Feasibility Test of a Pediatric Web-Based Care Planning Guide

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Study Location(s):
Children's Participation in Environment Research Laboratory, 1919 West Taylor Street (AHSB) Rooms 716, 744, and 745

Sponsor: [Name and contact information - Delete if not applicable]

IND/IDE: [Include IND and/or IDE number - Delete if not applicable]

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LIST OF ABBREVIATIONS

HIPPA	Health Insurance Portability and Accountability Act
IRB	Institutional Review Board
PHI	Protected Health Information
PI	Principal Investigator

1.0 Project Summary/Abstract

- *Orients the reviewer to the project.*
- *Provide a summary of the proposed activity that should be informative to other persons working in the same or related fields and insofar as possible understandable to a scientifically or technically literate lay reader.*
- *Schemas are welcomed and often provide a nice visual reference for the project.*

The goal of the proposed research is to achieve a major advance in promoting effective and efficient delivery of pediatric occupational therapy services towards improving participation-level outcomes for young children with developmental disabilities and delays. This research will examine the usability and feasibility of PEM-Plus, an innovative web-based (mobile friendly) care-planning guide, when used in conjunction with newly validated YC-PEM proxy questionnaire. PEM-Plus enables parents to design activity-specific solutions to their young child's participation-related problems in their own space and on their own schedule, as well as electronically share their solutions with providers and/or parents for improved care planning.

2.0 Background/Scientific Rationale

- *Describe the research problem and provide rationale for the research.*

The goal of the proposed research is to achieve a major advance in promoting effective and efficient delivery of pediatric occupational therapy services for young children with developmental disabilities. To evaluate PEM-Plus usability (Aim 1), ten parents will be recruited to perform tasks related to navigating the PEM-Plus interface. Data on completion rate and time, and user satisfaction, will be analyzed to guide PEM-Plus improvements. Then, in Aim 2, we will examine the feasibility and scientific basis for using the revised PEM-Plus to improve goal setting, care plan development, and parental self-efficacy. Study results will yield a final version of PEM-Plus that is ready for larger-scale testing in a pediatric efficacy trial. This project is aligned with the newly released AOTF research priority of improving care coordination towards improved participation in meaningful activities.

- *Briefly summarize prior experience and/or history relevant to the research.*

Members of our research team pioneered some of the first participation and environment measures that are commonly used in pediatric research and practice (Sections 1.3 and 1.4). The PEM approach represents a significant departure from prior efforts to measure children's participation because we explicitly combined the assessment of children's participation and environment within the same instrument. Development of a web-based application to help parents participate in planning their child's care is a highly innovative and logical next step for our research team. To our knowledge, no other group has developed a web-based application to empower and assist parents in developing their own solutions to promote their child's participation. We expect that PEM+ can advance the quality and efficiency of care planning in pediatric occupational therapy to achieve participation-level outcomes. Our multi-site, transnational research team has established an 8-year track record of continuous extramural funding. We developed and tested the PEM-CY and YC-PEM for research purposes and built a Knowledge Hub to facilitate knowledge uptake and resource exchange about children's participation and environment among key stakeholders (researchers, parents, and providers). We believe that PEM+ will significantly improve the uptake of the PEM approach in practice.

- For research involving the testing of drugs, biologics, or devices:
  - *Identify any investigational agents, drugs, devices, or biologics that will be administered or implanted into subjects.*
  - *Summarize relevant preclinical data*
  - *Summarize relevant clinical data to date*

- *Provide a rationale for the dosing or use of the device, risks to subjects, and potential benefits to subjects*

- *Discuss briefly any literature important to the study and include references in Section 14.*

3.0 Objectives/Aims

- *This section helps to clarify the questions the researcher expects to answer*
  - *Identify hypotheses being tested/primary endpoints/primary purpose of the protocol*

Aim 1 Objective: Examine the usability (technical effectiveness, efficiency, and user satisfaction) of the PEM+ interface by parents of young children with developmental disabilities and delays (Months 1-5).

