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This document approved by the CMH IRB for use from 11/18/2011 to 10/3/2014

For Office Only
IRB #: 11 10-163X

Pediatric Institutional Review Board

REQUEST FOR EXEMPT DETERMINATION

Instructions: If the ONLY involvement of human subjects will be in one or more of the following categories AND all the answers in one or more categories is 'True' (except as noted in statements 7 and 10 below), the research may be eligible for exemption. However, the research must be declared exempt by the CMH Pediatric IRB on the basis of the following answers. This form should be completed and submitted to the IRB when an investigator claims the project satisfies as exempt under 45 CFR 46.101(b).

A. General Information

Principal Investigator:	Jennifer Verrill Schurman, PhD.	Phone:	816-983-6668.
Department:	Section of Developmental & Behavioral Sciences.	Email:	jschurman@cmh.edu.
Office Location:	4602.39.	Primary contact name:	Kevin Mroczka, MHA.
Sponsor:	Pfizer Medical Education Group	Primary contact email:	kmmroczka@cmh.edu.
Protocol Title:	Improving pain prevention strategies during childhood immunization: A quality improvement project		
Has the protocol received exempt status at another institution?	☐ Yes ☐ No ☒ N/A If yes, attach approval letter indicating exempt status.		

B. Objectives

Objective(s): The abstract should begin with a clear statement of the precise objective or questions to be addressed by the project. If more than one objective addressed, the main objective should be indicated and only key secondary objectives stated.

☐ See sponsor protocol starting at page . (Attach)

1. Increase the use of pain prevention techniques for children immunized in the ambulatory primary care clinic as measured by one (or more) evidence-based pain prevention options documented as being offered during >80% of applicable patient visits at CMHC within 6 months.

2. Improve parent/guardian pain management satisfaction rating by achieving a score of at least 4/5 (on a 5-point scale) for >80% of applicable patient visits within 6 months.

C. Background

Give brief overview, including previous use in pediatrics, deficiencies in previous studies, relevance to pediatric health care; attach a bibliography. If the study involves treatment, state how study is different from routine care.

Instructions: This section is based on your objective(s). How are the possible answers to the objective(s) explained and defended? What are assumptions and relationships? What are the working hypotheses? Justification of your conducting this study based on existing knowledge and your research question. Describe the disease including incidence. Provide a summary of previous studies, relevant clinical studies, or any epidemiological data if available include references with citations from the literature.

☐ See sponsor protocol starting at page . (Attach)

Pain is a common adverse effect experienced by children undergoing routine medical procedures. Failure to treat a child's pain from even ìminorî medical procedures such as needlesticks is now known to potentially result in greater sensitivity to future pain and other enduring negative effects via the rewiring of a child's pain transmission pathways and the encoding of pain memories. These long-term effects can be prevented or substantially reduced through appropriate preemptive pain management interventions, and several policy statements exist to provide the rationale and evidence-based guidance for prevention of procedural pain in children. Nevertheless, pain from routine medical procedures often remains undertreated or ignored.

Immunizations are the most frequent painful medical procedure in childhood and established evidence-based methods exist for preventing needlestick pain. We have evaluated through electronic medical record query the extent to which one of the most commonly used procedural pain prevention strategies (topical analgesics) has been ordered during routine immunizations given to children ages 0-5 years of age in the ambulatory primary care clinic at CMHC. During the time period from January 2011 to May 2011, of the 4,601 vaccination visits for children ages 0-5 years of age, only 0.32% of visits had a pain score documented and only 0.04% of visits had a topical analgesic ordered for pain prevention during the immunization. Thus, the approximate baseline estimate of pain prevention implementation during immunization visits in the ambulatory primary care clinic is less than 1%, representing a considerable knowledge-practice gap in the treatment of pediatric procedural pain.

The ambulatory care clinic thus represents an ideal opportunity for quality improvement efforts in needlestick pain prevention, and both a physician champion and a nurse manager from this clinic are part of the interdisciplinary quality improvement group formed for this project.

