can enroll in the study.

After all participating clinicians within an Intervention arm practice have completed in-person training, and after the study coordinator in that practice has completed study protocol training via telephone (both described in Section 13 c, Step 6), an introductory letter (Attachment Q) and study information sheet (Attachment R) will be sent by the University of Michigan study team, on practice letterhead and on behalf of the practice, to all eligible families in that practice via US mail and email. Eligible families will include those identified as such by CHOP (Section 13c, Step 4) and not excluded by a study clinician (Step 13c, Step 5). The introductory letter describes the purpose of the study, provides a number to which parents can send a text message if they wish to actively enroll (RDs will follow-up with an "invitation" phone call), and provides opt-out information. The study information sheet provides more detailed information about the study, and includes all required elements of informed consent and HIPAA authorization.

Step 2: Parents will be recruited in one of two ways.

Step 2a: Within 2 weeks of sending the introductory letter, RDs located in the centralized call center at the University of Michigan will call all eligible parents, except those who opted out of the study / refused to participate based on information provided in the introductory letter described above in Step 1, or did so at their child's doctor's office (see below).

The RD will review the study information sheet and obtain verbal consent and HIPAA authorization as described in Section 15d. The RD will then activate that parent's study dashboard account, document their consent and HIPAA authorization via the dashboard, and provide them with a link to the account, as well as a unique access code, via phone and / or email. Parents will be encouraged to reset their account password at that time.

If a parent opts out of the study, refuses to participate during the RD "invite call", or cannot be reached after 11 call attempts, their contact information will be deleted from all study databases and they will not be enrolled in the study. At least monthly during the intervention period, Mr. Nowak or his designee at the University of Michigan will sign an attestation letter (Attachment H.4) stating that all such contact information has been appropriately deleted, and send that to Dr. Wright at the AAP.

Approximately weekly, the University of Michigan study team will electronically transmit to PCC study ID and practice ID for children whose parent:

→ enrolled and provided consent and HIPAA authorization via UMich

→ opted out / refused to participate via UMich

→ could not be contacted by UMich

PCC will routinely update corresponding status flags in the EHR during the parent enrollment period; an automatic email notification will also be sent to the practice study coordinator.

If a parent has already provided consent and HIPAA authorization at their child's doctor's office (see Step 2b below), the RD will use the "invite call" as an opportunity to schedule the parent's first RD counseling session.

Step 2b: After all participating clinicians within an Intervention arm practice have completed in-person training, and after the study coordinator in that practice has completed study protocol training via telephone (both described in Section 13 c, Step 6), eligible parents may be approached by their child's clinician during an office visit. Once the clinician opens the patient's chart in the EHR, he/she will see one or more clinical alerts that indicate:

→ eligible but not yet enrolled
→ enrolled and provided consent and HIPAA authorization
→ opted out / refused to participate
→ could not be contacted
→ withdrawn (see section 13c / step 10c)

If the parent is eligible to participate but has not yet been enrolled by the Univ. of Michigan study team, the clinician will review the study information sheet and obtain verbal consent and HIPAA authorization as described in Section 15d. The clinician will document consent and HIPAA authorization by marking two separate checkboxes in the EHR. The study coordinator will then alert the study team at the University of Michigan by sending the first and last names of the consented parent and their eligible child to the study team at the University of Michigan via secure fax.

If the parent has already provided consent and HIPAA authorization as described above in Step 2a, the clinician does not need to obtain consent and HIPAA authorization.

If the parent has opted out or refused to participate during an "invite" call with an RD (described in Step 2a above), a clinical alert will appear in the EHR indicating that the clinician should not discuss the study with the parent.

15. INFORMED CONSENT PROCESS

a. **Indicate the consent process(es) and document(s) to be used in the study. Check all that apply.** *Please provide copies of documents and/or complete relevant forms, as needed. For more information, see OHRP Tips on Informed Consent; OHRP Informed Consent Checklist; and, OHRP Informed Consent FAQs.*

☒	Informed Consent – Form ➔**Attach Consent Form** which includes all federally required elements of informed consent 1) Participating clinicians (Attachment E)	☐	Assent – Verbal Script ➔**Attach Script** OR Assent – Form ➔**Attach Form**
☒	Informed Consent – Verbal Script ➔ **Complete and attach *Waiver or Alteration of Informed Consent Request Form*** 1) Participating parents (Intervention arm ONLY) (Attachment R – parent study information sheet; Attachment S – verbal consent and HIPAA authorization scripts for use by RDs and clinicians)	☒	Waiver or Alteration of Informed Consent or Assent ➔ **Complete and attach *Waiver or Alteration of Informed Consent Request Form*** 1) Alteration of Informed Consent for participating parents in the Intervention arm, since they are providing verbal consent

☐	Other, explain:		

b. **Who will obtain consent from participants or their legally authorized representatives?** *Check here if not applicable:* ☐ *N/A*

Participant	Type of Consent	Obtained by
Clinicians in both study arms	Written	PROS staff
Parents in the Intervention arm	Verbal (with a Study Information Sheet)	Participating clinicians (in-person during an office visit) or Registered Dieticians (over the phone during "invite" call)

c. **Who will provide consent or permission (i.e., participant, legally authorized representative, parent and/or guardian)?** *Check here if not applicable:* ☐ *N/A*

See tables in 15b and 15d.

d. **Describe the consent process, including how the federally required information will be presented to subjects (consent form, orally, information sheet, etc.). Include when and where consent will be obtained and how subjects and/or their legally authorized representatives will be provided sufficient opportunity to consider participation.** *Check here if not applicable:* ☐ *N/A*

Clinicians (both arms):

PROS staff will send clinicians an enrollment packet that contains a consent form (Attachment E) via e-mail, fax, or US mail/express courier (FedEx/UPS). PROS staff, the AAP IRB Administrator, and the study PI will be available by phone and email to address any questions and concerns during this process. All participating clinicians (1-2 max) within a practice must return signed consent forms to PROS staff before that practice can be randomized.

Parents (Intervention arm only): After the introductory letter (Attachment Q) and study information sheet (Attachment R) have been sent to all eligible parents in the Intervention arm, they can provide consent to participate and HIPAA authorization in one of two ways:

Type of Consent	When & with whom	Procedure
Verbal	During "invite" call with Registered Dietician (RD)	• RD will use a verbal consent and HIPAA authorization script (Attachment S.1) to review study information sheet (Attachment R) with parent. RD will allow ample opportunity for parent to ask questions. RD will obtain verbal consent and HIPAA authorization and document it via the dashboard interface

		• Approximately weekly, the University of Michigan study team will send PCC an electronic list of study IDs and practice IDs corresponding to children whose parents have been enrolled by RDs and provided consent and HIPAA authorization. • PCC will update separate status flags for "verbal consent" and "HIPAA authorization" for each of these patients in the EHR; this will generate a clinical alert so that clinicians know that the parent has enrolled.
Verbal	During office visit with study clinician	• Clinician will use a verbal consent and HIPAA authorization script (Attachment S.2) to review study information sheet (Attachment R) with parent. Clinician will allow ample opportunity for parent to ask questions. Clinician will obtain verbal consent and HIPAA authorization. • Clinician will document verbal consent and HIPAA authorization by updating separate "verbal consent" and "HIPAA authorization" status flags directly in the EHR • Study coordinator will send names of parents (and their eligible child) who consent and provide HIPAA authorization to the study team at the University of Michigan via secure fax.

e. **Explain how the possibility of coercion or undue influence will be minimized in the consent process.** *Check here if not applicable:* ☐ *N/A*

Clinicians (both arms): In the clinician consent form, we state that participation is voluntary and participants can withdraw from the study at any time without penalty. This is also reinforced by the online human subjects protections course that is required of all participating clinicians. The voluntary nature of their participation will be additionally reiterated during study protocol training.

Parents (Intervention arm only): On the study information sheet, we state that participation is voluntary and participants can withdraw from the study at any time without penalty. This will be re-iterated during ensuing discussions with study clinicians or RDs, prior to securing their verbal consent and HIPAA authorization.

f. **How will it be determined that the subjects or the subjects' authorized representatives understand the information presented?** *Check here if not applicable:* ☐ *N/A*

Clinicians (both arms): The clinician consent forms state "I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a copy of this form for my records and future reference."

Parents (Intervention arm only): Study clinicians and RDs will be provided with a script (Attachments S.1 and S.2) that guides their review of the parent study information sheet prior to obtaining verbal consent and HIPAA authorization. This script directs them to proactively ask whether parents have any questions about the study.

g. **Describe additional information regarding the consent process, if applicable.**

Data extractions will include IRB-approved, HIPAA-limited EHR and billing data elements for all children in all study practices that meet age eligibility criteria within a practice, regardless of whether or not their clinician is participating in the study. These data are needed to meet the analytic requirements for population-level effects (Study Aim #3). Therefore, there will be patient-level EHR and billing data obtained from practices, which will include data entered from clinicians not participating in the study. The signed Data Use Agreements (Attachment F.1) give permission for this patient-level data to be extracted and sent to the study team at CHOP and the University of Michigan for purposes of this study.

We believe that it is necessary for all clinicians within Intervention arm practices to be informed as to what the study is about. Therefore, we have created an information sheet (Attachment T) that will be given to the contact practitioner to share with other clinicians in the office, so that they have a clear understanding of all of the components of the study, how the patient-level data are protected and what implications this study may have for them. Contact practitioners will be provided with these information sheets before the baseline data pull.

16. CONFIDENTIALITY OF DATA

Explain how information is retained, including storage, security measures (as necessary), and who will have access to the information. Describe for both electronic and hard copy records. *If there are different sources of data and different levels of access, please attach a table to clearly outline who has access to what data.*

a. **Who will have access to the data?**

The Protection of Data document (attachment G.2) lists all data elements and the study staff that will have access to each.

AAP staff (Dr. Shone, Dr. Wright, and Ms. Steffes) will have access to raw data and all study information for monitoring purposes when on-site at the University of Michigan.

b. **What are the methods to be used to ensure the confidentiality of data obtained (e.g., use of study codes, password protection, encryption, limited access, secure storage in locked locations).**

Comprehensive measures will be implemented to maintain subject confidentiality and anonymity as appropriate.

Clinician intake forms, consent forms, and surveys: All electronic data will be kept on a secure password-protected server at the AAP with access restricted to PROS staff. All hardcopies will be kept in a locked file cabinet at the AAP.

EHR and billing data:

CHOP: All data will be stored on a secure HIPAA compliant password protected server at CHOP.

The CHOP research server infrastructure is designed to accommodate a wide variety of applications, including database services, web-based applications, and file sharing. A secure Storage Area Network (SAN) is set up to facilitate centralized backup and recovery, as well as business continuity capabilities.

Enterprise backup services include traditional agent-based backup, as well as data snapshots, which are taken twice daily and retained on the system for seven days. Full system and data backups are performed bi-weekly and stored for 2 months. Although most backups are saved to disk, full backups are copied to encrypted tapes on a bi-monthly basis, and moved to a secure off-site document storage facility.

All network accounts are created and maintained by a centralized access administration group within the CHOP Information Services (IS) department. User IDs and passwords are required for access to all information

systems, and sharing of access credentials is strictly prohibited. Password controls, such as password length, complexity, and lifespan, are enforced to establish common criteria for managing passwords across multiple systems. Database account information will be stored in a password vault.

University of Michigan: The Center for Health Communications Research uses virtualized servers provided by the University of Michigan Information Technology Services group. Server virtualization is the masking of server resources, including the number and identity of individual physical servers, processors, and operating systems, from server users. The server administrator uses a software application to divide one physical server into multiple isolated virtual environments. The virtualized servers at University of Michigan are housed at two redundant datacenters. These datacenters provide protection from lengthy outages, 24/7 staffing, restricted physical access and disaster recovery. Virtual servers are backed up automatically onto encrypted tapes for recovery and security. The datacenters also reduce the use of physical resources such as electricity and air conditioning.

All servers and the back-end databases are password protected. The server runs the Red Hat Enterprise Linux operating system and security patches and updates are downloaded and installed regularly. Each server is also protected by firewalls to restrict network access to the server. More details are available at http://services.it.umich.edu/miserver/.

MiShare (https://mishare.med.umich.edu/) will be utilized for the secure transfer of 1) HIPAA limited datasets between CHOP and the University of Michigan and 2) fully identified contact file between PCC and the University of Michigan. MiShare is a secure collaborative file transfer system provided by Michigan Center for Information Technology. The MiShare infrastructure provides a method approved by the University of Michigan Health System Compliance Office for UMHS personnel, non-UMHS business partners, patients and researchers to securely transfer files, including files that contain electronic Protected Health Information (ePHI), protected research data, or other sensitive information. Files are encrypted while being uploaded or downloaded, and are encrypted while they are on the MiShare server.

Use of study IDs

Unique identifiers will be utilized in place of practice, clinician, and / or patient names whenever possible.

- The study statistician will only receive practice IDs (NOT names) for the purposes of randomization
- The data coordinating center at CHOP will only receive clinician and patient study IDs (NOT names) for the purposes of identifying eligible children at baseline.
- The crosswalk between **clinician study ID** and name will be created by PCC and only shared with the study team at the University of Michigan. The study team at the University of Michigan needs this in order to communicate effectively with participating Intervention arm practices.
- The crosswalk between **patient study ID** and parent contact information (for eligible Intervention arm parents only) will be created by PCC and shared with the study team at the University of Michigan for recruitment purposes (allowed by the BAA in Attachment F.6) and intervention delivery (allowed by the HIPAA authorization in Attachment R). As described in Section 13c / step 11, all clinical notes will be de-identified and all contact information and identifiers will be deleted from all datasets and servers at the University of Michigan after the study team has completed their adverse event monitoring. The final analytic dataset will contain study IDs but will not include names, contact information, or any other identifiers.

Other:

All results of the study will be published in aggregate only, and raw data will be restricted to study staff responsible for its analysis. Data used for analysis will be contained in databases separate from those that contain information linking data to individual practice sites, clinicians, and patients. Any information linking the clinicians and patients will be destroyed after the data analysis.

AAP staff will only have access to data while on site at the University of Michigan, for purposes of study monitoring.

c. **Will you record any direct identifiers, names, social security numbers, addresses, telephone numbers, etc.? If yes, explain why it is necessary to record findings using these identifiers. Describe the method you will use to protect against disclosure of these identifiers.**

Who	What	Data collection method	Why	Protection
Clinician - both arms	Name and email address	Study participation form sent to PROS	Practice recruitment / enrollment	Password protected secure AAP server; file access restricted to PROS staff; Password-protected secure server at Univ. of Michigan
Clinician - both arms	Name	Clinician eligibility survey & clinician obesity experience survey	Clinician recruitment / enrollment; outcomes analysis	Password protected secure AAP server; file access restricted to PROS staff; Password-protected secure server at Univ. of Michigan
Clinician - both arms	Facial images, voices, potentially names	Videorecording and audiorecording of standardized patient encounters	MI training	Password-protected secure server at Univ. of Michigan
RD	Facial images, voices, potentially names	Videotape and audiotape of standardized patient encounters	MI training	Password-protected secure server at Univ. of Michigan
Study coordinator - Intervention arm	Name and email address	Study participation form sent to PROS	Practice recruitment	Password protected secure AAP server; file access restricted to PROS staff; Password-protected secure server at Univ. of Michigan
Parent - Intervention arm	*From PCC:* Patient study ID Account ID Patient age (months) Child first and last name Parent / guardian first and last name Parent / guardian mailing address Parent / guardian email address Parent / guardian home phone number Parent / guardian cell phone number Name and study ID of assigned clinician Name, address, phone number, and ID of practice	Fully identified contact file extracted by PCC and sent to Univ. of Michigan	Parent recruitment (baseline) and intervention delivery (intervention period)	Password-protected secure server at Univ. of Michigan

Who	What	Data collection method	Why	Protection
Child - both arms	Date of birth of child Date of death of child Date(s) of service Patient study ID	HIPAA-limited Electronic Health Record (EHR) and billing dataset extracted by PCC and cleaned by CHOP	Eligibility determination (baseline) and outcomes analysis (end of intervention period, end of study as a whole).	Password-protected secure server at Univ. of Michigan
Parent and child (Intervention arm)	*From fully identified contact file:* Patient study ID Account ID Patient age (months) Child first and last name Parent / guardian first and last name Parent / guardian mailing address Parent / guardian email address Parent / guardian home phone number Parent / guardian cell phone number Name and study ID of assigned clinician Name, address, phone number, and ID of practice *From HIPAA-limited dataset:* Date of birth of child Date of death of child Date(s) of service Patient study ID	*At end of intervention period:* Merge HIPAA-limited dataset from CHOP with parent survey responses, RD clinical counseling notes, and full contact information.	Fully identified dataset reviewed for potential adverse events as described in step 11 of Section 13c; contact information and any potential identifiers found in RD clinical notes deleted upon completion of this review	Password-protected secure server at Univ. of Michigan

Who	What	Data collection method	Why	Protection
Parent and child (Intervention arm)	*From HIPAA-limited dataset:* Date of birth of child Date of death of child Date(s) of service Patient study ID *From RD clinical counseling sessions:* Appointment date	*At end of study as a whole:* Merge HIPAA-limited dataset from CHOP with parent survey responses and RD clinical counseling notes (de-identified)	Final analytic dataset	Password-protected secure server at Univ. of Michigan
Parent / RD - Intervention arm	Voices, parent and child name; potential names or geographic identifiers discussed during clinical counseling sessions with RDs	Audiorecording of RD-delivered telephone counseling sessions; clinical counseling notes	RD training and feedback; clinical counseling notes	Password-protected secure server at Univ. of Michigan

d. **What are the plans for data storage? Where, how long, and in what format (e.g., paper, electronic) will data be kept?**

The Protection of Data document (attachment G.2) lists the plan for storage of all data elements.

e. **What are the plans for the final disposition or destruction of the data?**

Clinician consent forms: All hard copy or electronic consent forms will be destroyed 10 years following the end of the study as a whole.

Clinician intake forms and surveys: Data from clinician intake and survey forms will be entered into and stored in an electronic analytic file, without clinician names, indefinitely. Hardcopies of these forms will be destroyed 10 years after the end of the study as a whole. Per standard practice, data from PROS intake forms, including clinician and practice names, will be stored in the PROS membership database indefinitely.

Parent surveys: All information from parent surveys will be stored in an electronic analytic file, without identifiers, indefinitely.

Contact file for eligible children in Intervention arm practices: All contact information will be destroyed after the study team at the University of Michigan has completed their adverse event monitoring (described in Section 13c / Step 11).

RD clinical counseling notes: Clinical counseling notes will be scrubbed of all potentially identifying content after the study team at the University of Michigan has completed their adverse event monitoring (described in Section 13c / Step 11). De-identified clinical counseling notes will be stored in an electronic analytic file indefinitely.

EHR and billing data (HIPAA limited datasets): Extracted EHR and billing data will be saved on a secure server at CHOP and the University of Michigan for up to 10 years after the end of the study as a whole. At the end of 10 years, all dates will be adjusted by +/- 15 days so that no real dates remain, and the final analytic dataset and documentation will be kept indefinitely.

Individualized clinician feedback reports (for optional MOC QI activity): Copies of feedback reports will be stored on a secure server at the University of Michigan until all feedback calls with clinicians are completed. These reports will then be transferred to the MOC office at the University of Michigan to be managed per MOC procedures.

RD audiorecordings: All audiorecordings of RD-delivered telephone counseling sessions will be securely stored at the University of Michigan. Audiorecordings will be transcribed and coded, and destroyed at the end of the study as a whole. Transcriptions will be retained without identifiers indefinitely.

Clinician video / audiorecordings: All videorecordings and audiorecordings of standardized patient encounters will be stored on a secure server at the University of Michigan, and will be destroyed at the end of the study as a whole.

Final analytic dataset: The final analytic dataset, which will be used for all outcomes analysis, will be stored on a secure server at the University of Michigan for up to 10 years after the end of the study as a whole. This dataset contains HIPAA limited data (including study id, date of birth, date of death, and dates of service for all age-eligible children in all practices), parent survey responses (Intervention arm only), and RD clinical counseling notes (Intervention arm only, scrubbed of any identifiers as described in Section 13c / step 11). At the end of 10 years, all dates will be adjusted by +/- 15 days so that no real dates remain, and the final analytic dataset and documentation will be kept indefinitely.

De-identified dataset: At the end of the study as a whole, the University of Michigan study team will provide AAP/PROS with a full analytic dataset (see "final analytic dataset" above) that has been stripped of all identifiers (study IDs and all dates removed). AAP/PROS will retain this dataset indefinitely on secure servers. The University of Michigan study team will also send this dataset to the Inter-university Consortium for Political and Social Research (ICPSR) as described below.

Public access: A final deidentified dataset will be shared with the scientific community to the extent that this is possible through the ICPSR at the University of Michigan. ICPSR is an ideal data repository, as it maintains strict data storage and confidentiality protocols but also provides generous technical support to users of archived data. More information can be found at https://www.icpsr.umich.edu/icpsrweb/.

17. HIPAA RESEARCH AUTHORIZATION

Will you or any member of your research team collect or have access to any protected health information – PHI (individually identifiable health information that a covered entity creates or receives)? *For information on HIPAA, see "Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule."*

The following are considered identifiers:

- Names
- All geographic subdivisions smaller than a state (street address, city, county, precinct, zip code)
- Telephone numbers and fax numbers
- E-mail addresses
- All elements of dates (except year) including date of birth, admission, discharge, and death
- Social security numbers
- Medical record numbers

- Health plan numbers
- Account numbers
- Certificate / license numbers
- Vehicle ID numbers
- Device identifiers and serial numbers
- Web URLs
- IP address numbers
- Biometric identifiers (finger and voice prints)
- Facial photos / images
- Other unique identifying numbers

☐ NO ➔ Skip to 18.

☒ YES

Which method will you use that allows PHI to be used by researchers according to the HIPAA regulations?

☐	All data are de-identified. **Please explain in this section how the data will be de-identified** (e.g., all 18 elements described in HIPAA will be removed; or a person with appropriate expertise has determined, justified, and documented that the risk is very small that the information could be used alone or in combination with other available information - attach documentation). Explanation:
☒	Limited Data Set. **Please complete and attach, "HIPAA Limited Data Set for Research Request Form"** (*Form can be obtained from the IRB administrator or can be found on the AAP intranet).* CHOP will receive HIPAA limited datasets from PCC, and U. Michigan will receive HIPAA limited datasets from CHOP.
☒	Patient Authorization. **Please attach a consent form that includes the required elements for a valid authorization or a separate stand-alone authorization form.** Parents in the Intervention arm will receive a study information sheet by mail and email which includes all required elements of informed consent and HIPAA authorization (Attachment R); verbal authorization will be obtained via informed consent and HIPAA authorization script for use by RDs and clinicians (Attachment S)
☒	Waiver of Authorization. **Please complete and attach, "HIPAA Waiver for Research Request Form"** (*Form can be obtained from the IRB administrator or can be found on the AAP intranet).* Waiver of HIPAA authorization for recruitment purposes – the University of Michigan will have a Business Associate Agreement (BAA) with PCC (see Attachment F.6), which allows the study team at the University of Michigan to receive a fully identified contact file for the purposes of parent recruitment.
☐	Other. Please describe here.

18. DATA ANALYSIS

Identify primary research questions and provide a brief overview of the analyses (data sources and variables to be used). Detailed statistical plans are NOT needed.

All variables will be examined for out of range values, distributional qualities, and missing values. There is no "one size fits all" solution to violations of distributional assumptions or universal approaches to addressing missing data issues, but as they arise, the experienced data team will meet to discuss available transformations as needed for violations of distributional assumptions, and appropriate (if any) imputation methods for missing data. Any imputations or transformations to the raw data will be carefully documented and be made transparent in any analysis or presentation. Tables comparing intervention versus control groups will be created to assess effectiveness of randomization, and will help determine which additional variables should be included as additional covariates in multivariable analyses.

Analysis of Primary Outcome (AIM 1 –effectiveness among patients of study clinicians trained in MI): The primary outcome is BMI z-score at 2 years from baseline. BMI values will be converted to Z scores using the CDC macro we have used in prior projects (https://nccd.cdc.gov/dnpabmi/Calculator.aspx). A Generalized Linear Mixed Model (GLMM) will be the primary analytic approach where BMI z-score at 2 years is the primary outcome, and a 2 level primary independent variable "TX": Usual Care=0, MI Training=1, along with baseline BMI z score as a covariate. Potential covariates include: days since baseline, sex, age, and ethnicity. The study employs a nested cohort design, with practices assigned to condition, as such, outcome variables at the individual level are correlated. To control for cluster randomization effects (i.e. this induced correlation) we will utilize SAS/PROC MIXED. For all mixed analyses, practice will be treated as a random effect with TX condition nested in practice. Various autocorrelation structures will be tested, although simple unstructured (un) or variance components (vc) will be used for the random practice effect. Dr. Vaughan, our chief statistical consultant, is an expert in mixed models and will guide these analyses for our study analyst. Key potential effect modifiers include age, race, and gender and on the provider level, pediatrician vs. family practitioner.

Analysis of Secondary Outcome (AIM 2 – effectiveness among patients of study clinicians trained in MI and whose parent actively participates in the intervention): Although the primary *intention to treat* analyses described analytically above for Aim 1 will include all patients assigned to groups regardless of intervention exposure, we feel it will be useful, as a secondary analysis, to examine effects among the subsample of children who parents actively participated in the intervention. As indicated, *active participation* is defined as a parent receiving at least 1 MI counseling session from either a trained clinician or registered dietician. The same GLMM modeling approach discussed above will be employed to test this secondary aim.

Analysis of Sub-AIM 2a – dose-response: To further investigate how exposure to the intervention influences change in BMI, we will investigate the dose response relationship. Dose can be computed by the intensity/duration values associated with each CPT code. Dose will be classified in several ways (no exposure versus any exposure) and by type/amount of exposure (PCP only, RD telephone only, and PCP and RD telephone). Within the latter groups we will further categorize patients as above and below threshold which for PCPs is 4 sessions and for RDs 6 sessions. Using these categories we will examine dose response effects using BMI z-score as the outcome using the same GLMM framework described above. In addition, in an effort to understand if there is a monotonic change in the outcome across increasing dose, we will also replace the TX variable in the regression equations with an ordinal variable corresponding to the number of intervention sessions actually received, both among the intervention group only, and then including the control group with ordinal score of zero.

Analysis of AIM 3 – population level effects: To assess the effect of the intervention on the primary outcome at the population level, we will employ a Generalized Linear Mixed Model (GLMM) approach, similar to the analytic plan for AIM I, where BMI z-score at 2 years is the primary outcome, and a 2 level primary independent variable "TX": Usual Care=0, MI Training=1, along with baseline BMI z score as a covariate. Data from all age-eligible children in all participating practices will be included in the analysis.

Revenue Analyses. Although the long term trend in reimbursement suggests models such Accountable Care Organizations, Pay for Performance, and bundled payments will replace traditional fee for service, in the near term it is nonetheless important to understand how obesity related services are reimbursed. Therefore, we will examine obesity counseling-related revenue generated between Intervention arm and Usual Care arm practices using electronic billing data. We will examine any counseling or nutrition therapy CPT events that have an obesity-related diagnosis code (e.g., 783, 280). The actual revenue generated can be determined by applying the contract rate for each CPT code. For example at U of M a 99213 episode is reimbursed at $74.26 from BCBS and $19.07 from Medicaid whereas for a 99214 we receive $108.47 from BCBS and $30.91 from Medicaid. Nutrition therapy by an RD, which is only reimbursed by BCBS, is billed at $35 per 15 minutes. We will obtain the payor rates for all potential obesity-related counseling services for each major payer of our practices. Revenue generated will be compared between groups using mixed effects regression as noted above for BMI z.

RE-AIM analyses and their associated metrics are described below. During grant years 4 and 5 we will continue to monitor intervention implementation (physician and RD counseling rates), reach (parental uptake of MD and RD counseling), and impact (BMI Z) in the initial intervention group as well as the UC group practices that will receive the MI training in grant year 4. This will enable us to determine both long term adoption patterns among the original intervention group as well as document initial implementation among the UC practices. All of these metrics are captured using the data collection instruments described above.

RE-AIM MEASURES

Dimension	Definition	Metrics
Reach	The absolute number, proportion, and representativeness of individuals who are willing to participate in a given initiative, intervention, or program.	Number and proportion of patients recruited per practice and arm; Representativeness of the participants determined by SES and clinical data between those that participate and decline.
Effectiveness	The impact of an intervention	Change in BMI z score at 2 year follow-up.
Adoption	The absolute number, proportion, and representativeness of settings and intervention agents (people who deliver the program) who are willing to initiate a program.	Number and proportion of eligible clinic sites that agree to participate in the program. Representativeness of delivery agents (clinicians) participating in the program compared to other PROS and overall AAP membership
Implementation	At the setting level, implementation fidelity to the various elements of an intervention, including consistency of delivery as intended and the time and cost of the intervention. At the individual level, implementation refers to clients' use of the intervention strategies.	Process indicators such as billing patterns from EHRs; Monitoring fidelity to MI including review of a random selection of calls scored by the MI supervisor, and tracking forms completed after each encounter; Uptake of MI by UC practices based on post-trial EHR data
Maintenance	The extent to which a program/policy becomes institutionalized or part of the routine organizational practices and policies. In addition, maintenance can be applied to the individual-level outcomes 6 + months after the most recent intervention contact.	Individual: BMI Z will be monitored in both Intervention and Usual Care arms through years 4 and 5 Organizational: Clinic billing records in Int and UC practices monitored throughout the study assess if MI strategies are still being employed.

Attrition Analyses. We will compare baseline characteristics of children lost to follow-up (defined as no follow up BMI data at least one year from the baseline value) with cohort members to examine selective or differential attrition. For instance, did children with higher levels of BMI disproportionately drop out of the program before follow-up height/weight assessments? Selective attrition (i.e., do cohort members differ from drop outs for the entire sample) will be considered as a threat to external validity, i.e., generalizability. Presence of differential attrition (difference in drop outs between treatment groups) will be reported as a threat to internal validity.