Aim 2 Objective: Examine PEM+ feasibility and preliminary effects for goal setting and care planning (Months 6-12).

Hypothesis: Based on our prior intervention research to promote participation among children with physical disabilities, we expect that PEM+ will initially take up to 4 weeks with more intensive coaching support needed to generate viable activity-specific goals and action plans, and less time in subsequent iterations. There will be no significant age group differences in PEM+ feasibility.

- *Describe secondary endpoints (if applicable)*
- *Substudy endpoints (if applicable)*
- *Study duration*
- **Per funder guidelines, this project will be completed between 7/1/2016-6/30/2017.**

4.0 Eligibility

- *Identify the subject population being evaluated by the protocol.*
- *Indicate the source of subjects.*
- *Identify who will assess and determine subject eligibility.*

Participants will be issued automated emails with study flyers to self-enroll in both aims of the project. Hence, all recruitment comes from UIC (1919 W. Taylor Street, AHSB Rooms 716-744-745, Chicago, IL 60612-7250). Participants will self-enroll in the study and complete screening questions online to confirm eligibility. This confirmation of study eligibility will take place prior to online informed consent. We have successfully piloted this process in an NIH-funded pilot proposal, resulting in

enrollment of 39 study subjects in a 2-month period (IRB approval obtained in Colorado, at PI's prior institution, and is active from 2015-2016).

- *Indicate how and where eligibility will be documented.*

Participant confirms his/her eligibility based on a set of screening questions (e.g., what is your primary language, What is your child's date of birth, for how long has your child been receiving services). The portal and platform will no longer be hosted by Northwestern University. All data collected, including documenting participants who confirm their eligibility to enroll, via the web-based application that is being hosted via an Amazon cloud account will be pushed and stored in REDCap at UIC via API.

- *Attach an eligibility checklist to the protocol.*

4.1 Inclusion Criteria

1) **The inclusion criteria will no longer include the age group 4-5 year olds. It will include parent of a child with a developmental disability between 0-3 years old; 2) reads, writes, and speaks English; 3) owns a Mac or PC and has broadband internet access; and 4) resides in the U.S.**

4.2 Exclusion Criteria

1) **Exclusion criteria will no longer include parent of a child more than 5 years old. It will include parent of a child more than 3 years old; 2) does not read, write, and speak in English, 3) does not have broadband internet access, or 4) does not reside in U.S.**

4.3 Excluded or Vulnerable Populations

For Aim 2, respondents are not eligible if they do not speak English (because the questionnaires are only available in English), are less than 18 years old.

5.0 Subject Enrollment

- *Describe screening and enrollment.*
- *Describe from where subjects will be recruited and any advertising or recruitment materials that will be used.*
- **Participants self-enroll online via web link on flyer and provide online consent via the first part of the platform being hosted in REDCap at UIC. The first part of the platform involves consent, demographic, and YC-PEM completion. Hence, UIC (1919 W. Taylor Street, AHSB Rooms 716-744-745, Chicago, IL 60612-7250)**

- *Describe what happens with screen failures and any data obtained from screen failures.*
- *Describe the methods to minimize coercion and undue influence on the subjects.*
- **Automated emails and study flyers will be sent to families in 2 listserves. These families have enrolled in prior research in Colorado and have consented to future contact. Eligible and interested caregivers will self-enroll in the study and self-administer the questionnaires and care planning guide. Caregivers can enroll on their personal computer, using information including weblink to study site that is located on the study flyer. Hence, all data collection can occur outside of research involvement and/or service provision to minimize undue coercion on study enrollment. Once enrolled, no providers and/or family members will know which caregivers have enrolled unless the caregiver chooses to share his/her summary report with him/her.**
- *Describe the procedures to separate clinical responsibilities and influence from research responsibilities and influence.*

6.0 Study Design and Procedures

- *List any collaborating sites where human subjects research will be performed, and describe the role of those sites and collaborating investigators in performing the proposed research (if applicable).*
- *Describe the study design. The description should be capable of meeting the study objectives.*
- *Provide a thorough description of all study procedures, assessments and subject activities in a logical and sequential format.*
- *Indicate what study activities happen when and where, including, when applicable, a study schedule that notes number and length of study visits for subjects, such as any of the following:*
  - *Screening for eligibility*
  - *Enrollment/baseline*
  - *Treatment/Intervention period*
  - *Follow-up*
  - *Final study visit*
  - *Early termination visit*
  - *Unscheduled visits*
- *Indicate which procedures are standard of care and which procedures are being done for research purposes.*

There are 2 aims to this year long project. All tasks are being performed for research, not service provision.

