PROJECT TITLE:

Photo-Narrative Pilot RCT Study

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PARTICIPATING SITES[1]: N/A

Contents

1. Objectives

1.1. Purpose, specific aims, or objectives:

The objective of this study is to conduct a pilot randomized controlled trial (RCT) of a photo-narrative communication intervention developed by our study team with patients/parents/LAR of children with severe neurological impairment (SNI) and their pediatric intensive care unit (PICU) clinicians to assess feasibility, acceptability, and early efficacy.

1.2. Hypotheses to be tested:

We hypothesis that the intervention will be feasible and acceptable. Preliminary efficacy findings will include better post intervention scores adjusted for baseline scores in the intervention group compared to the usual care group for parent/LAR stress, perceived therapeutic alliance, and clinician prosocial behaviors.

2. Background

2.1. Relevant prior experience and gaps in current knowledge:

Supporting surrogates during critical decision-making is mandated by the Institute of Medicine and core to palliative care.[1-4] These critical decisions, defined as those regarding technology use, goals of care, and end-of-life care are stressful and often result in conflict between parents and clinicians.[5-9] Similar to dependent adult patients where surrogate decision-making is the norm (e.g., severe dementia), these problems are common for children with severe neurological impairment (SNI) who have global central nervous system injuries and/or conditions resulting in significant alterations in health and quality-of-life.[10,11] These children make up <1% of the pediatric population, but disproportionally account for 14% of patients in children's hospitals, 25% of hospital bed days, and 29% ($12 billion) of hospital charges, and their impact on the pediatric healthcare system is growing.[12]

Children with SNI live with many comorbidities and significant mortality; only 25% survive to age 30 years and over 50% die in the PICU.[13-16] Despite their intensive healthcare needs, parents of children with SNI report poor communication and conflict with clinicians during critical decision-making in the hospital for their children.[17]

Previous studies have identified important ways clinicians can support surrogates in critical decision-making among adults with advanced illnesses and among parents of children with terminal cancer.[18-21] A crucial factor of success is therapeutic alliance, which is the sense of mutual understanding, caring, and respect important for compassionate medical decision-making.[22] Therapeutic alliance is likely to be even more important to communication and decision-making for children with SNI, but remains under-explored.

We have completed the next proximal steps towards building strong therapeutic alliances between parents/LAR of children with SNI and clinicians and, in turn, alleviating conflict and facilitating communication by developing an evidenced-based photo-narrative intervention that builds therapeutic alliance by meeting the unique needs of these patients and families. The study will address the crucial next steps for piloting the intervention in an RCT.

2.2. Relevant preliminary data:[2]

Clinicians recognize strained communication with parents of children with SNI**.** In a national mixed methods study of clinicians across subspecialties caring for children with complex chronic conditions, including SNI, clinicians reported feeling a "lack of expertise" in caring for children with SNI that stemmed from limited training on how to build a therapeutic alliance with parents when cure was not possible.[23] Studies have also examined the needs of various pediatric

subspecialists in communicating with parents of children with SNI and found a pervasive need for tools to elicit a family's priorities and perceptions of their child's quality of life.[24] Similar barriers have been found in studies among multidisciplinary clinicians during end of life care for children with serious illness, including children with SNI in the hospital.[25]

Psychosocial well-being of parents of children with SNI is impacted by poor communication. To address this, we completed a qualitative study to explore the psychosocial needs of parents of children with SNI in regard to their communication with clinicians. Findings suggest parents need to communicate their perspectives about their child's health and the values that guide their care decisions to manage the sustained stress, caregiving burdens, and communication challenges with clinicians during their child's critical illness. Findings also alluded to positive psychosocial tools; in that parents find benefit, strength, and resilience from advocating for their child, sharing their narrative, and from connections with clinicians. Together, these findings suggest that a program supporting parent narratives and perspectives may help both parents, their children, and the clinical team.

We have used these findings to iteratively develop the photo-narrative communication intervention. Specifically, we conducted 4 rounds of stakeholder-inclusive design with a national multidisciplinary team of researchers, clinicians (physicians, nurses, social workers, and psychologists), and parents with expertise in the care needs of children with SNI. With user-centered design strategies, we first proposed the intervention scaffold based on previous studies. The stakeholder focus group completed a group cognitive think aloud to revise and refine the scaffold. We then repeated the process 3 more times until we arrived at the current tool which both clinicians and parents agreed met parent needs and would be feasible to implement. We subsequently have been refining the tool in the PICU among parents/LAR and clinicians using both surveys and user-centered design to further refine the intervention which is now ready for pilot testing.

2.3. Scientific or scholarly background:

Care for children with SNI is increasing in the United States, where these children account for a large proportion of inpatient pediatric hospital resources. More importantly, children with SNI have a limited lifespan and also live with significant morbidity from multiple comorbidities such as intractable seizures, recurrent pain, and respiratory insufficiency, with most being technology dependent with one or more devices such as gastrostomy tubes, central venous catheters, and tracheostomies/ventilators.[7,26] Care for children with SNI involves a large number of primary and subspecialty clinicians, which results in significant challenges on consistent communication and understanding of unique context and family values important to care decisions.

Due to these complexities, parents of children with SNI face countless critical decisions including those regarding technology use, location of care, quality-of-life, and end-of-life care.[10] These decisions directly impact the child and their entire family, as children with SNI require lifelong dependent care for all activities of daily living such as transferring, toileting, and nutritional intake.[10] Studies specific to children with SNI have reported intensive home care needs with parents spending approximately 9 hours per day on the direct care needs of their child to sustain an average of 5 life-sustaining technologies.[7] These parents report significant stress associated with caring for their child that is compounded by poor communication with clinicians. For example, recent research with parents of children with SNI suggested that parents perceive that they must gain a clinician's trust before their input about their child is valued – despite feeling that they are the experts in their child's care.[26] Even more problematic is the perception of parents of children with SNI that clinicians undervalue the life of their child.[26] Studies have, in fact, demonstrated that clinicians underrate the quality-of-life of children with disabilities compared to the patients and families themselves.[27-29] Other studies have implicated that clinicians' feeling a sense of a lack of expertise in the care of children with SNI as a barrier that, in turn, results in clinicians' lack of self-

efficacy in caring for these patients.[30] Multiple subspecialty teams add to conflict and distress in communication and decision-making efforts, as various teams and team members may have different perspectives.[30]

To address this, effective parent-clinician communication during critical decision-making and hospital care is essential.[3,31] This is fundamental not only to parental satisfaction with care[32], but also vital to enabling parents to continue feeling like they are the best parents to their child even when cure is not possible and at end-of-life.[3,31-33] Despite extensive knowledge about evidence-based communication techniques,[34-36] national communication training programs,[37] and clinicians' good intentions[38] – parents continue to report poor communication during critical decision-making in the hospital and decisional conflict.[17] This includes parent reports of distress caused by the uncaring delivery of bad news, lack of empathy, and careless remarks about their child at end-of-life by members of their child's clinical team.[36,37]

Evidence suggests that relationship-building is the fundamental ingredient that may allow families to feel that they are a part of critical decision-making, that their child's life is valued, and that they made a good decision for their child.[39] We have now improved our understanding of the associations between psychosocial outcomes in parents of children with SNI and perceived therapeutic alliance with clinicians during hospital admissions and developed/refined a communication intervention that builds therapeutic alliance by meeting the unique needs of these patients and families. We now need to pilot this intervention through a RCT to examine feasibility, acceptability and early efficacy among parents/LAR of children with SNI and their clinicians with the eventual aim of enhancing parents' perceptions of the therapeutic alliance with their child's clinicians and, in turn, decreasing parental stress and improving parent and child outcomes.

2.4. Prior approvals:

N/A

3. Study Endpoints[3]

3.1. Primary and secondary endpoints:

The primary endpoints will be feasibility (defined as >70% enrollment [enrolled parents/total approached] and completion [parents completing intervention/total randomized to the intervention], and acceptability (defined as >70% of the intervention parents likely or very likely to recommend the intervention to others/total randomized). We will also be assessing early efficacy by examining parent perceptions of stress measured by the Perceived Stress Scale (PSS) and therapeutic alliance with their child's clinicians measured by the Human Connection Scale (HCS) in the PICU.

3.2. Primary or secondary safety endpoints:

N/A

4. Drugs, Devices and Biologics[4]

4.1. Manufacturer and name of all drugs, devices and biologics:

N/A

4.2. Description and purpose of all drugs, devices and biologics:

N/A

4.3. Regulatory status of all drugs, devices and biologics:[5]

N/A

4.3.1. Drugs or Biologics:
☐ IND Exempt. Explain:[6] N/A
☐ IND.

4.3.2. Devices:
☐ IDE Exempt. Explain:[7] N/A
☐ Abbreviated IDE / Non-Significant Risk. Explain:[8] N/A
☐ IDE / Significant Risk.

4.4. Plans to store, handle, and administer any study drugs, devices and biologics so they will be used only on subjects and be used only by authorized investigators:
N/A

5. Procedures Involved

5.1. Study design:[9]

This pilot RCT study involves N=40 total parents/LARs of children with SNI whose children are admitted to the PICU at Seattle Children's Hospital. After giving consent to participate, parents will complete a brief 15-minute survey at the time of enrollment, then they will be randomized to either usual care [n=20] (involving routine PICU care which includes social work, child life, and other psychosocial supports) or the intervention [n=20]. Parents/LARs in the intervention will complete the photo-narrative intervention with study staff and have it placed in their child's PICU room. Parents/LARs will complete a discharge survey at the time of their child's PICU discharge. Clinicians caring for the children/families that enroll in the study will be approached by email or in-person about study participation which will involve pre/post intervention surveys. One to up to 3 clinicians will be selected per child/parent participant to better understand the photo-narrative intervention impact among a diverse multidisciplinary group of clinicians. A subset of parents (n=20) and clinicians (n=20-60) who were involved in the intervention will also complete brief 30-minute interviews about the intervention for further refinement. Demographic information about the participants will also be collected.

