Total Child Health
Longitudinal SUBJECT INFORMATION AND INFORMED CONSENT FORM

Protocol Title: A clinical Process Support System for primary care to address family stress
Protocol #: **R44HD089785**
Sponsor: n/a
Principal Investigator: Dr. Barbara J. Howard, MD.
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KEY INFORMATION ABOUT THIS RESEARCH STUDY

We are excited to invite you to participate in an important project called "A clinical process support system for primary care to address family stress."

Before we tell you more about this study, and before you decide if you want to participate, we need to know that you are eligible to join.

Please indicate your relationship with this child

Are you a main caregiver of this child? Yes No

Are you a legal guardian (and not a foster parent) of this child? Yes No

[If the parent is not a legal guardian, the screen says the below, and the questionnaire is done.
"Thank you for answering. As you are not a legal guardian, you cannot consent to
participate in this project.
Please provide the email address of a legal guardian:_____ to whom we could
offer participation."]

This is a study of a method for improving how pediatricians can help parents with family stressors to improve outcomes for their children. We need parents to complete some extra questionnaires about parenting when your child is 4, 18 and 24 months old. We will also ask you about your opinion of the care your child received at 18 and 24 months. We will review your child's medical record. We will

be sending a list of participant names to the state protective services agency and the agency will send us back a total count of children who were reported. Your or your child's name or other identifying information will not be in any of the reports for this project. You will be paid to help the study. The only risk of participating is rare risk of loss of privacy.

The following table is a concise and focused presentation of key information to assist you in understanding why you might or might not want to participate in the research.

Purpose	This project is to see if identifying problems, providing resources and helping your doctor with solutions using CHADIS will help child wellbeing.
Experimental/ Investigational	Your child will not receive any experimental drugs or procedures as part of this study.
Voluntary Participation	Your decision to be in this study is voluntary.
Withdrawal	If you decide to be in this study and then change your mind, you can leave the study at any time without penalty.
Length of Participation	Your participation is expected to last about 2 years.
Procedures	You will complete research questionnaires at your well child visits over a 2 year period.
Risks	There are not expected to be any physical risks to your child as part of this study.
Benefit	You and your child may not directly benefit from participating in this study but knowledge may be gained from your participation that may help other families in the future.
Costs	There is no cost to participate in this research study.
Confidentiality	There are provisions in place by the study protocol and study site to help protect the privacy and confidentiality of you and your child's personal health information and study information.

This overview does not include all of the information you need to know before deciding whether or not to take part. Much additional detail is given in the full consent document, which can be found on the pages that follow. Be sure to review the rest of this consent form before deciding about participation.

INFORMED CONSENT FORM

This consent form explains the research study. Before you decide to be a part of this study, you need to know why the research is being done, what it will involve and the risks and benefits. Ask the study doctor and study staff to explain anything in this form or if you want more information. Please take time to read this form carefully. Feel free to discuss it with your relatives, friends and your primary care physician. If you agree to take part in this research study, you must sign this consent form.

DISCLOSURE OF FINANCIAL INTERESTS

The National Institute of Health is providing funds to Total Child Health for conducting this research study. Some of the researchers may be able to benefit from the overall results of the study.

PURPOSE OF THE STUDY

Why are we doing this study? This project is to see if identifying problems, providing resources and helping your child's doctor with solutions using CHADIS will help child wellbeing.

Why was I chosen? You were chosen because you are the parent or guardian of a child under 4 months old and attending a clinic that uses a web system called CHADIS. Your child's doctor uses CHADIS to review questionnaire information needed to identify and address health risks.

NUMBER OF SUBJECTS AND LENGTH OF STUDY PARTICIPATION

About 8250 subjects are expected to participate in this study at 30 research sites in the United States.

Your participation in this study is expected to last about 2 years.

STUDY PROCEDURES

If you agree to the study, you will fill out a few extra questionnaires about you and your child now and two more times during the next 2 years. The extra set of questionnaires will take up to 30 minutes each time. If a cell phone number is provided we may send you occasional text messages related to your questionnaires. You will also give permission for the research staff to access your child's medical record. You will give permission for the research staff to obtain the total number of children with protective service reports from the entire list of children participating with no names or identifying information revealed to the staff or doctors. No information identifying you or your children will be disclosed or included in research results.

RISKS AND DISCOMFORTS

Are there any risks? There are few risks to the study and these may include accidental loss of privacy and discomfort at some of the questions asked in the questionnaires.

What are the potential benefits? You may not directly benefit from participating in this study but knowledge may be gained from your participation that may help other families in the future.

COSTS OF PARTICIPATION

Will it cost me anything to participate? There is no cost to participate in this research study. You will not lose any legal rights by signing this form.

REIMBURSEMENT

You will receive a $10 gift card after completing each of the 3 sets of research questionnaires for a total of $30.

COMPENSATION FOR INJURY

For medical emergencies please call 911.

Because this study involves only the sharing of medical information and requires no specific procedures, tests, or treatments, no research-related injuries are expected. No other compensation will be offered by Total Child Health or the sponsor or the Biomedical Research Alliance of New York.

You are not waiving any legal right to seek additional compensation through the courts by signing this form.

New Information

If any new information is learned about this study that might affect your willingness to stay in this study, you will be told about it promptly.

ALTERNATIVES TO PARTICIPATION

Your alternative to being in this study is to not take part.