Aim 1 data source: In addition to demographic data, numerical and narrative data will be stored with unique ID number on the backend of the PEM+ platform (secure, password-protected and backed up to central server daily) during data collection and then exported and stored as an SPSS file for access by the UIC team.

We will opt to administer SEQ after every individual task. We will assess for Ease of Use, Ease of Learning, and Satisfaction at the end of PEM+, using the USE that estimates user satisfaction based on response to items on ease of use, ease of learning, and satisfaction (22 questions, each using a 7 point scale from [1] strongly disagree to [7] strongly agree). We will assess for overall ease using the SEQ after every individual task (1 question, using a 7 point scale from [1] very difficult to [7] very easy.
Mean percent completion and task completion time will be computed for each task. Narrative data will be exported and stored as an MS Word file and content analyzed using NVivo 11.0 in order to identify recurrent points of user feedback to guide PEM+ revisions.

Aim 1 Sampling and Data Collection:

To examine the usability of the PEM-Plus for use in conjunction with the YC-PEM, there is no longer a need to sample caregivers of the age group 4-5 years old. Instead, a larger and more diverse sample of caregivers of the age group 0-3 years old will be recruited, for an overall target sample of 10 participants.
We have obtained permission to recruit participants from 1 active listserve of families raising young children with developmental disabilities (n=832 ages 0-3 years) who reside in both urban and small town communities in Colorado. We will also be recruiting caregivers who have a child attending Blue Bird Day School in Chicago, IL. This will allow for a larger and broader pool of participants for this study.

These families have consented to future contact for research and in some cases have completed the YC-PEM assessment for other ongoing research projects that are IRB approved at Dr. Khetani's (PI) prior institution (Colorado State University).

Inclusion criteria: The inclusion criteria will no longer include the age group 4-5 year olds. It will include parent of a child with a developmental disability between 0-3 years old; 2) reads, writes, and speaks English; 3) owns a Mac or PC and has broadband internet access; and 4) resides in the U.S.

For participants coming from Colorado and Blue Bird Day School, recruitment flyers will be sent electronically to all families in each of the listserve directories. Eligible and interested participants will be directed to PEM+ via web link on the flyer to self-enroll in the project. The participant will obtain a user account to enter the first platform which is a password protected study site hosted on REDCap at UIC. The participant will proceed to confirming study eligibility, then online consent form, followed by demographic questionnaire completion and YC-PEM completion. Upon YC-PEM completion, the participant will provide contact

information for study subject payment and then be issued a YC-PEM summary report. There will be a web link on the summary report to guide the participant to a PEM+ platform that is being hosted by an Amazon cloud account and UIC. The portal and platform will no longer be hosted by Northwestern University. All data collected via the web-based application that is being hosted via an Amazon cloud account will be pushed and stored in REDCap at UIC via API. The participant will then proceed to the PEM+ usability test.

For participants coming from Blue Bird Day School, those who sign a consent will fill out electronic forms for the YC-PEM and demographic information. Upon receipt, research staff will create a user account and manually enter consent, demographic, and YC-PEM data for the participant into the REDCap platform. Participants will be emailed a weblink to access their YC-PEM summary report when ready along with a link to begin the PEM+ usability test.

The PEM+ usability test will take 60 minutes and involve having participants complete a series of 8 tasks that correspond to key functions of PEM+ (e.g., you decide to go to sleep and wish to exit the platform after completing Step 1. Save your progress and log off). Following task completion, participants will complete the Single Ease Question (SEQ) after every individual task, while Usefulness, Satisfaction, and Ease of Use (USE) will be administered at the end of PEM+ to all participants. Each participant will receive a $20.00 mailed payment.