19. BENEFITS & INCENTIVES

Describe the benefits to the individual. State if there are no direct benefits to individual participants. If subjects will receive compensation or other incentives to participate, describe the incentive, including the amount and timing of all payments.

Clinicians

- During the practice recruitment phase, clinicians interested in learning more about the BMI2+ study may receive small gifts (e.g., pens, water bottles, and thumb drives) at PCC-sponsored conferences
- Participating clinicians will attend an in-person training workshop with all expenses paid. This will occur prior to parent recruitment for Intervention arm clinicians, and will be offered to Usual Care arm clinicians after the conclusion of the 2-year intervention period.
- Board certified pediatricians in both arms will be eligible to receive optional Maintenance of Certification (MOC) Part 2 points and live activity CME credits upon completion of the in-person training workshop.
- Intervention arm clinicians will be eligible to receive optional MOC Part 4 points and performance improvement CME credits for completing an 18-month quality improvement project with repeated feedback cycles.
- Participating clinicians in both study arms will receive training in billing and coding for obesity-related services (in-person for Intervention arm clinicians, and via recorded webinar for Usual Care arm clinicians).
- Intervention Arm practices will be reimbursed $2000 for the research work that is required for being in this study. Specifically, they will receive $500 after participating clinicians (n=1-2) and the study coordinator complete training, another $500 approximately 1 year after the baseline data pull, and $1000 upon completion of the 2-year trial. Usual Care practices will receive ½ of this amount ($250 after completion of study protocol training, $250 approximately 1 year after the baseline data pull, and $500 at the end of the 2-year trial), since they will not need a study coordinator and will not be asked to help enroll or provide MI counseling to eligible parents. On a practice-by-practice basis, the clinicians will decide how to distribute the total remuneration.
- Pediatric clinicians and RDs may experience benefits of in-depth MI training beyond the proposed study period, as MI counseling is applicable to a wide range of health behaviors.
- A less tangible benefit to individual clinicians is that the results of this study could impact training, policy, and reimbursement of obesity care in pediatric primary care practices.

Study coordinators

- Study coordinators in participating Intervention arm practices may receive small gifts (such as pens, water bottles, etc…) as a token of appreciation throughout the study

Parents / children (Intervention Arm only)

- Parents and families may benefit from information on healthy eating, physical activity, and screen time habits.
- All telephone MI counseling sessions with Registered Dieticians (RDs) will be provided free of charge.
- Parents will receive education materials on the study dashboard free of charge (Attachment J).

20. RISKS

Describe the potential risks to the subject and precautions that will be taken to minimize them. Consider the range of risks, including physical, psychological, social, legal, and economic.

Risks to participating clinicians and parents, and to the children of participating parents, will be minimal.

Clinicians

- There may be inconveniences to clinicians in both arms for the time spent completing surveys.
- There may be inconveniences to clinicians in the Intervention Arm for the time spent delivering MI counseling to enrolled parents, and to study coordinators for the time spent completing study procedures.
- Practice staff may experience some risk of discomfort among parents who are uncomfortable discussing weight issues in their family.

Parents / children

- There is a minimal risk of loss of confidentiality, including potential disclosure of a child's personal health information (PHI). As described in Section 16b, we will implement numerous safeguards to avoid any potential breach of such information.
- There may be inconveniences to parents in the Intervention arm for the time spent completing surveys and participating in the MI counseling sessions.
- Parents may be required to pay co-pays for clinician-delivered MI counseling sessions, depending on their insurance plan.
- Parents might experience discomfort discussing their own or their child's weight issues and lifestyle behaviors; the MI training offered to pediatric clinicians is designed to help allay this potential discomfort.
- A theoretical risk for children during the trial is excessive weight loss and / or disordered eating. Although there was no evidence of this in our prior study, our Data Safety and Monitoring Board (DSMB) will monitor these potential adverse reactions. Every 6 months, during a telephone counseling session, RDs will ask four questions that elicit information about disordered eating behaviors and excessive weight loss. The four questions are:

    1) Are you worried at all that your child binge eats or loses control over how much he or she eats?
    2) Are you worried at all that your child is too thin or losing too much weight?
    3) Are you worried at all that your child is preoccupied with his or her body shape or weight?
    4) Are you worried at all that your child is overly restrictive with what he or she eats?

    Clinicians will also ask these questions as needed throughout the 2-year intervention period (based on their clinical judgement).

    The RDs and clinicians will probe positive responses to any of these 4 questions to determine the existence of clinically meaningful disordered eating or excessive weight change. Disordered eating or excessive weight change warranting referral for additional screening or treatment will be considered a potential adverse event.

    If there is any evidence of a possible adverse event, the following steps will be taken:

    1) The RD or clinician will contact the PI within 2 days of becoming aware of such an event. If an RD detects such an event, they will flag this event on the study dashboard, and Dr. Kendrin Sonneville – lead RD on the University of Michigan study team – will call the study coordinator or clinician at the relevant practice within 2 days to alert them of this event.
    2) the PI will contact the AAP project manager, the AAP IRB, the University of Michigan IRB, and the study DSMB.
    3) The DSMB will assess the relationship of the adverse event as not related, possibly related, or definitely related to the intervention using standard criteria for clinical trials. Serious adverse events are highly unlikely in this minimal risk trial, in which no medications are administered. Should they occur, the funder will be notified.
    4) Clinicians will utilize the follow-up / referral plan that they have in place in their practice.

5) Approximately 1 month after alerting the practice to a potential adverse event (see step 1 above), Dr. Sonneville will call the study coordinator or clinician to ensure that the referral was made.

21. ALTERNATIVE TO THE RESEARCH

Describe any alternatives available to the subjects.

Children of parents participating in the study, of those who decline to participate, and of those who withdraw from the study will continue to receive the current standard of medical care from their clinicians. However, it should be noted that HIPAA limited datasets that contain EHR and billing data for all age-eligible children in a practice will be utilized for study analyses, regardless of whether their parent is participating in the study or not.

22. RESEARCH RELATED COSTS

Describe any costs that will be incurred as a result of the research procedures that are over and above what would be incurred by standard treatment (e.g., additional diagnostic tests, additional patient visits, drugs, etc.), and indicate who will be responsible for payment for them.

Parents may be required to pay co-pays for clinician-delivered MI counseling sessions, depending on their insurance plan. These costs will not be covered by the research team.

Practices in the Intervention Arm are required to identify at least 1 study coordinator to facilitate execution of the study within the practice and communication with study team members at AAP/PROS and the University of Michigan. The $2000 incentive is meant to offset this cost, although practices can choose how to allocate those funds.

Clinicians in the Intervention Arm will not be able to see patients, and will not be reimbursed for their time, during the in-person training session. This is clearly stated in the clinician consent form (Attachment D).

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I 23. ASSURANCES:

Principal Investigator:

I agree to follow all applicable federal regulations, guidance, state and local laws related to the protection of human subjects in research, as well as professional practice standards and generally accepted good research practices for lnvestigators, including. but not limited to, the responsibilities described in AAP IRB Policy and Procedures Manual - Responsibilities of Principal Investigators.

I verify that the information provided in this Application for Initial Review of Human Subjects Research is accurate and complete. I will initiate this research only after having received written notification of final IRB approval.

	6/5/17
Principal Investigator	**Date**
	6-6 17
	Date
AAP Senior Vice President	7/6/17 **Date**
AAP Chief Compliance Officer	:t/w/fr **Date**

REVIEW CATEGORIES

Research activities in which the *only* involvement of human subjects will be in one or more of the following categories may be reviewed by the Institutional Review Board through the expedited review procedure.

Research Categories

1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

   (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
   (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

   (a) From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
   (b) From other adults and children considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3) Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) Hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive that routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5) Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis.) (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

6) Collection of data from voice, video, digital, or image recordings made for research purposes.

7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance

methodologies. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.101 (b)(2) and (b)(3). This listing refers only to research that is not exempt.)

8) Continuing review of research previously approved by the convened IRB as follows:
   (a) Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
   (b) Where no subjects have been enrolled and no additional risks have been identified; or
   (c) Where the remaining research activities are limited to data analysis.

9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

LIST OF ATTACHMENTS

A. Human subjects training certificates for study team (removed for CT.gov)
B. Clinician eligibility survey
C. Study participation form
D. Clinician obesity experience survey
E. Clinician consent form
F. Data Use Agreement (DUAs), Data Transfer Agreement (DTA), and Business Associate Agreement (BAA)
    - F.1 Diagram of required DUAs, DTA, and BAA
    - F.2 AAP-practice BMI2+ Study DUA
    - F.3 Existing PCC-practice BAA
    - F.4 University of Michigan-CHOP BMI2+ Study DUA
    - F.5 University of Michigan-practice BMI2+ Study DTA
    - F.6 University of Michigan-PCC BMI2+ Study BAA
    - F.7 PCC-practice BMI2+ Study addendum to existing BAA
G. Data flow and protection of data
    - G.1 Diagrams of data flow at baseline, during the 2-year intervention period, and at the end of the 2- year intervention period and end of study as a whole
    - G.2 Protection of data
H. Data transfer checklists
    - H.1 PCC-CHOP
        - H.1a PCC attestation for HIPAA limited dataset to CHOP at baseline, end of 2-year intervention period, and end of study as a whole
    - H.2 PCC-University of Michigan
        - H.2a PCC attestation for fully identified contact file to University of Michigan at baseline
    - H.3 University of Michigan attestation for 1) deletion of identifying content from RD clinical counseling notes and 2) contact information after post-intervention period adverse event monitoring is complete
    - H.4 University of Michigan attestation for deletion of contact information for parents who opt out, refuse to participate, cannot be contacted, or withdraw from the study
I. Process to prevent data breach and to report breach should one occur
    - I.1 PCC-CHOP
    - I.2 PCC-University of Michigan
J. Parent education materials
K. Parent baseline brief survey
L. Parent baseline extended survey
M. RD counseling guide
N. Parent follow-up survey
O. Study paragraph for PCC
P. Recruitment flyer
Q. Introductory letter to parents
R. Parent study information sheet

S. Verbal consent and HIPAA authorization scripts
    - S.1 Script for RDs
    - S.2 Script for MDs
T. Study information sheet for non-participating clinicians
U. HIPAA limited dataset for research request form
V. HIPAA waiver of authorization requirement request form
W. Alteration of informed consent request form

ATTACHMENT B

Clinician Eligibility Survey

Clinician Eligibility Survey

Please answer the questions below and return this form to AAP PM, PhD via email (mwright@aap.org and cc to prosops@aap.org) or fax (847-434-8910).

Clinician name: _____

1. Have you received training in Motivational Interviewing within the past 10 years?

   ☐No

   ☐Yes ➔ Approximately how many hours of MI training did you receive? _____

2. How skilled do you currently feel in Motivational Interviewing?

   ☐ ☐ ☐ ☐ ☐ ☐

   0 1 2 3 4 5

   Not at all Extremely

3. Do you currently work 6 or more sessions per week (> half time)?

   ☐No

   ☐Yes

4. Will you have you been employed by your current practice for at least 1 year on or before July 1, 2017?

   ☐No

   ☐Yes

5. If your practice is randomized to the Intervention arm, which of the following in-person training sessions - held from Friday at 12 pm through Sunday at 12 pm in the Chicagoland area - can you attend?

   *Please select **ALL** dates that you are available.*

   ☐October 13-15, 2017

   ☐November 3-5, 2017

   ☐Neither of these

ATTACHMENT C

Study Participation Form

Study Participation Form

Please check "Yes" or "No" to participation and return this form to AAP PM, PhD via email (mwright@aap.org and cc to prosops@aap.org) or fax (847-434-8910), even if your practice decides not to participate.

☐ Yes, my practice is interested in participating in the BMI^{2+} Study

→ Please complete all questions below

☐ No, my practice does not want to participate in the BMI^{2+} Study

→ Please complete the "Practice Information" section only (so we know who to remove from our list)

Practice Information

Practice name: _____

Address: _____

Phone: _____ Fax: _____

Email: _____

Authorized signatory name: _____

Phone: _____ Email:_____

Please list up to 2 providers (MDs, NPs, DOs, PAs that work > half time) that are interested in participating in the study.

Name: _____ Degree: __ Email: _____

Name: _____ Degree: __ Email: _____

Please designate a study coordinator to help facilitate study execution within your practice and communicate with the research team.

Name: _____ Email: _____

Best time to contact: _____

Does your practice offer a comprehensive weight loss program and / or Registered Dietician services?

☐ Yes

☐ No

The BMI^{2+} study has been approved by the American Academy of Pediatrics (AAP), University of Michigan, and Children's Hospital of Philadelphia Institutional Review Boards.

Some practices (typically hospital or university-based) may need to obtain local IRB approval before the study can begin in that practice.

Please check a response in the box below to indicate whether or not your practice requires local IRB approval.

☐ Local IRB approval is *not* required.

☐ Local IRB approval *is* required in my practice

- ☐ An IRB Authorization Agreement is sufficient – we can rely on the American Academy of Pediatrics' IRB to provide oversight of this study
- ☐ We will need to submit an application to our local IRB

ATTACHMENT D

Clinician Obesity Experience Survey

Clinician Obesity Experience Survey

Please answer the questions below and return this form to AAP PM, PhD via email (mwright@aap.org and cc to prosops@aap.org), fax (847-434-8910), or US mail.

Clinician name: _____

Practice name: _____

THE FOLLOWING QUESTIONS APPLY TO CHILDREN AGED 2 YEARS AND OLDER

1. How often do you or your staff do the following at well child visits?

Please select ONE response for EACH item.

	Never	Rarely	At some well visits	At most well visits	At every well visit
Calculate BMI	☐	☐	☐	☐	☐
Plot BMI on an age and sex appropriate growth curve	☐	☐	☐	☐	☐
Visually assess for overweight/obesity	☐	☐	☐	☐	☐

2. For each of the following topics, please indicate whether you or your staff discuss the topic with all patients, only those with overweight/obesity, or generally do not discuss during well child visits.

Please select ONE response for EACH topic.

	Discuss with **all** patients (regardless of weight status)	Discuss **only** with patients with overweight/ Obesity	Generally don't discuss
Amount of sugar-sweetened beverages consumed	☐	☐	☐
Frequency of eating fast foods/eating out	☐	☐	☐
Eating meals together as a family	☐	☐	☐
Being physically active	☐	☐	☐
Amount of TV, computer, cellphone, and video game time	☐	☐	☐
Parent and child roles in food selection and consumption	☐	☐	☐
Positive role modeling by parents for nutrition and activity	☐	☐	☐

3. Which of the following do you do when you identify a child with (A) overweight, (B) obesity without complications, and (C) obesity with complications:

Please select Yes or No in EACH column for EACH topic.

	(A) Overweight (between 85th and 95th percentile)		(B) Obesity (≥95th percentile) **without complications**		(C) Obesity (≥95th percentile) **with complications**	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**
Monitor BMI more frequently	☐	☐	☐	☐	☐	☐
Evaluate for obesity-related comorbid conditions more frequently	☐	☐	☐	☐	☐	☐
Assess readiness for changing behaviors	☐	☐	☐	☐	☐	☐
Conduct follow-up visits focusing on behaviors that the patient/family identify as important	☐	☐	☐	☐	☐	☐
Refer to a dietitian	☐	☐	☐	☐	☐	☐
Refer to a weight management program in the community (e.g., YMCA, Weight Watchers)	☐	☐	☐	☐	☐	☐
Refer to a weight management program in a hospital or clinical setting	☐	☐	☐	☐	☐	☐

4. How strongly do you agree or disagree with the following statements on obesity prevention and management?

Please select ONE response for EACH statement.

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
Pediatricians can help prevent childhood obesity	☐	☐	☐	☐	☐
Parents/patients are not interested in addressing obesity	☐	☐	☐	☐	☐
Pediatricians should address pediatric obesity at well child visits	☐	☐	☐	☐	☐
Pediatricians should counsel parents on avoiding restrictive and/or permissive practices around food at well child visits	☐	☐	☐	☐	☐
There is little that pediatricians can do to treat/manage patients with obesity	☐	☐	☐	☐	☐
There are effective means of treating pediatric obesity	☐	☐	☐	☐	☐
Clinical management of children with obesity should vary by the severity and/or presence of comorbidities	☐	☐	☐	☐	☐
Time constraints make treatment, including counseling, difficult	☐	☐	☐	☐	☐

5. How strongly do you agree or disagree with the following statements about counseling on and treating childhood obesity?

Please select ONE response for EACH statement.

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
I do not want to offend families by talking about weight	☐	☐	☐	☐	☐
There is adequate time during preventive care visits to counsel on overweight and obesity	☐	☐	☐	☐	☐
There is a lack of adequate services/resources in my practice area to refer children/families for weight management	☐	☐	☐	☐	☐
I am unfamiliar with billing codes for obesity counseling/treatment	☐	☐	☐	☐	☐
I am usually paid by insurers for obesity counseling as part of a follow-up visit distinct from regular well child care	☐	☐	☐	☐	☐
There is insufficient payment by insurers for obesity counseling	☐	☐	☐	☐	☐
I am usually paid by insurers for obesity treatment as part of a follow-up visit distinct from regular well child care	☐	☐	☐	☐	☐
Dietitian services are generally not covered by health insurance	☐	☐	☐	☐	☐
Weight management programs are generally not covered by health insurance	☐	☐	☐	☐	☐
Many of my patients are not able to pay for uncovered services	☐	☐	☐	☐	☐

6. Please select one response for each of the questions listed below:

	Not at all	Slightly	Somewhat	Very
Overall, how well prepared do you feel you are to counsel patients and their parents about obesity?	☐	☐	☐	☐
How comfortable do you feel discussing obesity with patients with obesity and their parents?	☐	☐	☐	☐
How effective do you think your counseling on ***prevention*** of obesity is among patients and their parents?	☐	☐	☐	☐
How effective do you think your counseling on obesity ***management*** is among your patients and their parents?	☐	☐	☐	☐
How comfortable are you using behavior change techniques like motivational interviewing in the treatment of obesity?	☐	☐	☐	☐
How comfortable are you monitoring behavior change goals of patients with obesity?	☐	☐	☐	☐

7. How would you rate your ability to perform the following?

Please select ONE response for EACH topic.

	Poor	Fair	Good	Very good	Excellent
Take family history of overweight and obesity	☐	☐	☐	☐	☐
Begin the discussion of overweight/obesity in the clinical visit	☐	☐	☐	☐	☐
Assess behaviors (e.g., nutrition, activity, screen time/sedentary, sleep)	☐	☐	☐	☐	☐
Evaluate for obesity-related medical comorbid conditions	☐	☐	☐	☐	☐
Evaluate for obesity-related psychosocial comorbid conditions (e.g., teasing, bullying, depression)	☐	☐	☐	☐	☐
Counsel families on healthy behaviors	☐	☐	☐	☐	☐
Use motivational interviewing/shared decision-making strategies for behavior change	☐	☐	☐	☐	☐

THESE NEXT QUESTIONS ARE ABOUT YOU.

We are interested in learning more about you. We will use this information to study whether clinician characteristics are linked with the approach(es) they take to treating overweight and obese pediatric patients.

1. How many years have you been practicing pediatrics?
- ☐ 1 year or less
- ☐ 2-4 years
- ☐ 5-7 years
- ☐ Greater than 7 years

2. Which gender do you identify with?
- ☐ Male
- ☐ Female
- ☐ Non-binary / third gender
- ☐ Prefer to self-describe: _____
- ☐ Prefer not to say

3. How old are you?
- ☐ 18-24
- ☐ 25-34
- ☐ 35-44
- ☐ 45-54
- ☐ 55-64
- ☐ 65-74
- ☐ 75+

4. **Are you Hispanic, Latino/a, or Spanish origin?**
   - ☐ Yes
   - ☐ No

5. **How would you describe your racial or ethnic background?** ***Check all that apply.***
   - ☐ American Indian or Alaska Native
   - ☐ Asian
   - ☐ Black or African American
   - ☐ Native Hawaiian
   - ☐ Other Pacific Islander
   - ☐ White
   - ☐ Other: _____

6. **Would you say that in general your health is poor, fair, good, very good, or excellent?**
   - ☐ Poor
   - ☐ Fair
   - ☐ Good
   - ☐ Very good
   - ☐ Excellent

Thank you for taking the time to answer these questions. We greatly appreciate it. Your answers will be very helpful to us.

ATTACHMENT E

Clinician Consent Form

Clinician Consent for Participation

Study Title: Population Effects of Motivational Interviewing on Pediatric Obesity in Primary Care (BMI^{2+})
Principal Investigator: Ken Resnicow PhD
Funder: National Heart, Lung, and Blood Institute (Grant #1R01HL128231)

Introduction

This consent form describes a research study and what to expect if you decide to participate. You are encouraged to read this consent form carefully and ask any further questions before making your decision about whether or not to participate. This study is being conducted by Dr. Ken Resnicow – Professor of Health Behavior and Health Education at the University of Michigan School of Public Health – and the American Academy of Pediatrics (AAP) / Pediatric Research in Office Settings (PROS) Network. It has been approved by the AAP Institutional Review Board (IRB).

We are recruiting up to 2 clinicians from each of 18 pediatric primary care practices across the US to participate in this study. You are being asked to participate because your practice uses the Physician's Computer Company (PCC) Electronic Health Record system.

Purpose of Study

The overall goal of this study is to test the effectiveness of Motivational Interviewing – a patient-centered behavioral counseling approach – delivered by clinicians and Registered Dietitians to parents of overweight or obese children 3-8 years old on child health outcomes. The study will last 2 years.

Main Outcomes

Data collected during this study will be used to study the effectiveness of the intervention versus usual care on body mass index (BMI), and will answer two overarching questions:

- Can visits with MI-trained clinicians and RDs help parents reduce their child's BMI?
- If some clinicians in a practice are trained in MI, is there an overall effect at the practice level on child obesity?

Practice Inclusion Criteria

Pediatric primary care practices that utilize the PCC Electronic Health Record system. Practices randomized to the Intervention arm must also assign a member of their office staff as study coordinator for this project.

Practice Exclusion Criteria

Practices are ineligible if a comprehensive weight loss program and / or access to a Registered Dietitian is offered at the practice. Making referrals for either of these services is not an exclusion criterion.

Clinician Exclusion Criteria

Clinicians are ineligible if they received $\geq$ 1 day of training in Motivational Interviewing within the last 10 years, and / or previously participated in the American Academy of Pediatrics' BMI^2 (Brief Motivational Interviewing to Reduce Child BMI) or HLS (Healthy Lifestyles Study) studies.

Study Procedures for Both Arms

If you/your practice decides to participate in this study, you (and / or a member of your care team) will be asked to:

1. Provide written, informed consent
2. Complete and return PROS intake forms
3. Complete and return surveys
    - Eligibility survey (baseline only)
    - Obesity experience survey (baseline and end of intervention period)
4. Work with PROS to complete IRB procedures as appropriate for your practice (rely on AAP IRB or seek local IRB review and approval). PROS will provide protocol language and assistance with applications to local IRBs.
5. Complete the Individual Investigator Agreement (IIA), verifying Human Subjects training, which is required for all PROS studies
6. Enter into a Data Use Agreement with the AAP, which allows PCC to securely share a HIPAA limited electronic dataset about your practice and patients with the data coordinating center at The Children's Hospital of Philadelphia (CHOP) for purposes of this study
7. Enter into a Data Transfer Agreement with the University of Michigan, which, in conjunction with parent consent and HIPPA authorization, allows for the free exchange of study related and clinical information between your practice, RDs, and the study team at the University of Michigan.
8. Agree to be randomized to one of two study arms – Intervention or Usual Care

Additional Study Procedures for Practices Randomized to the Intervention Arm

9. Have the assigned study coordinator in your practice receive training about study procedures by phone
10. 1-2 clinicians must participate in an all-expenses paid 2 ½ day training workshop. Two identical workshops will be held in fall 2017. During the workshop, you will:
    a. Receive training in Motivational Interviewing, behavioral therapy, obesity treatment guidelines, coding and billing for obesity-related services, and study procedures
    b. Have your skills assessed using a videotaped standardized patient encounter
        i. Participate in one additional standardized patient encounter, over the phone, approximately 6 months after the training workshop
    c. Receive CME and MOC Part II credits upon completion of the training workshop, should you desire
11. Review a list of your patients that the study team has identified as eligible, and make further exclusions based on your clinical judgement and knowledge
12. Agree to have PCC securely share your eligible patients' contact information with the study team at the University of Michigan. *Note that the University of Michigan will have a Business Associate Agreement (BAA) with PCC, allowing them to receive and use such data for recruitment purposes.*
13. Agree to share your practice letterhead and have study team members at the University of Michigan send an introductory letter, on your practice letterhead, to families of eligible children in your practice.

14. At office visits, help recruit* up to 50 parents (per practice) of children that are overweight or obese and 3-8 years of age to participate in the study. Parent recruitment involves:
    d. Briefly reviewing the introductory material described in # 12 above with parents
    e. Obtaining verbal consent and HIPAA authorization and documenting them in the EHR

    **We anticipate that the vast majority of parent enrollment and consent / HIPAA authorization will occur over the phone with Registered Dietitians located at the University of Michigan.*

15. Schedule up to four 15-minute Motivational Interviewing counseling sessions in your office with participating parents over the course of 2 years. If you wish, utilize behavioral goals identified and prioritized by parents during RD counseling sessions to inform your own MI counseling sessions.

16. Receive electronic or hardcopy RD-generated clinical counseling notes on a recurring basis from the University of Michigan.
    f. RDs will be trained in MI and conduct up to 6 telephone counseling sessions with participating parents over the course of 2 years.
    g. RD clinical notes are generated after their counseling sessions, and capture any clinical concerns or improvements, as well as health goals (and progress therein) identified by parents for their children.
    h. RD clinical notes will be sent to your study coordinator to upload into the EHR.
    i. Should you desire, you can utilize the behavioral goals identified and prioritized by parents during RD calls to inform your own MI counseling sessions.

17. Decide whether to participate in the optional Maintenance of Certification (MOC) Part IV quality improvement project and Performance Improvement CME.

Additional Study Procedures for Practices Randomized to the Usual Care Arm

9. Receive training about study procedures, coding and billing for obesity-related services, and current obesity treatment guidelines via phone and webinar

10. 1-2 clinicians in your practice can participate in an in-person, all-expenses paid training workshop at the conclusion of the intervention period. PARTICIPATION IS OPTIONAL. During the workshop, you will:
    a. Receive training in Motivational Interviewing and behavioral therapy
    b. Have your skills assessed using a videotaped standardized patient encounter
    c. Receive CME and MOC Part II credits upon completion of the training workshop, should you desire

Risks of Participation

The risks of participation are minimal and include:

- Time required to attend in-person MI training sessions. During this workshop, you will not be able to see patients and will not be remunerated for your time. Note that all travel and training costs will be paid for by the study.
- Time required to complete surveys
- Time required to help enroll parents of eligible children, deliver MI counseling sessions to participating parents, and complete other study procedures as necessary (Intervention arm only)
- Loss of confidentiality. There is a minimal risk of loss of confidentiality, including potential disclosure of a child's personal health information (PHI). We will implement numerous safeguards to avoid any potential breach of information.

Benefits of Participation

- All expenses paid, extensive, in-person training in Motivational Interviewing, billing, and best practices in pediatric obesity management / treatment
    - Maintenance of Certification (MOC) Part II and CME credits available (optional)
    - Potential improvements in reimbursement for obesity-related services
    - Benefits of training may extend beyond the study, as MI is applicable to a wide range of health behaviors
- MOC Part IV and performance improvement CME credits available for clinicians in the Intervention arm that chose to participate in a quality improvement project (optional)

Additional Costs

There will be no additional costs to you to participate in this research study.

Practice Compensation*

	Usual Care arm	**Intervention arm**
Upon completion of in-person (Intervention arm) or telephone / webinar (Usual Care arm) training	$250	$500
12 months after baseline data pull	$250	$500
Upon completion of the intervention period	$500	$1000

*Note that Usual Care arm practices receive less compensation since they will not need a study coordinator nor will be asked to help enroll or provide MI counseling to eligible parents.

Confidentiality of Records

While we make every effort to maintain confidentiality, it cannot be absolutely guaranteed. Comprehensive measures will be implemented to maintain patient, clinician, and staff confidentiality. Records which identify you and the consent form signed by you may be inspected by a regulatory agency and/or the American Academy of Pediatrics. The results of this research study may be presented at meetings or in publications; however, your name will not appear in any such documents.

All clinician consent forms, surveys, and any other hard copy study-related materials will be kept in a secured location at the American Academy of Pediatrics for 10 years following the completion of the study as a whole and then destroyed. Data from these forms will be entered into and stored in an electronic analytic file, without names or any other identifiers, indefinitely. You will be identified in EHR and billing data using a unique clinician identifier, never by name. The file that links your unique clinician ID with your name and practice will be maintained by PCC and only shared with study team members at the University of Michigan. Video- and audio-recordings of standardized patient encounters that you participate in during Motivational Interviewing training sessions will be stored securely at the University of Michigan, and will be destroyed at the end of the study as a whole.

All patients will be assigned a unique study identifier. Their contact information will be maintained by PCC and shared only with study team members at the University of Michigan (for the purposes of recruitment and intervention delivery). This contact file will be destroyed after the intervention period has ended. Parent survey data and RD clinical counseling notes (scrubbed of any identifying content) will be stored in an

electronic analytic file at the University of Michigan indefinitely. Telephone counseling sessions between parents and RDs will be audiorecorded for training purposes only; these recordings will be transcribed and coded, and then destroyed. Transcriptions will be retained without identifiers indefinitely.

Additionally, a description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Voluntary Participation

Participation in this study is voluntary. You are free not to participate or to withdraw at any time, for whatever reason. If you do withdraw from this study, the information you have already provided may continue to be used for study purposes.

Contact Persons

If you have any additional questions or concerns about the study, you may contact:

- Ken Resnicow, PhD at (734) 647-0212 – Principal Investigator
- Erin Kelly, PhD at (847) 434-4075 – AAP Institutional Review Board (IRB) Administrator

Participant Consent

I have read the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a copy of this form for my records and future reference.