5.2. Research procedures:[10]

Parent/LAR participants: The study team will coordinate with clinical leaders to present this study at division and clinical team meetings in the Seattle Children's Hospital where parent participants will be recruited, and surveys and interviews will take place. We will also share information about the study with the social work and interpreter services departments at Seattle Children's.

After consenting, participants will complete enrollment surveys on study team SCH iPads preloaded with the REDCap enrollment survey (see Parent Enrollment Survey). For remote enrollment or per parent preference, parents will be securely sent the REDCap survey via an anonymous survey link. Participants will have the option of also receiving electronic survey links by text. Parents will also be able to complete the survey on paper or verbally with a member of the study team. The study team will use the child's electronic medical record to complete the Case Report Form for the study after parent participant consent. The case report form will be completed by the study team on a weekly basis to document any changes in information (i.e. the child's health status).

Subsequent to enrollment surveys, parents/LARs will be randomized using a random number generator. Those in the usual care arm will receive usual PICU care which consists of standard supportive care provided for all patients including an assigned social worker; referrals to child life, chaplaincy, palliative care, and art-, music-, developmental-therapy which can be requested by the parent or clinician. Those randomized to the intervention arm will complete the photo-narrative intervention administered at enrollment (or another time preferred by the parent/LAR) over 1-2 x 30-60 minute sessions where the intervention is introduced, completed, and the photo-narrative is displayed at the child's bedside. The photo-narrative intervention asks parents to share photos representing topics such as: "who is important in our family, what strengthens our family during stressful times, things our child likes or activities they enjoy, how we know when our child is feeling well, and important family traditions or aspects of our family culture." Parents can also select photos about other things they want to share. Families will be instructed to use their own device (smartphone, scan, family resource center at Seattle Children's) to send the photos electronically via secure email/text to the study team. Parents will be asked to limit the content of the photos to immediate family to minimize incidental subjects and to consider the privacy of those in the photographs such that people included in the photos would be agreeable to their picture being shared. The selected photos will be entered into the photo-narrative and then printed and placed at the child's bedside. Parents will also be able to enter the photos into the tool themselves and then send the completed photo-narrative electronically to the study team. If the study team does not have the ability to print and place the completed tool on the patient's bedside, the parents can complete and print the photo-narrative, and place it at the bedside on their next visit to the patient. We will also send electronic copies to the parents and participating clinicians via secure email. Clinician emails will include the completed photo-narrative which includes prompts to help them further explore the photos with parents/LARs.

It is very unlikely that parents would not have a phone that would permit the electronic transmission of the photos. Despite this, for participating parents who have any type of difficulty with providing the photos to the study team, alternative procedures will be available including use of resources through the Family Resource Center at Seattle Children's which provides photo, printing and internet services free of charge to parents and/or use of the study team camera which includes 2x 2 photo-printing. If the study team is presented with any participant who is unable to complete the activity due to being economically or educationally disadvantaged, a modification would be submitted providing other options for these individuals.

At the time of the child's PICU discharge, surveys will be sent to parents/LARs via REDCap by the same processes above. Parent will receive a maximum of six attempts (with a maximum of 3 attempts wherein direct communication is achieved, such as leaving a voicemail message or having a conversation with the potential participant) to complete the survey, as parents have appreciated multiple reminders given how busy they are both while their child is in the hospital and after discharge with their child's complex care needs and medical complexity. If the child is admitted longer than 12 weeks, we will consider study participation complete and parents will be sent the discharge survey and notified of their study completion.[40]

Parent/LAR participants in the intervention arm (n=20) will be asked to complete interviews around the time of their child's hospital discharge. Interviews will be approximately 30-minutes and will consist of 2 parts. Part 1 query parents about their experience with the photo-narrative intervention including content, process, and implementation of the tool using cognitive interviewing and think aloud techniques. Part 2 will explore parent perspectives regarding their coping and therapeutic alliance with their child's hospital clinicians (see Parent Interview Guide).

Interviews will be audio-recorded at the bedside using a recording device, or in one of the unit-

based conference rooms in the Seattle Children's. Interviews will be conducted in private and no shared patient rooms will be used. Interviews conducted over the phone/Zoom video will be done in private quiet locations in a private meeting. Zoom videoconferencing will require a password for entry and the private chat will be disabled. We will use the most updated version of Zoom. We will re-confirm consent for audio-recording at the beginning of any recorded session. No video-recording will take place prior to obtaining consent. Audio-recordings will be downloaded to SCH encrypted and secure computers of study staff and removed from cloud and/or recording devices. We will include up to 2 audio-recordings for each interview as a precautionary measure using study team SCH devices that are password protected and encrypted. The interviewer will take notes during the interview and repeat back a summary to participants for further clarification and/or elaboration. The interviewers for this study will all be experienced in conducting qualitative interviews and will not be directly responsible for any of the participant's child's clinical care during the study. We will use professionally translated documents for Spanish speaking participants. An in-person, video, or phone interpreter will be used for all Spanish-speaking parent participant conversations, including interviews.

Clinicians: As above, the study team will present the study to clinical pediatric teams at Seattle Children's Hospital. Here, participants will be selected based on caring for the parent/child on study at the time of enrollment and during the PICU stay. Eligible participants will be sent an email invitation to participate in the study or be approached in person or by phone. The email will also include information about the study, how they were identified, how we received their contact information, instructions on how to request not to be contacted further about the study (see Clinician Email Invitation and Clinician Information Sheet). Following the approach, clinician participants will be emailed/called to complete the study enrollment survey (pre-intervention) and again at the time of the child's PICU discharge, the discharge survey (post-intervention). Those clinicians in the intervention arm will set up a date, time and location for their interview in a quiet place on the Seattle Children's Hospital campus of their choice or phone/Zoom video for their 30-minute interview. Eligible participants will be sent 3 email reminders to set up an interview time, as clinicians have told us that many reminders are needed given their busy schedules and time away from work email (such that another reminder bringing the study invitation to the top of their email is helpful). If there is no response or if the clinician is unable or unwilling to participate, alternates will be chosen based on those who have provided PICU care for the child. We will use the same process to recruit alternate clinicians.

For clinician interviews, we will follow the same interview procedures as above, performing 2 audio-recordings of the 30-minute interview after consent is confirmed verbally (see Clinician Information Sheet). Similar to the parent participants, the interviewer will take notes during the interview and repeat back a summary to participants for further clarification and/or elaboration. Interview questions will focus on the photo-narrative intervention for further content, process, and context refinement as well as how they think it impacted therapeutic alliance (see Clinician Interview Guide).

5.3. Data sources that will be used to collect data about subjects:[11]

Data for this study will come from 3 sources:

1. Parent surveys on REDCap, interview recordings and completed photo-narrative intervention.
2. Clinician surveys on REDCap and interview recordings.
3. Child data on REDCap case report form from the Seattle Children's Hospital electronic medical record.

5.4. Data to be collected, including long–term follow–up data:[12]

Parent Data: Parent data collected will include audio-recordings of the interviews and survey demographic information collected on REDCap. The demographic information will include date of interview, caregiver type (mother, father, legal guardian, etc), gender, race/ethnicity, age, level of education, annual income, sources of support, and number of people living in the home. The survey also includes validated measures of parent stress, stigma, benefit-finding, resilience, respect, and therapeutic alliance. The survey also provides a place for open-ended feedback about the study (see Parent Survey). Data will also be collected about the child using the electronic medical record and this data will be entered directly into the REDCap case study form by the study team on a weekly basis. Information collected will include name, medical record number, date of birth, zip code, primary diagnosis, secondary diagnoses, technologies used in the last 12 months, number of hospitalizations in the last 12 months, resuscitation status, Pediatric Risk of Mortality (PRISM) score, Pediatric Logistic Organ Dysfunction (PELOD) score, number of subspecialists, date of admission, goals of care discussions, and family and team meetings (see Case Report Form). Information will also be recorded in the case report form regarding parent name, email, date of birth, and home address for gift card compliance. For parents in the intervention arm, these participants will also complete the photo-narrative intervention and photos that are collected and entered into the photo-narrative and placed at the bedside. The photo-narrative will also be shared securely with the parent and the clinicians who consents to participate.

Clinician data: Clinician data collected will include audio-recordings of the interviews and pre/post surveys with demographic information collected on REDCap. Survey data will include name, clinician discipline, years of experience in profession, number of children cared for with SNI in the last month, and the number of children with SNI cared for that died in the last 12 months as well as validated measures of empathy and perspective-taking. Participants will also be asked about their confidence in having conversations with parents of children with SNI about goals of care and quality of life, and how important and how often they assess parents' perspectives on their child's health and well-being (see Clinician Survey).

6. Data and Biospecimen Banking[13]

6.1. Complete list of the data and/or biospecimens to be included in the bank:[14]

De-identified interview transcripts, completed photo-narratives with photos of incidental subjects blurred, and REDCap survey data excel downloads from parents, clinical data collected about the children, and survey and interview transcripts from clinician participants will be retained for use in future studies.

6.2. Location of data and/or biospecimen storage:[15]

Data will be stored on the encrypted and password protected work computer of Principal Investigator Jori Bogetz which has security maintained by UW Department of Pediatrics IT Support.

6.3. List of those with direct access to data and/or biospecimens in the bank:

Jori Bogetz, MD study principal investigator.

6.4. Length of time data and/or biospecimens will be stored in the bank:

Approximately 15 years.

6.5. Procedures for protecting the confidentiality and privacy of the subjects from whom the data and/or biospecimens were collected:[16]

Data will be coded (with name, medical record number, date of birth removed from the banked research dataset), and interview and survey data of participants will be linked through a study identification number. Banked completed photo-narratives would have all incidental subjects faces or any other identifying characteristics blurred prior to banking. The key that links identifiers with the rest of the study data will be maintained separate from the banked information and would only be accessible to the PI, the gatekeeper of the bank. The key and identity of individuals would not be disclosed to any other investigator requesting to use data from the bank.

6.6. How the data and/or biospecimens will be made available for future use:

Data will only be made available with permission of Principal Investigator Jori Bogetz for use in future studies.