D. Significance

Discuss the anticipated contributions of the proposed project in terms of anticipated outcomes, i.e., how the project results may be used in the CMH healthcare system. ☐ See sponsor protocol starting at page . (Attach)

Completion of this project is expected to yield measurable improvements in pain prevention during immunizations for young children (0-5 years) served in the CMH primary care clinic.

E. Methodology

Methodology: Indicate the methods used. State whether project is descriptive or experimental, basic or applied research, single or multi-centered, number of sites, blinded, randomized or convenience sample, etc. Indicate selection procedures, entry criteria, and expected numbers of study subjects entering and finishing the study. Describe the essential features of any interventions (if applicable), including the method and duration. The primary study outcome measure(s) should be indicated as planned before data collection began. ☐ See sponsor protocol starting at page . (Attach)

The current study is primarily quality improvement, with iterative phases based on identification of barriers to achieving desired outcomes as identified in study objectives listed above. However, identification of barriers will involve completion of 3 anonymous survey components (outlined below), as well as a pain/satisfaction measure completed by parents at the completion of immunization visits (also outlined below). For this reason, the entire protocol is being submitted for consideration of exempt status.

Process Measures: The primary process measure is the proportion of applicable Pediatric Care Clinic patient visits (i.e., visits for a child 0-5 with an immunization needlestick) in which a pain prevention strategy (e.g., topical analgesic, sucrose solution, distraction tool) was documented as being offered. The system for electronically tracking this outcome at baseline and during the quality improvement intervention phase of the project is currently under pilot development and will be finalized prior to the start of the project.

Outcome Measure: The primary outcome measure is parent/guardian pain management satisfaction ratings obtained following Pediatric Care Clinic visits in which a child received a needlestick. Consumer satisfaction with pain management is recommended as a key outcome variable for pain intervention trials and is regarded as a critical outcome in the context of needlestick pain in children given that it is predictive of return immunization visits. A subset of 6 items has been adapted from the Pain Treatment Satisfaction Scale, which uses a 5-point scale (ìvery satisfiedî to ìvery dissatisfiedî) to assess satisfaction with and perceived benefit of pain interventions. In addition, one item has been added to this measure to assess parent-perceived pain during the immunization process on a 3-point scale ("same", "better", or "worse" pain than evidenced in response to prior immunizations). This series of 7 questions will be asked by a nurse or research team member unaffiliated with the child's visit at the end of the visit, prior to discharge from clinic. This nurse will write parent/caregiver responses on a form with no identifying information that will be collected in a central location and sent periodically in batches to the principal investigator for data entry. This strategy should preseve the anonymity of the child and parent/caregiver by acting as a "Chinese wall" keeping personal identifiers from being associated with any data collected, while still allowing maximal information to be collected for quality improvement purposes.

Planning the Intervention

Phase 1 (Conceptual Phase): Prior to implementing efforts toward changing current pain management practices, the quality improvement team will work to identify barriers preventing more frequent use of pain prevention options during immunization needlesticks. The team has already reviewed the literature on physician, nurse, or consumer (parent/guardian) barriers to pain prevention during medical procedures (e.g., lack of knowledge, incorrect assumptions, perceived lack of time to implement an intervention, availability of device/product). Using the reviews of the extant literature as a foundation, the team has developed surveys to assess potential physician, nurse, and consumer (parent/caregiver) pain prevention barriers within the Pediatric Care Clinic at Children's Mercy Hospitals and Clinics (see attached appendix for copies of these surveys). Surveys containing no identifying information will be administered electronically to all CMH primary care clinic nursing and provider staff, as well as all residents (as they will be rotating through the primary care clinic at some time during their training), using the institution's internal electronic survey software system. Surveys containing no identifying information will be given to all parents/caregivers with a child 0-5 years of age who are attending a CMH primary care clinic appointment at initial presentation to the reception desk; they will be asked to complete the survey and drop it in a secure lockbox within the clinic prior to being called back by a nurse for the child's appointment. All staff and parent/caregiver surveys will be kept anonymous and collated for determination of barriers that may be appropriate targets for intervention in later phases.

Phase 2 (Prioritization Phase): Data (see Section F below) will be analyzed to determine barriers that are most frequently endorsed, and these particular barriers will subsequently be the target of quality improvement interventions.