CONFIDENTIALITY

To the extent allowed by law, every effort will be made to keep your personal information confidential. However, information from this study will be submitted to the study sponsor (NIH). Medical records, which identify you and the consent form signed by you, may be looked at by the sponsor or the sponsor's representatives, and the Institutional Review Board (Biomedical Research Alliance of New York). While these parties are aware of the need to keep your

information confidential, total confidentiality cannot be guaranteed. The results of this research project may be presented at meetings or in publications; however, neither you nor your child will be identified in these presentations and/ or publications.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you. If you choose to be in this study, the study doctor will get personal information about you and your child. This may include information that might identify you or your child. The study doctor may also get information about your child's health, including:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Billing records

Information about your child's health may be used and given to others by the study doctor and staff. They might see the research information during and after the study. Your child's information may be given to the sponsor of this research (NIH). Information about you and your child and your child's health which might identify you or your child may be given to:

- Department of Health and Human Services agencies
- Biomedical Research Alliance of New York (BRANY)
- The Institutional Review Board
- Data safety monitoring boards

Your and your child's personal health information may be further shared by the groups above. However, these groups are committed to keeping your personal health information confidential. If you give permission to give your and your child's identifiable health information to a person or business, the information may no longer be protected. There is a risk that your and your child's information will be released to others without your permission.

Information about you, your child and your child's health that might identify you or your child may be given to others to carry out the research study. The information may also be used to meet the reporting requirements of governmental agencies.

This authorization does not have an expiration date. If you do not withdraw this authorization in writing, it will remain in effect indefinitely.

By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. You do not have to sign this consent form. If you choose not to sign this consent form, you will not be able to be in this research study. Your decision not to sign this consent form will not have any effect on your child's medical care and you and your child will not lose any benefits or legal rights to which you are entitled. You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you may not be allowed to look at or copy your

information until after the research is completed.

You may withdraw or take away your permission to use and disclose your child's health information at any time. You do this by sending written notice to the study doctor at the address on the front of this informed consent form. If you withdraw your permission, you will not be able to continue being in this study, but you will not have any penalty or loss of access to treatment or other benefits to which you are entitled. When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Collection of Identifiable Private Information:
Identifiers might be removed from your identifiable private information. After such removal, the information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent (or consent from your legally authorized representative).

CERTIFICATE OF CONFIDENTIALITY

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

the Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by The National Institutes of Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of such as child abuse and neglect, or harm to self or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

Notice Concerning HIV-Related Information: HIV-related information that either is collected as part of the research or that may already exist in your medical record might be accessed for the research by the research staff and the study sponsor, but will not be shared with others without

your authorization, unless federal or state law requires the disclosure. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the agencies responsible for protecting your rights.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your and your child's participation in this study is voluntary. You may decide not to participate or you may stop your and your child's participation at any time, without penalty or loss of benefits or medical care to which your child is otherwise entitled. If you decide to leave the study, please tell the study doctor.

Your and your child's participation in this study may be stopped without your consent at any time and for any reason by the study doctor, the sponsor, the FDA and other regulatory authorities. Reasons you or your child may be withdrawn from the study include if it is determined to be in your or your child's best interest, your child needs treatment not allowed in this study, you do not follow the study instructions, the study is stopped, or for other administrative reasons.

CONTACTS FOR QUESTIONS, COMPLAINTS, CONCERNS

If you have any questions or requests for information relating to this research study or your or your child's participation in it, or if you want to voice a complaint or concern about this research, or if you have a study related injury, you may contact Dr. Barbara J. Howard, MD. at 888-424-2347.

If you have any questions about your or your child's rights as a research subject or complaints regarding this research study, or you are unable to reach the research staff, you may contact a person independent of the research team at the Biomedical Research Alliance of New York Institutional Review Board at 516-318-6877. Questions, concerns or complaints about research can also be registered with the Biomedical Research Alliance of New York Institutional Review Board at www.branyirb.com/concerns-about-research.

STATEMENT OF CONSENT

By signing this form, I confirm the following:

- I have read all of this consent form.
- All of my questions have been answered to my satisfaction.
- I can leave the study at any time without giving a reason and without penalty.
- I agree to the collection, use, sharing and analysis of my and my child's personal health information and study information collected as part of this study by the sponsor and other authorized persons and regulatory agencies as described in this form.
- I will be able to print a copy of this signed and dated consent form to keep or have one mailed to me.
- I and my child do not give up any legal rights that we would otherwise have if we were not in this study.

I voluntarily agree to participate and for my child to participate in this study.

Please chose one of the three options below:

- I agree to the study. By clicking the box for "I agree" and typing my name in the box below, I am agreeing to participate and for my child to participate in this study.
  Signature (Type your full name in the box.)

  Also, please provide a phone number of a relative or friend who can help us contact you if your phone number changes during the study:

- Please call to tell me more about this study so I can decide whether to join.

- I do not agree to be in the study.

Do we have permission to contact you about future studies? □ yes □ no

Please choose how you would like to receive your gift card (choose one):

*If you don't have a personal email address or cell phone, please provide one for someone you trust.

- I would like to receive a $10 Amazon Gift card emailed to _____@_____
- I would like to receive a $10 Amazon Gift card texted to my cell phone _(____)____-_____
- would like to receive a $10 CVS gift card emailed to _____@_____

***Please note: You can print this completed form from your own printer in the 30 days after you submit it. Log into CHADIS, click the 'Review' button next to the questionnaire titled 'Family Stress Consent Form', scroll to the bottom, then click 'Print'. Or you may contact the research team at 443-738-4503 or O@chadis.com to request a mailed copy of the form.