6.6.1. Who can request data and/or biospecimens from the bank:

Researchers conducting research aimed at understanding how to best support families of children with SNI may request to use data from the bank.

6.6.2. Format in which data and/or biospecimens will be provided:

Coded transcripts (interview data) and coded excel spreadsheets (survey data). The completed photo-Narratives with photos will be stored as provided by parents, but if the picture includes any incidental subject (e.g., sibling, grandparent) who did not consent to participate in the research, their faces or any other identifying characteristic will be blurred.

6.6.3. Process for investigators to request data and/or biospecimens:[17]

Researchers can approach Dr. Bogetz to use the banked data. As the gatekeeper of the bank, the Dr. Bogetz will ensure prior to release, that the investigator has proper IRB approval to use the data and that the aims of the study are consistent with the aim for which this data is being banked (see section 6.6.4).

6.6.4. Restrictions on future use:[18]

The banked information would be used in future research aimed at understanding how to best support families of children with SNI.

6.6.5. Plan for providing data results from banked data/biospecimens:

There is no plan to provide results from research studies that use banked data.

7. Sharing of Results

7.1. Plan to share results with subjects/others:[19]

Parents/LARs who participate in the intervention can receive an electronic copy of their photo-narrative that they completed. Participants may also learn of study results through presentations and publications of final study findings.

8. Study Timelines

8.1. Duration of an individual subject's participation in the study:

Parents' participation time for this study will vary depending on how long their child is in the PICU. If the child is in the PICU for longer than 12 weeks, the study will be considered complete and parents will be notified. Enrollment and discharge surveys (pre/post intervention surveys) are anticipated to take 15 minutes per survey based on pilot testing. Interviews with a subset of parents (n=20) should take approximately 30 minutes.

Clinicians will participate in this study for < 2 hours total, during which they will complete their pre/post surveys and, if applicable, interviews.

8.2. Duration anticipated to enroll all study subjects:

Enrollment will occur over an estimated 24-month period based on the anticipated number of children with SNI admitted to the PICU at Seattle Children's meeting eligibility criteria.

8.3. Estimated date for the investigators to complete this study:

This study should be completed in the estimated 24-month study period.

9. Study Population[20]

9.1. Inclusion criteria for each subject population (e.g., patients, parents, providers):

Patient inclusion criteria will include: 1) ages 3 months-25 years; 2) SNI (including congenital/chromosomal, chronic central nervous system static or progressive conditions, or child >6 months after severe traumatic brain injury; 3) admitted to the PICU at Seattle Children's and with medical team permission to approach; 4) expected length of stay >1 week; 5) life expectancy >4 weeks; and 6) previous discharge home.

Parent/LAR inclusion criteria will include: 1) parent/legal guardian; 2) English and/or Spanish speaking (most common languages spoken at SCH making up 95% of patients and families); and 3) >18 years of age.

Incidental subjects via photos shared by the patient's family.

Clinician Inclusion Criteria: Clinicians will be licensed physicians, fellows, residents, advanced practice nurse practitioners, nurses, or respiratory therapists working in the PICU at Seattle Children's.

9.2. Exclusion criteria for each subject population:

Parent/Child Exclusion Criteria: Parent of a child with a diagnosis of SNI < 3 months prior to enrollment (or < 6 months for acute traumatic brain injury).

Clinician Exclusion Criteria: None.

9.2.1. If individuals will be excluded from the research based on language, socioeconomic status, physical characteristics (e.g., gender identity, age, ethnicity), sexual orientation, religion, or access to technology provide a justification for each exclusion criterion:[21]

We will be excluding participants who prefer a language other than English and Spanish given the feasibility and rationale for this study. At this time, we are piloting the photo-narrative tool among these two populations given that we are in preliminary stages of understanding feasibility and acceptability. This is typically done when developing a new intervention at such an early stage. We will extend to participants speaking other languages in future studies. Including English and

Spanish participants will enable us to have >90% eligibility of participants at SCH based on language. We are not excluding participants based on race, gender, ethnicity, or access to technology. We are including patients age 3 months to 25 years of age given this is a pediatric study. All of the patients in this study will have neurologic disabilities.

9.3. Plan to ensure that subject selection is equitable:[22]
We will be screening for eligible patients/participants throughout the week and will be making our study team available in the mornings and evenings as well as during regular business hours. We will be contacting the primary team to confirm eligibility, but will not have any other restrictions on participation other than our inclusion/exclusion criteria. We will perform interim analyses of our data to ensure that we are meeting targets of 20% or more enrollment of participants from different racial, ethnic, and other minority groups – including gender of parent participants.

9.4. Populations with special considerations, involved in the study:[23]

☒ Children/Teenagers[24]
Risk assessment specific to this vulnerable population and additional safeguards:[25]
Children (<18 years) will not be actively participating in this study aside from the study team reviewing their electronic medical records for pre-screening for eligible study participants and for collection of demographic survey data after parent consent (see Case Report Form). Their parents will be discussing details about their children's care. The only anticipated risk is loss of confidentiality, and there are protections in place to mitigate this.

☐ Children who are Wards of the State[26]
Risk assessment specific to this vulnerable population and additional safeguards:
N/A

☒ Adults Unable to Consent [27]
Risk assessment specific to this vulnerable population and additional safeguards:
Young adults (ages 18-25 years) participating in this study will all have SNI and therefore be unable to consent for this study. Their participation is needed because this is the specific population that the photo-narrative intervention is being developed for. These participants will have the study team reviewing their electronic medical records for pre-screening for eligible study participants and for demographic survey data collection after parent/LAR consent (see Case Report Form) and photo-narrative creation with their photo(s). Their legally authorized representative (LAR) will be discussing details about their care on surveys and in interviews. The anticipated risk of loss of confidentiality is low in relation to what can be learned in the study about how to improve communication between parents/LARs of children with SNI and clinicians through the photo-narrative intervention. There are protections in place to mitigate loss of confidentiality. The study could not be conducted without including these participants, and is not prohibited by law. Participants will be closely monitored and removed from the study if unduly distressed.

Additionally, there may be incidental subjects whose pictures are included in photos shared by participating parents in the photo-narrative intervention. We have no plans to consent these individuals and have completed a Waiver of Consent for this.

☒ Individuals who use a language other than English[28]
Anticipated language(s) for subjects and their parent(s)/LAR:

We will be enrolling English and Spanish speaking study participants which make up >90% of the patient population at SCH.

Process to ensure study information is available throughout the research to individuals who use a language other than English:[29]

Once we receive IRB approval, we will have all of our patient/participant facing forms professionally translated into Spanish. Additionally, we will only use professional interpreters for this study.

☐ Neonates of Uncertain Viability or Non–Viable Neonates[30]

Risk assessment specific to this vulnerable population and additional safeguards:

N/A

☐ Pregnant Women[31]

Additional safeguards:

N/A

☐ Prisoners[32]

Additional safeguards:

N/A

☒ Economically or educationally disadvantaged persons[33]

Additional safeguards:

Some parent participants may be economically or educationally disadvantaged. This will not impact their ability to participate in this study nor should they be impacted by any part of this study due to these disadvantages. All parent/LAR participants will receive a $50 gift card as an incentive for participating in this study, which is a small amount relative to housing and food costs around Seattle Children's Hospital. Gift cards will be delivered in-person to parents or sent by mail or email. Eligible participants will also be informed that whether or not they choose to participate will not impact their child's care in any way and that participation is voluntary. All members of the study team approaching eligible participants about the study will not be providing direct care for the patient or family at the time of the study.

10. Number of Subjects

10.1. Total number of subjects to be enrolled locally:[34]

Parent/Child Participants n=40 (along with their 40 children)
Clinician Participants n=40-120 (1-3 clinicians per parent/child participant)
Incidental subjects - unknown

10.2. Total number of subjects to be enrolled across all participating sites:[35]

N/A

10.3. Number of screened subjects versus the actual number enrolled in the research:[36]

The anticipated screen to enroll ratio is approximately 10:1.

10.4. Power analysis:

To explore the relationship between stress (perceived stress score) and other parent-reported outcomes at each time point we will use correlation coefficients and bivariate linear regressions.

We should have *80% power* to detect a modest correlation coefficient (r=0.4) and a significance level of 0.05 between perceived stress score and therapeutic alliance with a sample size of 40 parent/LAR participants.

11. Withdrawal of Subjects

11.1. Anticipated circumstances under which subjects will be withdrawn from the research without their consent:

Parent participants will be withdrawn if their child unexpectedly dies prior to study completion. We will write or call the parents within 2-4 weeks of their child's death to offer condolences and remove them from the study. We will call Spanish-speaking families to offer condolences and to provide the information that we will remove them from the study so that we can use professional interpretation to answer family questions in real-time. We will use the approved condolence letter as a script and starting point for the conversation. Although data from participants whose child dies will be examined, it will not be included in the final study analysis given the small sample size and a new parent-child dyad will be recruited. Parent and clinician participants may also be withdrawn if the study team thinks that the study is causing excessive emotional distress.

11.2. Procedures for orderly termination:

Participants will be informed by the study staff that they have been withdrawn from the study and that data collected up to the time of study withdrawal may be examined. They will also be informed of the reason for withdrawal and given study Principal Investigator Jori Bogetz' contact information if they have any further questions about their withdrawal.

11.3. Procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection and withdrawal from data/biospecimen banking:

Study participants who decide they no longer wish to participate may withdraw at any time. No additional information will be collected by the study team.
Interviews: A participant can decide not to answer any questions in the interview that they do not want to discuss. If a participant agrees to allow the audio recording and then changes their mind, the already-collected information will be kept but no new information will be collected.
Surveys: If a participant decides to withdraw from the study, survey data that has already been collected will be used but no further information will be collected.

If the data has already been used for publication, the use of the data cannot be withdrawn.
In cases of incidental subjects introduced via photos, if we are made aware from the individual that they do not wish for their picture to be shared for purposes of the research, we would ask the family to select another photo, and the one previously provided by the family would be destroyed from the study records. Other incidental subjects' photos will be blurred in any publications/presentations and for banking.