Phase 3 (Improvement Phase): We will use Plan-Do-Study-Act cycle methodology to plan and trial quality improvement interventions to obtain the proposed metrics for quality pain management during needlesticks in the Pediatric Care Clinic. Although the choice of quality improvement interventions will depend upon data gathered on physician, nurse, and parent/caregiver barriers for pain prevention during immunizations, possibilities include changes to the electronic medical record system (e.g., changes in documentation of pain during needlesticks, creation of ìPowerPlansî in which a list of evidence-based pain prevention strategies are pre-populated for selection when an immunization is ordered), pre-visit parent handouts, clinic postings, educational offerings to healthcare providers, and increased visibility of possible interventions (e.g., distraction tool kits, sucrose solution, and topical analgesics). Planned interventions will first be trialed within one of the four provider-specific teams housed in the Pediatric Care Clinic, and subsequently successful interventions will be successively rolled out to other teams. Process and outcome measure data will be collected in one-month bursts pre-/post-intervention in each cycle .

Briefly describe the number and type (patient population).

Inclusion Criteria	Exclusion Criteria
• List the disease or disorder under study • How will it be documented, i.e. diagnostic methods, criteria for classification, etc. • Demographic characteristics (e.g., gender, age) as applicable	• List specific clinical contraindications. • Specify any specific grades of signs/symptoms.
Inclusion: Target partient population: Patients 0-5 years of age with an appointment in the CMH Pediatric Care Clinic. Participants: Parents/caregivers of a child 0-5 years of age with an appointment in the CMH Pediatric Care Clinic (survey). Parents/caregivers of a child 0-5 years of age receiving an immunization in the CMH Pediatric Care Clinic (interview). Nursing/provider staff working in the CMH Pediatric Care Clinic. Residents at CMH.	Exclusion: Inability of parent/caregiver to read/write in English may limit participation in completion of the barriers survey only. (Translation services may be provided for oral interview questions regarding satisfaction and pain assessment post-immunization.)

List the statistical methods to be used to address the primary and secondary objectives. Provide a description of a data analysis plan and, if considerations of statistical power are not addressed, a justification for the analysis plan should be provided. Specify any confounding variables for which it is anticipated adjustment will be made. Explain how missing data and outliers, will be handled in the analyses.
Data Analysis: Outcome data during each intervention implementation period will be analyzed in collaboration with co-investigator and quality improvement data analyst Dr. Steve DeLurgio.

For the primary process measure, the proportion of applicable visits where pain prevention strategies are offered will be plotted monthly on a p-chart using Excel QI Macros and compared to 12 months of preliminary data. The chart, having been subdivided into provider-specific teams, will be annotated with each intervention (PDSA cycle) and analyzed at each point of change for statistical trends using QI macros software.

For the primary outcome measure, the proportion of survey responses regarding satisfaction with pain management during the immunization visit where the parent/guardian answered 4-5/5 (on a Likert scale of 5) will be plotted monthly on a p-chart. The chart will be annotated with each intervention (PDSA cycle) and analyzed at each point of change for statistical trends using QI macros software.

Sample size determination: What sample size will you be able to get and does your suggested samples size has enough of power to deliver the significant results? Provide the rationale for the sample size, the calculations on the power of the trial and the clinical justification. Include plan of accounting for missing, unused and spurious data.

The Pediatric Care Clinic at Children's Mercy Hospital provides care to pediatric patients in the Kansas City Metropolitan area from birth until 18 years of age. The staff comprises 28 physicians, 12 Advanced Practice Nurses, 28 nurses, and 16 care assistants who see patients for ill visits, follow-up care, and for preventative/well child visits. All staff physicians/APNs (n=42) and nursing staff (n=37) will be sent an invitation and link to the provider/nurse survey. In addition, all residents who will work in the PCC at some point during their residency (n=98) will be sent an invitation and link to the provider/nurse survey. We anticipate that at least 20% of those invited will choose to participate and complete an online survey based on typical survey response rates. This number should be sufficient to assess general knowledge, attitudes, and barriers that may be appropriate targets for QI intervention in the second phase.