Study Participant (Print Name): _____

Study Participant (Signature): _____ Date: _____

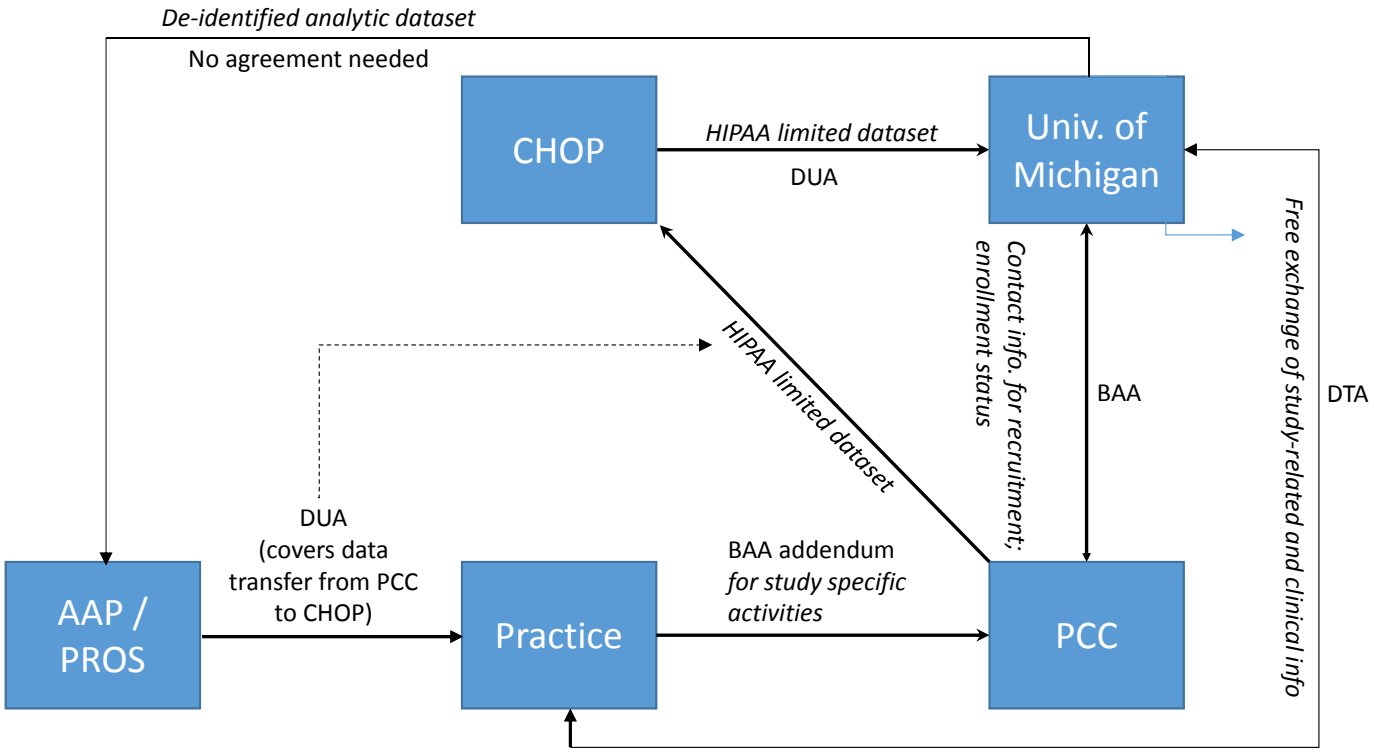
Please return a signed copy of this form to AAP PM, PhD via email (mwright@aap.org and cc to prosops@aap.org), fax (847-434-8910), or US mail. Please keep one copy for your files.

ATTACHMENTS F.1-F.7

F.1	Diagram of Required DUAs, DTA, and BAA
F.2	AAP-practice BMI2+ Study DUA
F.3	Existing PCC-practice BAA
F.4	University of Michigan-CHOP BMI2+ Study DUA
F.5	University of Michigan-practice BMI2+ Study DTA
F.6	University of Michigan – PCC BMI2+ Study BAA
F.7	PCC-practice BMI2+ Study addendum to existing BAA

Attachment F.1

Diagram of Data Use Agreements(DUAs), Data Transfer Agreement (DTA), and Business Associate Agreements (BAAs) for the BMI2+ Study



American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

American Academy of Pediatrics
Pediatric Research in Office Settings (PROS)
DATA USE AGREEMENT
Award #: 1R01HL128231-01A1 **Grant #:** RO1HL128231
Study Title: Population Effects of Motivational Interviewing on Pediatric Obesity in Primary Care (BMI^{2+})

This Agreement is effective on _____, 20____, and is made between «PracName» and the **American Academy of Pediatrics**, an Illinois not-for-profit corporation ("AAP") ("Recipient").

Pursuant to federal law, ***«PracName»***, as a Covered Entity, is not permitted to authorize fully-identified health information to be used by, or disclosed to, the Recipient. In accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule Regulations, the Recipient may use, or ***«PracName»*** may disclose to the Recipient, a Limited Data Set of information, for research, public health, or healthcare operations purposes. **«PracName»** is permitted to authorize the use or disclosure of a Limited Data Set of health information by the Recipient only if it first obtains a Data Use Agreement from Recipient.

Background:

In the execution of this Data Use Agreement, the Covered Entity is authorizing the Physician's Computer Company (PCC) ("Data Transfer Agent") to extract and transfer to the Data Recipient(s) a limited dataset (as defined in the HIPAA Privacy Regulation described in Section 1 below), comprised of the defined patient-level data elements included in this agreement (and the date associated with each data element), derived from the electronic medical record and other data sources under the authority of the Covered Entity, using secure HIPAA-compliant data transfer processes. The recipient is contractually bound to observe the obligations and parameters of authority as delineated in Section 3 below.

All limited datasets acquired under this data use agreement can be analyzed by the research study team: The American Academy of Pediatrics (AAP) and The Children's Hospital of Philadelphia, a Pennsylvania nonprofit corporation ("CHOP"). CHOP has agreed to adhere to the same restrictions and conditions that apply through this Agreement, with respect to such information

THEREFORE, in consideration of the mutual covenants contained in this Agreement and intending to be legally bound hereby, the parties agree as follows:

Section 1. Definitions

(a) A Limited Data Set consists of health information that has had all direct identifiers concerning the subject of the record (and his or her employer, family, and household members) deleted, that is, the information excludes all of the following:

(i) names;
(ii) postal address information other than town or city, state, and zip code;
(iii) telephone numbers;
(iv) FAX numbers;
(v) electronic mail addresses;
(vi) social security numbers;
(vii) medical record numbers;
(viii) health plan beneficiary numbers;
(ix) account numbers;
(x) certificate/license numbers;
(xi) vehicle identifiers and serial numbers, including license plate numbers;
(xii) device identifiers and serial numbers;
(xiii) web universal resource locators (URLs);
(xiv) internet protocol (IP) address numbers;
(xv) biometric identifiers, including finger and voice prints;
(xvi) full-face photographic images and any comparable images.

(b) Terms used, but not otherwise defined, in this Agreement shall have the same meaning as those terms in the HIPAA Privacy Regulations, 45 C.F.R. 160.103 and 164.501.

Section 2. Scope and Purpose

2a. Data Extraction Study:

Except as otherwise specified herein, Data Recipient, American Academy of Pediatrics (AAP) may make all Uses and Disclosures of the Limited Data Set necessary to conduct the research described herein: to compare the effectiveness of a clinician- and dietician delivered Motivational Interviewing intervention versus usual care on child health outcomes in pediatric primary care practices across the US. The BMI^{2+} intervention involves training pediatric clinicians and registered dieticians (RD) in Motivational Interviewing (MI), and subsequent delivery of up to 10 MI-counseling sessions to parents of overweight or obese youth 3-8 years old at enrollment. ("Research Project").

2b. Scope:

Patient Cohort: Data will be extracted from the electronic medical record and other data sources under the authority of the Covered Entities' electronic record(s) for patients meeting the following criteria:

All patients who are at least 3, but not yet 8, years of age on the date of the baseline data pull.

After the initial data extraction (which will include data from 24 months prior to the initial pull up to, and including the date of the initial pull), we will conduct data pulls as needed, throughout the course of the project (5/31/2021). We expect that these data pulls will occur at the end of the intervention period, and again at the end of the study as a whole.

Data Elements: The following clinical and billing data elements will be extracted from the practice EHR and other data sources under the authority of the Covered Entity.

HIPAA limited dataset

1. A unique study-specific patient identifier, which must be unique across all patients in the study – created by PCC for this study.
2. A unique study-specific clinician identifier, which must be unique across all clinicians in the study – created by PCC for this study.
3. A unique study-specific practice identifier, which must be unique across all practices in the study – created by PCC for this study.
4. Patient sex. This may be retrieved from a patient-level record in the EHR, rather than an encounter-specific record.
5. Patient date of birth.
6. Patient date of death.
7. Unique encounter identifier. The practice will assign this value, which must be unique across all data extracted from that practice.
8. Practice type or department of encounter.
9. Date of visit.
10. Race
11. Ethnicity
12. Payor. Insurance payor category at time of visit.
13. Patient's height (ideally in cm)
14. Patient's weight (ideally in kg)
15. All systolic and diastolic blood pressure readings
16. All growth measurements and all vital signs
17. Diagnoses associated by a clinician with the encounter using an ontology such as ICD9 or ICD10.
18. All associated Evaluation & Management billing codes, encounter dates, ICD9 codes, other vendor or nomenclature specific code such as IMO, ICD10, SNOMED, and billed CPT codes.
19. Priority of diagnoses. For each diagnoses extracted, a notation will be made of whether it was a primary or secondary diagnosis for the encounter. If the EHR does not distinguish between primary and other diagnoses, all diagnoses will be considered primary.
20. Medication code(s) present anywhere in the EHR and other data sources under the authority of the Covered Entity (e.g., prescriptions, medication list) according to The National Drug Code (NDC) System – a system providing all drugs in the United States with a specific 11-digit number that describes the product.
    (a) Medication name,
    (b) Quantity to give per administration in milligrams,
    (c) Route of administration,
    (d) Number of times to administer per day,

(e) Number of hours between administrations,
(f) Indication whether or not this med is to be administered on an "as needed" basis,
(g) Amount dispensed,
(h) Number of refills permitted,
(i) Start and end date of prescription,
(j) Preferred medication descriptor for this medication formulation,
(k) Generic name for medication including dose formulation,
(l) Pharmaceutical class,
(m) Pharmaceutical sub-class, and
(n) Therapeutic class
(o) Information about prescription filled (dates fulfilled)

21. Problem list
    (a) Date problem was noted
    (b) Date problem was resolved
    (c) Text description of the diagnosis code
    (d) Past medical history
22. Family medical history when available (no open text fields / notes will be extracted)
23. All allergies noted in the EHR.
24. Immunization data
    (a) Codes for vaccine administered
    (b) Vaccine name
    (c) Date administered
    (d) Status, such as given, abstracted, not done, deleted
25. The following lab information, as well as associated dates of service:
    (a) Basic metabolic panel (BMP)
    (b) Hepatic/liver function test
    (c) Glycated hemoglobin (HbA1c)
    (d) Lipid profile
    (e) Pancreatic enzymes
    (f) Complete blood count (CBC) with differential
    (g) Coagulation tests
    (h) Thyroid Function Tests (TFT)
    (i) Magnesium (Mg++)
    (j) Phosphorous
    (k) Calcium
    (l) Iron studies
    (m) Vitamin D studies
    (n) Other obesity-related labs (e.g., insulin, pre-albumin, and related tests)
    (o) Urinanlysis (UA) results
26. Referral orders
27. Study-specific patient status flags, as well as associated dates
28. Study arm assignment

Section 3. Obligations and Activities of Recipient

American Academy of Pediatrics (AAP) shall:

(a) not use or further disclose the Limited Data Set other than as permitted or required by this Agreement or by law;

(b) not re-identify a Limited Data Set, nor attempt to contact any individual who is the subject of a Limited Data Set provided to Recipient, except as allowed by explicit parent/legal guardian consent and HIPAA authorization, or as permitted by law;

(c) use appropriate safeguards to prevent the use or disclosure of the Limited Data Set, other than as provided for by this Agreement;

(d) promptly report in writing to PROS member practice and the AAP IRB any use or disclosure of the Limited Data Set not provided for by this Agreement of which the Recipient becomes aware; and

(e) ensure that any agent, including a subcontractor, to whom the Recipient provides Limited Data Set agrees to the same restrictions and conditions that apply through this Agreement to Recipient with respect to such information.

Section 4. Permitted Uses and Disclosures by Recipient

Except as otherwise limited in this Agreement, Recipient may use or disclose Limited Data Set only for the purposes identified in subsequently submitted and mutually agreed upon addenda. All limited datasets acquired under this data use agreement can be analyzed by the research study team: The American Academy of Pediatrics (AAP) and The Children's Hospital of Philadelphia, a Pennsylvania nonprofit corporation ("CHOP").

Section 5. Obligations and Activities of Covered Entity *«PracName»*

«PracName» shall:

(a) The Covered Entity may use or disclose a limited data set that meets the definition provided herein if the Covered Entity enters into this data use agreement with the data recipient.

(b) The Covered Entity is exempt from the Accounting of Disclosures Policy for disclosures of a limited data set.

(c) The Covered Entity may use or disclose a limited data set only for the purposes of research, public health or health care operations.

Section 6. Term and Termination

(a) Term. This data use agreement will remain in effect from the date of execution until May 31, 2021 unless otherwise cancelled in writing by either the covered entity or the American Academy of Pediatrics.

(b) Termination for Cause. Upon ***«PracName» or recipient*** knowledge of a pattern of activity or practice of the Recipient that constitutes a material breach or violation of this Agreement, recipient shall attempt to directly cure, or cause the cure of, the breach or end the violation. If unsuccessful, both parties agree to the discontinued disclosure of PHI and agree to report the problem as required by law.

Section 7. Other Terms and Conditions

(a) Regulatory References. A reference in this Agreement to a section in the HIPAA Privacy Regulations means the section in effect, or as amended.

(b) Amendment. The parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for all parties to comply with the requirements of the HIPAA Privacy Regulations and the Health Insurance Portability and Accountability Act, Public Law 104-191.

(c) Survival. The obligations of Recipient under Sections 2, 3, 4 and 7(e) of this Agreement shall survive the termination of this Agreement.

(d) Interpretation. Any ambiguity in this Agreement shall be resolved to permit all parties to comply with the HIPAA Privacy Regulations.

(e) Indemnity. The Recipient shall defend, indemnify, and hold harmless ***«PracName»*** (including trustees, directors, officers, staff, employees, agents, and affiliates) from and against any and all liability, damages, expenses, fees (including reasonable attorney's fees), costs, and fines (collectively called "Liability") arising from Recipient's breach or violation of this Agreement, except to the extent the Liability is attributable to ***«PracName»'s*** illegal, negligent, or willful misconduct.

(f) Modification. This document states the entire agreement between the parties regarding Limited Data Sets exchanged between all identified parties. It may not be amended or modified except through a later written agreement, signed by both parties, and expressly referencing this Agreement.

(g) Data Retention and Destruction. All data will be kept on secure computers for up to 10 years after the end of the study as a whole. At the end of 10 years, all dates for an individual will be randomly adjusted by +/- 15 days so that no real dates will remain in the dataset and that dataset will be kept indefinitely.

(h) Dispute Resolution. The parties agree that any cause of action arising out of or related to the data must commence within one year after the cause of action arose; otherwise such cause of

action is permanently barred. This Agreement shall be governed by and interpreted in accordance with the laws of Illinois (excluding conflict of laws rules thereof). All disputes under this Agreement will be resolved in the applicable state of federal courts of Illinois.

<<PracName>>

Authorized Practice Signatory:

Name: _____

Title: _____

Signature: _____

Date: _____

Recipient Signatory:

Organization: American Academy of Pediatrics (AAP)

Name: V. Fan Tait, MD FAAP

Title: Chief Medical Officer and Senior Vice President, Child Health and Wellness

Signature: _____

Date: _____

Business Associate Agreement between (ACRO) and Physician's Computer Company

1) This Agreement is entered into by Physician's Computer Company and ACRO to set forth the terms and conditions under which protected health information ('PHI') created, received, or maintained by Physician's Computer Company on behalf of ACRO may be used or disclosed. All terms used in this Agreement have the same meaning as they have in the Health Insurance Portability and Accountability Act of 1996 and regulations thereunder ('HIPAA Privacy Regulations') including changes to the regulations made on January 25, 2013 and shall be construed so as to be consistent therewith.

1) Physician's Computer Company and ACRO agree that Physician's Computer Company is permitted to use and/or disclose PHI created or received on behalf of ACRO for purposes related to Physician's Computer Company's health care operations. Services provided by Physician's Computer Company related to ACRO's health care operations are outlined in Physician's Computer Company's Client Agreement. Physician's Computer Company agrees that subsequent purchases of additional such services by ACRO will also be subject to the terms and conditions of this Client Agreement, including such amendments as may be made from time to time, unless otherwise agreed in writing.

2) Physician's Computer Company and ACRO further agree that Physician's Computer Company is permitted to use and/or disclose PHI created, received, or maintained on behalf of ACRO as necessary for proper management and administration of Physician's Computer Company, as necessary to carry out Physician's Computer Company's legal responsibilities, or as otherwise permitted by HIPAA Privacy Regulations. Disclosures under this paragraph are authorized only where (a) the disclosure is required by law; or (b) Physician's Computer Company obtains reasonable assurance, evidenced by written contract, from any person or organization to which Physician's Computer Company will disclose such PHI and that the person or organization will hold such PHI in confidence and use or further disclose it only for the purpose for which Physician's Computer Company disclosed it or as required by law and that Physician's Computer Company will be promptly notified of any instance where the confidentiality of the PHI was breached. Physician's Computer Company will in turn promptly notify ACRO of such a breach.

3) Physician's Computer Company typically does not come in contact with PHI unless ACRO provides it to us or asks us to access PHI on ACRO's system in order to assist ACRO with its health care operations. PHI accessed by Physician's Computer Company will be only the minimum amount of PHI reasonably necessary to accomplish the intended purpose of use.

4) Physician's Computer Company further agrees not to use or disclose PHI except as expressly permitted by this Agreement or applicable law, and to use appropriate safeguards to prevent use or disclosure of PHI other than as so permitted or required as defined in Subpart C of the HIPAA Security Rule.

5) Physician's Computer Company agrees to maintain the security and privacy of all PHI in a manner consistent with applicable state and federal laws and regulations, including the HIPAA Privacy Regulations. Physician's Computer Company will advise of the existence or enactment of any state law or regulation that may impose greater restrictions than those imposed by the HIPAA Privacy Regulations. Preemptive state provisions will be incorporated into this Agreement by addendum as requested by Physician's Computer Company and mutually agreed upon in writing.

6) Physician's Computer Company will not disclose PHI created, received, or maintained by Physician's Computer Company on behalf of ACRO to a person, including any agent or

subcontractor of Physician's Computer Company, but not including a member of Physician's Computer Company's own workforce, until such person provides reasonable assurance, evidenced by written contract, that such person will comply with the same privacy and security obligations as Physician's Computer Company under this Agreement.

7) Physician's Computer Company will not disclose PHI to any member of its workforce unless Physician's Computer Company has appropriately informed such person of Physician's Computer Company's privacy and security obligations under this Agreement.

8) Physician's Computer Company agrees to maintain a record of such disclosures of PHI, as are necessary to comply with the accounting requirements under the HIPAA Privacy Regulations. The disclosure accounting will include: (a) the disclosure date; (b) the name and (if known) address of the person or entity to whom Physician's Computer Company made the disclosure; (c) a brief description of the PHI disclosed; (d) a brief statement of the purpose of the disclosure. Physician's Computer Company need not record disclosure information or otherwise account for disclosures of PHI that this Agreement or Company in writing permits or requires.

9) ACRO will promptly notify Physician's Computer Company in writing of any request potentially involving Physician's Computer Company for an accounting disclosure, an amendment of PHI, or access to PHI. Within thirty (30) days of receiving a written notification from ACRO, Physician's Computer Company will provide to ACRO such information as ACRO deems necessary to enable Physician's Computer Company to respond to such request in accordance with HIPAA Privacy Regulations. ACRO will afford Physician's Computer Company an opportunity to cure the disclosure upon mutually agreeable terms.

10) Physician's Computer Company will report to ACRO any use or disclosure of PHI not permitted by this Agreement or by ACRO in writing. Physician's Computer Company will make the report within five (5) business days after Physician's Computer Company learns of such non-permitted use or disclosure. Physician's Computer Company will report at least: (a) the nature of the non-permitted use or disclosure; (b) the PHI used or disclosed; (c) who made the non-permitted use and/or received the non-permitted disclosure; (d) what corrective action Physician's Computer Company took or will take to prevent further non-permitted uses or disclosures; and (e) identify what Physician's Computer Company did or will do to mitigate any deleterious effect on the non-permitted use or disclosure.

12) Physician's Computer Company will make its internal practices, books, and records, relating to its use and disclosure of PHI it creates, receives, or maintains from ACRO available to ACRO and to the U.S. Department of Health and Human Services to determine Physician's Computer Company's compliance with 45 Code of Federal Regulations Part 164.

12) This Agreement shall coincide with the start of your Comprehensive Care Plan Agreement and the obligations of this Agreements will continue in effect as long as Physician's Computer Company uses, discloses, creates, maintains, or otherwise possesses any PHI created, received, or maintained on behalf of ACRO, and until all PHI created, received, or maintained by Physician's Computer Company on behalf of ACRO is destroyed or returned to ACRO.

13) Upon termination of this Agreement, for any reason, Physician's Computer Company will within ninety (90) days return to ACRO or destroy, as requested in writing by ACRO, the PHI in Physician's Computer Company's possession and retain no copies or back-up tapes. Physician's Computer Company will, within ninety (90) days certify an oath in writing to ACRO that such return or destruction of that PHI has been completed. Physician's Computer Company will deliver to ACRO the identification of any PHI for which return or destruction is

infeasible, and Physician's Computer Company agrees to be permanently bound by obligations of confidentiality and nondisclosure with respect to said PHI; and Physician's Computer Company agrees to limit further uses to those purposes that make the return or destruction of the PHI infeasible.

14) This Agreement will automatically terminate without any further action of the parties upon the termination or expiration of any pre-existing business contracts between the parties. This Agreement may be modified, amended, or otherwise replaced at any time, in writing and by mutual agreement. Should any law, policy, regulation or binding interpretation affecting the use, disclosure, or security of PHI be enacted or announced, the parties agree to amend this Agreement as necessary to ensure compliance with the law.

16) In the event that Physician's Computer Company materially breaches its obligations to ACRO under this Agreement, ACRO will afford Physician's Computer Company reasonable opportunity to cure the breach or end the violation on mutually agreeable terms, as applicable. Should such curative efforts be unsuccessful, ACRO may exercise the right to terminate Agreement by providing Physician's Computer Company written notice of termination, stating the breach of the Agreement that provides the basis for the termination. Any such termination will be effective immediately or at such other date specified in ACRO's notice of termination. Such termination of this Agreement will result in the automatic and immediate termination of all underlying service agreements that ACRO has with Physician's Computer Company. If termination is not feasible Physician's Computer Company will report the breach to the Secretary of HHS.

16) This document and its referenced addenda constitute the entire agreement between Physician's Computer Company and ACRO regarding the HIPAA Privacy Regulations. It supersedes any previous agreements and is binding upon and will inure to the benefit of the parties and their successors and assigns.

17) If any one or more of the provisions in this Agreement shall be held invalid, illegal, or unenforceable in any respect, such provisions shall not affect any other provision, and each remaining provision of this Agreement shall be enforced to the full extent permitted by law.

18) This Agreement, together with all of the respective rights of the parties hereto, shall be governed by and construed and enforced in accordance with the laws of the State of Vermont.

_____ _____

(ACRO) Date

_____ _____

Physician's Computer Company Date

Data Use Agreement

This data use agreement (the "Agreement") is by and between The Regents of the University of Michigan ("Recipient"), a Michigan constitutional corporation with its principal place of business in Ann Arbor, Michigan, and The Children's Hospital of Philadelphia, a Pennsylvania nonprofit corporation with its principal place of business located at 3401 Civic Center Boulevard, Philadelphia, PA 19104 ("Provider") and is effective as of the 10th day of June, 2017 (the "Effective Date").

WHEREAS, Recipient is conducting a research project titled the "BMI2+" to gather information for research of motivational interviewing and child health outcomes. (the "Project");

WHEREAS, Provider wishes to provide medical record information for individuals that have enrolled in the Project received from Physician's Computer Company and cleaned by Provider, to Recipient:

NOW, THEREFORE, the parties, in consideration of the mutual promises and obligations set forth herein, the sufficiency of which is hereby acknowledged, and intending to be legally bound, agree as follows:

1. Provider shall provide Recipient with access to medical record information, via entry into a MiShare database, in the form of a Limited Data Set of Protected Health Information (the "PHI"), as that term is defined at 45 CFR § 164.514(e), in accordance with the terms and conditions of this Agreement.

2. The following individuals (the "Authorized Parties") are authorized to use the PHI or any part of it on behalf of Recipient and have read and acknowledge the terms of this Agreement:

   Name: _____ Signature: _____

   Name: _____ Signature: _____

   Name: _____ Signature: _____

   Use an attachment to list any additional research staff under the direction of an Authorized Party. The attachment must be signed by the Authorized Parties and authorized representatives of Provider and Recipient.

3. Recipient, any Authorized Party on Recipient's behalf, and any Recipient research staff with a need-to-know for the purposes of the Project may use the PHI only for the purposes of the Project, as follows:

   Research of motivational interviewing and child health pursuant to all applicable informed consents and HIPAA Authorizations as approved under Recipient's IRB HUM00109155 (the "Purpose").

4. Recipient agrees as follows:

   a. Not to use or further disclose the PHI or any information contained therein other than as necessary for the Purpose as permitted by this Agreement or required by applicable law.

   b. To use appropriate technical, administrative, and procedural safeguards to prevent use or disclosure of the PHI other than as provided for by this Agreement.

   c. To report to Provider within five (5) days any use or disclosure of the PHI or any part of it not provided for by this Agreement of which Recipient or any Authorized Party becomes aware.

   d. To ensure that any agents, including subcontractors, to whom Recipient or an Authorized Party provides the PHI or any part of it to agree to the same restrictions and conditions that apply to the Recipient and Authorized Parties under this Agreement.

   e. To use the information contained in the PHI to identify and contact the individuals whose information is contained in the PHI only regarding future research opportunities as permitted for the Purpose.

5. This Agreement shall begin as of the Effective Date, and terminate when all PHI has been returned to Provider or destroyed by Recipient. This obligation shall extend to any PHI maintained by a third party on behalf of Recipient.

6. In the event Provider becomes aware of any use of the PHI or any part of it that is not authorized under this Agreement or required by applicable law, Provider may (i) terminate this Agreement upon notice, whereupon Recipient shall return or destroy all PHI in its possession or in the possession of a third party on behalf of Recipient; and/or (ii) disqualify (in whole or in part) the Recipient and/or any Authorized Parties from receiving PHI in the future.

7. To the extent permitted by law, Recipient shall defend, indemnify, and hold harmless Provider (including Provider's trustees, directors, officers, staff, employees, agents, and affiliates) from and against any and all liability, damages, expenses, fees (including reasonable attorney's fees), costs, and fines (collectively called "Liability") arising from the Recipient's and/or any Authorized Parties' breach or violation of this Agreement, except to the extent the Liability is attributable to Provider's illegal, negligent, or willful misconduct.

8. Any ambiguity in this Agreement shall be resolved to permit Provider to comply with the HIPAA Privacy Regulations.

9. Terms used, but not otherwise defined, in this Agreement shall have the same meaning as those terms in the HIPAA Privacy Regulations, 45 C.F.R. §§ 160.103 and 164.501.

WHEREFORE, the parties, through their authorized representatives, hereby accept and agree to the terms and conditions of this Agreement.

THE REGENTS OF THE UNIVERSITY OF MICHIGAN

Signature: _____

Name (Printed): _____

Title: _____

Date: _____

PROVIDER

Signature: _____

Name (Printed): Title: _____

Vice President, OTTCI

Date: _____

Amendment 1

To Data Use Agreement

WHEREAS, The Regents of the University of Michigan ("Recipient"), a Michigan constitutional corporation with its principal place of business in Ann Arbor, Michigan, and The Children's Hospital of Philadelphia, a Pennsylvania nonprofit corporation with its principal place of business located at 3401 Civic Center Boulevard, Philadelphia, PA 19104 ("Provider") (Recipient and Provider, collectively referred to as the "Parties") have signed a Data Use Agreement with an effective date of June 10, 2017 (the "Agreement");

WHEREAS, the above mentioned Parties desire to amend the Agreement to replace Paragraph 4(e);

NOW, THEREFORE, the Parties agree as follows:

1. Paragraph 4(e) of the Agreement shall be deleted and replaced in its entirety with the following:

e. To not use the information in the Limited Data Set to attempt to contact or re-identify any individual who is the subject of the Limited Data Set provided to Recipient, except as allowed by explicit parent/legal guardian consent, HIPAA authorization, or as permitted by law;

2. All provisions of the Agreement not specifically revised herein shall remain unchanged and in full force and effect.

WHEREFORE, the parties, through their authorized representatives, hereby accept and agree to the terms and conditions of this Agreement effective as of June 10, 2017.