12. Risks to Subjects

12.1. Reasonably foreseeable risks to subjects (include each study population, each arm, and optional procedures):

Parent Participants: There is risk of potential loss of confidentiality. Survey results and interview transcripts will be viewed by members of the study team after identifiers are removed and they are coded. In addition, the participants may find the surveys and/or interviews emotionally distressing. Additionally, participants may experience emotional distress by talking about their psychosocial well-being and communication/therapeutic alliance with clinicians.

Clinician Participants: There is risk of potential loss of confidentiality. Survey results and interview transcripts will be viewed by members of the study team after identifiers are removed and they are coded. Additionally, participants may experience emotional distress by talking about communication and therapeutic alliance with parents. Parent/LAR participants may also share information about clinicians caring for their child on surveys and/or interviews. This information will be kept confidential/private and only shared if it poses a danger to the individual sharing the information or another person.

Incidental subjects: The only anticipated risks are those associated with privacy and confidentiality presented by the photos the family may share.

12.2. Procedures with unforeseeable risks:
None anticipated.

12.3. Procedures with risks to an embryo or fetus should the subject be or become pregnant:
N/A

12.4. Risks to others who are not subjects:
Incidental subjects may be included on photos selected by parent participants. Parents will be asked to limit the content of the photos to immediate family to minimize incidental subjects and to consider the privacy of those in the photographs such that people included in the photos would be agreeable with their picture being shared.

Additionally, as the completed photo-narrative intervention will be posted at the bedside, clinicians who are not participating in the study may see the tool. We do not expect this to cause significant risk to clinicians not participating in the study, as it is customary and part of hospital practice to offer to place photos selected by families at the bedside. Many families already place photos that incorporate aspects of the photo-narrative intervention at their child's bedside as part of usual care.

12.5. Procedures performed to lessen the probability or magnitude of risks:
Confidentiality protections will be in place to protect and maintain the privacy and confidentiality of subjects. This study is anticipated to present minimal risks to subjects. However, the study team will meet quarterly to discuss subject participation, and any issues surrounding subject safety/emotional distress will be addressed within 24 hours of the study staff member becoming aware of the information. If any participants decide to withdraw from the study, this also will be evaluated by the study team to determine if changes need to be made to study procedures.

With parent participant knowledge, unit-based social workers will be contacted by the study team if additional child and/or parent needs are identified during the study. Psychosocial support for parents is provided through social work 24/7 at Seattle Children's and every patient/family has an assigned social worker during their child's admission per standard of care. The study team will also have a list of Seattle Children's Hospital employee provided mental health resources available through the employee assistance program for participating clinicians if needed. In the case of SCH workforce (clinicians), information collected about them will be maintained confidential and participation in this research study will have no impact on their financial standing, employability, or reputation. Participants will be able to

withdraw from the study or decide not to answer any questions they do not want to during the study.

Parents/LARs will be encouraged to only share photos that include only individuals who have consented or give their permission to participate in the study. If the parents share photos that include other people not part of the research (i.e., incidental subjects), the pictures of the individuals would be blurred as described in the study procedures. For purposes of use for publications/presentations and in banking activities for incidental subjects, the faces and any other identifying characteristic will be blurred.

13. Potential Benefits to Subjects

13.1. Potential benefits that individual subjects may experience from taking part in the research:[37]

The outcomes of this research may improve parent-clinician therapeutic alliance and communication in the hospital. Our aim is to diminish stress for parents of children with SNI. Participants may appreciate knowing that they may help other parents and clinicians in similar scenarios.

14. Data Analysis/Management

14.1. Data analysis plan, including statistical procedures:

Our primary outcomes will be feasibility and acceptability of the photo-narrative intervention. Feasibility and acceptability with be assessed qualitatively through interviews with parents and clinicians. In addition, to evaluate feasibility, we will calculate percent enrolled (enrolled parents/total approached) and percent completion (parents completing intervention/total in intervention arm). To evaluate acceptability, we will calculate the percentage of intervention parents likely or very likely to recommend the intervention to other parents on post-intervention surveys. We will use a benchmark of 70% for feasibility and acceptability based on previous studies examining psychosocial interventions among seriously ill children and their parents. We will explore preliminary efficacy by summarizing outcome changes in each study arm using means, medians, standard deviations, and inter-quartile ranges, together with linear regression modeling comparing therapeutic alliance scores at discharge in intervention and usual care control arms, adjusted for baseline scores. Potential covariates will include: 1) child age, length of illness, and illness severity (assessed at enrollment using the Pediatric Risk of Mortality (PRISM) score and then weekly using the validated a) Pediatric Logistic Organ Dysfunction (PELOD)score, and the b) Functional Status Score for the Intensive Care Unit (FSS-ICU); 2) parent age, sex, race/ethnicity, socioeconomic status, marital status, and social supports; and 3) clinician characteristics (discipline, years in practice, experience with SNI patients/families, previous longitudinal relationship with the study patient/family). We will use a similar approach for evaluating between-arm differences in discharge scores for other secondary outcomes of stress, stigma, benefit-finding, coping, and resilience at discharge. We expect to find better mean score change in the intervention arm compared to the usual care arm, for parent reported outcomes and prosocial behaviors in clinicians.

Interview audio-recordings will be sent via HIPAA compliant Dropbox to Tracey's Transcription Service (a SCH preferred vendor) for transcription and returned to the study team as text transcripts through the same mechanism. Content analysis, utilizing cloud-based Dedoose software, will be performed on the coded interview transcripts to identify themes representing different parent and clinician experiences. Those themes, in addition to representative quotes, will then be used to organize and inform feasibility and acceptability of the intervention, as well as intervention refinement and use in future studies. Demographic data will be used to characterize participants generally in aggregate for data interpretation and presentation/publication.

14.2. Quality control procedures for collected data:[38]

Data collected by the study team in the case report form will be reviewed by at least 2 study team members for the first 5 participants and then repeated on a quarterly basis. Survey data from parent participants will be reviewed on a weekly basis for data completion and to assess for parents reporting exceptionally high or low psychosocial outcomes.

During the interviews, the interviewer will take notes and repeat back a summary to participants for further clarification and/or elaboration (see Parent and Clinician Interview Guide).

15. Confidentiality and Privacy[39]

15.1. Procedures to secure research records[40], data, and/or biospecimens during storage, use, and transmission:

Participants will be assigned a study ID number. The research data will be coded with its relevant study ID number. The key linking study ID numbers to participant names and other identifiers will be stored separate from the research data on a password protected electronic file. All electronic data will be stored on encrypted, password protected SCH computers with access restricted to research team members. All surveys will be completed and stored within the UW ITHS REDCap system with access restricted to research team members.

Audio-recordings will be sent via HIPAA compliant Dropbox to Tracey's Transcription Service (an SCH preferred vendor) for transcription and returned to the study team as text transcripts through the same mechanism.

For photos shared by the parents that may include other individuals who did not consent to participate in the research, the study team will use the photos strictly as discussed in the procedures for this current study. However, for banking activities and for potential presentations/publications, the study team will blur the faces or any other identifying characteristic of any individual present in the photos who did not consent to participate in this research. For presentations/publications purposes, the study team will attempt to use photos that only include individuals who consented to be part of the research.

15.2. Steps that will be taken to protect the privacy interests throughout the study:[41]

We will regularly monitor study progress and ensure procedures are being conducted with the least amount of data collected and stored as is necessary. We will keep the study ID number separate from the data collected and de-identify data prior to analysis and for banking. We will use encrypted and locked devices. Parent/LAR participants may also share information about clinicians caring for their child on surveys and/or interviews. This information will be kept confidential/private and only shared if it poses a danger to the individual sharing the information or another person.

15.3. Location where the data and/or biospecimens will be stored:

The data will be stored on the password-protected electronic devices of the study Principal Investigator Jori Bogetz. Data will also be maintained in the REDCap system while the study is ongoing and until data collection is complete. Copies of signed consent forms and any paper copies of the coded research data will be stored in a locked cabinet in Principal Investigator Jori Bogetz's office at the Seattle Children's Research Institute and/or in the locked office of the pediatric palliative care service at Seattle Children's Hospital.

15.4. Length of time data and/or biospecimens will be stored:

Data will be stored for approximately 15 years consistent with Banking activities.

15.5. Individuals with access to data and/or biospecimens:
The research study team will have access to the data during the study and data analysis/interpretation. The study team includes members at Seattle Children's Hospital. Only coded data will be shared between study team members.

15.6. Process for the transmission of data and/or biospecimens outside Seattle Children's:
15.6.1. List of data and/or biospecimens that will be transmitted:
Audio-recordings will be sent to a HIPAA compliant transcription service via secure Dropbox and returned as text transcripts through the same mechanism. No parent/child or clinician participant recruitment, enrollment, or data collection will occur outside of Seattle Children's Hospital. All study team members will view study data on encrypted and password protected computers.

Aggregated data and results will be shared in research publications and at national research meetings and will be used to inform future studies.