For each of the 8 tasks, we will assess for Ease of Use, Ease of Learning, and Satisfaction at the end of PEM+, using the USE that estimates user satisfaction based on response to items on ease of use, ease of learning, and satisfaction (22 questions, each using a 7 point scale from [1] strongly disagree to [7] strongly agree). We will assess for overall ease using the SEQ after every individual task (1 question, using a 7 point scale from [1] very difficult to [7] very easy.

Aim 2 data source: There are 4 elements being assessed in this aim. For Process, data are derived via web analytics to ascertain recruitment and retention rates according to child's age. For Resources, data are also derived via web analytics for information about PEM-Plus completion time per iteration. For Management, web analytics are used to examine frequency and duration of tiered coaching (tier 1: videos, tier 2: email/text, tier 3: phone /Skype chat) and online progress notes entered into the platform by coaches are obtained to estimate type of support. For Scientific basis (preliminary effects), data sources are as follows: 1) web analytic data are used to estimate number of goals set and strategies developed in 4 weeks, and 2) modified CanChild Survey completion at 4 weeks is used to estimate perceived effectiveness of PEM-Plus for goal setting and strategy development

Aim 2 Sampling and Data Collection:

We will build on Aim 1 recruitment strategies to recruit 24 parents of children with developmental disabilities ages 0-3 years for PEM+ feasibility testing. The sample size estimate is similar to prior studies on participation outcomes (Verhoef, Miedema, Van Meeteren, Stam, and Roebroeck, 2013) and feasibility considerations. We will target recruitment of children in 1 age group (infants and toddlers between 0-3 years) to examine the feasibility of PEM+. Inclusion criteria: Same as Aim 1.

Automated email with study flyer will be sent to families on listserves. Parents who meet eligibility criteria will be directed via web link to create a user account to enter the YC-PEM study platform that is being hosted on REDCap at UIC. Participants will provide online consent and then proceed in completing a demographic questionnaire and YC-PEM online to receive a summary report, followed by phone consultation to interpret their report. Participants will then click a web link on the YC-PEM report to be directed to a revised PEM+ platform hosted via combination of Amazon cloud and REDCap at UIC. Participants will proceed through PEM+ to apply information from the report to generate participation goals for their child and potential intervention strategies. Parents will be given 4 weeks to develop as many goals and intervention strategies as possible, and they may opt for help using one or more of the following options for support: 1) text-based examples of priorities, goals, and strategies that are accessed by the parent in the PEM+ platform, 2) email coaching support (parent clicks on a link in the platform to email trained UIC staff with questions), and/or 3) phone or video conferencing (Skype) consult that participant can request in the platform, to be provided by master coach (Teplicky). No more than 6 participants will begin PEM+ each week to ensure feasibility, resulting in a total of 8 weeks for data collection (6 participants/week x 4 weeks/participant). Weekly text-message and email reminders will be issued to all participants to promote retention and completion rates. Final phone consultation and CanChild survey completion will take place at 4 weeks. Each participant will be paid $80.00 at 4 weeks ($40.00 prorated payment for completion of no more than 2 weeks.

During Aim 2, all study forms (informed consent form, PEM-Plus data capture, coaching logs) for each study subject will be linked using a non-identifying participant ID (usually numerical). During Aim 2 data collection, only UIC GRA and McMaster coach will have access to the the administrative end of the PEM+ platform during data collection to monitor participant progress, enter coaching notes, manage study subject payment, and transfer data. The master file containing ID and contact information will be transferred to UIC study staff to be stored separately from a coded dataset that will also be stored at UIC

- *Consider including a table or flow diagram for clarity.*

For particular types of studies, the following information should be considered and provided:

For Specimen Collection Studies [Delete if not applicable]