THE REGENTS OF THE UNIVERSITY OF MICHIGAN USER

Signature: _____ Signature: _____

Name (Printed): _____ Name (Printed): _____

Title: _____ Title: _____

Date: _____ Date: _____

Amendment 1

To HIPAA Business Associate Agreement

WHEREAS, The Regents of the University of Michigan ("BA"), a Michigan constitutional corporation with its principal place of business in Ann Arbor, Michigan, and Physician's Computer Company ("Covered Entity") (BA and Covered Entity, collectively referred to as the "Parties") have signed a HIPAA Business Associate Agreement with an effective date of June 16, 2017 (the "Agreement");

WHEREAS, the above mentioned Parties desire to amend the Agreement to replace Paragraph 4(e);

NOW, THEREFORE, the Parties agree as follows:

1. Paragraph 4.1 of the Agreement shall be deleted and replaced in its entirety with the following:

4.1 Permissible Use and Disclosure of PHI. Business Associate may use and disclose PHI received from Covered Entity for the contacting of potential subjects regarding enrollment for treatment and research of behavioral treatment for pediatric obesity as approved by IRB Protocol HUM 00109155 on October 21, 2016 and as amended as required by law, which shall include disclosing PHI back to Covered Entity for confirmation of which subjects consented to participation in the research Protocol. In addition to the uses and disclosures permitted by any base agreement(s) or this BAA, Business Associate may use and disclose PHI:

a. For its own proper management and administration,

b. To carry out its legal responsibilities,

c. To aggregate PHI in its possession to provide data aggregation services to Covered Entity as described in 42 C.F.R. § 164.504(e)(2)(i)(B),

d. To create De-Identified Data Sets and/or Limited Data Sets in compliance with the Privacy Rule; and to use or disclose information in such De-Identified Data Sets without further restriction; and to use or disclose information in such Limited Data Sets pursuant to a Data Use Agreement as permitted by the Privacy Rule; and

e. To report violations of law to appropriate Federal and State authorities, consistent with 45 C.F.R. § 164.502(j)(1).

All provisions of the Agreement not specifically revised herein shall remain unchanged and in full force and effect.

WHEREFORE, the parties, through their authorized representatives, hereby accept and agree to the terms and conditions of this Agreement effective as of June 10, 2017.

THE REGENTS OF THE UNIVERSITY OF MICHIGAN **PHYSICIAN'S COMPUTER COMPANY**

Signature: _____ Signature: _____

Name (Printed): _____ Name (Printed): _____

Title: _____ Title: _____

Date: _____ Date: _____

Attachment F.5

Data Transfer Agreement

This data use agreement (the "Agreement") is by and between The Regents of the University of Michigan ("Michigan"), a Michigan constitutional corporation with its principal place of business in Ann Arbor, Michigan, and _____ ("Site") and is effective as of July 1, 2017 (the "Effective Date").

WHEREAS, Michigan is conducting a research project titled "Population Effects of Motivational Interviewing on Pediatric Obesity in Primary Care" that examines the impact of a clinician- and dietician- delivered intervention and clinical treatment to parents / legal guardians of overweight or obese 3-8 year old patients, versus Usual Care, on child health outcomes (the "Project");

WHEREAS, Site may enroll parents / legal guardians of its patients directly and provide identifiable information (including but not limited to, names and dates) to Michigan to conduct the Project;

WHEREAS, Michigan wishes to provide medical record information including but not limited to, clinical counseling notes, dates, and names to Site for individuals that have enrolled in the Project and pursuant to a provided explicit consent and HIPAA authorization to do so or applicable law; Site may include this information in the individuals' medical records for further treatment purposes pursuant to authorizations of the individuals during the Project:

NOW, THEREFORE, the parties, in consideration of the mutual promises and obligations set forth herein, the sufficiency of which is hereby acknowledged, and intending to be legally bound, agree as follows:

1. Michigan shall provide Site with access to medical record information collected during the Project, for possible entry into the Site medical record, in the form of Protected Health Information (the "PHI"), as that term is defined at 45 CFR 160.103, on behalf of parents / legal guardians enrolled in the Project and who have provided explicit authorization for the disclosure of their child's PHI or a waiver from an applicable IRB was obtained, in accordance with the terms and conditions of this Agreement.

2. Site, if it enrolls parents / legal guardians of patients to participate in the Project, shall provide PHI to Michigan to contact the enrolled parents / legal guardians for the Project ("Site PHI").

3. The employees of Site and Michigan who have access to the individuals' medical records (the "Authorized Parties") are authorized to use the PHI and Site PHI, as applicable, or any part of it on behalf of Site or Michigan, as applicable, and have read and acknowledge the terms of this Agreement.

4. Site, any Authorized Party on Site's behalf, and any Site staff with a need-to-know for the purposes of the treatment of patients of the Project may use the PHI only for the purposes of the treatment of its patients who participated in the Project, pursuant to all applicable informed consents and HIPAA authorizations (the "Purpose"). Michigan, any Authorized Party on Michigan's behalf, and any Michigan staff with a need-to-know for the purposes of the Project, may use the Site PHI only for performance of the Project or further treatment.

5. Site agrees that it shall provide to Michigan, Site PHI derived only from those individuals who have provided written HIPAA authorization for the disclosure of Site PHI to Michigan for the Project. Michigan agrees that it shall provide to Site, PHI derived only from those individuals enrolled in the Project and for which transfer of PHI is allowed by written HIPAA authorization or applicable law.

6. Site agrees as follows:

    a. Not to use or further disclose the PHI or any information contained therein other than as necessary for the Purpose as permitted by this Agreement or required by applicable law.

    b. To use appropriate technical, administrative, and procedural safeguards to prevent use or disclosure of the PHI other than as provided for by this Agreement.

    c. To report to Michigan within five (5) days any use or disclosure of the PHI or any part of it not provided for by this Agreement of which Site or any Authorized Party becomes aware.

    d. To ensure that any agents, including subcontractors, to whom Site or an Authorized Party provides the PHI or any part of it to agree to the same restrictions and conditions that apply to the Site and Authorized Parties under this Agreement.

    e. To use the information contained in the PHI to identify and contact the individuals whose information is contained in the PHI only regarding future treatment purposes as permitted for the Purpose.

7. This Agreement shall begin as of the Effective Date, and terminate upon completion of the Project. This obligation shall extend to any PHI maintained by a third party on behalf of Site.

8. In the event Michigan becomes aware of any use of the PHI or any part of it that is not authorized under this Agreement or required by applicable law, Michigan may (i) terminate this Agreement upon notice, whereupon Site shall return or destroy all PHI in its possession or in the possession of a third party on behalf of Site; and/or (ii) disqualify (in whole or in part) the Site and/or any Authorized Parties from receiving PHI in the future.

WHEREFORE, the parties, through their authorized representatives, hereby accept and agree to the terms and conditions of this Agreement.

THE REGENTS OF THE UNIVERSITY OF MICHIGAN **SITE**

Signature: _____ Signature: _____

Name (Printed): _____ Name (Printed): _____

Title: _____ Title: _____

Date: _____ Date: _____

HIPAA BUSINESS ASSOCIATE AGREEMENT

THIS HIPAA BUSINESS ASSOCIATE AGREEMENT ("BAA") is entered into effective the 16th day of June, 2017 ("Effective Date"), by and between Physician's Computer Company ("Covered Entity"), and the Regents of the University of Michigan, a Michigan constitutional corporation on behalf of its affiliates ("Business Associate" "BA" or "UM").

Business Associate may perform functions or activities on behalf of Covered Entity involving the creation, receipt, maintenance, access, transmission, use and/or disclosure of protected health information ("PHI") received from or on behalf of Covered Entity. Therefore, Business Associate agrees to the following terms and conditions set forth in this BAA.

1.0 Definitions. For purposes of this BAA, any terms used herein, unless otherwise defined, shall have the same meanings as used in the HIPAA Privacy and Security Standards, as amended by the Health Information Technology for Economic and Clinical Health Act (Title XIII of the American Recovery and Reinvestment Act of 2009) and its implementing regulations ("HITECH") including modifications to the HIPAA Privacy, Security, Enforcement and Breach Notification Rules under HITECH.

2.0 Scope and Interpretation. This BAA shall apply only if and to the extent UM is considered a BA to Covered Entity. Subject to this limitation, the terms and conditions of this BAA shall provide for Business Associate's creation, receipt, maintenance, transmission, use and/or disclosure of PHI, in any form or medium, including electronic PHI ("ePHI"), in Business Associate's capacity as "Business Associate" to Covered Entity. Any ambiguity in this BAA shall be resolved to permit Covered Entity to comply with HIPAA.

3.0 Compliance with Applicable Law. Beginning with the relevant effective date, to the extent Business Associate meets the definition of a "business associate" of Covered Entity as such term is defined under HIPAA, Business Associate shall comply with its obligations under this BAA and with all obligations of a business associate under HIPAA, HITECH, as modified, and other related laws, for so long as Business Associate creates, receives, maintains, accesses, or transmits PHI.

4.0 OBLIGATIONS OF BUSINESS ASSOCIATE

4.1 Permissible Use and Disclosure of PHI. Business Associate may use and disclose PHI received from Covered Entity for the research of motivational interviewing and child health outcomes as approved by IRB Protocol HUM 00109155 on October 21, 2016 which shall include disclosing PHI back to Covered Entity for confirmation of which subjects consented to participation in the research Protocol. In addition to the uses and disclosures permitted by any base agreement(s) or this BAA, Business Associate may use and disclose PHI:

a. For its own proper management and administration,

b. To carry out its legal responsibilities,

c. To aggregate PHI in its possession to provide data aggregation services to Covered Entity as described in 42 C.F.R. § 164.504(e)(2)(i)(B),

d. To create De-Identified Data Sets and/or Limited Data Sets in compliance with the Privacy Rule; and to use or disclose information in such De-Identified Data Sets without further restriction; and to use or disclose information in such Limited Data Sets pursuant to a Data Use Agreement as permitted by the Privacy Rule; and

e. To report violations of law to appropriate Federal and State authorities, consistent with 45 C.F.R. § 164.502(j)(1).

4.2 Limitations on Use and Disclosure of PHI. Business Associate shall not, and shall ensure that its directors, officers, employees, agents, and subcontractors do not, use or disclose PHI in any manner that is not

permitted or required by any Base Agreement(s) or this BAA, or as Required By Law. All uses and disclosures of, and requests by Business Associate for, PHI are subject to the Privacy Standards' Minimum Necessary Rule and shall be limited to the information contained in a Limited Data Set, to the extent practical, unless additional information is needed to accomplish the intended purpose, or as otherwise permitted in accordance with Section 13405(b) of HITECH, and any other subsequently adopted guidance. Additionally, Business Associate shall ensure that neither it nor its directors, officers, employees, agents, or subcontractors, access, store, share, maintain, use or disclose PHI beyond the borders of the United States of America without agreement of Covered Entity.

4.3 **Security.** To the extent that Business Associate creates, receives, maintains, or transmits ePHI on behalf of Covered Entity, Business Associate shall:

a. Comply with the security provisions found at 45 C.F.R. §§ 164.308, .310, .312, and .316 in the same manner as such provisions apply to Covered Entity, pursuant to Section 13401(a) of HITECH, and otherwise implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of ePHI;

b. Ensure that any agent to whom Business Associate provides ePHI agrees in writing to implement reasonable and appropriate safeguards to protect such ePHI; and

c. Report to Covered Entity promptly after its discovery any Security Incident of which Business Associate becomes aware and which results in a use or disclosure of ePHI in violation of any Base Agreement(s) or this BAA. For those Security Incidents that do not result in a use or disclosure of ePHI in violation of any Base Agreement(s) or this BAA, reports may be made in the aggregate on at least a quarterly basis. In this context, the term "Security Incident" shall have the same meaning as such term is defined at 45 C.F.R. § 164.304.

4.4 **Privacy.** To the extent that Business Associate is to carry out one or more of Covered Entity's obligations under Subpart E of 45 C.F.R. Part 164, Business Associate shall comply with the requirements of Subpart E that apply to Covered Entity in the performance of its obligation(s) under this BAA. Business Associate shall also otherwise implement appropriate safeguards in accordance with the Privacy Standards to prevent the use or disclosure of PHI other than pursuant to the terms and conditions of this BAA.

4.5 **Mitigation of Harmful Effects.** Business Associate agrees to mitigate, to the extent practicable, any harmful effect of a use or disclosure of PHI by Business Associate in violation of the requirements of this BAA, including, but not limited to, compliance with any state law or contractual data breach requirements.

4.6 **Breach of Security or Privacy Obligations.**

a. Business Associate shall report to Covered Entity, within ten (10) business days of discovery, a use or disclosure of PHI not provided for in this BAA by Business Associate, its officers, directors, employees, agents, or subcontractors or by a third party to whom Business Associate disclosed PHI.

b. Business Associate shall report to Covered Entity, within ten (10) business days of discovery, a breach of unsecured PHI in accordance with the requirements set forth in 45 C.F.R. §§ 164.400-.414. Business Associate shall fully cooperate with Covered Entity's breach notification and mitigation activities, and shall be responsible for all costs incurred by Covered Entity for those activities.

4.7 **Agreements by Third Parties.** Business Associate shall enter into an agreement with any agent or subcontractor of Business Associate that will have access to PHI hereunder. Pursuant to such agreement, the agent or subcontractor shall agree to be bound by the same restrictions, terms, and conditions that apply to Business Associate under this BAA with respect to such PHI. Business Associate agrees to provide Covered Entity a list of all its agents or subcontractors upon request.

Ages to Information. Covered Entity acknowledges and agrees that Business Associate does not, within the scope of its services, collect, retain or maintain Designated Record Set infonnation. Accordingly, Business Associate has no obligation to comply with the access provisions of 45 C.F.R. § 164.524.

4.9 Availability of PHI for Amendment Covered Entity acknowledges and agrees that Business Associate does not, within the scope of its services, collect, retain or maintain Designated Record Set information. Accordingly, Business Associate has no obligation to comply with the amendment provisions of 45 C.F.R. § 164.526.

i11 Doc11mentation of Disclosures. Business Associate agrees to document uses and disclosures of PHI and information related to such uses and disclosures as required for Covered Entity to respond to a request by an individual for an accounting of disclosures of PHI in accordance with 45 C.F.R. § 164.528.

!.!1 Accountin.: of Disclosures. Within ten (10) business days of notice by Covered Entity to Business Associate that Covered Entity has received a request for an accounting of disclosures of PHI regarding an individual during the six (6) year period prior to the date on which the accounting was requested, Business Associate shall make available to Covered Entity information to permit Covered Entity to respond to the request for an accounting of disclosures of PHI, as required by 45 C.F.R. § 164.528. In the case of an electronic health record maintained or hosted by Business Associate on behalf of Covered Entity, the accounting period shall be three (3) years and the accounting shall include disclosures for treatment, payment, and health care operations, in accordance with the applicable effective date of Section 13402(a) of HITECH. In the event the request for an accounting is delivered directly to Business Associate, Business Associate shall forward such request to Covered Entity within five (5) business days ofreceipt.

W Restrictions. Business Associate shall comply with any restrictions on disclosure of PHI requested by an individual and agreed to by Covered Entity in accordance with 45 C.F.R. §164.522.

i11 Judicial and Administrative Proceedin s. In the event Business Associate receives a subpoena. court or administrative order or other discovery request or mandate for release of PHI, Business Associate shall notify Covered Entity in writing prior to responding to such request to enable Covered Entity to object. Business Associate shall notify Covered Entity of the request as soon as reasonably practicable, but in any event within two {2) business days of receipt of such request.

4.14 Availability of B-0oks and Recotdi. Business Associate agrees to make its internal practices, books, and records relating to the use and disclosure of PHI available to the Secretary of the Department of Health and Human Services for purposes of determining Covered Entity's compliance with the Privacy Standards.

4.15 Breach of Contract by Business Associate. In addition to any other rights Covered Entity may have in the Base Agreement(s), this BAA, or by operation of law or in equity, Covered Entity may, upon a breach or violation of this BAA, provide a reasonable opportunity for Business Associate to cure or end any such violation within the time specified by Covered Entity. If cure is not possible or if Business Associate does not cure such breach or violation, Covered Entity may immediately tenninate the Base Agreement(s). Covered Entity's option to have a breach cured shall not be construed as a waiver of any other rights Covered Entity has in the Base Agreement(s), this BAA, or by operation of law or in equity.

4.16 Effect of Termination of Aereement(s). Upon the tennination of the Base Agreement(s) or this BAA for any reason, Business Associate shall return aU PHI created by Business Associate or received from Covered Entity to Covered Entity or., at Covered Entity's direction, destroy all PHI received from Covered Entity that Business Associate maintains in any form, recorded on any medium, or stored in any storage system. This provision shall apply to PHI that is in the possession of Business Associate, its agents and subcontractors. If it is not feasible for the Business Associate to return or destroy PHI, Business Associate further agrees to extend any and all protections, limitations, and restrictions contained herein to Business Associate's use and disclosure of any PHI retained after tennination of this BAA, and to limit any further uses and/or disclosures to the purposes that make the return or destruction of PHI infeasible. Business Associate shall retain no copies of the PHI. Business Associate shall remain bound by the provisions of this BAA, even after

termination of the Base Agreement(s) or this BAA, until all PHI has been returned or otherwise destroyed as provided in **this** Section.

4.17 Indemnification. Business Associate acknowledges that Covered Entity is **making** PHI available to it in its capacity as a business associate for pediatric physician practices ("Additional Covered Entities"). Business Associate shall indemnify and hold harmless Covered Entity and Additional Covered Entities and their officers, trustees, employees, agents, and subcontractors from **any** and all claims, penalties, fmes, costs, liabilities, or damages, including but not limited to reasonable attorney fees, incurred by Covered Entity or Additional Covered Entities arising from a violation by Business Associate of its obligations under this BAA, to the extent of **its** negligence **and** the extent permitted by **law.**

5.0 OBLIGATIONS OF COVERED ENTITY

M **Notice of Privacy Practices.** Covered Entity shall notify Business Associate of any limitation(s) in Covered Entity's Notice of Privacy Practices in accordance with 45 C.F.R. § 164.520, to the extent such limitations affect Business Associate's use or disclosure of PHI.

s.1 **Revocation of Authorization of Individual.** Covered Entity shall notify Business Associate of any changes in, or revocation of, pennission by an Individual to use or disclose PHI, if and to the extent such changes affect Business Associate's use and disclosure of PHI.

Restrictions on Use and Disclosure. Covered Entity shall notify Business Associate of **any** restriction on the use or disclosure of PHI that Covered Entity has agreed to in accordance with 45 C.F.R. § 164.522, to the extent such restriction may affect Business Associate's use or disclosure of PHI.

6.0 MISCELLANEOUS

fil **Third Part y Ripts.** The tenns of this BAA do not grant any rights to any third parties.

Independent Contractor Status. For the purposes of this BAA, Business Associate is an independent contractor of Covered Entity, and shall not be considered an agent of Covered Entity.

Chanies in the Law. The parties shall amend this BAA to conform to any new or revised legislation, rules, or regulations to which Covered Entity is subject now or in the **future** including, without limitation, HIPAA, HITECH, the Privacy Standards, Security Standards or Transactions Standards.

M **Owner of PHI.** Under no circumstances shall Business Associate be deemed in **any** respect to be the owner of any PHI of Covered Entity.

This **BAA** becomes binding when signed by authorized representatives of **both** parties.

Name:_____ =------Project Represep.tative

Title: -

_ Date:

PHYSICIAN'S COMPUTER COMPANY:

Release of Relevant PHI Agreement

My practice has an agreement with the AAP to participate in the IRB-approved "Population Effects of Motivational Interviewing on Pediatric Obesity in Primary Care (BMI2+)" study. This agreement authorizes PCC to release and transfer relevant PHI from my practice for the purposes of this research project.

I understand that this project will encompass the following activities:

- Throughout my participation in the BMI2+ Study, PCC will extract HIPAA-limited clinical data for patients 3-8 years of age and this data will be delivered securely to a study team at the Children's Hospital of Philadelphia.

- If my practice is randomized to the intervention arm of the study, PCC will extract a fully identified contact file containing Protected Health Information (PHI) for patients 3-8 years of age, at baseline only, and securely transfer this file to the study team at the University of Michigan. PCC will have a Business Associate Agreement with the University of Michigan, which allows the study team to contact these families for the purposes of recruitment.

- All necessary legal agreements are in place to ensure the protection of privacy of my practice and all of our patients.

- PCC will extract only the information required for the completion of this project.

- PCC will make every effort to make the data extraction process invisible to me and my staff.

- If our office has any questions, we will contact Tim Proctor at PCC at (800)-722-7708 or via email (tim@pcc.com).

_____
Practice Name

_____ _____
Practice Representative Date

_____ _____
Physician's Computer Company Representative Date

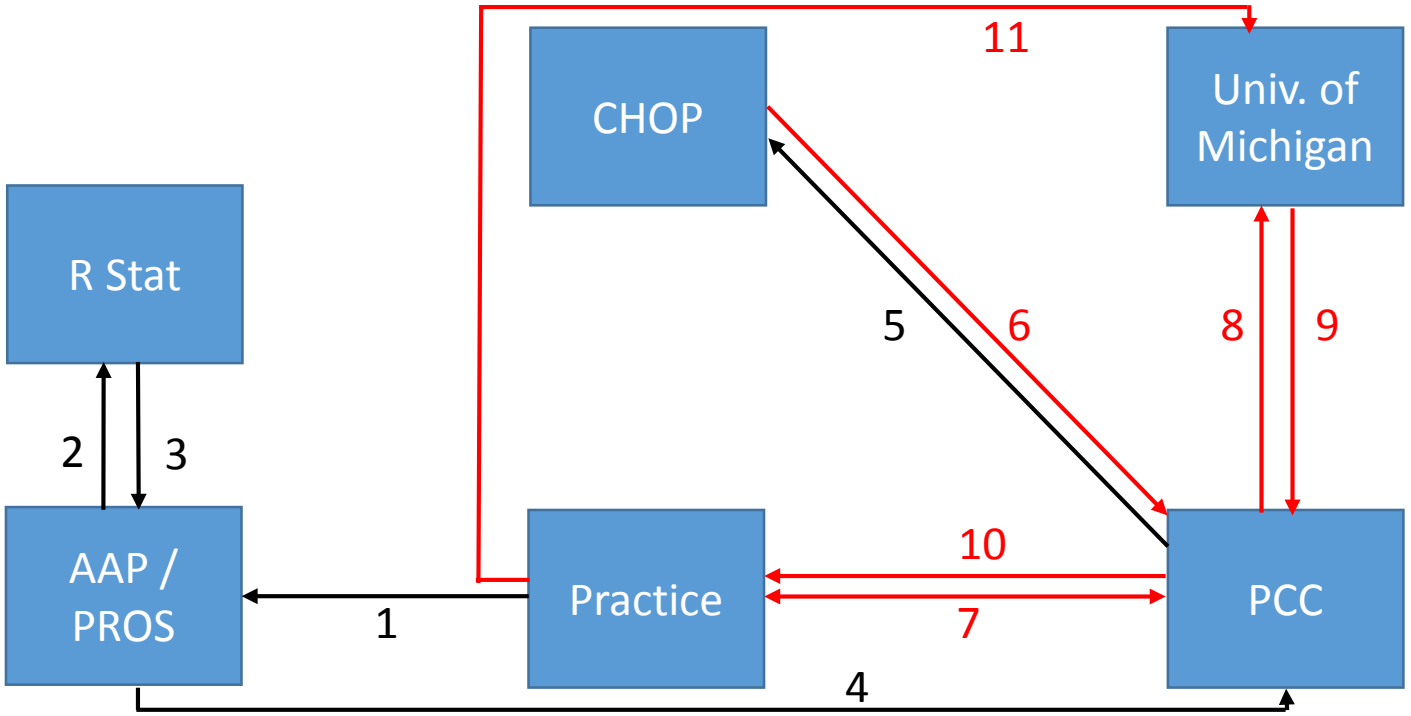
PCC Pediatric EHR Solutions

ATTACHMENTS G.1 and G.2

G.1	Diagrams of Data Flow
G.2	Protection of Data

Data Flow: Study Baseline

Attachment G.1
Slide 1

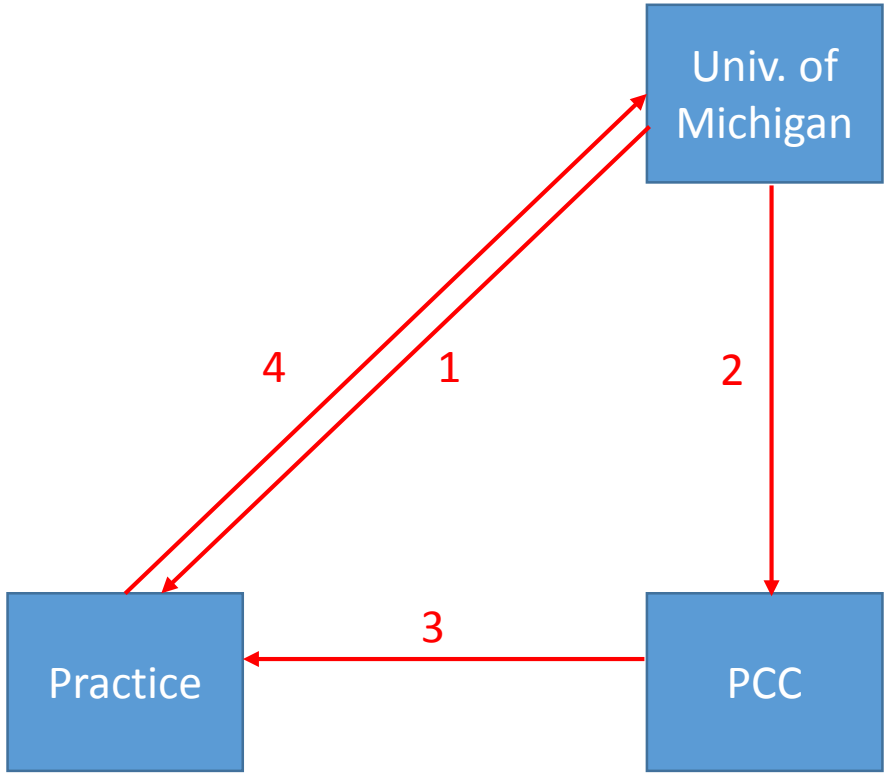


Intervention Arm only
Both study arms

1. Practice sends completed intake forms, consent form, surveys, and signed AAP-practice Data Use Agreement and UMich-practice Data Transfer Agreement to AAP / PROS via email, fax, or US mail.
2. AAP/PROS securely transfers spreadsheet containing PROS practice ID and practice characteristics (including estimated percentages of patients by race / ethnicity as reported on intake forms) to Dr. Vaughan @ RStat for practice randomization. *(See IRB application: section 13c, step 2)*
3. Dr. Vaughan @ RStat securely transfers spreadsheet from #2, with assigned study arm, to AAP / PROS. *(See IRB application: section 13c, step 2)*
4. AAP/PROS securely transfers table linking clinician name, practice name, and study arm assignment to PCC. *(See IRB application: section 13c, step 3)*
5. PCC securely transfers HIPAA limited dataset (all 3-8 year old children within all participating practices) and table linking participating clinicians with their practice's assigned study arm to CHOP. CHOP cleans growth data, applies inclusion & exclusion criteria, and determines the cohort of children whose parents are eligible to participate within each participating practice. *(See IRB application: section 13c, steps 3 and 4)*
6. CHOP securely transfers table linking patient study IDs (for children whose parents are eligible to participate) with clinician study ID (CHOP assigns clinician to each child during eligibility review) and practice ID to PCC. *(See IRB application: section 13c, step 5)*
7. PCC adds "BMI2+ eligible" flag in the practice EHR for each patient from #6. Practice uses flag to generate list of eligible patients; participating clinicians in that practice review list and make exclusions; final list securely transferred from practice server to PCC server. *(See IRB application: section 13c, step 5)*
8. PCC securely transfers fully identified contact file and patient study IDs to the study team at the University of Michigan for parent recruitment. *(See IRB application: section 13c, step 5)*
9. University of Michigan study team securely transfers patient study ID and practice ID to PCC when parents a) consent, b) opt out / refuse to participate, or c) cannot be reached after 11 call attempts by an RD. *(See IRB application: section 14b, step 2a)*
10. PCC updates "consent", "HIPAA authorization", "opt out / refusal", and / or "cannot be contacted" status flags in practice EHR and sends automatic email notification to practice study coordinator. *(See IRB application: section 14b, step 2a)*
11. Practice study coordinator securely transfers patient and parent first and last names to the study team at the University of Michigan when parents a) consent or b) opt out / refuse to participate at the practice. Information updated in study dashboard. *(See IRB application: section 14b, step 2b)*

Attachment G.1
Slide 2

Data Flow (Intervention Arm ONLY): During Intervention Period

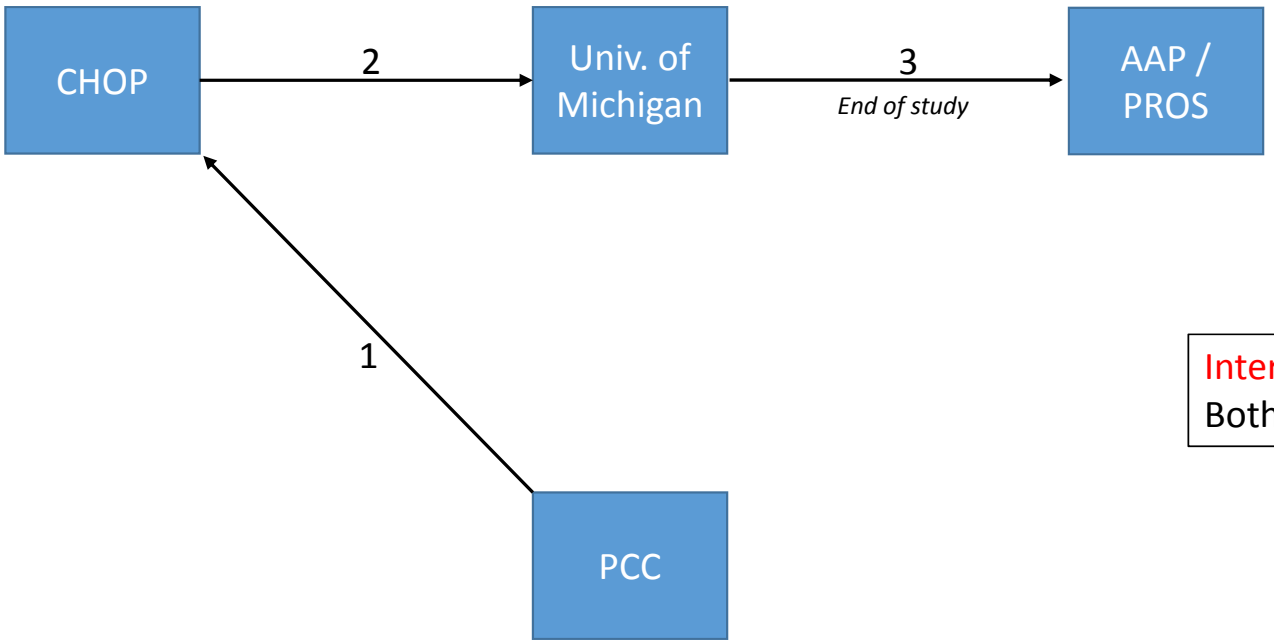


Intervention Arm only
Both study arms

1. RD at University of Michigan sends counseling notes, appointment date, and child first / last name to practice via secure fax. Practice study coordinator uploads counseling notes to EHR. *(See IRB application: section 13c, step 10a)*
2. Study team at the University of Michigan securely transfers patient study ID and practice ID to PCC when a parent withdraws from the study through the PI or an RD. *(See IRB application: section 13c, step 10c)*
3. PCC updates "withdrawal" status flag in practice EHR and sends automatic email notification to practice study coordinator. *(See IRB application: section 13c, step 10c)*
4. Practice study coordinator securely transfers patient and parent first and last names to the study team at the University of Michigan when parents withdraw from the study at the practice. Information updated in study dashboard. *(See IRB application: section 13c, step 10c)*