15.6.2. Individual(s) who will transmit data:
Jori Bogetz study principal investigator

16. Provisions to Monitor Data to Ensure the Safety of Subjects[42]

16.1. Plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe:[43]
N/A

16.2. Data reviewed to ensure safety of subjects:
N/A

16.3. Safety information collection procedures:
N/A

16.4. Frequency of cumulative data review:
N/A

16.5. Conditions that trigger an immediate suspension of the research:
N/A

17. Use of Social Media

17.1. Types of social media to be used and how:
N/A

17.2. Measures in place to protect the privacy or confidentiality of subjects:[44]
N/A

17.3. Types of communications that will be submitted to the IRB for review:[45]
N/A

17.4. If user-generated content will be active, how it will be monitored and what actions will be taken to ensure subject safety and study integrity:
N/A

18. Research Related Injury[46]

18.1. Available compensation in the event of research related injury:
N/A

19. Recruitment Methods[47]

19.1. When, where, and how potential subjects will be recruited[48]:

Parent/Child Participants: The study team will coordinate with clinical leaders to present this study at clinical team meetings Seattle Children's where parent participants will be recruited. We will use professionally translated documents for Spanish speaking participants. An in-person, video, or phone interpreter will be used for all Spanish-speaking parent participant conversations, including interviews, as well as condolence calls. For parent participant recruitment, the study team will review the inpatient census list and approach pediatric hospital teams after rounds about potential eligible participants. Once an eligible parent participant is identified, we will check with the medical team prior to approaching parents to ensure (1) that the child has SNI and (2) that participating in a research study would not be overly burdensome for the family based on the medical team's assessment. We will ask a member of the clinical team to inquire if the family would be interested in hearing about a research study they would be eligible for. If they are, the study team member will meet with the parent in-person or by phone to explain the study and complete the consent process. Recruitment will occur either in person (inpatient hospital rooms) or by phone/Zoom video call (i.e, direct contact by study staff). Patients will either be approached inpatient (including initial approach by the patient's nurse or other known member of the medical team) or, for English-speaking families, will be e-mailed introducing them to the study and giving them the opportunity to "opt out" of future contacts if desired. If potentially eligible patients who receive the email do not opt-out of being approached about the study, we may call them to assess their interest and arrange to discuss the study by phone/Zoom video or meet them in-person. Study staff will reach out to potential participants (by phone/Zoom video, email, or inpatient) to try and gauge interest in the study for a maximum of six attempts (with a maximum of 3 attempts wherein direct communication is achieved, such as leaving a voicemail message or having a conversation with the potential participant). These additional attempts are needed given the complex care families are providing for their child both in the hospital and at home to remind them to follow up for the study. Text communication will occur only after initial contact is made with a family via a non-text method and the participant has agreed to receive text messages. These procedures have been used in other Seattle Children's IRB approved studies among seriously ill patient populations and their caregivers. Aside from sending survey links, we will

not be emailing or texting Spanish-speaking participants. Instead we will use in-person, video or phone communication (same order and procedures as above related to call then Zoom) so that we can utilize professional interpreters to ensure we respond to questions and/or concerns in real-time.

Clinician Participants: Clinician participants will be selected based on caring for the parent/child on study at the time of enrollment and during the PICU stay. Eligible participants will be sent an email invitation to participate in the study or be approached in person or by phone. Follow up email will also include instructions on how to request not to be contacted further about the study (see Clinician Email Invitation).

19.2. Steps that will be taken to protect privacy during the recruitment process:[49]
For potential parent prospective subjects, they will first be approached by their child's bedside nurse or other clinical team member already known to the family about their interest in participating in a research study. Only those families who have expressed interest will be contacted by the study team.
For clinicians, SCH maintains a directory listserv of all clinicians serving the department. Clinicians will only be approached via this method and their decision to participate or not will have no impact on their financial standing, employability, educational achievement, or reputation. The study team will send the study invitation email only to those who have not indicated they do not wish to be contacted further about the study.

19.3. Sources of subjects:[50]
Parent participants will be identified based on review of the inpatient census list of the hospital. Clinicians will be selected based on caring for the parent/child on study at the time of enrollment and during the PICU stay.

19.4. Methods that will be used to identify potential subjects:
Parent participants will be identified based on review of the inpatient census list of the hospital patient lists for eligible participants. Clinicians will be selected based on caring for the parent/child on study at the time of enrollment and during the PICU stay. The study flyer is being used in the PICU to raise awareness about the study, so that when eligible participants are approached, they may have some prior knowledge/context about the study.

19.5. Materials that will be used to recruit subjects:[51]
Parents and clinicians will be sent an email invitation to participate in the study (see Parent Email Invitation and Clinician Email Invitation). This email includes information about the purpose of the study, why they have been selected to participate, how their contact information was received, how to opt-out of participating in the study, and who to contact if they have questions about the study. We also will have a study flyer and will post the flyer in the Seattle Children's Hospital. We will use email and phone communication as well for simple follow up communication such as reminders about surveys and/or interview scheduling.

19.6. Recruitment methods not controlled by Seattle Children's:
N/A

20. Consent/Assent/Permission[52]

20.1. Consent/assent/permission process:[53]
Consent may take place in-person or over the phone/Zoom video. If eligible participants site challenges with participation due to their ability to be at the hospital to consent in-person, the

study will use a remote consent process via videoconferencing or phone. Parent participants will be able to review the consent form sent by email before agreeing to participate. Electronic consent will occur on REDCap during Zoom conferences so questions can be answered by a member of the study team. Parents will be given the time they need, including following up at a later time over Zoom or in-person to consider participation. Electronic consent on REDCap should take <60 minutes and parents will be able to return to previous sections for their review. Once the consent forms are completed, an electronic copy will be emailed to participants. These consent discussions will not be audio or video recorded. Notably, the study will obtain documentation of informed consent in-person whenever possible. Parents will be given paper, electronic, or both copies of the consent form.

For clinician participants, the consent will take place through discussion with the research team and/or within REDCap as an opening to the survey. The Clinician Information Sheet will also be attached to recruitment emails that contain the survey link.

The study team will be available for all participants to answer questions in-person or via phone/video call, depending on their preference and what would be more convenient for them. They will receive copies of the Clinician Information Sheet.

20.1.1. Alternative way of obtaining consent/assent/permission information for individuals who are not able to receive/access/use the electronic consent system being used or explanation as to why an alternative process is unnecessary:[54]
We will be using multiple ways of obtaining informed consent including in-person and remote options. Whenever possible we will obtain consent in-person.

20.1.2. Where the consent/assent/permission process will take place:

For parents, the consent process will take place in their child's hospital room at Seattle Children's Hospital, in another quiet private location on the Seattle Children's Hospital campus, or over the phone in a private space. We will preferentially conduct the consent conference in-person and will only obtain consent by Zoom videoconference or phone if in-person consent is otherwise not possible/feasible. This is to enable as many eligible parents to participate as possible, given that some parents may have limited access to WiFi, computers, and/or ability to spend time in the hospital given other childcare, family, or other personal obligations. Parents will be able to sign consent forms in-person, electronically on REDCap or verbally consent for the study.

Clinician interviews will take place in a quiet location on the Seattle Children's Hospital campus or by phone/video.

20.1.3. Steps that will be taken to protect privacy during the consent/assent/permission process:[55]
Only approved trained study staff will be involved in the consent process after the family or clinician have already been approached about the study and expressed interest in participating. Consent conferences will take place in a private place.

20.2. Plan for documenting consent/assent/permission:[56]
We will obtain signatures from participants directly on consent forms completed in-person. We will only obtain consent by Zoom videoconference or phone if in-person consent is otherwise not possible/feasible. This is to enable as many eligible parents to participate as possible, given that some parents may have limited access to WiFi, computers, and/or ability to spend

time in the hospital. Parents will be able to sign consent forms in-person or electronically on REDCap for the study.

A waiver of written documentation of consent has been requested for Clinician participants.

20.2.1. Plan to confirm that the individual who provides the electronic signature[57] is the subject (or their parent/LAR), when the signature is not personally witnessed by a member of the study team or explanation as to why such a plan is unnecessary:[58]
N/A

20.2.2. If using electronic consent, plan to manage consent documentation over the life of the study in a way that maintains integrity and accessibility:[59]
N/A

20.2.3. If consent/permission will be documented in writing (check one):

☒ "SOP: Written Documentation of Consent (HRP-091)" will be followed.

☐ "SOP: Written Documentation of Consent (HRP-091)" will not be followed.
Process of documenting consent:[60]
✍Click here to enter text.

20.2.4. If consent/permission will not be documented in writing (check all that apply, *complete Section 21.11 to request a Waiver of Documentation of Consent*)[61]

☒ A written statement/information sheet describing the research will be provided to subjects.[62]

☐ A written statement/information sheet describing the research will not be provided to subjects. Explain: ✍Click here to enter text.

☐ A consent script will be used.[63]

20.3. Waiting period available between approach and obtaining consent/assent/permission:
Prospective subjects will have the time they need to consider participation in the study. If parent participants need more time to consider participating in the study, the study team will return in the following days/week to answer questions or answer questions by phone/Zoom video. For clinician participants, they will have the Clinician Information Sheet sent to them in an email requesting their participation prior to surveys and interviews and therefore they should have time to consider participating in the study. No research activity will take place until participants consent to their participation.

20.4. Process to ensure ongoing consent/assent/permission:
Parents will be provided with the contact information of study staff each time they are sent a REDCap survey to complete to contact with questions and/or if they want to withdraw from the study.

20.5. If this box is checked, "SOP: Informed Consent Process for Research (HRP-090)" will be followed: ☒

20.6. If "SOP: Informed Consent Process for Research (HRP-090)" will not be followed, address the following:[64]

20.6.1. Role of the individuals listed in the application as being involved in the consent process:

N/A

20.6.2. Time that will be devoted to the consent discussion:
N/A

20.6.3. Steps that will be taken to minimize the possibility of coercion or undue influence:
N/A

20.6.4. Steps that will be taken to ensure the subject's understanding:
N/A

20.7. **Individuals who use a language other than English**

20.7.1. Presentation of Research Information and Documentation:

☒ Appendix A-10 of the Investigator Manual will be followed[65]

☐ Short form procedures may be used per HRP-091. If so, choose applicable box(es):

☐ Per section 5.5.1

☐ Per section 5.5.2

☐ Appendix A-10 of the Investigator Manual will not be followed. Explanation of procedures not following Appendix A-10:
N/A

20.8. **Subjects Who Are Not Yet Adults (Infants, Children, Teenagers)**

20.8.1. Process used to determine whether an individual has not attained the legal age of consent under the applicable law of the jurisdiction in which the research will be conducted (e.g., individuals under the age of 18 years):[66]
Patient participant's age will be determined by their medical record. Parents or Legally Authorized Representative (LAR) will be inquired about their age during enrollment.

20.8.2. Permission will be obtained from:[67]

☐ Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child, or LAR.

☒ One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child, or LAR.

☐ Permission will not be obtained.[68]

20.8.3. Process used to ensure permission is obtained from an individual or individuals (when two parent permission is required) with legal authority to provide such permission::[69]
Permission will always be obtained from the parent or legally authorized representative for the patient. The study team will consult EPIC to verify the consenting authority of parents/guardians to ensure consent can be provided for research purposes.