- *Describe the specimens to be collected.*
- *Describe aliquoting and any plans for retention specimens.*
- *Describe tracking and labeling system.*
- *Describe where the specimens be stored and who will be responsible for care of specimens during storage.*
- *Describe how long the specimens will be kept.*
- *Describe how specimens will be destroyed at study completion.*
- *If specimens will be banked for future use, describe what the process is for providing investigators with access to the bank.*
- *Describe how such requests and access with be tracked.*
- *Describe how specimens will be analyzed (type and state of development of assay, controls, etc.)*

Behavioral Intervention Studies [Delete if not applicable]

- *Describe how the behavioral intervention will be developed or adapted for use.*
- *Describe how fidelity of the intervention process will be assured.*
- *Describe how competence or compliance with fidelity will be demonstrated.*
- *Describe how fidelity and competence will be maintained and demonstrated throughout the study.*
- *Describe how compliance with intervention will be ascertained.*
- *Describe what will be done with any audio or video tapes after the study is completed.*

For Studies that Collect Existing or Prospective Data [Delete if not applicable]

- *Describe the source of the information.*
- *Describe whether data are to be collected prospectively (come into existence after the protocol submission).*
- *Describe whether data are collected retrospectively (exist at the time of the protocol submission).*
- *Describe the time period of the medical information under review.*
- *Describe who will have access to collected information.*
- *Describe how long the information will be kept.*
- *Describe plans for destroying the data or other handling once the study is completed.*
- *Describe any plans for de-linking, coding, or de-identifying collected information.*

Focus Group Requirements [Delete if not applicable]

- *Describe qualifications of facilitator or individual supervising facilitation. Expectations include:*
  - *Prior experience facilitating groups*
  - *Adequate knowledge of the topic*
  - *Understands the purpose of group*

- *Provide script or discussion questions that will be used in focus group.*
- *Describe any literacy or foreign language concerns or accommodations.*
- *Describe how information will be captured.*
- *Describe how information from focus group will be presented and used.*
- *How will focus group responses be summarized and integrated?*
- *How will contradictory responses be handled?*
- *Will there be thematic or qualitative coding of transcribed discussions?*
- *Will focus group responses be used to guide the development of education materials, measures, interventions or other research procedures, publication, or inform study design?*
- *Describe whether information drawn from focus group will be shared with group subjects.*
- *Describe what will be done with any audio, image, video or digital records after the study is completed.*

Survey studies [Delete if not applicable]

- *Describe interview methodology.*
- *Describe development or selection of questionnaire.*
- *Describe any literacy or foreign language concerns or accommodations.*
- *Indicate whether questionnaire is validated.*
- *Describe how questionnaire will be tested (e.g., piloted).*
- *Describe how missing or incomplete information will be handled in analysis.*

Studies involving use of product [Delete if not applicable]

- *Name and description of product.*
- *Route of administration, dosing, dosage regimen and duration.*
- *Describe how compliance with product will be ascertained.*
- *Include information on how product will be obtained, stored, and tracked.*
- *Describe how any adverse events or serious adverse events will be handled.*
- *List/describe the expected adverse events based on the product label.*

7.0 Expected Risks/Benefits

- *Include expected risks and benefits to subjects and/or society.* ***NOTE:*** *Risks can be psychological, physical, social, economic, or legal.*
  - **We do not anticipate that this research will pose significant risks to study subjects. YC-PEM will measure a number of aspects of child and family need. Thus, it is possible that families will experience psychological distress as these needs are identified. While this risk may be likely, the probability and magnitude of harm or discomfort anticipated in the research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests associated with participating in therapeutic services (which routinely measure and/or addresses maternal mental health, infant health and development, and family resources). An additional potential risk is loss of confidentiality in Aim 2 is confidentiality due to participant receipt of a summary report specific to their child (and with identifying information such as the child's name and photo on the report) upon YC-PEM survey and PEM+ care planning guide completion.**
  - **The participant's contribution to the occupational therapy field and financial benefit are designed to minimize the effect of any discomfort or fatigue resulting from participation in this study. Each participant will be recognized for his or her participation in two ways. First, each participant will be sent a $20.00 gift card payment (for Aim 1) or $80.00 gift card payment (for Aim 2) as compensation for their time and effort. In addition, all participants will receive a summary report with the results from their YC-PEM questionnaire. Participants in Aim 2 will also receive a PEM care plan that they have drafted using PEM+ web interface, following completion of the YC-PEM questionnaire online.**
  - **Aside from this, there are no direct benefit to subjects. There is a potential for indirect benefit to subjects. For example, parents may gain improved awareness of their child's functioning (areas of strength as well as areas for growth), as well as their priorities and needs, which may encourage parents to begin engaging in intervention planning with their providers to improve these types of outcomes.**
  - **The potential risks to subjects (i.e., minimal psychological distress and risk of loss of confidentiality) are outweighed by the potential for improvement for therapeutic service delivery for young children with disabilities.**