Approximately 45,000 patient visits occur in the PCC annually, and children receive vaccines at approximately 40% of these visits. The parent/caregiver survey will be given to every family with a child 0-5 who presents to the PCC for a scheduled visit during the 8 week survey collection period. We will distribute surveys until we have collected 300 completed surveys in order ot ensure a representative cross-section of patients and sufficient saturation. We would set the upper limit at 350 to allow time for informing the administrative support staff to cease distributing the surveys and allow those surveys already distributed to be completed and placed into the anonymous drop boxes. Assuming 1000 patient visits in this age range per month, and a 20% response rate, reaching the suggested 300 surveys would take approximately 6 weeks, with a 2 week contingency added on to make the total data collection period last a maximum of 8 weeks. Data collection will be ended earlier, as described above, if we reach 300 completed surveys prior to 8 weeks elapsing.

Given the large number of children seen, and the iterative nature of this project, we anticipate no issues with regard to insufficient power in collecting pre-/post-intervention interviews. We propose collecting this data in 1 month bursts to provide sufficient data without overwhelming our capacity for data entry, verification, and analysis. All statistical analysis will be conducted with the assistance of Dr. Steve DeLurgio, who will aid in decisions related to treatment of missing, unused, and spurious data, as needed.

F. Data Collection Procedure

Describe the method for identifying candidates for the study:
1. A link will be sent to the provider/nursing survey to all part- and full-time physician, APN, and nursing staff of the CMH Pediatric Care Center. A link to the provider survey also will be sent to the entire resident class, as all will rotate through the CMH Pediatric Care Center at some time during their training.

2. A hard copy of the parent/caregiver survey will be given to each parent/caregiver checking in a child aged 0-5 years (inclusive) for an appointment in the CMH Pediatric Care Center. The administrative support staff has agreed to distribute the survey packet (survey with cover letter attached) to all target families at the time of PCC visit check in.

3. During each 1 month data collection burst pre-/post-intervention, all children aged 0-5 years who have an immunization ordered during their visit to the CMH Pediatric Care Center will be identified and their accompanying parent/caregiver will be asked to participate in the 7 question interview at the conclusion of the immunization procedure.

4. All children aged 0-5 years seen in the CMH Pediatric Care Center who have had an immunization ordered during their visit will be included in the ongoing process monitoring for quality improvement purposes.

Describe the procedure for obtaining data:
1. Provider/nursing survey data will be collected and captured electronically and saved to a secure database for analysis.

2. Parent/caregiver survey data will be completed and placed in a secure lockbox within the waiting room of the CMH Pediatric Care Center. Surveys will be collected and sent in batches to the Principal Investigator for oversight of data entry on a weekly basis.

3. Parent/caregiver satisfaction and pain assessment will be collected orally and transcribed on a written form, collected in a central location, and sent in batches to the Principal Investigator for oversight of data entry on a weekly basis during the 1 month data collection bursts.

4. Process measures will be abstracted electronically from the medical record system using automated reporting functions.

Describe the type of data to be collected and timeframe, i.e., lab tests, procedure outcome, length of stay, etc. Attach a sample of the database elements to be collected or Data Collection Form. The type of data collected must enable the objectives to be met and/or hypothesis answered.
Please see attached appendix for copies of all surveys and the parent/caregiver interview, as well as a sample report pulled for ongoing process monitoring. Although the provider/nursing survey will be implemented via an online survey tool, these copies contain all database elements to be captured. No timeframe for data collection is specified, as it is as yet unclear how many plan-do-act cycles will be required to achieve the quality improvement goals specified.

Indicate what information will be retained for each subject and by whom. Describe methods for maintaining confidentiality of subject records.

No identifying information will be collected or kept with any data completed. This is intended to be primarily a quality improvement project, with exempt surveys used to establish potential barriers to pain prevention strategy use to be targeted in later intervention phases. As an extra precaution, all data will be housed on a secure server in a network folder accessible only to team members listed on this application.

G. Projected Study Time Line

Anticipated project start date:	As soon as approved	Anticipated project end date:	Not anticipated to end until objectives for process and outcome measures met.