Attachment G.1
Slide 3

Data Flow: End of Intervention Period and End of Study as a Whole



Intervention Arm only
Both study arms

1. PCC securely transfers HIPPA limited dataset (all 3-8 year old children within all participating practices) with patient study IDs to CHOP. CHOP cleans growth data. *(See IRB application: section 13c, steps 11 and 12)*
2. CHOP securely transfers cleaned HIPAA limited dataset from #1 to study team at University of Michigan. At the end of the intervention period, study team at the University of Michigan merges cleaned HIPAA limited dataset with parent survey responses, RD clinical counseling notes, and full contact information via patient study ID for possible adverse event monitoring *(See IRB application: section 13c, step 11)*. At the end of the study as a whole, study team at the University of Michigan merges cleaned HIPAA limited dataset with parent survey responses and RD clinical counseling notes (de-identified) via patient study ID for outcomes analysis *(See IRB application: section 13c, step 12)*.
3. Study team at the University of Michigan securely transfers a fully de-identified dataset to AAP / PROS for secondary analyses *(See IRB application: section 13c, step 12).*

Attachment G.2

Institution		**Role**
University of Michigan		Study Principal Investigator
	U-M PM	Project Manager
	Shannon Considine	Motivational Interviewing Supervisor
	Kendrin Sonneville	Lead Registered Dietician
		Lead – data team
		Lead – data team
		Data team
		Data team
		Data team
		Data team
American Academy of Pediatrics / Pediatric Research in Office Settings		PROS Director
		PROS Associate Director
		Director of the Division of Primary Care Research
		Project Manager
		PROS staff
		PROS staff
		PROS staff
R Stat		Biostatistician
The Children's Hospital of Philadelphia (CHOP)		CHOP Site PI
		Data analyst

#	Data Source	Data Elements	Storage	Access to Data	Attach G.1 Reference
1	Study clinician Authorized signatory	Intake forms, consent forms, surveys AAP-practice Data Use Agreement (DUA) University of Michigan-practice Data Transfer Agreement (DTA)	Transferred to PROS staff and stored on secure server at AAP	AAP PROS staff	Slide 1, Step 1
2	AAP PROS	Table linking: • PROS practice ID • Practice characteristics (as reported on intake forms)	Password-protected spreadsheet transferred to Roger Vaughan and stored on secure RStat computer	(RStat)	Slide 1, Step 2
3	RStat	Table linking: • PROS practice ID • Practice characteristics (as reported on intake forms) • Assigned study arm	Password-protected spreadsheet transferred to AAP / PROS and stored on secure server at AAP	AAP PROS staff	Slide 1, Step 3
4	AAP PROS	Table linking: • Names of consented clincians • Names of participating practices • Assigned study arm	Password-protected spreadsheet transferred to PCC and stored on secure server	PCC staff	Slide 1, Step 4
5	Practice server → PCC server	Patient Criteria: All patients who are at least 3, but not yet 8, years of age on the date of the baseline data pull. Data Elements: The following clinical and billing data elements will be extracted from the practice EHR, and other data sources (i.e.; practice management system,	Securely transferred from PCC to CHOP Research Information Systems Storage Area	CHOP staff:	Slide 1, Step 5 AND Slide 3, Step 1

#	Data Source	Data Elements	Storage	Access to Data	Attach G.1 Reference
		billing system) which fall under the authority of the Covered Entity. <u>HIPAA limited dataset</u> 1. A unique study-specific patient identifier, which must be unique across all patients in the study – created by PCC for this study. 2. A unique study-specific clinician identifier, which must be unique across all clinicians in the study – created by PCC for this study. 3. A unique study-specific practice identifier, which must be unique across all practices in the study – created by PCC for this study. 4. Patient sex. This may be retrieved from a patient-level record in the EHR, rather than an encounter-specific record. 5. Patient date of birth. 6. Patient date of death. 7. Unique encounter identifier. The practice will assign this value, which must be unique across all data extracted from that practice. 8. Practice type or department of encounter. 9. Date of visit. 10. Race 11. Ethnicity 12. Payor. Insurance payor category at time of visit. 13. Patient's height (ideally in cm) 14. Patient's weight (ideally in kg)	Network (SAN) server		

#	Data Source	Data Elements	Storage	Access to Data	Attach G.1 Reference
		15. All systolic and diastolic blood pressure readings 16. All growth measurements and all vital signs 17. Diagnoses associated by a clinician with the encounter using an ontology such as ICD9 or ICD10. 18. All associated Evaluation & Management billing codes, encounter dates, ICD9 codes, other vendor or nomenclature specific code such as IMO, ICD10, SNOMED, and billed CPT codes. 19. Priority of diagnoses. For each diagnoses extracted, a notation will be made of whether it was a primary or secondary diagnosis for the encounter. If the EHR does not distinguish between primary and other diagnoses, all diagnoses will be considered primary. 20. Medication code(s) present anywhere in the EHR and other data sources under the authority of the Covered Entity (e.g., prescriptions, medication list) according to The National Drug Code (NDC) System – a system providing all drugs in the United States with a specific 11-digit number that describes the product. (a) Medication name, (b) Quantity to give per administration in milligrams, (c) Route of administration, (d) Number of times to administer per day,			

#	Data Source	Data Elements	Storage	Access to Data	Attach G.1 Reference
		(e) Number of hours between administrations, (f) Indication whether or not this med is to be administered on an "as needed" basis, (g) Amount dispensed, (h) Number of refills permitted, (i) Start and end date of prescription, (j) Preferred medication descriptor for this medication formulation, (k) Generic name for medication including dose formulation, (l) Pharmaceutical class, (m) Pharmaceutical sub-class, and (n) Therapeutic class (o) Information about prescription filled (dates fulfilled) 21. Problem list (a) Date problem was noted (b) Date problem was resolved (c) Text description of the diagnosis code (d) Past medical history 22. Family medical history when available (no open text fields / notes will be extracted) 23. All allergies noted in the EHR. 24. Immunization data (a) Codes for vaccine administered (b) Vaccine name (c) Date administered			

#	Data Source	Data Elements	Storage	Access to Data	Attach G.1 Reference
		(d) Status, such as given, abstracted, not done, deleted 25. The following lab information, as well as associated dates of service: (a) Basic metabolic panel (BMP) (b) Hepatic/liver function test (c) Glycated hemoglobin (HbA1c) (d) Lipid profile (e) Pancreatic enzymes (f) Complete blood count (CBC) with differential (g) Coagulation tests (h) Thyroid Function Tests (TFT) (i) Magnesium (Mg++) (j) Phosphorous (k) Calcium (l) Iron studies (m) Vitamin D studies (n) Other obesity-related labs (e.g., insulin, pre-albumin, and related tests) (o) Urinanlysis (UA) results 26. Referral orders 27. Study-specific patient status flags, as well as associated dates 28. Study arm assignment			
6	PCC server	Criteria: All clinicians who have consented to participate in the study Table linking: • Clinician study ID • Practice ID • Assigned study arm	Securely transferred from PCC to CHOP Research Information Systems Storage Area	CHOP staff: Bob Grundmeier, Lihai Song	Slide 1, Step 5

#	Data Source	Data Elements	Storage	Access to Data	Attach G.1 Reference
			Network (SAN) server		
7	CHOP server	Patient criteria: Children whose parents are eligible to participate in the study (Intervention arm practices ONLY): Table linking: 1. Patient study ID 2. Clinician study ID 3. Practice ID	Securely transferred from CHOP to PCC and stored on secure server	PCC assigned staff	Slide 1, Step 6
8	PCC server	Patient Criteria: children whose parents are eligible to participate in the study (Intervention arm practices ONLY) Data elements: 1. BMI2+ eligibility status flag	Practice server	Clinicians in Intervention arm practices	Slide 1, Step 7
9	Practice server	List of children further excluded by study clinicians (from #8 above)	Datafile copied from practice server to PCC server	PCC assigned staff	Slide 1, Step 7
10	PCC server	Patient Criteria: children whose parents are eligible to participate in the study (from #7 above) and who were not further excluded during clinician review (from #9 above) (Intervention arm practices ONLY) Data elements: <u>Fully identified contact file</u> 1. Patient study ID 2. Patient first and last name 3. Patient age (in months) 4. Account ID 5. Parent / guardian first and last name 6. Preffered contact method	Securely transferred from PCC to University of Michigan server	University of Michigan:	Slide 1, Step 8

#	Data Source	Data Elements	Storage	Access to Data	Attach G.1 Reference
		7. Parent / guardian home phone number 8. Parent / guardian mobile phone number 9. Parent / guardian email address 10. Parent / guardian postal address 11. Patient primary language 12. Clinician study ID 13. Study clinician name 14. Practice ID 15. Practice name 16. Practice address 17. Practice phone number			
11	University of Michigan server	Patient criteria: children whose parents provide 1) verbal consent and HIPAA authorization to RDs, 2) opt out / refuse to participate, 3) cannot be reached by an RD after 11 call attempts, or 4) withdraw from the study through the PI or an RD (Intervention arm practices ONLY) Data elements: 1) Patient study ID 2) Practice ID	Securely transferred from Univ. of Michigan to PCC server	PCC staff	Slide 1, Step 9 AND Slide 2, Step 2
12	PCC server	Data elements: 1) Updated status flags from #11	Securely transferred to practice server	Study clinicians in that practice	Slide 1, Step 10 AND Slide 2, Step 3
13	Practice	Patient criteria: children whose parents provide verbal consent and HIPAA authorization, opt out / refuse to participate, or withdraw from the study at their child's doctor's office (Intervention arm practices ONLY) Data elements: 1) Patient first and last name	Securely transferred from practice study coordinator to Univ. of Michigan study team	University of Michigan: Ken Resnicow; U-M PM; Kendrin Sonneville; Shannon Considine;	Slide 1, Step 11 AND Slide 2, Step 4

#	Data Source	Data Elements	Storage	Access to Data	Attach G.1 Reference
		2) Parent first and last name		University of Michigan staff	
14	University of Michigan server	Patient criteria: active study participants (Intervention arm practices ONLY) Data elements: 1) RD counseling session notes (including summary notes for clinicians and summary notes for parents) 2) Appointment date 3) Patient first and last name	Securely transferred from Univ. of Michigan to practice by HIPAA-compliant fax; uploaded by study coordinator to secure practice EHR; also viewable via dashboard interface	Study coordinators; study clinicians; Parents (summary notes for parents only); University of Michigan: Chang	Slide 2, Step 1
15	University of Michigan server	Parent surveys (see attachments K, L, M, and N)	University of Michigan server	University of Michigan: Ken Resnicow; U-M PM; Kendrin Sonneville; Shannon	N/A

#	Data Source	Data Elements	Storage	Access to Data	Attach G.1 Reference
16	CHOP server	HIPAA limited dataset See #5 above for specific patient criteria and specific data elements. Additional data elements: 2. Cleaned growth data	Securely transferred to University of Michigan server	University of Michigan: Ken Resnicow; U-M PM; Kendrin Sonneville; Shannon Considine	Slide 3, Step 2
17	University of Michigan servers	Merged file with identifiers (end of intervention period): 1. Patient study ID 2. Patient first and last name 3. Patient age (in months) 4. Account ID 5. Parent / guardian first and last name 6. Preffered contact method 7. Parent / guardian home phone number 8. Parent / guardian mobile phone number 9. Parent / guardian email address 10. Parent / guardian postal address 11. Patient primary language 12. Clinician study ID 13. Study clinician name 14. Practice ID 15. Practice name 16. Practice address 17. Practice phone number	University of Michigan server	University of Michigan: Ken Resnicow; U-M PM; Kendrin Sonneville; Shannon Considine	N/A

#	Data Source	Data Elements	Storage	Access to Data	Attach G.1 Reference
		18. RD clinical counseling notes, including summary notes for clinicians and for parents 19. Appointment date 20. Parent survey responses 21. HIPAA limited dataset (see #16 above)			
18	University of Michigan servers	<u>Merged file with contact information removed (after adverse event monitoring complete):</u> 1. Patient study ID 2. Patient age (in months) 3. Patient primary language 4. Clinician study ID 5. Practice ID 6. RD clinical counseling notes, including summary notes for clinicians and for parents (de-identified) 7. Appointment date 8. Parent survey data 9. HIPAA limited dataset (see #16 above)	University of Michigan server	University of Michigan: Ken Resnicow; U-M PM; Kendrin Sonneville; Shannon Considine	N/A
19	University of Michigan servers	<u>Final analytic dataset (end of study as a whole)</u> 1. Patient study ID 2. Patient age (in months) 3. Patient primary language 4. Clinician study ID 5. Practice ID 6. RD clinical counseling notes including summary notes for clinicians and for parents (de-identified) 7. Appointment date 8. Parent survey responses 9. HIPAA limited dataset (see #16 above)	University of Michigan server	University of Michigan: Ken Resnicow; U-M PM; Kendrin Sonneville; Shannon Considine	N/A
20	University of Michigan server	<u>Fully de-identified analytic dataset sent at end of study as a whole</u>	Securely transferred from UMich	AAP PROS staff	Slide 3, step 3

#	Data Source	Data Elements	Storage	Access to Data	Attach G.1 Reference
		1. RD clinical counseling notes including summary notes for clinicians and for parents (de-identified) 2. Parent survey responses 3. Dataset from #16 above, EXCLUDING date of birth of child, date of death of child, date(s) of service, and patient study ID	to AAP server		
21	PCC	Optional MOC QI activities for intervention group: Individualized clinician feedback reports on HEDIS measures	To UM study team (via secure email) for purposes of feedback call with clinician; reports then sent to UM MOC office for management per MOC procedures. *NOT* stored by research team.	Interim access by UM study team: Ken Resnicow; Emerson Delacroix; Shannon Considine Upon completion of feedback call, access only by MOC office personnel per MOC procedures.	N/A
22	Univ of Michigan server	Audio tapes of RD counseling calls	University of Michigan server	University of Michigan: Ken Resnicow; Emerson Delacroix; Kendrin Sonneville; Shannon Considine	N/A
23	Univ of Michigan server	Audio and videotapes of clinician and RD standardized patient encounters	University of Michigan server	University of Michigan: Ken Resnicow; Emerson Delacroix; Kendrin	N/A

#	Data Source	Data Elements	Storage	Access to Data	Attach G.1 Reference
				Sonneville; Shannon Considine	

Kaylee#1

ATTACHMENTS H.1, H.1a, H2, H.2a, H.3, and H.4

H.1	Data transfer checklist: PCC-CHOP
H.1a	PCC attestation for HIPAA limited datasets to CHOP
H.2	Data transfer checklist: PCC-University of Michigan
H.2a	PCC attestation for fully identified contact file to University of Michigan
H.3	University of Michigan attestation for deletion of contact information and identifying content in RD clinical counseling notes
H.4	University of Michigan attestation for deletion of contact information for parents who: • opt out • refuse to participate • cannot be contacted • withdraw from the study

Checklist for BMI^{2+} PCC-CHOP Data Transmission Procedures

Pre-Transmission Checklist:

- ☐ PCC has sent signed attestation to AAP PM [or designee], informing her that data are ready for transfer.
- ☐ AAP PM [or designee] has reviewed the attestation and has confirmed that the attestation is appropriate and all needed regulatory materials are in place for data transfer to occur.
- ☐ AAP PM [or designee] has notified the following of the results of the review (either further action needed or data ready to transfer):
  - ☐ Statistical Lead
  - ☐ PCC Staff
  - ☐ Dr. Shone
- ☐ PCC staff has emailed Statistical Lead [or designee] that data are ready to transfer.
- ☐ Data have been transferred.

Approximately One-Week Post Transmission:

- ☐ Statistical Lead [or designee] has reviewed data to confirm that only allowable PHI elements are included.

- IF UNAUTHORIZED DATA IS INCLUDED -

- ☐ Statistical Lead or his designee has immediately contacted AAP PM, the AAP project manager, or her designee and informed her of the situation.
- ☐ AAP PM has immediately notified the study PI , PROS Director, Director of the AAP Division of Primary Care Research, and Director of the AAP Department of Research.
- ☐ Drs. Resnicow or Fiks has immediately contacted PCC informing them of the issue.
- ☐ CHOP staff, under the direction of Statistical Lead, has worked with IT staff to appropriately delete the data from the CHOP server.
- ☐ Within two working days of finding the breach, the PI has notified, in writing, Dr. Erin Kelly - the AAP IRB administrator – and Dr. Scott Denne – AAP IRB Chair -informing them of the situation.

CONTACT INFORMATION		

ATTACHMENT H.1a

To:

From:

Re: BMI^{2+} data extraction, <<date>>

The purpose of this letter is to inform you that I have reviewed the dataset prior to it leaving Physician's Computer Company and confirm that it includes only the allowable protected health information data elements:

(i) date of birth
(ii) date of death
(iii) date of visit(s)

Furthermore, I confirmed that the dataset excludes all of the following:

(i) names;
(ii) postal address information other than town or city, state, and zip code;
(iii) telephone numbers;
(iv) FAX numbers;
(v) electronic mail addresses;
(vi) social security numbers;
(vii) medical record numbers;
(viii) health plan beneficiary numbers;
(ix) account numbers;
(x) certificate/license numbers;
(xi) vehicle identifiers and serial numbers, including license plate numbers;
(xii) device identifiers and serial numbers;
(xiii) web universal resource locators (URLs);
(xiv) internet protocol (IP) address numbers;
(xv) biometric identifiers, including finger and voice prints;
(xvi) full-face photographic images and any comparable images.

Signature Here

Date

Checklist for BMI^{2+} PCC-University of Michigan Data Transmission Procedures

Pre-Transmission Checklist:

- ☐PCC has sent signed attestation to AAP PM [or designee], informing her that data are ready for transfer.
- ☐AAP PM [or designee] has reviewed the attestation and has confirmed that the attestation is appropriate and all needed regulatory materials are in place for data transfer to occur.
- ☐AAP PM [or designee] has notified the following of the results of the review (either further action needed or data ready to transfer):
  - ☐ U-M CHCR staff
  - ☐ U-M CHCR staff
  - ☐ PCC Staff
  - ☐ AAP
- ☐PCC staff has emailed U-M CHCR staff that data are ready to transfer. ☐Data has been transferred.

Approximately One-Week Post Transmission:

- ☐ U-M CHCR staffhas reviewed data to confirm that only allowable PHI elements are included.

- IF UNAUTHORIZED DATA IS INCLUDED -

- ☐ U-M CHCR staff has immediately contacted the AAP project manager, or her designee and informed her of the situation.
- ☐ AAP PM has immediately notified the study PI, PROS Director, Director of the AAP Division of Primary Care Research, and Director of the AAP Department of Research.
- ☐ The PI or PROS DIrector has immediately contacted PCC informing them of the issue.
- ☐ University of Michigan staff, under the direction of U-M CHCR staff has worked with IT staff to appropriately delete the data from the University of Michigan server.
- ☐ Within two working days of finding the breach, The PI has notified, in writing, the AAP IRB administrator – and the AAP IRB chair, informing them of the situation.

CONTACT INFORMATION		

ATTACHMENT H.2a

To:

From:

Re: BMI^{2+} data extraction, <<date>>

The purpose of this letter is to inform you that I have reviewed the dataset prior to it leaving Physician's Computer Company and confirm that it includes only the allowable protected health information data elements:

(i) names
(ii) postal address information
(iii) telephone numbers
(iv) electronic mail addresses
(v) account numbers

Furthermore, I confirmed that the dataset excludes all of the following:

(i) date of birth
(ii) date(s) of visit(s)
(iii) FAX numbers
(iv) social security numbers
(v) medical record numbers;
(vi) health plan beneficiary numbers;
(vii) certificate/license numbers;
(viii) vehicle identifiers and serial numbers, including license plate numbers;
(ix) device identifiers and serial numbers;
(x) web universal resource locators (URLs);
(xi) internet protocol (IP) address numbers;
(xii) biometric identifiers, including finger and voice prints;
(xiii) full-face photographic images and any comparable images.

Signature Here

Date

To:

From:

Re: BMI^{2+}: deletion of full contact information, as well as identifying content in RD clinical counseling notes, after review for possible adverse events <<date>>

The purpose of this letter is to inform you that all contact information for all enrolled parents has been deleted from all servers and datasets. Deleted contact information includes:

(i) names
(ii) postal address information
(iii) telephone numbers
(iv) electronic mail addresses
(v) account numbers

In addition, all RD clinical counseling notes (including summary notes generated for the clinician and parent) have been reviewed for the presence of identifying content, and all such content has been deleted from all servers and datasets.

The remaining analytic dataset includes only the allowable protected health information data elements:

(i) date of birth
(ii) date of death
(iii) date of visit(s)

Signature Here

Date

ATTACHMENT H.4

To:

From:

Re: BMI^{2+}: deletion of contact information during the intervention period, <<date>>

The purpose of this letter is to inform you that all contact information for parents that have opted out, refused to participate, could not be contacted, or withdrew from the study during the following time period <<insert date range>> has been deleted from our study files and databases. Deleted contact information includes:

(i) Patient first and last name
(ii) Account ID
(iii) Parent / guardian first and last name
(iv) Parent / guardian home phone number
(v) Parent / guardian mobile phone number
(vi) Parent / guardian email address
(vii) Parent / guardian postal address
(viii) Study clinician name (associated with the parent's data)
(ix) Practice name (associated with the parent's data)
(x) Practice address (associated with the parent's data)
(xi) Practice phone number (associated with the parent's data)

Signature Here

Date

ATTACHMENTS I.1 and I.2

I.1	Process to Prevent / Report Data Breach: PCC-CHOP
I.2	Process to Prevent / Report Data Breach: PCC-University of Michigan

AAP Process for ensuring only authorized data is included in EHR dataset, and reporting a breach should one occur

For transfer of data from PCC to CHOP

After PC C has extracted the limited dataset which includes only the data elements included in the Data Use Agreement, they will send an email to AAP PM, or her designee, letting her know that the dataset is ready to be sent to CHOP. Included in the email w ill be a document that certifies that the dataset has be en reviewed and only allowable PHI data element s (date of birth, date of death, date of visit) are included .

Once AAP PM or her designee receives this email and notifies Statistical Lead (CHOP) and (AAP), PCC will securely transfer the limited dataset to CHOP.

Within approximately 1 week of data transfer, Statistical Lead or his assigned designee will review the data to confirm that only allowable PHI elements are included. If unauthorized data is included, the following steps will be taken

CHOP Statistical lead or his designee will immediately contact AAP PM, the AAP project manager, or her designee and inform her of the situation. AAP PM will immediately notify the study PI, PROS Director, Director of the AAP Division of Primary Care Research , and Director of the AAP Department of Research

The PI or AAP PROS Director will immediately contact PCC informing them of the issue.

CHOP staff, under the direction of Statistical Lead, will then work with IT staff to appropriately delete the data from the CHOP server.

Within two days of the breach, the PI will send an email to the AAP IRB administrator (Erin Kelly PhD) and AAP IRB chair (Scott Denne MD), informing them of the situation.

AAP Process for ensuring only authorized data is included in EHR dataset, and reporting a breach should one occur

For transfer of data from PCC to University of Michigan

After PC C has created a datafile containing the study IDs and contact information for eligible children in Intervent ion arm practices, they will send an email to AAP PM or her designee, letting her know that the dataset is ready to be sent to the University of Michiga n. Included in the email will be a document that certifies that the dataset has been reviewed and only allowab le PHI data elements are included.

Once Dr . Wright or her designee receives this email and notifies U-M CHCR staff and M(Univ. of Michigan) and(AAP),PCC will securely transfer the contact file to University of Michigan.

Within approximately 1 week of data transfer, U-M CHCR staff will review the data to confirm that only allowable PHI elements are included. If unauthorized data is included, the following steps will be taken

U-M CHCR will immediately contact the study PI (Ken Resnicow PhD) and the AAP project manager (AAP PM or designee) and inform them of the situation. A A P P M will immediately notify the PROS Director Director of the AAP Division of Primary Care Research and Director of the AAP Department of Research (Director of the AAP Division of Primary Care Research.

The PI or AAP PROS Director will immediately contact PCC informing them of the issue.

University of Michigan staff, under the direction of Mr. Nowak, will then work with IT staff to appropriately delete the data from the University of Michigan server.

Within two days of the breach, the PI will send an email to the chair (informing them of AAP IRB administrator and AAP IRB the situation.

ATTACHMENT J

Parent Education Materials

The following educational materials will be accessible via the parent-facing pages of the study dashboard

BMI
Revised: June 1, 2017

Eating Out

Eating Well While Eating Out

Eating out is convenient, fast, and can be cheap. It can be a fun family experience! However, like anything else, the key is finding the right balance between meal splurges and healthy eating. It can be hard to find healthy options when you're eating out, and eating too many unhealthy options can lead to health problems.

Eating on the go

It can be easy to make healthy choices at a fast-food restaurant, the mall, or even the cafeteria! Most cafeterias and fast-food places offer healthy choices that are also tasty, like grilled chicken or salads. Be mindful of portion sizes and add-ons that are high in saturated fat and salt, like dressings, sauces, or cheese sauce.

Here are some pointers that may help when eating out:

- **Go for balance**. Choose meals that contain a balance of lean proteins (like fish, chicken, or beans), fruits and vegetables, and whole grains. A turkey sandwich on whole wheat bread with lettuce and tomato is a healthier choice than a cheeseburger on a white bun.
- **Watch portion sizes.** The more we are served, the more we eat. Because most restaurant portions are way larger than the average serving size, we end up eating way more than we need when we eat out. Think about asking for half portions, sharing an entrée with a friend, or taking leftovers home. Teach your kids that it's ok to leave food on your plate, you can always take it home to eat at the next meal.
- **Drink water or low-fat milk.** Regular sodas, juices, and energy drinks contain a lot of sugar, but don't give you much else. Stick with water or milk at meals.
- **Look for healthy choices.**
    - A single slice of veggie pizza
    - Deli sandwiches on whole-grain bread
    - A small hamburger on whole-grain bread or wrapped in lettuce
    - A bean burrito
    - A baked potato
    - A side salad with dressing on the side
- **Modify menu items.** You can make items healthier just by changing how you order them.
    - Ask for sauces and salad dressing on the side.
    - Use salsa and mustard instead of mayonnaise.
    - Order baked, broiled, or grilled lean meats including turkey, chicken, or seafood.
    - Substitute fries and other less healthy sides with salads, vegetables, or fruit.

- When ordering coffee drinks or smoothies, use nonfat or low-fat milk instead of whole milk or cream.

BMI
Revised: June 1, 2017

Eating Sweets and Desserts

Some families like to use sweets and desserts as a way of celebrating achievements and rewarding good behavior. Others have dessert as part of their daily routine after dinner is finished. Generally, kids are getting too much sugar in their diet and this can lead to health problems.

Don't worry! You don't have to cut out sweets and desserts completely. Instead, cut down at first. Then, make it your goal to limit yourself and your kids to just 1 dessert or 1 sweet a few times a week.

Every family is different, but these are ideas that some families have found helpful.

What if anything might work for you?

- Instead of an large bowl of ice cream, enjoy a single scoop. Cut a smaller slice of cake, or grab 1 or 2 small cookies instead of a handful. Enjoy smaller-portion sizes rather than try to give up sweets completely.
- If you're ordering dessert at a restaurant, split the dessert between 2 or more people. Restaurant portions are usually large so there should be more than enough to share.
- Replace high-sugar desserts with naturally sweet foods like fruit.
- Keep dried fruit in the house like cherries, bananas, or apples. They are a sweet substitute for candy!
- Have sorbet, fresh fruit popsicles, or frozen yogurt instead of ice cream.
- Reduce the amount of sugar in the desserts you make. Depending on the recipe, you could cut down on the amount of sugar or experiment with swapping in fruit, applesauce, or oatmeal.
- Choose fresh or frozen fruit over canned as many canned fruits have sugar added as a preservative.
- You choose what your child is allowed to have. Then let your child choose *when* they'll have their sweet.
- Take a half portion of dessert, then load on the fruit. Cake, ice cream, and cookies all taste great with some berries on the side!
- Smoothies are a great alternative to a sugary dessert. Throw a banana, a couple strawberries, and a handful of blueberries into a blender with some yogurt and milk. Super sweet and super healthy!

BMI
Revised: April 26, 2017

Fruit

Fruit is naturally low in calories, high in fiber, and loaded with important vitamins and minerals for healthy growth and development. The sweetness in fruit makes them a great replacement for sugary snacks and desserts. Unfortunately, most kids aren't eating enough fruit.

How can you get your kids to eat more fruit?