- *Describe the expected frequency, degree of severity, and potential reversibility of the risks.*
- *Describe any dose modifications as a results of adverse events, as applicable.*
- ***NOTE**: This information will be used to determine whether an event is "Expected" and therefore not an unanticipated problem requiring expedited reporting.*

8.0 Data Collection and Management Procedures

- *Outline the process for data procurement.*
- *Describe source documents and how data will be collected from source documents and incorporated into the database.*
- *Describe the methods in which the data will be collected and stored (i.e., electronic, hard copy, specimens, artifacts, etc.).*
- *Describe where each method of data will be stored and how each method will be maintained in a secured manner (i.e., encryption, password protection, use of Qualtrics or REDCap, etc.).*

- **For both aims, consent, demographic, YC-PEM, and contact information for study payment will be collected via REDCap (HIPAA compliant) at UIC. UIC PI and study staff are the only members of the research team to access these data via REDCap, which will be exported to SPSS for analyses. Moreover, IT systems at the University of Illinois at Chicago employs multiple measures to ensure data safety: network isolation from the internet, HIPAA and FERPA compliance, restricted facility access, multilevel firewalls (software, hardware, private IPs, limited MAC addresses), and user access limited to need-to-know. There is no longer a need for Northwestern University to store PEM+ data during data collection. Data will be collected using REDCap at UIC and stored at the University of Illinois at Chicago. All access to this application will be provided over encrypted-TLS communication and all servers are locked and managed in a physically secure facility with Marlok identity management.**

  - *Describe who will have access to each method of data and how each method of data will be transferred to any collaborators.*

9.0 Data Analysis

- *Describe arrangements for data analysis.*

10.0 Quality Control and Quality Assurance

- *Describe how data will be evaluated for adherence with the protocol and for accuracy in relation to source documents.*

- *Describe who is responsible for the evaluation of data quality and how frequently this will be done.*
- *For multi-site studies, describe who is responsible for the monitoring of the research, the evaluation of the data quality, etc.*

11.0 Data and Safety Monitoring

- *Addresses how problems/side effects will be identified and handled.*
- *For studies that are minimal risk, describe how potential problems will be monitored and handled (e.g., breaches of confidentiality, emotional upset).*

- **In the event of any real or suspected breach of confidentiality or security (e.g., loss of data disc, violation of password-protection, etc) the party discovering such breach will immediately (within 48 hours) notify the PI. A joint determination will subsequently be made as to the appropriate remedy for the real or suspected breach. Remedies may range from outright stoppage of the project, to changes in data handling procedures as jointly deemed suitable by the parties.**

    - *For research involving more than minimal risk to subjects, describe:*
        - *Who will monitor adverse events (AEs) and unanticipated problems (UPs) involving risks to subjects or others and when events will be assessed.*
        - *How AEs or UPs will be recorded and communicated amongst research team members and who is responsible for making the reports.*
        - *The composition of the Data and Safety Monitoring Board (DSMB) and how frequently the DSMB meets, if one has been formed for the study.*
        - *Identify how often AEs and UPs will be monitored and what events will be reported to the sponsor and/or the IRB.*
        - *Describe stopping rules for the study.*
        - *Describe what occurs if a subject withdraws prematurely.*