20.8.4. Assent will be obtained from:[70]

☐ All children.

☐ Some children. Specify: N/A

☒ None of the children. Explain: All children participating in this study will have severe neurological impairment and therefore a developmental level < 7 years of age and be unable to give consent.

20.8.5. Procedures for obtaining and documenting assent:

N/A

20.8.6. Plan for re-approaching children who have reached the age of majority to obtain consent:[71]

For participants who reach the age of majority, the study team will confirm that they are unable to provide consent due to neurological impairment. If a child's LAR does change during the study, we will re-consent the LAR if surveys and interviews are still being conducted and we are still collecting new information but request a waiver for when we are no longer actively communicating with the subjects and only using banked data.

20.9. **Cognitively Impaired Adults/Adults Unable to Consent**[72]

20.9.1. Process used to determine whether an individual is capable of consent:

All adult patients participating in this study will have severe neurological impairment and therefore a developmental level < 7 years of age and be unable to give consent.

20.9.2. Individuals from whom permission will be obtained in order of priority:[73]

We will follow HRP-013 SOP for legally authorized representatives, children, and guardians. Permission to participate in this study will be obtained by the legally authorized representative of the adult patient. Written HIPAA Authorization will be obtained written from the participant's legally authorized representative.

20.9.3. Assent will be obtained from:

☐ All of these subjects.

☐ Some of these subjects. Specify: N/A

☒ None of these subjects. Explain: All adult patients participating in this study will have severe neurological impairment and therefore a developmental level < 7 years of age and be unable to give consent.

20.9.4. Process for obtaining and documenting assent:[74]

N/A. Permission to participate in this study will be obtained by the parent and/or legally authorized representative of the adult patient. All children and young adult patients in this study will have severe neurological impairment and therefore lack capacity to assent or consent to study participation. Consent will be obtained by their parent/LAR for their study participation.

20.10. **Waiver or Alteration of Consent/Assent/Permission**[75]

20.10.1. Reasons for requesting a waiver or alteration of informed consent/assent/permission:[76]

Incidental Participants: There is the possibility that parents may share photos that include incidental subjects. We request a waiver of informed consent for these potential incidental subjects.

Waiver of Re-Consent at Age 18 for All Participants: For participants who reach the age of majority, we request a waiver for re-consent when we are no longer actively communicating with the subjects and only using banked data.

20.10.2. Consent/Assent Waiver/Alteration Criteria justifications:[77]

20.10.2.1. The research involves no more than minimal risk to the subjects because:

Incidental Participants: The study team will not know or collect any information about these individuals, other than the photo that the patient's family may share as part of their participation on the research study.

Re-Consent at Age 18 Request: The research involves no more than minimal risk to the subjects because the only anticipated risks are loss of confidentiality and that participants may experience psychosocial distress. There are protections in place to mitigate both risks.

20.10.2.2. The waiver or alteration will not adversely affect the rights or welfare of the subjects because:[78]

Incidental Participants: Parents will be asked to limit the content of the photos to immediate family for consideration of the privacy of those in the photographs, such that people included in the photos would be agreeable to their picture being shared. However, it is important to note that it is customary and part of hospital routine practice to offer to place photos selected by families at the bedside. Many families already place photos that incorporate aspects of the photo-narrative intervention at their child's bedside as part of usual care and these photos often include family members/siblings/grandparents and/or friends. Photos that may include these incidental subjects would be used as outlined in the procedures for this study, but in the event of publications/presentations, and for banking activities, the faces and any other identifying characteristic of those individuals will be blurred.

Re-Consent at Age 18 Request: Assent is not being obtained as all children participating in this study will have severe neurological impairment and therefore a developmental level < 7 years of age and be unable to provide assent upon enrollment and consent when they turn 18. The legal guardian would be providing consent fom them and the facts of the study would be the same as when parental permission was previously provided (either at time of initial enrollment or a change that required re-consent to continue participation). The overwhelming majority of children with severe neurological impairment continue to have the same legal guardian into adulthood (as parents often do not undergo the formal guardianship process due to expense and the lengthiness of the process and this almost never

occurs during an acute PICU hospitalization when our study is taking place). If a child's LAR does change during the study, we will re-consent if surveys and interviews are still being conducted and we are still collecting new information but request a waiver for when we are no longer actively communicating with the subjects/LARs and only using banked data.

20.10.2.3. The research could not practicably be carried out without the waiver or alteration because:[79]

Incidental Participants: The study team will have no contact with individuals who may be in these pictures, and, we would not collect any type of information about them.
Re-Consent at Age 18 Request: All children participating have permanent or progressive neurological impairments and will continue to have their developmental level of < 7 years despite their chronological age/ when they enter into adulthood. For participants who reach the age of majority, the study team will confirm that they are unable to provide consent due to neurological impairment. Since all child participants will continue to be unable to provide consent given that neurological impairment is required for inclusion in the study, we are requesting a waiver of re-consent once the child reaches age 18, as the specifics of the study (including risks and benefits) remain unchanged. If a child's LAR does change during the study, we will re-consent the LAR if surveys and interviews are still being conducted and we are still collecting new information but request a waiver for when we are no longer actively communicating with the subjects and only using banked data.

20.10.2.4. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format because:[80]
Incidental Participants: The study team will not be collecting any information about the incidental subject individuals other than the photos shared by the patient's family. It is necessary that families be able to share photos that are important to them in their child's photo-narrative – as these photos convey important information about (1) who is important in the child's family, (2) values/quality of life of the child and family, and (3) likes/dislikes of the child. Incidental participants may be important parts of photos representing these topics.

Re-Consent at Age 18 Request: The study plan is to retain coded information which is needed to link to banked data and other study information (e.g. surveys, interviews).

20.10.2.5. Whenever appropriate, the subjects will be provided with additional pertinent information after participation:

N/A

20.10.3. If the research involves a waiver of the consent process for emergency research, provide sufficient information for the IRB to make it determinations:[81]

N/A

20.11. **Waiver of Written Documentation of Consent/Permission (address one option):**

20.11.1. Option 1:

The research involves no more than minimal risk to the subjects because:
The risks involved in this study are loss of confidentiality and psychosocial distress causes by surveys/interviews. There are protections in place to mitigate both of these risks. We are requesting a waiver of documentation of informed consent to approach potential study subjects remotely and complete consent conferences over the phone or via Zoom video. In these instances, we will not be collecting signature consent.

We request for a waiver of documentation for the participating clinicians.

The research involves no procedures for which written consent is normally required outside of the research context because:
The proposed research procedures for clinician participants involving electronic survey completion and interview (including audio recording) procedures do not require a written consent outside of the research context. The retention of data for future use also does not require written signatures outside of the research context.

20.11.2. Option 2:

- The principle risk of a signed consent document would be the potential harm resulting from a breach of confidentiality because:
  N/A
- Both are true:

  ☐ The only record linking the subject and the research would be the consent document

  ☐ The subject or LAR will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.

20.11.3. Option 3:

- The research involves no more than minimal risk to the subjects because:
  N/A
- The subjects or LARs are members of a distinct cultural group or community in which signing forms is not the norm. Explain:
  N/A
- There is an appropriate alternative mechanism for documenting that informed consent was obtained. Explain:
  N/A

21. HIPAA Authorization and RCW Criteria

21.1. HIPAA Authorization (check all boxes that apply):

☐ The study does not involve the receipt, creation, use and/or disclosure of protected health information (PHI).[82]

☒ HIPAA authorization will be obtained as part of a signed consent form.

☒ The study will access PHI without prior authorization from subjects (including for recruitment purposes – e.g., reviewing the medical record to determine eligibility). *Complete Section 21.2 to request Waiver of HIPAA Authorization*.

☒ Subjects will review a written statement/information sheet with the appropriate HIPAA language but will not provide a written signature. *Complete Section 21.2 below to request an Alteration of HIPAA Authorization*.[83]

☐ Other. Explain:[84]
N/A

21.2. HIPAA Waiver/Alteration Criteria: [85]

21.2.1. Reasons for requesting a waiver or alteration of HIPAA Authorization:
A HIPAA waiver is being requested. A waiver is needed for recruitment purposes.

21.2.2. The use or disclosure of PHI involves no more than a minimal risk to privacy of individuals, based on, at least the presence of the following elements:

21.2.2.1. An adequate plan to protect the identifiers from improper use and disclosure:
A HIPAA waiver is being requested. A waiver is needed for recruitment purposes. For study subjects, we will keep PHI and will protect it from improper use and disclosure in the ways described in sections 15 and 21.2.

All PHI will be removed prior to data analysis and interpretation and data will be coded. No PHI will be sent between study team members. PHI will be stored on the cloud-based and password protected REDCap database and download only to the study principal investigator's encrypted and password protected computer.

21.2.2.2. An adequate plan to destroy identifiers at earliest opportunity consistent with conduct of research:
After survey collection, interview transcription and distribution of gift cards. all PHI will be removed from the study data files as outlined in the confidentiality protections.

21.2.2.3. Assurances that PHI will not be reused or disclosed to any other party or entity, except as required by law or for authorized oversight of the research:
PHI will not be reused or disclosed to any other party outside of the aims described in the protocol, except if required by law.

21.2.3. The research could not practicably be conducted without the waiver or alteration of authorization:
To conduct this study, the study team will need to assess identifying information pertinent to subject recruitment. The waiver for recruitment purposes is only applicable for enrollment of the child patient and identifying the parent for study participation.

21.2.4. The research could not practicably be conducted without access to and use of the PHI:[86]
Access and use of PHI is necessary to identify eligible subjects.

22. Payments/Costs to Subjects[87]

22.1. Amount, method, and timing of payments to subjects:[88]

All parent participants will receive a $50 gift card when they enroll in the study to thank them for participating. Clinician participants will not receive an incentive.