1. Eat together. If you snack on fruit in front of your kids, they're more likely to meet their fruit requirements. Kids are notorious for wanting to eat what others around them eat. Be the fruity role model!
2. Keep trying. Many children reject new foods because they're afraid, not because they don't like the taste. Don't give up. You may need to offer a new fruit 10 times or more before they'll accept it.
3. Don't force kids to finish a fruit they may not like. Encourage them to try just one bite this time!
4. Slice or peel fruit. Your kids may be more likely to want sliced fruit than whole fruit. They may like it better peeled than with the skin on it.
5. Use stickers. If you stick a popular cartoon character on a piece of fruit, you may find your child more excited about eating it.
6. Let them pick their fruit. Allowing them to pick their fruit from the grocery store makes them more excited about eating it.
7. Involve them. Kids often want to eat something they prepared on their own. Depending on their age, kids can help with slicing, peeling, or cutting fruit up. There are kid-friendly knives, choppers, and slicers to make this activity safer for them.
8. Mix it up. Offer fruit in a variety of forms, textures, and shapes. Experiment with frozen, freeze-dried, canned, fresh and dried fruit, as well as 100% juice.
9. Make fun no-cook creations. Think of ways to make fruit a little more exciting. Make homemade popsicles, smoothies, and apple pizzas (peanut butter spread on a round apple slice topped with raisins).
10. Pick your own. Depending on where you live, you may be able to pick seasonal fruits at a local farm. Sometimes the excitement of a new food can be an adventure for everyone.
11. Grow your own. Getting kids outside in the garden, and teaching them how their food grows can interest them in trying something new.
12. Add it to meals. Kids love pancakes, cereal, oatmeal, frozen yogurt. Add the fruit on top!
13. Try to offer fruit at most meals and snacks.

Serving Size

Children need 1-2 cups of fruit per day, depending on their age and activity level. One serving is equal to:

- 1 cup of fruit
- 1 cup of 100% fruit juice
- ½ cup dried fruit

What can you try at home to get your kids to eat more fruit?

BMI
Revised: April 26, 2017

PA

Kids and Exercise

When most adults think about exercise, they imagine working out in the gym, going to an exercise class, running on a treadmill, or lifting weights.

But for kids, exercise means playing and running around, and being physically active. In addition to team sports, kids exercise when they have gym class at school, during recess, at dance class, while riding bikes, or when playing at the park.

The Many Benefits of Exercise

Everyone can benefit from regular physical activity. Kids who are active will:

- Have stronger muscles and bones
- Have a leaner body
- Decrease the risk of developing type 2 diabetes
- Lower blood pressure and blood cholesterol levels
- Have a better outlook on life
- Sleep better
- Be better able to handle physical and emotional challenges
- Have better academic performance

Three Kinds of Exercise

There are three types of exercise – endurance, strength, and flexibility. If you've ever watched kids on a playground, you've seen the three kinds of exercise in action:

- **Endurance**. Running away from the kid who is "it".
- **Strength.** Crossing the monkey bars.
- **Flexibility.** Bending down to tie their shoes.

Endurance

Endurance develops when kids regularly get aerobic activity. During aerobic exercise, the heart beats faster and a person breathes harder. When done regularly and for extended periods of time, aerobic activity strengthens the heart and improves the body's ability to deliver oxygen to all its cells. Some examples of endurance activities include:

- Basketball
- Bicycling
- Skating

- Soccer
- Swimming
- Running/track
- Jumping Rope
- Climbing (rock walls, trees, structures)
- Dance
- Hockey/lacrosse

Strength

It is **not** recommended that kids ages 2-8 lift weights. Instead, kids can do:

- Push-ups
- Stomach crunches
- Pull-ups
- Gymnastics
- Martial Arts
- Yoga

Flexibility

Stretching exercises help improve flexibility. When you are flexible, your muscles and joints bend and move easily through their full range of motion. Kids get chances every day to stretch when they:

- Reach for a toy
- Practice a split
- Do a cartwheel
- Bend down to tie their shoes

Cutting Down on Screens

One of the best ways to get kids to be more active is to limit the amount of time spent in sedentary activities, especially watching TV or other screens. The American Academy of Pediatrics recommends parents:

- Put limits on the time spent using media, including TV, social media, and video games.
- Limit screen time to 1 hour a day or less
- Keep TVs, computers, and video games out of children's bedrooms

How Much Exercise is Enough?

It's up to you to make sure that your kids get enough activity. Kids should get 60 minutes or more of moderate to vigorous physical activity daily. Young children should not be inactive for long periods of time – no more than 1 hour unless they're sleeping. School-age children should not be inactive for periods longer than 2 hours.

The National Association for Sport and Physical Education offers these activity guidelines:

Age	Minimum Daily Activity	Comments
Toddler	1 ½ hours	30 minutes planned physical activity and 60 minutes unstructured physical activity (free play)
Preschooler	2 hours	60 minutes planned physical activity and 60 minutes unstructured physical activity (free play)
School age	1 hour or more	Break up into bouts of 15 minutes or more

Raising Healthy Kids

Combining regular physical activity with a healthy diet is the key to a healthy lifestyle. Here are some tips for raising healthy kids:

- Help your kids participate in a variety of age-appropriate activities
- Establish a regular schedule for activity
- Make being active a part of daily life, such as taking the stairs instead of the elevator
- Embrace a healthier lifestyle yourself, so you'll be a positive role model for your family.
- Keep it fun! Physical activity shouldn't feel like a chore or a punishment.
- Team sports can be great for building friendships and learning about teamwork. But, try not to limit your child too soon to just one activity. Let them develop a variety of skills and try a lot of different activities.
- Try not to get wrapped up in winning, professional aspirations, and scholarships. Let kids learn to love sports without pressure!

BMI
Revised: April 26, 2017

Screen Time

By the time kids reach grade school, most are very familiar with things like TVs, tablets, and smartphones. Chances are they'll want to spend a lot of time using those devices, too.

TV, interactive video games, and the Internet can be a great source of education and entertainment for kids. It's easy to let them spend too much time watching tv or on small screens. However, kids' bodies and minds are still growing at this age. It's important for them to get plenty of exercise and lots of unstructured, screen-free playtime.

Screen time is any time that is spent looking at or interacting with any device that has a screen. It can even include things like doing like homework on the tablet or researching a school project on the computer. It can also include less productive things, like watching TV or playing video games. But, too much screen time can have unhealthy side effects. That's why it's wise to monitor and limit the time your kids spend playing video games, watching TV, and using the Internet.

How much is too much?

Parents should place consistent limits on the use of any media.

- Preschoolers: 0-1 hour a day of age-appropriate shows.
- Kids and teens: 0-2 hours a day on screen time, including TV, social media, and video games.
- For kids of all ages, screen time should not replace time needed for sleeping, eating, playing, studying, and interacting with family and friends.

Tips for Reducing Screen Time

- Try a weekday ban. Schoolwork, sports activities, and joy responsibilities make it tough to find extra family time during the week. Record shows or save video games for weekends, and you'll have more family togetherness time to spend on meals, games, and physical activity during the week.
- Make sure kids have a variety of free-time activities, like spending time with friends and playing sports.
- Turn off all screens during family meals and at bedtime. Keep devices with screens out of your child's bedroom after bedtime and don't allow a TV in a child's bedroom.
- Don't allow your child to watch TV while doing homework.
- Treat screen time as a privilege that kids need to earn, not a right that they're entitled to. Tell them that screen time is allowed only after chores and homework are completed.

- Set a good example. Limit your own screen time.
- Come up with a family TV schedule. Make it something the entire family agrees on. Then post the schedule in a visible place so that everyone knows which programs are OK to watch and when.

Video and Interactive Computer Games

- Look at the ratings. Video games do have ratings to indicate when they have violence, strong language, sexual themes, and other content that may be inappropriate for kids, or content you're not comfortable with your kids seeing.
- Preview the games. Play them yourself so you know that your children will be seeing.

Internet Safety

- Become computer literate. Learn how to block objectionable material.
- Keep the computer in a common area. Keep it where you can watch and monitor your kids.
- Share an email account with younger children. You can monitor who is sending them messages.
- Teach your child about internet safety. Discuss rules for your kids to follow while they're using the Internet, such as never revealing personal information, including address, phone number, or school.
- Bookmark your child's favorite sites. Your child will have easy access and be less likely to make a typo that could lead to inappropriate content.
- Spend time online together. Teach your kids appropriate online behavior.

BMI
Revised: April 26, 2017

Sugar Sweetened Beverages

Beverages like juice, energy drinks, sports drinks, lemonade, sweetened teas, and soda are extremely high in sugar. Consuming too much sugar can make you feel sluggish and can increase hunger and cravings. Having too much sugar can also lead to health problems in the future.

The average 12 oz can of soda has just about 10 teaspoons of sugar. That's more than most servings of candy!

Sugar can come with lots of names, like high fructose corn syrup, which is a very common syrup made from corn starch that is used as a sweetener, just like sugar. Check the ingredients on the nutrition label! All of these words mean the same as sugar:

- High fructose corn syrup
- Dextrose
- Fructose
- Sucrose
- Maltose
- Lactose

Because it can be difficult to figure out which ingredients are actually sugar, reading the nutrition label of any drink is the easiest way to find out how much sugar it has. Look for the grams of sugar per serving on the label and see how many serving sizes are in the container. Every 4 grams of sugar is equal to one teaspoon of sugar.

What should my child be drinking?

- Plain water, cold, with ice, warmed, or hot; most of a child's fluid intake should be plain water
- Try slicing up berries, cucumbers, mint, oranges, limes, or lemons into a pitcher of water
- Try seltzer or carbonated water
- Dilute any sugar sweetened beverage like juice or lemonade
- Choose 100% fruit juice
- Unsweetened iced tea
- Unsweetened, herbal tea

Juice boxes, lemonade, and fruit juices should only be allowed in moderation. Limit those drinks to no more than 1 per day.

BMI
Revised: April 26, 2017

Vegetables

Vegetables provide many of the vitamins and minerals we need for good health. Veggies are naturally low in calories, and the fiber in them helps us feel full. And, as an extra bonus, you can eat as many as you want!

Choosing variety is important when it comes to vegetables: Dark green vegetables (like broccoli, spinach, and kale) provide different nutrients from orange vegetables (like squash, carrots, and sweet potatoes). While fresh generally taste best, canned, dried, and frozen vegetables can be great alternatives. It's best to choose ones that have been packed in water or natural juice, rather than those with added sugar or salt.

Serving Size
Children need 1 ½ - 2 ½ cups of vegetables per day, depending on their age and activity level.

1 serving is equal to:

- 1 cup of raw vegetables
- 1 cup cooked vegetables
- 1 cup vegetable juice
- 2 cups raw leafy greens

How can you get your kids to eat more vegetables?

- Have chopped veggies in the refrigerator as a ready-to-go snack for you and the kids.
- Have your kids cut, slice and prepare their own veggies to experiment with different types of preparation.
- Try different dips for your raw veggies like hummus, tzatziki, mustards, nut butters or guacamole.
- Pack vegetable sticks in your child's lunchbox. Many kids like carrots and peppers.
- Try vegetable kebabs with your dinner
- Top your pizza with sliced mushrooms, green pepper, or onion.
- Add veggies to your eggs like a frittata, quiche or omelet.
- Shred veggies and bake them into morning muffins.
- Add veggies to your stews, soups, pasta, and rice dishes.
- Try the same veggies raw, steamed, baked to see which your child likes best. For example, they may not like steamed broccoli, but love it raw.
- Try new veggies mixed into a dish or with other veggies. Then try them separate to see which they like better.
- Try to offer vegetables with most meals and snacks.

What can you try at home to get your kids to eat more vegetables?

BMI
Revised: April 26, 2017

Whole Grains

Breads and cereals are good sources of fiber, carbohydrates, protein, and a wide range of vitamins and minerals. This food group should form the main source of energy in your diet. Grains are an important part of a healthy diet, providing nutrients and energy for a child's normal growth and development.

There are two types of grains: whole grains and refined grains. Refined grains have had the outer parts of the grain kernel removed. When the outer part is removed, so are many of the nutrients. Whole grains are the best choice because they contain more fiber, vitamins, and minerals. Both kids and adults should aim for at least half of their daily servings to be from whole-grain sources.

What are the health benefits of whole grains?

- Whole grains help control blood glucose (the sugar in your blood)
- Reduced risk for diabetes
- Reduced risk for heart disease and stroke
- Keep you regular

What are some examples of whole grains?

- Oatmeal
- Whole wheat bread
- Brown rice
- Whole grain barley
- Bulgur
- Popcorn
- Quinoa
- Whole wheat pasta
- Whole wheat ready-to-eat cereals.

Why is whole-grain bread healthier than white bread?

Bread is made out of flour that comes from grain kernels. A grain kernel has three parts. In whole grain bread, all part of the grain kernel are used. But in white bread, only one of the three parts of the kernel is used. Removing the other two parts leads out important nutrients, including vitamins, minerals, healthy fats, protein, and fiber.

When you're buying packaged bread in the supermarket, be sure to look on the label for "whole grain" or "whole wheat." Those are the breads that are best for your kids.

Serving size

Children need 4-6 servings of grains per day, depending on their age and activity level. One serving is equal to:

- 1 slice of bread
- 1 cup of ready-to-eat cereal
- ½ cup cooked rice
- ½ cup cooked pasta
- ½ cup cooked cereal

How do I include more whole grains in my kid's diet?

- Replace white bread, white rice and white pasta with a whole grain variety
- Add barley or bulgur in soups, stews, casseroles, or stir frys
- Instead of using refined pancake, muffin, or waffle mixes, use a whole wheat mix or make your own.
- Trade out the crackers in your pantry for whole grain crackers
- Eat whole grain ready-to-eat cereals
- Add whole wheat flour or oatmeal when making cookies or sweets
- Have popcorn as a snack
- Use whole corn meal for corn breads and muffins

What can you try at home to get your kids to eat more whole grains?

ATTACHMENT K

Parent Baseline Brief Survey

[illegible]

[illegible]

Questions directly relevant to Motivational Interviewing counseling / clinical care

[illegible]
- [illegible]
- [illegible]

[illegible]
- A – [illegible]
- B
- C
- D
- F – [illegible]

[illegible]
- A – [illegible]
- B
- C
- D
- F – [illegible]

[illegible]
- A – [illegible]
- B

- C
- D
- F –

d

A –

B

C

D

F –

d

A –

B

C

D

F –

d

A –

B

C

D

F –

d

A –

B

C

D

F –

- A – [illegible]
- B
- C
- D
- F – [illegible]

- A – [illegible]
- B
- C
- D
- F – [illegible]

- A – [illegible]
- B
- C
- D
- F – [illegible]

- A – [illegible]
- B
- C
- D
- F – [illegible]

- A – [illegible]
- B
- C
- D
- F – [illegible]

How would you describe your child's current weight?

- Very underweight [VeryUnder]
- A little underweight [LittleUnder]
- About average [Average]
- A little overweight [LittleOver]
- Very overweight [VeryOver]

Required
ChildConcernedWt
On a scale of 0 to 10 where 0 is not at all concerned and 10 is very concerned, how concerned is **your child** about his or her own weight?
_____ (drop down, 0-10)

Required
ParentConcernedWt
On a scale of 0 to 10 where 0 is not at all concerned and 10 is very concerned, how concerned **are you** about your child's weight?
_____ (drop down, 0-10)

Required
ParentConcernedHealth
On a scale of 0 to 10 where 0 is not at all concerned and 10 is very concerned, how concerned are you about your child's overall health?
_____ (drop down, 0-10)

Research questions

Family History

Required
Hispanic
Is your child of Hispanic origin?

- No [No]
- Yes [Yes]

Required
Race
What is your child's race? (check all that apply)

- ☐ White [White]
- ☐ Black or African America [Black]
- ☐ Asian [Asian]
- ☐ Native Hawaiian or other Pacific Islander [NatHaw]
- ☐ American Indian or Alaska Native [AmIn]

RaceOther

- ☐ Other, please describe: _____ (length, 30)

Required

Gender

What gender is your child?

- Male [Male]
- Female [Female]

GenderOther

- Other [Other]

_____

Required

Pronoun

What pronouns would you like us to use for your child?

- He/Him/His
- She/Her/Hers
- They/them/their
- Zie/zim/zis

Required

Education

Please check the highest grade in school that you have finished.

- 8th grade or less [Less8th]
- 9th-12th grade, but not a high school graduate [Less12th]
- High school graduate or equivalent (GED) [HS]
- Some college; no degree or certificate [SomeCollege]
- Associate's degree or technical school graduate [AssocDeg]
- Bachelor's degree [BachDeg]
- Graduate or professional degree such as Masters, PhD, JD, MD [Grad]

HealthInsurance

Is your child currently covered by any kind of health insurance or health coverage plan?

- Yes [Yes]
- No [No] (go to Texts)
- I don't know [DK]

InsuranceEmployer

Is your child covered by Insurance through a current or former employer or union?

- Yes [Yes]
- No [No]
- I don't know [DK]

PrivateInsurance

Is your child covered by Insurance purchased directly from an insurance company?

- [illegible]
- [illegible]
- [illegible]

[illegible]

[illegible]

- [illegible]
- [illegible]
- [illegible]

[illegible]

[illegible]

- [illegible]
- [illegible]
- [illegible]

[illegible]

[illegible]

- [illegible]
- [illegible]
- [illegible]

[illegible]

[illegible]

- [illegible]
- [illegible]
- [illegible]

[illegible]

[illegible]

- [illegible]
- [illegible]

[illegible]

[illegible]

- [illegible]
- [illegible]

- [illegible]
- [illegible]
- [illegible]
- [illegible]
- [illegible]

[illegible]

ATTACHMENT L

Parent Baseline Extended Survey

BMI2+

Baseline Survey Extended

Thank you for participating in this important program. Please answer these questions about your child's diet and physical activity. Your answers will help our team tailor the counseling that you will receive.

All questions are directly relevant to Motivational Interviewing counseling / clinical care

Values

ValuesChild

Which of these values, traits, or characteristics are important for your child? Please pick the 2 that are most important.

- ☐ Being healthy [Healthy]
- ☐ Being strong [Strong]
- ☐ Having many friends [Friends]
- ☐ Being fit [Fit]
- ☐ Not feeling abnormal [Abnormal]
- ☐ Not being teased [NotTeased]
- ☐ Not feeling left out [NotLeftOut]
- ☐ Being able to communicate his/her feelings [CommFeelings]
- ☐ Fulfilling his/her potential [Potential]
- ☐ Having high self-esteem [SelfEsteem]

ValuesParent

Which of these values, traits, or characteristics are important to you? Please pick the 2 that are most important.

- ☐ Being a good parent [GdParent]
- ☐ Being responsible [Respon]
- ☐ Being disciplined [Disc]
- ☐ Being a good spouse [GdSpouse]
- ☐ Being respected at home [Respt]
- ☐ Being on top of things [OnTop]
- ☐ Being spiritual [Spiritual]

ValuesFamily

Which of these values, traits, or characteristics are important for your family? Please pick the 2 that are most important.

- ☐ Being cohesive [Cohesive]
- ☐ Being healthy [Healthy]
- ☐ Having peaceful meals [PeaceMeals]

- ☐ Getting along [GetAlong]
- ☐ Spending time together [Together]

Eating Fruits and Vegetables

Please answer these questions about how many servings of fruits and vegetables your child eats.

Required

Fruits

How many servings of **fruits** (fresh fruit, frozen fruit, canned fruit, but NOT including juice) does your child eat on a typical day? A serving is one medium piece of fruit or one half-cup of raw fruit.

- ○ None / less than 1 per day [None]
- ○ 1 [1]
- ○ 2 [2]
- ○ 3 [3]
- ○ 4 [4]
- ○ 5 or more [5Plus]

Required

Vegetables

How many servings of **vegetables** (fresh, frozen or canned, but NOT including potatoes) does your child eat on a typical day? A serving is one half-cup of cooked vegetables or one cup of raw vegetables.

- ○ None / less than 1 per day [None]
- ○ 1 [1]
- ○ 2 [2]
- ○ 3 [3]
- ○ 4 [4]
- ○ 5 or more [5Plus]

Drinking

DrinkJuice

How many servings of **juice (such as 100% juice, orange/apple/grape etc),** does your child drink on a typical day? One serving of juice is an 8-ounce glass.

- ○ None / less than 1 per day [None]
- ○ 1 [1]
- ○ 2 [2]
- ○ 3 [3]
- ○ 4 [4]
- ○ 5 or more [5Plus]

DrinkFruitDrinks

How many servings of **fruit drinks (such as Hi-C, Hawaiian punch, lemonade, Koolaid, Capri-Sun)** does your child drink on a typical day? One serving is an 8-ounce glass.

- None / less than 1 per day [None]
- 1 [1]
- 2 [2]
- 3 [3]
- 4 [4]
- 5 or more [5Plus]

DrinkSports

How many servings of **sports drinks (such as Gatorade, Powerade)** does your child drink on a typical day? One serving is an 8-ounce glass.

- None / less than 1 per day [None]
- 1 [1]
- 2 [2]
- 3 [3]
- 4 [4]
- 5 or more [5Plus]

DrinkSoda

How many servings of **regular soda** does your child drink on a typical day? One serving is an 8-ounce glass.

- None / less than 1 per day [None]
- 1 [1]
- 2 [2]
- 3 [3]
- 4 [4]
- 5 or more [5Plus]

DrinkSweetTea

How many servings of **sweetened tea** does your child drink on a typical day? One serving is an 8-ounce glass.

- None / less than 1 per day [None]
- 1 [1]
- 2 [2]
- 3 [3]
- 4 [4]
- 5 or more [5Plus]

DrinkWater

How many servings of **water** does your child drink on a typical day? One serving is an 8-ounce glass.

- None / less than 1 per day [None]

- 1 [1]
- 2 [2]
- 3 [3]
- 4 [4]
- 5 or more [5Plus]

DrinkMilk

How many servings of **milk** does your child drink on a typical day? One serving is an 8-ounce glass.

- None / less than 1 per day [None]
- 1 [1]
- 2 [2]
- 3 [3]
- 4 [4]
- 5 or more [5Plus]

DrinkChocMilk

How many servings of **chocolate or flavored milk** does your child drink on a typical day? One serving is an 8-ounce glass.

- None / less than 1 per day [None]
- 1 [1]
- 2 [2]
- 3 [3]
- 4 [4]
- 5 or more [5Plus]

DrinkOtherMilk

How many servings of **other milk products (soy, rice, almond milk**) does your child drink on a typical day? One serving is an 8-ounce glass.

- None / less than 1 per day [None]
- 1 [1]
- 2 [2]
- 3 [3]
- 4 [4]
- 5 or more [5Plus]

Snacks

SnacksDay

How many snacks (not full meals) does your child eat on a usual day?

- None / less than 1 per day [None]
- 1 [1]
- 2 [2]
- 3 [3]

- 4 [4]
- 5 or more [5Plus]

SnacksType

Of the following foods, which did your child eat in the past week? Please select all that apply.

- ☐ Chips, including potato chips, tortilla chips (like Tostitos), corn chips (like Fritos), or nacho chips (like Doritos or Cheetos) [Chips] [-]
- ☐ Pretzels [Pretz] [+]
- ☐ Popcorn [Popcorn] [+]
- ☐ Crackers (like Cheeze-its, Goldfish, Wheat Thins, or Triscuits), including peanut butter or cheese-filled sandwich crackers [Crackers] [+]
- ☐ Animal crackers, graham crackers, or vanilla wafers [Grahams] [+]
- ☐ Gummy or fruit flavored candy (like Skittles, Sour Patch Kids, or jelly beans) [FruitCandy] [-]
- ☐ Chocolate candy or candy bars [Choc] [-]
- ☐ Snack cakes or breakfast pastries (like muffins, Twinkies, Donuts, Pop Tarts, Little Debbies) [Pastry] [-]
- ☐ Cookies, brownies, or cake [Cookies] [-]
- ☐ Pudding [Pudding] [-]
- ☐ Jello [Jello] [-]
- ☐ Fruit Rollups, dried fruit, or fruit snacks [FruitSnacks] [+]
- ☐ Ice cream [IceCream] [-]
- ☐ Yogurt or yogurt tubes (like Go-GURT) [Yogurt] [+]
- ☐ Cheese, including string cheese or cheese sticks [Cheese] [+]
- ☐ Fruit [Fruit] [+]
- ☐ Vegetables [Veg] [+]
- ☐ Granola bars (like Nature Valley or Quaker Chewy) or cereal bars (like NutriGrain) [Granola] [+]
- ☐ Snack bars or energy bars (like Kind, Lara, Clif, or Luna) or energy bars [EnergyBar] [+]
- ☐ Trail Mix [TrailMix] [+]
- ☐ Nuts [Nuts] [+]
- ☐ Cereal [Cereal] [+]
- ☐ Sandwich [Sandwich] [+]
- ☐ Pizza or bagel bites [Pizza] [-]

SnacksOther

- ☐ Other, please describe: _____ (fill in, 100 characters)

Activity

WeekdaySports

On a typical week day, how many hours is your child involved in sports or active play?

- None / Less than 1 hour per day [None]
- 1-2 hours [1_2Hours]
- 2-3 hours [2_3Hours]

- 3-4 hours [3_4Hours]
- 4-5 hours [4_5Hours]
- Over 5 hours [Over5]

WeekendSports

On a typical weekend day, how many hours is your child involved in sports or active play?

- None / Less than 1 hour per day [None]
- 1-2 hours [1_2Hours]
- 2-3 hours [2_3Hours]
- 3-4 hours [3_4Hours]
- 4-5 hours [4_5Hours]
- Over 5 hours [Over5]

TV

On an average school day, how many hours does your child watch TV?

- None / Less than 1 hour per day [None]
- 1-2 hours [1_2Hours]
- 2-3 hours [2_3Hours]
- 3-4 hours [3_4Hours]
- 4-5 hours [4_5Hours]
- Over 5 hours [Over5]

Games

On an average school day, how many hours does your child play video or computer games or use a computer for something that is not school work? (Count time spent on things such as Xbox, PlayStation, an iPad or other tablet, a smartphone, texting, YouTube, Instagram, SnapChat, Facebook, or other social media.)

- None / Less than 1 hour per day [None]
- 1-2 hours [1_2Hours]
- 2-3 hours [2_3Hours]
- 3-4 hours [3_4Hours]
- 4-5 hours [4_5Hours]
- Over 5 hours [Over5]

For the following statements answer on a scale of 0-10, with 0 being not at all sure, and 10 being very sure.

ChildSuccess

On a scale of 0-10 with 0 being not at all sure and 10 being very sure, how sure are you that your child will succeed in achieving a healthy weight?
1-10, dropdown

ChangeEat

On a scale of 0-10 with 0 being not at all sure and 10 being very sure, how sure are you that your family will be able to make changes in your eating?
1-10, dropdown

ChangePA
On a scale of 0-10 with 0 being not at all sure and 10 being very sure, how sure are you that your family will be able to make changes in your physical activity?
1-10, dropdown

ChangeTV
On a scale of 0-10 with 0 being not at all sure and 10 being very sure, how sure are you that your family will be able to make changes in your TV/video gaming.
1-10, dropdown

Track
On a scale of 0-10, with 0 being very little and 10 being a lot, how much do you keep track of, that is count or monitor, what your child eats?
1-10, dropdown

Energy
On a scale of 0-10, with 0 being very little and 10 being a lot, how much of **your energy** do you think it will take to change your child's eating or physical activity behavior?
1-10, dropdown

Thank you! Your dietician will be calling at your scheduled time for your first counseling appointment.

ATTACHMENT M

RD Counseling Guide

BMI2+ Study

RD Counseling Guide

(ask at call 2+)

GoalCheck

Looking at your goal from last week, would you say that you met your goal, exceeded your goal, or did not get started?

- Fully met goal [Met]
- Partially met my goal [Partially]
- Exceeded goal [Exceeded]
- Did not get started [NonStart]

GoalArea

What would you like to focus on today?

- Snack foods [Snacks]
- Drinking sweetened beverages [SweetBevs]
- Eating out/carry out dinners [EatOut]
- Eating fruits [Fruit]
- Eating vegetables [Veg]
- Eating whole grains [WholeGrains]
- Eating sweets and desserts [Sweets]
- Watching TV/Screen time [Screen]
- Playing video games/internet [VideoGames]
- Physical activity/exercise [PA]

Snacks

(ask at call 2+)

Snacks

Instruction to Dietitian: Based on notes from previous week, please mark but don't ask.

You said you wanted to focus on the snacks your child eats. Is this a new goal or are you continuing with this goal from a previous session?

- New goal [New]
- Continuing goal [Continue]

SnacksChange

Would you like to decrease or maintain the number of snacks your child is eating?

- Decrease [Decrease]
- Maintain [Maintain]

SnacksCurrent

How many snacks is your child eating now (per day)?

_____ (drop down 0-20)

SnacksChange==”Decrease”

SnacksDecrease

How many snacks would you like your child to be eating (per day)?

_____(drop down 0-20)

SnacksImportant

On a scale of 0 to 10, where 0 is not at all important, and 10 is very important, how important is reducing snacks to you? [0,1,2,3,4,5,6,7,8,9,10]

0	1	2	3	4	5	6	7	8	9	10
Not at all Important										Very Important

SnacksReady

On a scale of 0 to 10, where 0 is not at all ready and 10 is very ready, how ready are you to [make changes to/maintain] your child’s daily snacks? [0,1,2,3,4,5,6,7,8,9,10]

0	1	2	3	4	5	6	7	8	9	10
Not at all Ready										Very Ready

SnacksConfident

On a scale of 0 to 10 where 0 is not at all confident and 10 is very confident, how confident are you that you will be able to [cut down on/maintain] your child’s daily snacks? [0,1,2,3,4,5,6,7,8,9,10]

0	1	2	3	4	5	6	7	8	9	10
Not at all Confident										Very Confident

SnacksGoal

When are you going to start?

- Today or tomorrow [TodayTmrw]
- Over the next week [Week]
- Over the next month [Month]

Sweetened Beverages

(ask at call 2+)

SweetBevsTopic

You said you wanted to focus on the sweetened beverages your child drinks. Is this a new goal or are you continuing with this goal from a previous session?