12.0 Statistical Considerations

- *If a study incorporates qualitative rather than quantitative methods, indicate this and describe qualitative analysis and disregard the rest of this section.*
- *Describe how the data will be examined and statistically analyzed to answer the objectives.*
- *Provide a brief sample size calculation or description of sample size calculation. Include methods and assumptions such as loss to follow-up, as appropriate.*

13.0 Regulatory Requirements

13.1 Informed Consent

- *Describe how informed consent will be obtained and who will obtain it.*

  Participants will complete online informed consent in English. The online consent will be administered via REDCap. Participants will be prompted on screen and by provider to contact UIC study staff, each with human subjects training, as questions arise.

- *Describe the training that will be completed by each member of the research team prior to being delegated to obtaining informed consent.*

  UIC staff will be trained on the Aim 1 and 2 study protocol for assisting with recruitment and enrollment processes and online questionnaire completion (via REDCap) followed by PEM+ use via a web-based platform that they access via web link from their automated summary report following PEM survey completion in REDCap. This training will ensure that participants who complete online informed consent can access UIC staff as needed. Participants will also be prompted on screen to contact UIC study staff, each with human subjects training, as questions arise during survey completion in REDCap and/or PEM+ completion.

- *Describe where the informed consent document will be stored and who will have access to the informed consent documents.*
- *If research involves minors, describe assent process, as applicable.*
- *If research involves non-English speaking subjects, describe the consenting process, as applicable.*

- *Describe the use of any waivers, if applicable.*
  We request waiver of documentation for child assent because the data are being collected about the child from the caregiver's perspective, and the children are 0-3 years old and therefore are not going to engaged nor able to provide assent for a study of this scope.

13.2 Subject Confidentiality

- *Describe how the subject's confidentiality will be maintained.*

  Automated emails and study flyers will be sent to families in 1 listserve. These families have enrolled in prior research in Colorado and have consented to future contact. Eligible and interested caregivers will self-enroll in the study and self-administer the questionnaires and care planning guide. Caregivers can enroll on their personal computer, using information including weblink to study site that is located on the study flyer. Hence, all

data collection can occur outside of research involvement and/or service provision to minimize undue coercion on study enrollment. Once enrolled, no providers and/or family members will know which caregivers have enrolled unless the caregiver chooses to share his/her summary report with him/her.

Each subject will be given a study identification number online and the study platform will maintain a personal participation identification list (i.e., participant names with corresponding ID numbers) primarily for tracking study subject payment. All data collection will take place in the participant's personal space, not a group setting or in public. Finally, all written material related to and publications resulting from Aim 1 or 2 of the protocol and participant data will be grouped. Every effort will be made to maintain the confidentiality of participant database records. All dissemination of Aim 2 findings will be in aggregate form only, to further mitigate risks of confidentiality. The summary reports that contain identifying information (child name and photo) will be issued to the parent and not otherwise retained by UIC study staff upon data transfer.

Similarly, UIC study staff will not track data on when and how these reports are shared. There is no longer a need for Northwestern University to store PEM+ data during data collection. All YC-PEM and PEM+ data collected will be stored at UIC with UIC study staff.

- *Describe who will have access to the data.*

- *Describe whether the data will be de-identified, coded, or retain identifiers.*

- *Describe plans for the destruction of any identifiers.*

Destruction of any identifiers will be performed 5 years after study completion.

- *Provide justification for use of personally identifiable data or private health information (PHI).*

- *Describe whether a Certificate of Confidentiality will be required. See http://grants.nih.gov/grants/policy/coc/appl_extramural.htm.*

13.3 Unanticipated Problems

- *Describe process for reporting any unanticipated problems to IRB, sponsor (if applicable), and FDA (if an FDA-regulated study).*

14.0 References

- *Cite supporting material organized in a standardized bibliographical manner.*

APPENDICES

[Add appendices to your protocol here. Delete any appendices that are not applicable to your research.]

Demographic, YC-PEM, CanChild Usasbility Questionnaires