22.2. Reimbursement provided to subjects:[89]

N/A

22.3. Additional costs that subjects may be responsible for because of participation in the research:[90]

N/A

23. Community-Based Settings[91]

23.1. Site(s) or location(s) in the community where the research team will conduct the research:

All research will be conducted either on the Seattle Children's Hospital campus or by telephone/Zoom video/text. All in-person, phone and Zoom videoconferencing will occur in a private quiet setting.

23.2. Composition and involvement of any community advisory board:

N/A

23.3. For research conducted outside of the organization and its affiliates:[92]

23.3.1. Site-specific regulations or customs affecting the research:

N/A

23.3.2. Local scientific and ethical review structure:

N/A

24. Resources Available

24.1. Qualifications (e.g., training, education, experience, oversight) of investigator(s) to conduct and supervise the research:[93]

The study principal investigator Jori Bogetz is a faculty member at Seattle Children's Hospital and has completed two fellowships including (1) General Academic Pediatrics and (2) Hospice and Palliative Medicine. During these fellowships and as a faculty member, she has successfully completed research studies similar to this study. She has used research tools such as transcription services and REDCap previously. She also has used content analysis to analyze data in similar qualitative studies. Jori Bogetz has > 45 publications in the field of pediatric palliative care and research among children with SNI and their parents.

The study team also includes Scott Watson, MD, MPH who is the Associate Medical Director and Director of Research in the pediatric ICU at Seattle Children's Hospital. He has been engaged in clinical trials and long-term outcomes following pediatric critical illness for > 20 years, which applies greatly to this study. The study team also includes Joyce Yi Frazier, PhD who is a research scientist focused on resilience at Seattle Children's Research Institute.

24.2. Other resources available to conduct the research:[94]

A clinical research associate will be assisting with the conduct of this research, including conducting interviews with study subjects. Interviews will be conducted in a quiet space on the Seattle Children's Hospital campus. The clinical research associate will meet weekly with the study principal investigator Jori Bogetz to ensure consistency in study procedures.

25. Coordinating Center Procedures

25.1. Coordinating center institution:
N/A

25.2. If Seattle Children's is the coordinating center:

25.2.1. Process to ensure communication among sites:[95]
N/A

25.2.2. Process to ensure all site investigators conduct the study according to the IRB approved protocol and report all non-compliance:
N/A

25.2.3. Process to ensure all required approvals are obtained at each site:
N/A

25.2.4. Process to ensure all sites are informed of any problems and/or interim results:
N/A

26. International Center for Harmonization of Good Clinical Practice (ICH-GCP)

26.1. If you have committed to conducting the described study per ICH-GCP, check this box: ☐[96]

- This is generally applicable for contracts with industry-sponsored studies or sponsor protocols. See your contract/agreement or Sponsor Documentation if you are unsure.
- Note that completing GCP training is a separate activity and does not automatically mean that you have committed to conducting the study per ICH-GCP.
  If you check the box, upload a current curriculum vitae (CV) for the PI to the "Other Attachments" section of the "Local Site Documents" SmartForm.

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[1] Provide a list of the participating sites (pSITEs). pSITEs are those sites outside Seattle Children's that will rely on the Seattle Children's IRB as their IRB of record. All pSITEs should be listed even if no study procedures will occur at the site. Remove the heading if this is not a study where Seattle Children's IRB will serve as the IRB of record for other institutions.

[2] Include information if this protocol is associated with other IRB-approved studies (e.g. is this application the next part/phase of a previously approved application.

[3] In clinical trials, an endpoint is an event or outcome that can be measured objectively to determine whether the intervention being studied is beneficial. Some examples of endpoints are survival, improvements in quality of life, relief of symptoms, and disappearance of the tumor.

[4] Include information on a drug or biologic in this section if: (1) the study specifies the use of an approved drug or biologic; (2) the study uses an unapproved drug or biologic; (3) the study uses a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition; or (4) data regarding subjects will be submitted to or held for inspection by the Food and Drug Administration (FDA). Only include information on a device in this section if: (1) the study evaluates the safety or effectiveness of a device; (2) the study uses a humanitarian use device (HUD) for research purposes; or (3) data regarding subjects will be submitted to or held for inspection by the FDA. Please note that mobile medical applications may meet the definition of a device – see FDA Guidance.

[5] See the Investigator Manual HRP-103 for sponsor requirements for FDA-regulated research.

[6] Explain what IND exemption category applies to the drug and why. Note that a drug is not exempt from an IND unless all criteria for one category are met. See "HRP-306: Drugs" for more information.

[7] Explain what IDE exemption category applies to the device and why. Note that a device is not exempt from an IDE unless all criteria for one category are met. See "HRP-307: Devices" for more information.

[8] Explain why the device is NOT a significant risk device. A significant risk device means an investigational device that: (a) is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject; (b) is purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject; (c) is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or (d) otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

[9] Be sure to indicate if controls will be included and include information about why control arms are ethically acceptable.

[10] Describe all of the research procedures being performed. Be sure to make it clear which procedures apply to each subject population. When applicable, describe how research procedures differ from standard of care and/or affect standard of care. Describe any audio/video recording that will be involved.

[11] Attach all surveys, scripts, and data collection forms to the "Supporting Documents" page.

[12] Include information about the frequency of data collection.

[13] See HRP-001 - SOP – Definitions for definition of banking. Type N/A if not applicable. If the data is subject to NIH Genomic Data Sharing Policies or other data sharing policies (e.g. you will submit data to dbGaP, NDAR, FITBIR), indicate here. Note that sharing with federal policies requires information to be included the consent forms. See HRP-502 F Language Resource Text for sample language.

[14] If applicable, include a list of identifiers that will be banked.

[15] Be general (e.g., researchers' lab, clinic, etc.)

[16] Generally, data and/or biospecimens should be released in a coded, non – identifiable manner.

[17] Include a description of the process used to verify and document that any required approvals have been obtained prior to release of data/biospecimens from the bank.

[18] You can allow for use for broad purposes

[19] This includes putting results and/or data in the subject medical records.

[20] If your population will differ from the representative population where the study will take place (e.g., race, ethnic group, or gender), provide a rationale for the differences.

[21] Seattle Children's IRB prohibits the exclusion of populations based on language, socioeconomic status, physical characteristics (e.g., gender identity, age, ethnicity), sexual orientation, religion, or access to technology unless there is sufficient justification for the exclusion. Specifically for language, the cost of translation and/or interpreter services will not be considered sufficient justification for the exclusion of participants who use a language other than English in accordance with NIH guidelines, in most circumstances. ("Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources." 59 FR 11146, March 28, 1994). See Investigator Manual HRP-103 for additional information.

[22] The plan must take into consideration the purpose of the research and the setting in which the research will be conducted. The plan must ensure that no group of people is either unfairly over-represented or unfairly excluded from participating in research. Your response should include how the recruitment process and other aspects of the study (as appropriate) are designed to facilitate equitable selection.

[23] If you check a box below, be sure to include the additional considerations associated with the population.

[24] Refer to HRP-416 CHECKLIST: Children.

[25] If the study is minimal risk, explain why. For studies that present greater that minimal risk include, as applicable: (1) why direct benefits are anticipated, (2) why risks are justified by anticipated benefit and/or the relationship between risk and prospective benefit compared to available alternatives, (3) why risk represents only minor increase over minimal risk, (4) how study procedures are reasonably commensurate with those inherent to the child's actual or expected conditions, (5) whether the interventions/procedures are likely to yield generalizable knowledge about the participant's condition and why it is of "vital importance" to understanding or amelioration of the participant's underlying disorder or condition, and (6) an explanation of what alternative methods/approaches were considered to make the above assessments (as applicable). As applicable, provide evidence-based information to support your assessment.

[26] This population may be wards of the state or any other agency, institution, or entity. For studies that present greater than minimal risk, refer to HRP-416 CHECKLIST: Children, Section 6, for additional guidance on required considerations for this population.

[27] This refers to both cognitive impairments and adults who are incapacitated for any other reason. As applicable, refer to HRP-417 CHECKLIST: Cognitively Impaired Adults.

[28] This includes subjects and their parent(s)/LAR.

[29] Applicable to information conveyed in writing and verbally. For example, your plan could include translating all study documents and having a study team member or interpreter available who can speak the language to answer questions.

[30] Refer to HRP-413 CHECKLIST: Neonates and HRP-414 CHECKLIST: Neonates of Uncertain Viability.

[31] This box does not need to be checked if pregnant women are not a target population and pregnancy is irrelevant to risk considerations. Refer to HRP-412 CHECKLIST: Pregnant Women.

[32] Refer to HRP-415 CHECKLIST: Prisoners

[33] Indicate how you will ensure that there is no coercion or undue influence

[34] A subject is considered "enrolled" when they consent to be in the study.

[35] Only applicable for multisite studies.

[36] i.e., numbers of subjects excluding screen failures.

[37] Payment for participation is not considered a benefit.

[38] For example, data will be double entered, data will be reviewed by another study team member to ensure accuracy, etc.

[39] If your study is multisite and there are differences in how confidentiality will be maintained by the coordination center and our local site, this should be explained in this section (e.g. local site will have samples that are linked to a person's name, but the coordination center will only receive coded samples without any links). Confidentiality regarding use of Social Media will be explained in a protocol section below.

[40] Including the signed consent/assent/permission forms and any information/documentation collected during the consent process.

[41] Privacy refers to persons and their interests in controlling the access of others to themselves. For example, based on privacy interests, people want to control the time and place where they give information, the nature of the information they give and who receives and can use the information.

When providing a response, consider the subject population and nature of the study. For example, persons might not want to be seen entering a place that might stigmatize them, such as a pregnancy counseling center that is clearly identified as such by signs on the building.

[42] Applicable for studies that present more than minimal risk.

[43] Include information about who (describe in terms of role or group) will review the data.

[44] This should be specific to the social media you are using for the research.

[45] All communications that are directed towards subjects and specific to a particular study will require prior IRB review and approval. All non-IRB reviewable communications can be described in general terms by category – news stories, relevant publications – and representative examples of each can be provided.

[46] Applicable if the research involves more than minimal risk to subjects. If minimal risk, this section is N/A.

[47] If this is a multicenter study and subjects will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements) those methods should also be described here.