- New goal [New]
- Continuing goal [Continue]

SweetBevsChange
Would you like to decrease or maintain the number of sweetened beverages your child is drinking?

- Decrease [Decrease]
- Maintain [Maintain]

SweetBevsCurrent
How many 8 ounce cups of sweetened beverages does your child drink (per day)?
_____ (drop down 0-20)

SweetBevsChange=="Decrease"
SweetBevsDecrease
How many cups of sweetened beverages would you like your child to drink (per day)?
_____(drop down 0-20)

SweetBevsImportant
On a scale of 0 to 10, where 0 is not at all important, and 10 is very important, how important is it to you for your child to drink fewer sweet drinks? [0,1,2,3,4,5,6,7,8,9,10]

0	1	2	3	4	5	6	7	8	9	10
Not at all Important										Very Important

SweetBevsReady
On a scale of 0 to 10, where 0 is not at all ready and 10 is very ready, how ready are you to [make changes to/maintain] your child's sweetened beverages? [0,1,2,3,4,5,6,7,8,9,10]

0	1	2	3	4	5	6	7	8	9	10
Not at all Ready										Very Ready

SweetBevsConfident
On a scale of 0 to 10 where 0 is not at all confident and 10 is very confident, how confident are you that you will be able to [cut down on/maintain] your child's sweetened beverages? [0,1,2,3,4,5,6,7,8,9,10]

0	1	2	3	4	5	6	7	8	9	10
Not at all Confident										Very Confident

SweetBevsGoal
When are you going to start?

- Today or tomorrow [TodayTmrw]
- Over the next week [Week]
- Over the next month [Month]

Eating Out

(ask at call 2+)

EatingOut

You said you wanted to focus on eating out and ordering take out. Is this a new goal or are you continuing with this goal from a previous session?

- New goal [New]
- Continuing goal [Continue]

EatingOutChange

Would you like to decrease or maintain the number of times you eat out or order take out with your child?

- Decrease [Decrease]
- Maintain [Maintain]

EatingOutCurrent

How many times a week do you eat out or order take out with your child?

_____ (drop down 0-20)

EatingOutChange=="Decrease"

EatingOutDecrease

How many times a week would you like to prepare meals at home instead of eating out or ordering take out with your child?

_____(drop down 0-20)

EatingOutImportant

On a scale of 0 to 10, where 0 is not at all important, and 10 is very important, how important is it to you to reduce the amount of times you eat out or order take out? [0,1,2,3,4,5,6,7,8,9,10]

0	1	2	3	4	5	6	7	8	9	10
Not at all Important										Very Important

EatingOutReady

On a scale of 0 to 10, where 0 is not at all ready and 10 is very ready, how ready are you to [make changes to/maintain] the number of times you eat out or order take out? [0,1,2,3,4,5,6,7,8,9,10]

0	1	2	3	4	5	6	7	8	9	10
Not at all Ready										Very Ready

EatingOutConfident

On a scale of 0 to 10 where 0 is not at all confident and 10 is very confident, how confident are you that you will be able to [cut down on/maintain] the number of times you eat out or order take out? [0,1,2,3,4,5,6,7,8,9,10]

0	1	2	3	4	5	6	7	8	9	10
Not at all Confident										Very Confident

GoalEatingOut

When are you going to start?

- Today or tomorrow [TodayTmrw]
- Over the next week [Week]
- Over the next month [Month]

Fruit

(ask at call 2+)

Fruit

You said you wanted to focus on the fruit your child eats. Is this a new goal or are you continuing with this goal from a previous session?

- New goal [New]
- Continuing goal [Continue]

FruitChange

Would you like to increase or maintain the amount of fruit your child eats?

- Increase [Decrease]
- Maintain [Maintain]

FruitCurrent

How many servings of fruit does your child eat (per day)?

_____ (drop down 0-20)

FruitChange==”Increase”

FruitAdd

How many servings of fruit would you like your child to eat (per day)?

_____(drop down 0-20)

FruitFillIn

What are some of your child’s favorite fruits?

_____ (fillin, 100 characters)

FruitImportant

On a scale of 0 to 10, where 0 is not at all important, and 10 is very important, how important is it to you that your child eats fruit? [0,1,2,3,4,5,6,7,8,9,10]

0	1	2	3	4	5	6	7	8	9	10
Not at all Important										Very Important

FruitReady

On a scale of 0 to 10, where 0 is not at all ready and 10 is very ready, how ready are you to [make changes to/maintain] the amount of fruit your child eats? [0,1,2,3,4,5,6,7,8,9,10]

0	1	2	3	4	5	6	7	8	9	10
Not at all Ready										Very Ready

FruitConfident

On a scale of 0 to 10 where 0 is not at all confident and 10 is very confident, how confident are you that you will be able to [add more/maintain the current amount of] fruit into your child's day? [0,1,2,3,4,5,6,7,8,9,10]

0	1	2	3	4	5	6	7	8	9	10
Not at all Confident										Very Confident

FruitGoal

When are you going to start?

- Today or tomorrow [TodayTmrw]
- Over the next week [Week]
- Over the next month [Month]

Vegetables

(ask at call 2+)

Veg

You said you wanted to focus on the vegetables your child eats. Is this a new goal or are you continuing with this goal from a previous session?

- New goal [New]
- Continuing goal [Continue]

VegChange

Would you like to increase or maintain the amount of vegetables your child eats?

- Increase [Decrease]
- Maintain [Maintain]

VegCurrent

How many servings of vegetables does your child eat (per day)?

_____ (drop down 0-20)

VegChange=="Increase"

VegAdd

How many servings of vegetables would you like your child to eat (per day)?

_____(drop down 0-20)

VegFillIn
What are some of your child's favorite vegetables?
_____ (fillin, 100 characters)

VegImportant
On a scale of 0 to 10, where 0 is not at all important, and 10 is very important, how important is it to you that your child eats vegetables? [0,1,2,3,4,5,6,7,8,9,10]

0	1	2	3	4	5	6	7	8	9	10
Not at all Important										Very Important

VegReady
On a scale of 0 to 10, where 0 is not at all ready and 10 is very ready, how ready are you to [make changes to/maintain] the amount of vegetables your child eats? [0,1,2,3,4,5,6,7,8,9,10]

0	1	2	3	4	5	6	7	8	9	10
Not at all Ready										Very Ready

VegConfident
On a scale of 0 to 10 where 0 is not at all confident and 10 is very confident, how confident are you that you will be able to [add more/maintain the amount of] vegetables into your child's day? [0,1,2,3,4,5,6,7,8,9,10]

0	1	2	3	4	5	6	7	8	9	10
Not at all Confident										Very Confident

VegGoal
When are you going to start?
- Today or tomorrow [TodayTmrw]
- Over the next week [Week]
- Over the next month [Month]

Whole Grains

(ask at call 2+)
WholeGrainsTopic
You said you wanted to focus on the whole grains your child eats. Is this a new goal or are you continuing with this goal from a previous session?
- New goal [New]
- Continuing goal [Continue]

WholeGrainsChange

Would you like to increase or maintain the amount of whole grains your child eats?

- Increase [Decrease]
- Maintain [Maintain]

WholeGrainsCurrent

How many servings of whole grains does your child eat (per day)?

_____ (drop down 0-20)

VegChange=="Increase"

WholeGrainsAdd

How many servings of whole grains would you like your child to eat (per day)?

_____(drop down 0-20)

WholeGrainsFillIn

What are some of your child's favorite foods with whole grains?

_____ (fillin, 100 characters)

WholeGrainsImportant

On a scale of 0 to 10, where 0 is not at all important, and 10 is very important, how important is it to you that your child eats whole grains? [0,1,2,3,4,5,6,7,8,9,10]

0	1	2	3	4	5	6	7	8	9	10
Not at all Important										Very Important

WholeGrainsReady

On a scale of 0 to 10, where 0 is not at all ready and 10 is very ready, how ready are you to [make changes to/maintain] the amount of whole grains your child eats? [0,1,2,3,4,5,6,7,8,9,10]

0	1	2	3	4	5	6	7	8	9	10
Not at all Ready										Very Ready

WholeGrainsConfident

On a scale of 0 to 10 where 0 is not at all confident and 10 is very confident, how confident are you that you will be able to [add more/maintain the amount of] whole grains into your child's day? [0,1,2,3,4,5,6,7,8,9,10]

0	1	2	3	4	5	6	7	8	9	10
Not at all Confident										Very Confident

WholeGrainGoal

When are you going to start?

- Today or tomorrow [TodayTmrw]
- Over the next week [Week]
- Over the next month [Month]

Sweets and Desserts

(ask at call 2+)

SweetsTopic

You said you wanted to focus on the sweets and desserts your child eats. Is this a new goal or are you continuing with this goal from a previous session?

- New goal [New]
- Continuing goal [Continue]

SweetsChange

Would you like to decrease or maintain the number of sweets and desserts your child is eating?

- Decrease [Decrease]
- Maintain [Maintain]

SweetsCurrent

How many sweets and desserts is your child eating (per day)?

_____ (drop down 0-20)

SweetsChange=="Decrease"

SweetsDecrease

How many sweets and desserts would you like your child to be eating (per day)?

_____(drop down 0-20)

SweetsImportant

On a scale of 0 to 10, where 0 is not at all important, and 10 is very important, how important is reducing sweets and desserts to you? [0,1,2,3,4,5,6,7,8,9,10]

0	1	2	3	4	5	6	7	8	9	10
Not at all Important										Very Important

SweetsReady

On a scale of 0 to 10, where 0 is not at all ready and 10 is very ready, how ready are you to [make changes to/maintain] your child's sweets and desserts? [0,1,2,3,4,5,6,7,8,9,10]

0	1	2	3	4	5	6	7	8	9	10
Not at all Ready										Very Ready

SweetsConfident

On a scale of 0 to 10 where 0 is not at all confident and 10 is very confident, how confident are you that you will be able to [cut down on/maintain] your child's sweets and desserts? [0,1,2,3,4,5,6,7,8,9,10]

0	1	2	3	4	5	6	7	8	9	10

Not at all Confident

Very Confident

SweetsGoal

When are you going to start?

- Today or tomorrow [TodayTmrw]
- Over the next week [Week]
- Over the next month [Month]

Screen time

(ask at call 2+)

ScreenTime

You said you wanted to focus on the amount of tv your child watches. Is this a new goal or are you continuing with this goal from a previous session?

- New goal [New]
- Continuing goal [Continue]

ScreenChange

Would you like to decrease or maintain the amount of tv your child watches?

- Decrease [Decrease]
- Maintain [Maintain]

ScreenCurrent

How many hours of tv does your child watch (per day)?

_____ (drop down 0-20)

ScreenChange==”Decrease”

ScreenCut

How many hours of tv would you like your child to watch (per day)?

_____(drop down 0-20)

ScreenImportant

On a scale of 0 to 10, where 0 is not at all important, and 10 is very important, how important is it to you to reduce your child’s tv time? [0,1,2,3,4,5,6,7,8,9,10]

0 1 2 3 4 5 6 7 8 9 10

Not at all Important

Very Important

ScreenReady

On a scale of 0 to 10, where 0 is not at all ready and 10 is very ready, how ready are you to [make changes to/maintain] your child’s screen time? [0,1,2,3,4,5,6,7,8,9,10]

0 1 2 3 4 5 6 7 8 9 10

Not at all Ready | Very Ready

ScreenConfident

On a scale of 0 to 10 where 0 is not at all confident and 10 is very confident, how confident are you that you will be able to [make changes to/maintain] your child's screen time? [0,1,2,3,4,5,6,7,8,9,10]

0	1	2	3	4	5	6	7	8	9	10
Not at all Confident										Very Confident

ScreenGoal

When are you going to start?

- Today or tomorrow [TodayTmrw]
- Over the next week [Week]
- Over the next month [Month]

Video games

(ask at call 2+)

VideoGamesTopic

You said you wanted to focus on how often your child plays video games. Is this a new goal or are you continuing with this goal from a previous session?

- New goal [New]
- Continuing goal [Continue]

VideoGamesChange

Would you like to decrease or maintain the hours your child spends playing video games?

- Decrease [Decrease]
- Maintain [Maintain]

VideoGamesCurrent

How many hours does your child spend playing video games (per day)?

_____ (drop down 0-20)

VideoGamesChange=="Decrease"

VideoGamesDecrease

How many hours of video games would you like your child to play (per day)?

_____(drop down 0-20)

VideoGamesImportant

On a scale of 0 to 10, where 0 is not at all important, and 10 is very important, how important is it to you to reduce your child's video game time? [0,1,2,3,4,5,6,7,8,9,10]

0	1	2	3	4	5	6	7	8	9	10
Not at all Important										Very Important

VideoGamesReady

On a scale of 0 to 10, where 0 is not at all ready and 10 is very ready, how ready are you to [make changes to/maintain] your child's time spent playing video games? [0,1,2,3,4,5,6,7,8,9,10]

0	1	2	3	4	5	6	7	8	9	10
Not at all Ready										Very Ready

VideoGamesConfident

On a scale of 0 to 10 where 0 is not at all confident and 10 is very confident, how confident are you that you will be able to [make changes to/maintain] the amount of time your child spends playing video games? [0,1,2,3,4,5,6,7,8,9,10]

0	1	2	3	4	5	6	7	8	9	10
Not at all Confident										Very Confident

VideGamesGoal

When are you going to start?

- Today or tomorrow [TodayTmrw]
- Over the next week [Week]
- Over the next month [Month]

Exercise

(ask at call 2+)

Exercise

You said you wanted to focus on your child's exercise. Is this a new goal or are you continuing with this goal from a previous session?

- New goal [New]
- Continuing goal [Continue]

ExerciseChange

Would you like to increase or maintain the amount of exercise your child gets each day?

- Increase [Decrease]
- Maintain [Maintain]

ExerciseCurrent

How many minutes of exercise does your child get (per day)?

_____ (drop down 0-120)

ExerciseChange==”Increase”

ExerciseAdd

How many minutes of exercise would you like your child to get (per day)?
_____(drop down 0-120)

PAFillIn

What are some physical activities that your child enjoys?
_____ (fillin, 100 characters)

ExerciseImportant

On a scale of 0 to 10, where 0 is not at all important, and 10 is very important, how important is it to you that your child gets physical activity? [0,1,2,3,4,5,6,7,8,9,10]

0	1	2	3	4	5	6	7	8	9	10
Not at all Important										Very Important

ExerciseReady

On a scale of 0 to 10, where 0 is not at all ready and 10 is very ready, how ready are you to [make changes to/maintain] the amount of exercise your child receives each day? [0,1,2,3,4,5,6,7,8,9,10]

0	1	2	3	4	5	6	7	8	9	10
Not at all Ready										Very Ready

ExerciseConfident

On a scale of 0 to 10 where 0 is not at all confident and 10 is very confident, how confident are you that you will be able to [make changes to/maintain] the amount of time your child spends exercising? [0,1,2,3,4,5,6,7,8,9,10]

0	1	2	3	4	5	6	7	8	9	10
Not at all Confident										Very Confident

ExerciseGoal

When are you going to start?

- Today or tomorrow [TodayTmrw]
- Over the next week [Week]
- Over the next month [Month]

Disordered Eating

Note: This set of questions will only appear every 6 months. They will not be asked at every appointment.

EDControl

Are you worried at all that your child binge eats or loses control over how much he or she eats?

- Yes [Yes]
- No [No]

EDWorried

Are you worried at all that your child is too thin or losing too much weight?

- Yes [Yes]
- No [No]

EDBodyShape

Are you worried at all that your child is preoccupied with his or her body shape or weight?

- Yes [Yes]
- No [No]

EDRestrict

Are you worried at all that your child is overly restrictive with what he or she eats?

- Yes [Yes]
- No [No]

ATTACHMENT N

Parent Follow-Up Survey

BMI2+

Follow Up Survey

Thank you for your participation in this important program. Please answer the following questions as well as you can. Neither your child's doctor or the study dietitians will see your responses.

ProgramWeightChg
Overall, how much do you think this program overall helped change your child's weight?
- No change [No]
- A little change [Little]
- A lot of change [Lot]

ProgramChildEats
How much do you think this program changed what your child eats?
- No change [No]
- A little change [Little]
- A lot of change [Lot]

ProgramFamilyEats
How much do you think this program changed what your family eats?
- No change [No]
- A little change [Little]
- A lot of change [Lot]

ProgramChildActive
How much do you think this program changed how active your child is?
- No change [No]
- A little change [Little]
- A lot of change [Lot]

ProgramFamilyActive
How much do you think this program changed how active your family is?
- No change [No]
- A little change [Little]
- A lot of change [Lot]

When answering the next questions, please think about the time you spent with your child's doctor.

SatisfiedDoctor
Overall, how satisfied are you with how your doctor provided the BMI program?

- Very dissatisfied
- Somewhat dissatisfied
- Somewhat satisfied
- Very satisfied

LengthVisitsDoctor
The length of my visits for the BMI program with my child's doctor have been…
- Too short
- Just about right
- A little too long
- Much too long

LongDrSession
How long was your last session with the doctor?
(drop down 1 minute intervals, to 30 minutes)

SpeakVisitsDoctor
Who tends to speak more during your BMI program visits?
- I talked more than my doctor
- The doctor talked more than me
- We talked about the same amount of time

InfoDoctor
Overall, how much information about weight, nutrition, and exercise did your BMI doctor provide you?
- Not enough
- Just the right amount
- Too much

AdviceDoctor
Overall, how much advice about weight, nutrition, and exercise did your BMI doctor give you?
- Not enough
- Just the right amount
- Too much

How much do you agree or disagree with the following statements?

DrChangedView
My visits with the doctor changed the way I think about my child's health.
- Not at all [Not]
- A little [Little]
- Somewhat [Some]
- A lot [Lot]

DrOpinion
MY doctor asked my opinion about things.
- Not at all [Not]
- A little [Little]
- Somewhat [Some]
- A lot [Lot]

DrChoices
My doctor gave me choices about what to do.
- Not at all [Not]
- A little [Little]
- Somewhat [Some]
- A lot [Lot]

DrUnderstands
MY doctor understood what I was saying.
- Not at all [Not]
- A little [Little]
- Somewhat [Some]
- A lot [Lot]

DrListened
My doctor listened to me.
- Not at all [Not]
- A little [Little]
- Somewhat [Some]
- A lot [Lot]

DrRushed
My doctor rushed me through the sessions.
- Not at all [Not]
- A little [Little]
- Somewhat [Some]
- A lot [Lot]

DrQues
My doctor asked too many questions.
- Not at all [Not]
- A little [Little]
- Somewhat [Some]
- A lot [Lot]

DrPermission
My doctor asked permission before giving me information or advice.

- Not at all [Not]
- A little [Little]
- Somewhat [Some]
- A lot [Lot]

DrSupportive

My doctor was supportive/encouraging.

- Not at all [Not]
- A little [Little]
- Somewhat [Some]
- A lot [Lot]

DrValues

My doctor and I discussed the values that are important to me.

- Not at all [Not]
- A little [Little]
- Somewhat [Some]
- A lot [Lot]

DrDecision

My doctor left it up to me to decide whether or not to make changes in food or television viewing.

- Not at all [Not]
- A little [Little]
- Somewhat [Some]
- A lot [Lot]

DrFood

My doctor helped me to think about why changing my kid's food habits might be important to my family.

- Not at all [Not]
- A little [Little]
- Somewhat [Some]
- A lot [Lot]

DrThinkChanges

My doctor helped me think about why changing my kid's television habits might be important to my family.

- Not at all [Not]
- A little [Little]
- Somewhat [Some]
- A lot [Lot]

DrMakeChange

My doctor helped me feel like I could make changes in my kid's food or television habits, if I wanted to.

- Not at all [Not]
- A little [Little]
- Somewhat [Some]
- A lot [Lot]

DrPressure

I felt pressured by my doctor to make changes.

- Not at all [Not]
- A little [Little]
- Somewhat [Some]
- A lot [Lot]

When answering the next questions, please think about the time you spent talking with the dietitian/nutritionist assigned to you through the BMI program.

SatisfiedDietitian

Overall, how satisfied are you with the phone calls with the dietitian?

- Very dissatisfied
- Somewhat dissatisfied
- Somewhat satisfied
- Very satisfied

NumbCalls

What did you think about the number of calls you had with your dietitian?

- Too few
- Just right
- Too many

LengthCallsDietitan

The length of my calls with my child's dietitian were…

- Too short
- Just about right
- A little too long
- Much too long

LongDietitianSession

How long was your last session with the dietitian?
(5 minute increments for 60 minutes)

SpeakVisitsDietitian

Who tends to speak more during your calls?

- I talked more than my dietitian [Me]

- The dietitian talked more than me [Dietitian]
- We talked about the same amount of time [Equal]

InfoDietitian

Overall, how much information did the dietitian provide you?

- Not enough [NotEnough]
- Just the right amount [JustRight]
- Too much [TooMuch]

AdviceDietitian

Overall, how much advice did the dietitian give you?

- Not enough [NotEnough]
- Just the right amount [JustRight]
- Too much [TooMuch]

DietitianChangedView

My calls with the dietitian changed the way I think about my child's health.

- Not at all [Not]
- A little [Little]
- Somewhat [Some]
- A lot [Lot]

DietitianOpinion

My dietitian asked my opinion about things.

- Not at all [Not]
- A little [Little]
- Somewhat [Some]
- A lot [Lot]

DietitianChoices

My dietitian gave me choices about what to do.

- Not at all [Not]
- A little [Little]
- Somewhat [Some]
- A lot [Lot]

DietitianUnderstands

My dietitian understands what I am saying.

- Not at all [Not]
- A little [Little]
- Somewhat [Some]
- A lot [Lot]

DietitianListened

My dietitian listened to me.

- Not at all [Not]
- A little [Little]
- Somewhat [Some]
- A lot [Lot]

DietitianRushed

My dietitian rushed me through the calls.

- Not at all [Not]
- A little [Little]
- Somewhat [Some]
- A lot [Lot]

DietitianQues

My dietitian asked too many questions.

- Not at all [Not]
- A little [Little]
- Somewhat [Some]
- A lot [Lot]

DietitianPermission

My dietitian asked permission before giving me information or advice.

- Not at all [Not]
- A little [Little]
- Somewhat [Some]
- A lot [Lot]

DietitianSupportive

My dietitian was supportive/encouraging.

- Not at all [Not]
- A little [Little]
- Somewhat [Some]
- A lot [Lot]

DietitianValues

My dietitian and I discussed the values that are important to me.

- Not at all [Not]
- A little [Little]
- Somewhat [Some]
- A lot [Lot]

DietitianDecision

My dietitian left it up to me to decide whether or not to make changes in my kid's food or television viewing.

- Not at all [Not]
- A little [Little]
- Somewhat [Some]
- A lot [Lot]

DietitianFood
My dietitian helped me to think about why changing my food habits might be important to my family.
- Not at all [Not]
- A little [Little]
- Somewhat [Some]
- A lot [Lot]

DietitianThinkChanges
My dietitian helped me to think about why changing my television habits might be important to my family.
- Not at all [Not]
- A little [Little]
- Somewhat [Some]
- A lot [Lot]

DietitianMakeChange
My dietitian helped me feel like I could make changes in my kid's food or television habits, if I wanted to.
- Not at all [Not]
- A little [Little]
- Somewhat [Some]
- A lot [Lot]

DietitianPressure
I felt pressured by my dietitian to make changes.
- Not at all [Not]
- A little [Little]
- Somewhat [Some]
- A lot [Lot]

Texts==Yes
NumbTexts
What do you think about the number of text messages you received throughout the program?
- Too few
- Just right
- Too many

Texts==Yes

UsefulTexts
How useful or not useful were the text messages you received?

- Not at all useful [Not]
- A little useful [Little]
- Somewhat useful [Some]
- Very useful [Lot]

UsePortal
Did you use the parent website to view additional information, print the tracking diaries, or to reschedule or book an appointment with your dietitian?

- Yes
- No
- I don't know

UsePortal==Yes
UsefulPortal
How useful or not useful was the parent portal?

- Not at all useful [Not]
- A little useful [Little]
- Somewhat useful [Some]
- Very useful [Lot]

UsePortal==Yes
UsefulHandouts
How useful or not useful were the handouts on the parent portal?

- Not at all useful [Not]
- A little useful [Little]
- Somewhat useful [Some]
- Very useful [Lot]

General
Is there anything else you would like to tell us about this program?
(fill in, 500 characters)

That's the end of the questions. Thank you for completing this survey!

ATTACHMENT O

Study Paragraph for PCC

ATTACHMENT O

Receive free training in Motivational Interviewing for the treatment of pediatric overweight and obesity!

In collaboration with Pediatric Research in Office Settings (PROS), the practice-based research network of the American Academy of Pediatrics, we are excited to announce the launch of the *Brief Motivational Interviewing to Reduce Body Mass Index* (BMI^{2+}) project. This project, will:

- Test the effectiveness of brief Motivational Interviewing delivered by healthcare providers to parents of overweight and obese youth on child health outcomes;
- Provide free training in Motivational Interviewing to participating clinicians (1-2 per practice);
- Provide an opportunity for MOC part 2, MOC part 4, and CME credits.

Enrollment is now open - PROS can accept up to 2 clinicians from each of 18 pediatric primary care practices into this research study.

If you are interested in learning more about this project, please contact AAP PM, PhD via email (mwright@aap.org and cc to PROSops@aap.org) or phone (800-433-9016 ext. 7629) and she will reach out to you with more information and materials.

ATTACHMENT P

Recruitment Flyer

BMI^{2+}

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

Brief Motivational Interviewing to Reduce Child BMI

Principal Investigator:

- Ken Resnicow, PhD

BMI^{2+} is a collaboration between:

- American Academy of Pediatrics / Pediatric Research in Office Settings (PROS) research network
- University of Michigan
- Physician's Computer Company
- Children's Hospital of Philadelphia

Study Funder: National Heart, Lung, and Blood Institute (NHLBI), Grant # 1R01HL128231

About the BMI^{2+} study:

- Randomized trial testing the effectiveness of clinician and dietician behavioral counseling on weight outcomes in 3-8 year old children
- Will take place in up to 18 pediatric primary care practices across the US for 2 years
- Practices randomized to Intervention or Usual Care

Benefits of participation:

- In-person training in motivational interviewing and behavior therapy for 1-2 clinicians per practice (all expenses paid)
- Training to optimize billing and coding for obesity-related services
- MOC and CME credits
  - ⇒ MOC Part IV (Intervention arm)
  - ⇒ MOC Part II & CME (both study arms)

To join the study:

Please contact AAP PM, PhD via email (mwright@aap.org and cc to prosops@aap.org) OR phone (800-433-9016 ext. 7629)

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BMI^{2+} Frequently Asked Questions (FAQs)

Pediatric Research in Office Settings
A program of the American Academy of Pediatrics

What will I / my practice need to do if I participate in this study?

All participating clinicians will be asked to:

- Provide written, informed consent
- Complete and return PROS intake forms and surveys
- If needed, complete local IRB procedures (PROS will provide assistance)
- Complete Human Subjects Training

All participating practices will be asked to:

- Agree to have Physician's Computer Company (PCC) securely share practice electronic health record and billing data with the study team

If your practice is randomized to the Intervention arm, 1-2 clinicians will also be asked to:

- Participate in a 2.5-day Motivational Interviewing (MI) and obesity coding/billing training workshop in the Chicago area (all expenses paid) at the start of the trial
- Help enroll parents of eligible children
- Deliver up to 4 MI counseling sessions to enrolled parents over the course of 2 years. Trained registered dieticians at the University of Michigan will provide up to 6 counseling sessions during this time.

If your practice is randomized to the Usual Care arm, you will be asked to:

- Receive training about study procedures and coding & billing for obesity-related services via phone and / or webinar
- Option to participate in a 1.5-day MI training workshop in the Chicago area (all expenses paid) at the conclusion of the trial

How many clinicians can participate per practice?

Up to 2 clinicians in your office can participate and receive free MI training. If your practice is randomized to the Intervention arm, we also ask that someone in your office is designated as the study coordinator.

What is required for Human Subjects Training?

We will send you a link to an online training module, offered by the National Institutes of Health (NIH) Office of Extramural Research. This training only takes between 35-40 minutes to complete. This training is required in order to protect research study participants.

ATTACHMENT Q

Introductory Letter to Parents

ATTACHMENT Q (on practice letterhead)

Dear [NAME],

Our practice is excited to be participating in a new research study with partners at the American Academy of Pediatrics (AAP), the University of Michigan, and the Children's Hospital of Philadelphia (CHOP). As the parent or legal guardian of a child who is between 3 and 8 years old, you are eligible to participate with us!

The goal of this study is to learn whether talking with doctors and dietitians about healthy eating, physical activity, and screen time affects health outcomes in children. Discussions will take place between you - the parent / legal guardian, your child's doctor, and the study dietitian.

If you decide to enroll in this study, you will be asked to:

- Allow study dietitians at the University of Michigan to contact you via phone, email, and / or US mail for study-related purposes.
- Complete surveys that ask about your child's eating, physical activity, and screen time habits, your goals for changing these habits, your progress towards these goals, and your satisfaction with the study.
- Have up to four 15-minute office visits with your child's doctor (to talk about healthy eating, physical activity, and screen time habits).
- Have up to six 30-minute telephone visits with a study dietitian (to talk about healthy eating, physical activity, and screen time habits).

Your participation will last no longer than 2 years.

All telephone visits with a study dietitian will be provided at no cost to you.

Participation in this study is completely voluntary; you do not have to take part in order for your child to continue receiving care at our office. If you decide not take part, or if you enroll and then withdraw from the study at a later time, your child's medical care will not be affected by your decision.

If you are interested in participating in this study, please text "XXXX" to the following number (xxxxxxxxxxx), and a study dietitian will call you to discuss the study further. Please also review the enclosed Parent Study Information Sheet, which provides more details about the study.

If you are not interested in the study, you can either do nothing or contact Emerson Delacroix – Project Manager – by phone (734-764-2014) or email (emmed@med.umich.edu) to opt out of receiving any further study-related communications. Please note that if you do nothing, someone from the research team may contact you by phone.

We look forward to hearing from you!