H. Indicate the Exemption Requested

Instructions: Answer question 1 and 2 and then select the exempt category you are claiming and indicate whether the qualifying statements are true for your protocol.	**True**	**Not True**	**Regulation**
1. The research will not involve individuals as participants who are known to be prisoners.	☒	☐	45 CFR 46.303(c)
2. The research is not subject to FDA regulations, i.e. Experiments using a test article (e.g., investigational drug, device, or biological) on one or more human subjects that are regulated by the FDA or support applications for research or marketing permits for products regulated by the FDA. Products regulated include foods, including dietary supplements that bear a nutrient content claim or a health claim, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products that aid in diagnosis or treatment of injury or illness.	☒	☐	
☐ **Category 1 - For Educational Settings:**	**True**	**Not True**	
3. The research will only be conducted in established or commonly-accepted educational settings including but not limited to schools and colleges. (May include other sites where educational activities regularly occur.)	☐	☐	45 CFR 46.101(b)1(i)
4. The research will involve only normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.	☐	☐	45 CFR 46.101(b)1(ii)
☒ **Category 2 - For Educational Tests, Surveys, Interviews, Public Behavior Observation**	**True**	**Not True**	
5. The research will involve only the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior.	☒	☐	45 CFR 46.101(b)2
Address statement 6 only if the research will involve children as participants. If children will NOT participate, check N/A and continue with statement 7.		**N/A**	45 CFR 46.401(b)
6. The procedures will be limited to the use of educational tests (cognitive, diagnostic, aptitude, achievement) or observation of public behavior where the investigator will NOT participate in the activities being observed.	☐	☒	
'True' to either statement 7 or 8 will qualify for exemption.			
7. The information obtained from educational tests, survey procedures, interview procedures or observation of public behavior will be recorded in such a manner that human subjects CANNOT be identified, directly or through identifiers linked to the subjects.	☒	☐	45 CFR 46.101(b)2(i)
8. Any disclosure of the human subjects' responses outside the research could NOT reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.	☒	☐	45 CFR 46.101(b)2(ii)
☐ **Category 3 - For Educational Tests, Surveys, Interviews, Public Behavior Observation of Public Officials:**	**True**	**Not True**	
'True' to either statement 9 or 10 will qualify for exemption			
9 The research will involve only the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior AND the human subjects are elected or appointed public officials or candidates for public office. (Applies to senior officials such as mayor or school superintendent rather than a police officer or teacher.)	☐	☐	45 CFR 46.101(b)3(i)
10 The research will involve only the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior AND federal statute(s) require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.	☐	☐	45 CFR 46.101(b)3(ii)
☐ **Category 4 - For Existing Data, Documents and Specimens:**	**True**	**Not True**	
11 The research will involve only the collection or study of *existing* data, documents, records, pathological specimens, or diagnostic specimens. ("Existing" means existing before the research is proposed to the IRB to determine whether the research is exempt. All materials to be reviewed currently exist at the time of this exemption request.) Indicate the time frame for the records you want to review in month/day/year format. to . Example: You wish to review medical records from patients starting on 1/1/2005 to 1/1/2010.	☐	☐	45 CFR 46.101(b)4
12 The sources of the existing data, documents, records or specimens are publicly available **OR** the information will be recorded by the investigator in such a manner that participants cannot be readily identified either directly or through identifiers (such as a code) linked to them. **This means that the investigator cannot record medical record numbers, patient names, social security**	☐	☐	45 CFR 46.101(b)4