[48] If the study will enroll or seek permission from individuals who speak a language other than English and recruitment methods will differ for these individuals (e.g., they will be approached by a bi-lingual person outside the study team), be sure your description covers these methods as well.
[49] For example, subjects will be initially approached in a private room or a letter rather than a postcard will be sent when the study name may disclose health information about the potential subject.

[50] For example, medical records, CIS, clinical databases, other study records. If the study will access PHI for recruitment purposes without prior authorization from subjects, please address this in the HIPAA Authorization section below.

[51] Attach copies of these documents to the Recruitment Materials section of the study SmartForm. For printed advertisements, attach the final copy. For online advertisements, attach the final screen shots (including any images). When advertisements are taped for broadcast, send the final audio/video tape to IRB@seattlechildrens.org. You may attach the wording of the advertisement to the SmartForm prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.

[52] "Permission" refers to consent obtained from a parent or LAR.

[53]Address the following in the response, as applicable:

1. How you will ensure that subjects and/or their parent/LAR have sufficient opportunity to discuss and consider whether or not to participate in the research.
2. Speak to the suitability of the intended consent process for the intended audience, taking into consideration the subject's and/or parent/LAR's age, language, comprehension level, and familiarity with technology tools (if applicable).
3. If using an electronic process to send consent information or obtain documentation of consent (e.g., e-signature), identify the process to be used to send the consent information (e.g., e-mail).
4. If using an electronic process (e.g., e-mail), describe the procedures that ensure the electronic process allows subjects/parents/LARs to ask questions they may have before signing (e.g., by in-person discussions, telephone calls, videoconferencing). If conducting a consent conference, describe the method to be used for the conference (e.g., telephone call, video conference), specifying any programs (e.g., Zoom) to be used. If

applicable, indicate that the consent discussion will be audio or video recorded and whether recording will occur within any programs being used (e.g., Zoom).

5. If using an electronic process, describe how the subject and/or parent/LAR will navigate the consent materials, including whether the subject/parent/LAR will have the ability to move backwards and forwards within the electronic system and to stop and continue at a later time. Also indicate how long it will take.
6. The availability of study personnel to assist subjects and/or their parent/LAR in using the electronic process, if applicable.

[54] Some study teams are currently considering creative solutions for such individuals; these potential solutions include snail mail, drive through paperwork for consent, and loaner device/hotspots for e-consenting. If no alternative will be made available (meaning these individuals cannot be enrolled), the IRB will look for a sufficient rationale for this exclusion.

[55] For example, the consent discussion will take place in a private room.

[56] Address the following in the response, as applicable:

1. Identify the means of documenting consent/assent/permission (e.g., in writing, verbally, etc.). If obtaining an electronic signature, identify the specific software/application to be used.
2. Include a description of how the consent/assent form(s) will be delivered, including any programs (e.g. REDCap) to be used.
3. Include a list of any information about the individual that will be collected during the assent/consent/permission process.
4. If the research is conducted outside of Washington State, provide confirmation that the electronic documentation of consent is legally effective in that jurisdiction. Note, the study team's location while conducting the study dictates the jurisdiction. For single IRB studies, the participating site's study team location while conducting the study dictates the jurisdiction.

[57] Electronic signature in this context refers to a legally effective electronic signature (e.g., a signature obtained via DocuSign) and does not apply to procedures where a waiver of documentation of consent is requested.

[58] Indicate "N/A" if not obtaining an electronic signature. Researchers are encouraged to consider the risks and benefits of the research when determining whether it is necessary to verify the subject/parent/LAR identity. For example, consider how likely it is that someone other than the subject would provide the consent. Social behavioral minimal risk research will not typically warrant identity verification.

[59] For example, consent forms will be downloaded as soon as they are full executed and saved electronically in a location accessible to the study team.

[60] This section describes the ways in which the procedures will not follow Seattle Children's SOP.

[61] See "HRP-411: Waiver or Written Documentation of Informed Consent" for further information.

[62] An information sheet template (HRP-502D) can be found in the Click IRB Library and should be attached to the consent form of the study SmartForm. For internet research, the information sheet can be translated to an on-line format, if desired.

[63] The IRB sometimes requires a script if you are having the consent conversation over the phone rather than in person. Templates for a consent script are available on the IRB website on the Participant Recruitment page and should be attached to the study SmartForm.

[64] This section describes the way(s) in which the processes for this study will not follow Seattle Children's SOP.

[65] Note the Short Form Consent may only be used when certain conditions are met. See HRP-091 for requirements for Short Form consent form use.

[66] For research conducted in the state, review "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" to be aware of which individuals in the state meet the definition of "children." The age of majority in Washington is 18; however, sometimes younger children have ability to consent for certain types of care (e.g. sexual reproduction/health; mental health; drug/alcohol treatment). For research conducted outside of the state, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of "children" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)." If the sites in other states in the study are conducting their own IRB review, you do not need to worry about this--type N/A. If you are conducting research and are actively recruiting participants outside of Washington who are NOT coming to SCH to give consent and who will be covered under SCH IRB approval, this section should be addressed in your protocol.

[67] For minimal risk studies and greater than minimal risk studies that offer a prospect of benefit, the IRB generally requires one parent to provide permission for the child to participate.

[68] If permission will not be obtained, please address this in the Waiver or Alteration of Consent Process below.

[69] See HRP-013 for more information.

[70] The IRB generally follows the following guidelines for written assent: children 7-12 should provide written assent on the "simple" assent form (HRP-502G); children 13-17 should provide written assent by co-signing the parental permission form (HRP-502A). The IRB will consider other assent scenarios (e.g. verbal assent for some or all children; not requiring assent for some or all children; or waiving assent): please provide details about the plan for your study. See HRP-090 and HRP-416 for more information on waiving assent and when assent is not necessary.

[71] See Appendix A-13 of the Investigator Manual HRP-103 for requirements for re-consent at age 18. If you think you meet the conditions for a waiver at 18, please address this in the Waiver or Alteration of Consent Process below.

[72] See "HRP-417 Cognitively Impaired Adults" for further information.

[73] For example: durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child. If you are following HRP-013 in order to make this determination, simply state that in this section. For research conducted in the state, review "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" to be aware of which individuals in the state meet the definition of "legally authorized representative." For research conducted outside of the state, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in this research. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of "legally authorized representative" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)." If the sites in other states in the study are conducting their own IRB review, you do not need to worry about this--type N/A. If you are conducting research and are actively recruiting participants outside of Washington who are NOT coming to Washington to give consent and who will be covered under SCH IRB approval, this section should be addressed in your protocol.

[74] The IRB may allow the person obtaining assent to document assent on the consent document.

[75] Provide justifications/explanations for each subject population for which a waiver/alteration is being requested.

[76] For example: consent/parental permission will not be obtained, required information will not be disclosed, the research involves deception, waiver for participants who turn 18, waiver for information collected about a non-present parent, or other waivers as necessary.

[77] The IRB needs to make all the waiver findings and key to this determination is that the IRB understand why it is not practicable to do the research without a waiver of consent. You need to provide a rationale in order for the IRB to

consider whether the waiver criteria are met. See "HRP-410: Waiver or Alteration of the Consent Process" for further information.

[78] Possible reasons might include: a) you are not collecting information that could put subjects or their families at harm, e.g., affect eligibility for insurance, employability, stigmatization; b) you are not collecting information that would alter or affect the subject's care; c) any publication or presentation of research results would be done in a manner that would never reveal an individual's identity either directly or indirectly.

[79] Possible reasons could be: a) inability to locate families because of the lengthy time period over which the records/samples were created; b) many of the subjects whose records, data, or biospecimens will be used may have died and contacting the families about the research could cause harm and anguish to families; c) all eligible patients must be included in the study for the results to be meaningful.

[80] For example, identifiers are necessary, so that researchers can perform quality checks or identifiers are necessary to link data from multiple sources.

[81] See "HRP 419: Waiver of Consent for Emergency Research" for further information.

[82] PHI is health information that is also identifiable because it includes one or more of the 18 HIPAA identifiers. See Investigator Manual HRP-103 for the list of HIPAA identifiers.

[83] If your study involves using or creating PHI and your only contact with participants is online, you can request an alteration of HIPAA authorization to remove the signature requirement. As an alternative to a waiver of documentation of consent and an alteration of HIPAA authorization, you must demonstrate that the electronic consent signatures are compliant with applicable state/international law (in Washington, see RCW 19.34.300).

[84] For example: altering HIPAA elements for international research.

[85] Provide justifications/explanations for each subject population for which a waiver/alteration is being requested.

[86] Possible reason could be: the nature of the research is specific to individuals' health and requires access to individuals' health records.

[87] See "HRP-316: Payments" for further information.

[88] Methods of payment include check, ClinCard, gift cards, etc. Provide details on who will be the recipient of the payment (parent or child).

[89] Reimbursement is used when the subject is paid back for travel expenses such as transportation, food, childcare, or lodging. Reimbursement is generally distributed to person who incurred cost (usually parent) and requires receipts to be submitted.

[90] This could include things like fuel/transportation costs, parking, and/or childcare.

[91] Community-based settings may include community clinics, schools, non-profit organizations, etc.

[92] Type N/A if this section does not apply.

[93] Provide enough information to convince the IRB that the principal and/or co-investigator(s) are appropriately qualified to conduct and supervise the proposed research. When applicable, describe their prior clinical experience with the test article or study-related procedures, or describe their knowledge of the local study sites, culture, and society.

[94] For example, as appropriate: (1) Justify the feasibility of recruiting the required number of suitable subjects within the agreed recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit? (2) Describe the time that you will devote to conducting and

completing the research. (3) Describe the facilities in which the research will be conducted. (4) Describe the availability of medical or psychological resources that subjects might need as a result of an anticipated consequences of the human research. (5) Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.

[95] Including communication between sites of current study document versions and modifications.

[96] If you check the box, you are required to conduct your study according to the principles outlined at https://www.ich.org/products/guidelines/efficacy/efficacy-single/article/integrated-addendum-good-clinical-practice.html.