Sincerely,

<<practice designated closing>>

ATTACHMENT R

Parent Study Information Sheet

Parent Information Sheet

BMi 2+

Study Title: *Population Effects of Motivational Interviewing on Pediatric Obesity in Primary Care*

Principal Investigator: *Ken Resnicow, PhD*

What is the purpose of this research study?

Our office is participating in an exciting new study about eating, physical activity, and screen time behaviors in children. We are approaching you because your child is 3 to 8 years old and has a body mass index (BMI) ≥ 85th percentile.

Who is doing this study?

Our practice is one of 18 around the country that are working with researchers at the American Academy of Pediatrics (AAP), the University of Michigan, and the Children's Hospital of Philadelphia to carry out this study. The study has been approved by the Institutional Review Board (IRB) at the AAP. *An IRB is a committee that protects the rights and welfare of human subjects involved in research.*

What am I being asked to do for this study?

If you agree to participate, you will be asked to do the following during the 2-year study:

- Allow a dietitian at the University of Michigan to call or email you for study-related purposes. *A dietitian is an expert on diet and nutrition.*
- Complete several surveys, including:

  Two surveys at the start of the study (15-30 minutes each) that ask questions about your child's diet, physical activity, and screen time habits.

  One follow-up survey at the end of the study (5 minutes) that asks questions about how the study went for you and your child.
- Have up to four 15-minute office visits with your child's doctor. *You may be charged a co-pay for these visits, depending on your insurance.*
- Have up to six 30-minute telephone visits with a dietitian. These sessions will be recorded. *You will not be charged for these visits.*
- Schedule yearly well-child visits for your child.

What are the potential harms or risks if I join this study?

There is a small risk of loss of confidentiality. To protect you, all files will be secured, either using password protection and firewalls (if information is digital) or locked cabinets (if the information is on paper). *A firewall protects a computer from being used by the wrong people.* Only those involved in the study, as well as your child's doctor, will have access to your data. You may be uncomfortable talking with your child's doctor or a study dietitian, or answering survey questions, about your child's weight and lifestyle habits. You do not have to talk about anything or answer questions that make you uncomfortable. You may be charged a co-pay for office visits with your child's doctor.

What are the potential benefits if I join this study?

If you join the study, all telephone visits with dietitians will be free of charge. You'll get materials and activities to help you and your family improve eating, physical activity, and screen time habits, if you wish.

Will I be paid to be a part of this study?

No, families will not be paid for their participation.

How can I join this study?

If you would like to take part, please text "XXX" to the following number (XXXX), or let your child's doctor know at the next office visit. A dietitian from the University of Michigan will also reach out to you by phone within the next 2 weeks.

What will happen if I choose to not take part in the study?

This study is completely voluntary and you can choose to join or not, and can stop at any time. Your decision will not affect the care your child receives.

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Continued on next page

Confidentiality of records and HIPAA authorization

This section gives you information about what health information will be collected in this study, who will use this information and why, who the information will be shared with, your rights to access your health information during the study, and your right to withdraw your authorization (approval) for any future use of your health information. By law, we are required to get your permission to use your health information in the ways specified below, for the purposes of this study.

Data about you and your child will be collected by surveys (completed by you), during study office visits with your child's doctor, and during study telephone calls with a dietitian; this data will be linked with data from your child's medical record.

The researchers, dietitian and your child's doctor may share the following information during the 2–year study.

- Notes taken after each study visit with you. These notes will describe some of the things that you talked about during the telephone call or office visit, including your goals for your next visit.

This information will be sent to your child's doctor's office, and may be stored in your child's medical record.

Your child's doctor will also have access to the following information:

- Responses to some surveys that you complete during the study. These surveys ask about your child's eating, physical activity, and screen time habits; values, traits, and characteristics that are important to you; goal areas that you would like to focus on; and progress towards those goals.

This information will be stored on a secure computer at the University of Michigan that your child's doctor can access remotely.

It is important for you to know that:

- Only people who work for the study, as well as your child's doctor, will have access to your information.
- No child or parent will be identified by name in any of the study reports and papers.
- At the end of the study, all Protected Health Information (PHI) in study materials will be erased. *PHI is information about you and / or your child, including name, address, and phone number, that is collected by a doctor.*
- If you agree to this Authorization, you are giving permission for the researchers to look at, copy, use, share and discuss information about you and your child during the study with the research team (this includes researchers from the University of Michigan, the American Academy of Pediatrics, and the Children's Hospital of Philadelphia), review boards, and other persons who watch over the safety and conduct of research, and communicate with your child's doctor's office.
- You do not have to agree to this Authorization, but if you do not, you may not participate in the Research. This Authorization does not have an ending date.
- A description of this study will be available on ClinicalTrials.gov, as required by US law. This website will not include any information that can identify you or your child. At most, the site will include a summary of the results. You can search this site any time.

Can I take back this Authorization?

Being in this study is voluntary; if you join this study, you can change your mind and stop at any time. If you don't want to participate or if you stop participation at any time, the care that your child receives at his/her doctor's office will not be affected. You can take back this Authorization at any time. To do so, contact the principal investigator - Ken Resnicow, PhD - at the address or phone number listed below. If you take back this Authorization, your participation in this study will end. It will not affect your care as a patient. Also, even if you take back this Authorization, the researchers may continue to use and share the information they have already collected as permitted by this form.

Do you have any questions about the study?

If you have questions or concerns about the study, you may contact the director of this research, Ken Resnicow, PhD at 734-904-3888. If at any time you have questions about your rights as a research subject, or the protection of human subjects, you may contact Erin Kelly, PhD, IRB Administrator at the American Academy of Pediatrics, at 847-434-4075 or ekelly@aap.org.

ATTACHMENTS S.1 and S.2

S.1	Verbal Consent and HIPAA Authorization Script for Use by RDs
S.2	Verbal Consent and HIPAA Authorization Script for Use by Clinicians

ATTACHMENT S.1

Study Title: Population Effects of Motivational Interviewing on Pediatric Obesity in Primary Care (BMI^{2+})

Principal Investigator: Ken Resnicow PhD

Funder: National Heart, Lung, and Blood Institute (Grant #1R01HL128231)

Introduction

Hello, this is [insert name]. I'm a dietitian and am calling on behalf of [insert practice name]. Your child's doctor is working with researchers at the American Academy of Pediatrics, The University of Michigan, and the Children's Hospital of Philadelphia on a study to learn whether talking with doctors and dietitians about diet, exercise, and screen time can improve the health of children who are 3-8 years old.

The purpose of this call is to help you decide if you want to take part in this research study. I'd like to tell you about the study and your rights as a research participant.

This practice is one of 18 around the country that are participating in this study. If you decide to participate, discussions will occur between you, your child's doctor, and a dietitian. Your participation in the study will last 2 years.

If you agree to be in this study, you'll be asked to:

1. Allow a dietitian at the University of Michigan to contact you via phone, email, and / or US mail for study-related purposes
2. Complete three surveys that ask questions about your child's diet, physical activity, and screen time habits, as well as your satisfaction with the study
3. Go to up to four, 15-minute office visits with your child's doctor
4. Participate in up to six, 30-minute telephone visits with a study dietitian
    - Your telephone visits will be recorded
5. Schedule yearly well-child visits for your child with his or her doctor

It is important for you to understand that:

Being in this study is voluntary

- If you join this study, you can change your mind and stop at any time. If you choose not to participate or if you stop participation at any time, the care that your child receives at his/her doctor's office will not be affected.

- If you withdraw from the study, telephone sessions with RDs will end, as will any surveys. It will not affect your care as a patient. We will continue to use all data collected up until the date of your withdrawal.

There are risks to participating and it is important that you understand what these mean to you

- If you participate, there's a very small risk of loss of confidentiality. To protect you from this risk, all information will be stored securely at the University of Michigan, and only those involved in the study will have access to you and your child's data.

- Although the telephone visits will be provided to you at no cost, it is important for you to know that you may be required to pay co-pays for office visits with your child's doctor, depending on your insurance plan. There are no other costs to you to be in the study.

There are benefits to your participation

The benefits of this study are:

- All telephone visits with study dietitians are provided free of charge
- You'll get materials and activities that may you improve lifestyle behaviors.
- You and your child may benefit from information on healthy eating, physical activity, and screen time habits

Confidentiality of records and HIPAA authorization

No child or parent will be identified by name in any of the study reports and papers.

However, the health information that you provide to us may be used and shared in the ways that you have given us permission to do so. This includes any information you provide in surveys, during study office visits with your child's doctor, and during study telephone visits with a dietitian.

The dietitian and your child's doctor may exchange information about your study visits in order to better inform and personalize your sessions with them.

Specifically, your child's doctor and the research team will receive the following information from the study dietitian:

- Notes that the dietitian prepares after each telephone visit with you.

If you agree to participate in the study, this means you are giving permission for these notes to be:

- Sent to your child's doctor's office
- Securely stored in your child's medical record
- Used and discussed by the research team

- Securely stored at the University of Michigan
- Discussed with review boards, and other persons who watch over the safety, effectiveness, and conduct of research such as authorized representatives of the Office of Human Research Protections ("OHRP"), and our Institutional Review Board (IRB)

This study has been approved by the Institutional Review Board (IRB) at the American Academy of Pediatrics. An IRB protects the rights and welfare of human research subjects that participate in research activities.

You do not have to agree to authorize your participation in this study, but if you do not, you may not participate in the Research. This Authorization does not have an ending date.

To revoke or take back this Authorization, contact the principal investigator, Dr. Ken Resnicow, at 734-904-3888, or I can give you his mailing address. Even if you revoke this Authorization, the Researchers may continue to use the information they have already collected as permitted by the informed consent form.

If you have questions about your rights as a research subject, or the protection of human subjects, you may contact Erin Kelly, PhD, IRB Administrator at the American Academy of Pediatrics at 847-434-4075. A description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. Law. This site will not include information that can identify you. At most, the site will include a summary of the results. You can search this site at any time.

Do you have any questions today about the study?

You should have already received a written summary of all the details that we have discussed today, via email and / or mail. Would you like us to send you another copy?

- ☐ Yes, Email
- ☐ Yes, Mail
- ☐ No

Do you agree to participate?

- ☐ Yes
- ☐ No

Do you agree to release the personal information as described above?

- ☐ Yes
- ☐ No

Documentation that the parent or guardian verbally consented to participate in this study, and provided HIPAA authorization, will be made via the University of Michigan study dashboard and in the EHR.

ATTACHMENT S.2

Study Title: Population Effects of Motivational Interviewing on Pediatric Obesity in Primary Care (BMI^{2+})

Principal Investigator: Ken Resnicow PhD

Funder: National Heart, Lung, and Blood Institute (Grant #1R01HL128231)

Introduction

Hi! I wanted to let you know about an exciting new research study that our practice is participating in. You may have already heard about it, since the study team recently sent out a letter and information sheet to you. We are working with researchers at the American Academy of Pediatrics, the University of Michigan, and the Children's Hospital of Philadelphia to learn whether talking with doctors and dietitians about diet, exercise, and screen time can improve the health of children 3-8 years old. You are eligible to participate in this study, and I'd like to help you decide if you want to do so.

Our practice is one of 18 around the country that are participating in this study. If you decide to participate, discussions will occur between you, me, and a dietitian. Your participation in the study will last 2 years.

If you agree to be in this study, you'll be asked to:

- Allow a dietitian at the University of Michigan to contact you via phone, email, and / or US mail for study-related purposes
- Complete three surveys that ask questions about your child's diet, physical activity, and screen time habits, as well as your satisfaction with the study
- Come to up to four, 15-minute office visits with me at our practice
- Participate in up to six, 30-minute telephone visits with a study dietitian
    - Your telephone visits will be recorded
- Schedule yearly well-child visits for your child at our practice

It is important for you to understand that:

Being in this study is voluntary

- If you join this study, you can change your mind and stop at any time. If you choose not to participate or if you stop participation at any time, the care that your child receives here will not be affected.

- If you withdraw from the study, telephone sessions with RDs will end, as will any surveys. It will not affect your care as a patient. The study team will continue to use all data collected up until the date of your withdrawal.

There are risks to participating and it is important that you understand what these mean to you

- If you participate, there's a very small risk of loss of confidentiality. To protect you from this risk, all information will be stored securely, and only those involved in the study will have access to you and your child's data.
- Although the telephone visits will be provided to you at no cost, it is important for you to know that you may be required to pay co-pays for office visits with me, depending on your insurance plan. There are no other costs to you to be in the study.

There are benefits to your participation

The benefits of this study are:

- All telephone visits with study dietitians are provided free of charge
- You'll get materials and activities that may you improve lifestyle behaviors
- You and your child may benefit from information on healthy eating, physical activity, and screen time habits

Confidentiality of records and HIPAA authorization

No child or parent will be identified by name in any of the study reports and papers.

However, the health information that you provide may be used and shared in the ways that you have given us permission to do so. This includes any information you provide in surveys, during study office visits with me, and during study telephone visits with a dietitian.

The dietician and I may exchange information about your study visits in order to better inform and personalize your sessions with us.

Specifically, our office and the research team will receive the following information from the study dietitian:

- Notes that the dietitian prepares after each telephone visit with you.

If you agree to participate in the study, this means you are giving permission for these notes to be:

- Sent to our office
- Securely stored in your child's medical record
- Used and discussed by the research team
- Securely stored at the University of Michigan
- Discussed with review boards, and other persons who watch over the safety, effectiveness, and conduct of research such as authorized representatives of the

Office of Human Research Protections ("OHRP"), and our Institutional Review Boards (IRB)

This study has been approved by the Institutional Review Board (IRB) at the American Academy of Pediatrics. An IRB protects the rights and welfare of human research subjects that participate in research activities.

You do not have to agree to authorize your participation in this study, but if you do not, you may not participate in the Research. This Authorization does not have an ending date.

To revoke or take back this Authorization, contact the principal investigator, Dr. Ken Resnicow, at 734-904-3888, or I can give you his mailing address. Even if you revoke this Authorization, the Researchers may continue to use the information they have already collected as permitted by the informed consent form.

If you have questions about your rights as a research subject, or the protection of human subjects, you may contact Erin Kelly, PhD, IRB Administrator at the American Academy of Pediatrics at 847-434-4075. A description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. Law. This site will not include information that can identify you. At most, the site will include a summary of the results. You can search this site at any time.

Do you have any questions today about the study?

You should have already received a written summary of all the details that we have discussed today, via email and / or mail. Would you like another copy to take with you today?

- ☐ Yes
- ☐ No

Do you agree to participate?

- ☐ Yes
- ☐ No

Do you agree to release the personal information as described above?

- ☐ Yes
- ☐ No

Documentation that the parent or guardian verbally consented to participate in this study, and provided HIPAA authorization, will be made in the EHR and via the University of Michigan study dashboard.

ATTACHMENT T

Study Information Sheet for Non-Participating Clinicians

Study Information Sheet for Non-Participating Clinicians

About the BMI2+ Study

The Brief Motivational Interviewing to Reduce Child BMI (BMI^{2+}) study is a randomized controlled trial testing the effectiveness of clinician and dietician behavioral counseling on weight outcomes. 1-2 clinicians in your practice are participating in this national study.

BMI2+ is a collaboration between the American Academy of Pediatrics (AAP), the University of Michigan, Physicians Computer Company (PCC), and the Children's Hospital of Philadelphia (CHOP). This study is funded by the National Heart, Lung and Blood Institute (NHLBI), Grant # 1R01HL128231. The principal investigator is Ken Resnicow, PhD, at the University of Michigan.

What to Expect as a Non-Participating Clinician:

- At baseline, PCC will extract EHR and billing data for all children 3-8 years old in your practice, and securely transfer a HIPAA-limited dataset to the data coordinating center at CHOP. The dataset will contain patient and clinician study ID numbers – NO names will be included.
- The study team at CHOP will then generate a list of children whose parents are eligible to participate in the study. A parent can only participate if their child's most recent well-child visit was with a study clinician.
- Many patients in your practice will never be contacted by the study team -- only those whose last well-child visit was with a study clinician will be contacted.
- At the end of the 2-year trial, and once again approximately one year after that, PCC will extract EHR and billing data for all children 3-8 years old in your practice, and securely transfer a HIPAA limited dataset to the data coordinating center at CHOP.
- CHOP will then clean the data and securely transfer it to the University of Michigan for analysis.
- Therefore, your patients' data may be extracted to meet the analytic requirements of the study.

What will you need to do?

Nothing! Practice usual care and data extractions will occur behind the scenes, with no disruption to work flow and daily practice.

Questions?

For questions, please contact AAP PM, PhD by email (mwright@aap.org and cc to prosops@aap.org) or phone (800-433-9016 ext. 7629).

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ATTACHMENT U

HIPAA Limited Dataset Research Request Form

American Academy of Pediatrics
Institutional Review Board

HIPAA LIMITED DATA SET FOR RESEARCH REQUEST FORM

DATE: May 25, 2017

PRINCIPAL INVESTIGATOR: Ken Resnicow, PhD

PROTOCOL TITLE: Population Effects of Motivational Interviewing on Pediatric Obesity in Primary Care (BMI2+)

IRB # *(if known)***:**

Per the "Privacy Rule" (a Federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that protects certain health information - 45 CFR Part 160 and Subparts A and E of Part 164), the use of a limited subset of identifiers for research is allowable (45 CFR 164.514(e)(1)) if certain requirements have been met - 164.514(e)(2) and 164.514 (e)(3) and if the covered entity enters into a data use agreement with the limited data set recipient – 164.514 (e)(4). In order for the IRB to determine if the use of a limited data set is allowable, as described in 45 CFR 164.514(e)(1), please provide information for each of the questions and statements.

For more information on HIPAA, see "HIPAA Privacy Rule and Its Impact on Research" and "Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule."

1. Describe the protected health information (PHI – see last page of this form) for which use or access is requested, including the source(s) of the PHI and who will use or have access. *The subset of identifiers that is eligible to be used under the limited data set procedures include: 1) Dates of admission and discharge; 2) Dates of birth (year for >89 years old is allowable) and death dates; 3) five-digit zip code; 4) any geographic subdivision (state, county, city, precinct) larger than street name.*

   All protected health information (PHI) will be accessed electronically through the Electronic Health Record (EHR) and billing data extractions that are done by Physician's Computer Company (PCC). The following identifying elements will be collected:

   - Date of birth
   - Date of death
   - Dates of service

   We outline in Attachment G.2 all individuals who have access to this PHI and how and where the information will be stored.

2. Confirm that you will use the Limited Data Set only for purposes of research, public health, or health care operations.

   I confirm that we are using the Limited Data Set only for purposes of research.

3. Please attach a copy of the data use agreement which must, as specified by 164.514: A) Establish the permitted uses and disclosures; B) Establish who is permitted to use or receive the limited data set; C) Provide that the limited data set recipient will 1) not use or further disclose the information other than as permitted by the data use agreement or required by law; 2) use appropriate safeguards to prevent use or disclosure of the information; 3) report to the covered entity any use or disclosure of the information not provided for by its data use agreement; 4) ensure that any agents, including a subcontractor, to whom it provides the limited data set agrees to the same restrictions and conditions; 5) not identify the information or contact the individuals.

   Please see attachment F for the following Data Use Agreements (DUAs):

   Diagram of required DUAs, DTA, and BAAs (Attachment F.1)

   DUA used for all PROS practices (Attachment F.2)

   University of Michigan – Children's Hospital of Philadelphia (CHOP) DUA (Attachment F.4)

For IRB Use Only

This protocol meets the following requirements for a Limited Data Set:

☐ 1. Only date of admission and discharge, date of birth and death (year for > 89 years of age), five-digit zip code, and geographic subdivisions larger than street name is requested.

☐ 2. Only the minimum necessary information to meet the recipient's well-defined needs is requested.

☐ 3. There is a plan for all recipients to enter in a Data Use Agreement with all covered entities providing the health information, and the Data Use Agreement describes the permitted uses and disclosures of information and prohibits re-identifying or using the information to contact individuals.

This protocol has been reviewed according to HIPAA regulations regarding the use and disclosure of PHI and the protocol:

☐ **meets the above criteria for use of a Limited Data Set**

☐ **does not meet the criteria for use of a Limited Data Set**

What is Protected Health Information (PHI)?

The Privacy Rule protects all "individually identifiable health information" held or transmitted by a covered entity or its business associate, in any form or media, whether electronic, paper or oral. The Privacy Rule calls this information "protected health information (PHI). PHI means any information that is 1) created or received by a health care provider, or other Covered Entity; and 2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual; and identifies the individual or reasonably could be used to identify the individual. PHI is any health information that contains any of the following pieces of information:

1. Names
2. Geographic subdivisions smaller than a state (street address, city, county precinct, zip codes – exceptions for the initial 3 digits of a zip code exist)
3. Dates (except year) for dates directly related to an individual including dates of birth, service, admission, discharge, and death). For persons > 89 years, year of birth cannot be used
4. Telephone numbers
5. Fax numbers
6. Email addresses
7. Social security number
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers
13. Device identifiers and serial numbers
14. Web URLs
15. Internet protocol addresses
16. Biometric identifiers, including fingerprints and voice recordings
17. Full face photos and comparable images
18. Any unique identifying number, characteristic, code

ATTACHMENT V

HIPAA Waiver of Authorization Requirement Request Form

for contact information received for parent recruitment

American Academy of Pediatrics
Institutional Review Board (IRB)

HIPAA WAIVER OR ALTERATION OF THE AUTHORIZATION REQUIREMENT REQUEST FORM

DATE: May 31, 2017

PRINCIPAL INVESTIGATOR: Ken Resnicow, PhD

PROTOCOL TITLE: Population Effects of Motivational Interviewing on Pediatric Obesity in Primary Care (BMI2+)

IRB # *(if known)***:**

Per the "Privacy Rule" (a Federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that protects certain health information - 45 CFR Part 160 and Subparts A and E of Part 164), an IRB may approve a waiver or an alteration of the Authorization requirement in whole or in part if specific criteria, outlined in the questions and statements below, are met.

For more information on HIPAA, see "HIPAA Privacy Rule and Its Impact on Research" and "Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule."

Purpose of Request *(Double click on the box to check)*

☒ Full Waiver of Authorization (*For use when it is impractical or impossible to obtain a person's written Authorization*)

☐ Partial Waiver of Authorization

- ☐ To screen medical records, databases and systems, appointment logs, etc. to identify potentially eligible research participants
- ☐ For recruitment to contact potential participants in order to obtain their Authorization
- ☐ Other, please explain:_____

☐ Alteration of Authorization Requirements (*For use when the form or core components of the form are a barrier to obtaining Authorization*)

Based on federal regulations (45 CFR 164.514), please provide specific information for each of the questions and statements so the IRB can determine whether the alteration or waiver satisfies the required criteria. *Please use as much space as necessary to answer each question.*

1. **Describe the protected health information (PHI – see last page of this form) for which use or access is requested, including the source(s) of the PHI and who will use or have access.**

   A fully identified contact file containing the data elements listed below, for eligible children within Intervention arm practices, will be securely transferred from Physician's Computer Company (PCC) to the study team at the University of Michigan so that the study team can

contact these families for recruitment purposes. The University of Michigan and PCC will have a Business Associate Agreement (BAA; see Attachment F.6), and PCC will have an addendum to their existing BAA with each practice (see Attachment F.7), which permits the disclosure of these identifiers for this purpose.

1. Patient study ID
2. Patient first and last name
3. Patient age (in months)
4. Account ID
5. Parent / guardian first and last name
6. Preferred contact method
7. Parent / guardian home phone number
8. Parent / guardian mobile phone number
9. Parent / guardian email address
10. Parent / guardian postal address
11. Patient primary language
12. Clinician study ID
13. Study clinician name
14. Practice ID
15. Practice name
16. Practice address
17. Practice phone number

2. State why the use or disclosure of PHI involves no more than a minimal risk to the privacy of the individual subjects.

Information will be extracted from existing Electronic Health Records and securely transferred from PCC to the University of Michigan. No other members of the research team will have access to this data.

3. Describe the plan to protect the PHI from improper use and disclosure.

A plan is in place to protect the PHI from improper use and disclosure. See Attachment H.2 for a list of specific steps that will be taken prior to, and after, transmission of this data occurs. See Attachment I.2 for a list of specific steps that will be taken if there is a breach of PHI.

4. Describe when and how identifiers will be destroyed.

All names (patient, parent / guardian, clinician, practice), phone numbers (parent / guardian, practice), email addresses (parent / guardian), postal addresses (parent / guardian and practice), and account IDs will be destroyed after the study team completes its review for possible adverse events. These identifiers will be stripped from all datasets and servers at that time. Mr. Nowak – data team lead at the University of Michigan - or his designee will sign an attestation letter (Attachment H.4) stating that all contact information has been appropriately deleted, and send that letter to Dr. Wright at the AAP.

Patient age, primary language, patient study ID, clinician study ID, and practice ID will be retained as part of an analytic dataset indefinitely.

5. **Provide assurance that the protected information will not be reused or disclosed to any other person or entity, except as required by the law for authorized oversight of the research study.**

   The Business Associate Agreement (BAA) between the University of Michigan and Physician's Computer Company (see Attachment F.6) contains language regarding the permissible use and disclosure of PHI, as well as limitations on its use and disclosure.

6. **Describe why the research cannot practicably be conducted without the waiver.**

   The secure transfer of PHI from PCC to the University of Michigan for parent recruitment purposes is allowable under the provisions of the BAA (see Attachment F.6) between these parties, as well as the addendum to the existing BAA that PCC has with each of their clients (see Attachment F.7). A waiver is needed because recruitment of eligible families cannot proceed without their contact information; recruitment represents the study team's first contact with these individuals.

7. **Describe why the research could not be practicably conducted without access to and use of the protected health information.**

   An introductory letter (Attachment Q) and parent study information sheet (Attachment R) will be sent via email and US mail to the parents of eligible children in Intervention arm practices. The study team would be unable to send these materials without access to and use of the PHI.

Principal Investigator statement:

I plan to use or disclose Protected Health Information in conducting the above referenced research activity. I represent that the following statements are true and correct regarding such use and disclosure:

- I will abide by the plan for safeguarding participant information specified above;
- I assure that no research participant's Protected Health Information will be reused or disclosed to any other person, except as required or permitted by law;
- I represent that the described research cannot practicably be conducted without the requested Waiver of HIPAA Authorization;
- I represent that the described research cannot practicably be conducted without access to and use of the indicated Protected Health Information; and
- I represent that this research study involves not more than a minimal risk to the privacy of research participants.

I request that the AAP IRB approve this waiver as described above.

	5/31/17
Principal Investigator	Date
AAP Department Director	Date
AAP Senior Vice President	Date
AAP Chief Compliance Officer	Date

For IRB Use Only

This protocol meets the following requirements for a Waiver of Authorization:

☐ 1. The use or disclosure of subject's PHI involves no more than "minimal risk" because:
   a. There exists an adequate plan to protect the identifiers from improper use and disclosure.
   b. There exists an adequate plan to destroy all identifiers after the study is completed.
   c. PHI will not be reused or disclosed to any other person or entity, except as required by law, for oversight of the study.

☐ 2. The research could not practicably be carried out without waiver or alteration.

☐ 3. The research could not practicably be conducted without access to and the use and disclosure of PHI.

This protocol has been reviewed according to HIPAA regulations regarding the use and disclosure of PHI and the protocol:

☐ **meets the above criteria for Waiver of Authorization**

☐ **meets the above criteria for Partial Waiver of Authorization**

☐ **does not meet the criteria for approval of Waiver of Authorization**

IRB Chair/Reviewer Signature: _____Date:_____

What is Protected Health Information (PHI)?

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12. Vehicle identifiers and serial numbers
13. Device identifiers and serial numbers
14. Web URLs
15. Internet protocol addresses
16. Biometric identifiers, including fingerprints and voice recordings
17. Full face photos and comparable images
18. Any unique identifying number, characteristic, code

ATTACHMENT W

Alteration of Informed Consent Request Form

American Academy of Pediatrics
Institutional Review Board

WAIVER OR ALTERATION OF INFORMED CONSENT REQUEST FORM
45 CFR 46.116(d)

DATE: May 25, 2017

PRINCIPAL INVESTIGATOR: Ken Resnicow, PhD

PROTOCOL TITLE: Population Effects of Motivational Interviewing on Pediatric Obesity in Primary Care (BMI2+)

IRB # *(if known)***:**

Per federal regulations (**45 CFR 46.116(d)**) a consent procedure which does not include, or which alters, some or all of the elements of informed consent may be approved by the IRB under certain conditions. In order for the IRB to grant this waiver, the regulations require that **ALL** four of the following conditions be met. Please be specific in explaining why each statement is true for this research.

1. **The research involves no more than minimal risk to the subjects.**

   We are requesting:

   1) an alteration of written informed consent / HIPAA authorization for all participating parents in Intervention arm practices.

   Note that all participating clinicians in both study arms will provide written informed consent.

2. **The waiver or alteration will not adversely affect the rights and welfare of the subjects.**

   We believe that the alteration of written informed consent / HIPAA authorization will not affect the rights and welfare of the subject for the following reasons:
   1) The parent study information sheet (Attachment R) includes all required elements of informed consent and HIPAA authorization
   2) The parent study information sheet will be sent via email and US mail to the parent for their record, and provided again after verbal consent / HIPAA authorization should they so desire
   3) A trained Registered Dietician or study clinician will use a script (Attachments S.1 and S.2) to review the study information sheet with the parent, answer any questions the parent has, and verify (by documenting in the EHR and / or study dashboard) that the parent has consented to be in the study and has provided HIPAA authorization.

3. **The research could not practicably be carried out without the waiver or alteration.**

   This research could not be practicably carried out without the alteration of written informed consent / HIPAA authorization because Registered Dieticians (RDs), located in the central call center at the University of Michigan, will enroll eligible Intervention arm parents over the phone.

Study clinicians will also enroll and obtain consent / HIPAA authorization from eligible Intervention arm parents (albeit in person), although we do not expect that this will occur frequently.

4. **Whenever appropriate, the subjects will be provided with additional pertinent information after participation.**

   At the end of the study, we will provide the participating practices with the results so that they can share them with the families in their practices, as appropriate.