numbers, or any other patient identifiers and link the subject to the data set. As a consequence, the resulting research data set is completely **anonymous**. For example, once the information has been extracted from the medical record, it will not be possible for the investigator to go back to the medical record and add other patient-specific information to this research dataset. To qualify as exempt, the list from Medical Records would need to be discarded as soon as a study number was assigned. 13 Record review: (Instructions: Please be sure to specify in the methodology section the parameters of your record review, i.e. the scope of information you are acquiring.) a. Indicate expected # of records to review: Total study Number expected at CMH: *Note: This is the number of potential subjects you may review in order to get your sample—not just the number who actually meet inclusion criteria in the study.* b. Indicate the source of the records you are reviewing (i.e. CMH medical records, PHIS): c. Describe the criteria that will be provided to the data source to generate the list of records to be reviewed (must be the minimum necessary).			
☐ **Category 5 - For Public Benefit or Service Programs (Federal):**	**True**	**Not True**	
14 The project is a research or demonstration project conducted by or subject to the approval of a (federal) Department or Agency head and which is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those public benefit or service programs.	☐	☐	45 CFR 46.101(b)5
15 The program under study delivers a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act).	☐	☐	
16 The research or demonstration project will be conducted pursuant to specific federal statutory authority.	☐	☐	
17 There is no statutory requirement that the project be reviewed by an IRB.	☐	☐	
18 The project does not involve significant physical invasions or intrusions upon the privacy of participants.	☐	☐	
19 The exemption has authorization or concurrence by the funding agency.	☐	☐	
☐ **Category 6 - For Taste and Food Quality and Consumer Acceptance Studies:**	**True**	**Not True**	
20 The research involves only a taste and food quality evaluation or a food consumer acceptance study in which (i) wholesome foods without additives will be consumed **OR** (ii) food will be consumed that contains a food ingredient, agricultural chemical or environmental contaminant that is at or below the level found to be safe by the Food and Drug Administration or is approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.	☐	☐	45 CFR 46.101(b)6 21CFR 56.104(d)
☒ **Criteria that must be met for the research to be determined to be consistent with ethical standards**	**True**	**Not True**	
21. The research holds out no more than minimal risk to subjects. Give an explanation justifying your position this is a minimal risk study: This is primary a quality improvement study based on position statements regarding the need for pain prevention made by the AAP and other organizations and is intended to benefit the large group of children aged 0-5 years who receive immunizations through the CMH Pediatric Care Center. The survey component is anonymous and unlikely to contribute to any distress or provide any other substantial risk to the parent/caregiver.	☒	☐	
22. Selection of subjects is equitable.	☒	☐	

I. HIPAA

Instructions on HIPAA: Even if this project is exempt from the Common rule, HIPAA must still be addressed.

☒ 23. Project contains and/or requires the review of HIPAA defined identifiers and therefore HIPAA must be addressed. If this statement is true, a Request for Waiver of HIPAA Authorization must be submitted with this request.

☐ 24. Project contains no HIPAA identifiers and does not require the review of HIPAA identifiers (including the review of medical records); therefore HIPAA does not pertain. **Instructions:** Please sign below indicating your acknowledgement.

I attest that this project does not use or review of any of the 18 identifiers in the Privacy Rule (45 CFR 164.512) and understand that collecting, recording, or using any identifiers for this project would be in violation of IRB-approval given and result in referral to the office of Corporate Compliance.

PI Signature: Date:

J. Investigator Attestation

By signing below, you certify and attest that:

- I certify that the information in this application is complete and correct.
- I certify that no similar proposal has been disapproved by another IRB.

- I understand that as Principal Investigator, I have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by the IRB.
- I agree to comply with all CMH policies and procedures, as well as with all applicable federal, state, and local laws regarding the protection of human subjects in research, including, but not limited to, the following:
  - Implementing no changes in the approved project that would change the exempt status without first seeking proper IRB approval;
  - Providing accurate and timely information for continuing reviews; and
  - Reporting to the IRB if any investigator operating under an exempt approval (1) unexpectedly learns the identity of one or more living individuals involved in the project or (2) for previously unforeseen reasons now believes it is important to identify the individual(s).

Signature: .

Printed name: **Jennifer V. Schurman, PhD.** Date

K. Personnel Roster

Personnel Roster Instructions: Indicate the following information for all personnel working on this project.
If a conflict of interest is declared by any staff member (see page 3 (COI Declaration Page for definition), then also include page 3.

Name	Role in Project	Degree	Any conflicts of Interest to declare? (See next page for details.)	IRBECs completed? (If person is not engaged in research indicate N/A.)	Signature of Staff (All signatures must be present or the submission will be returned as incomplete)
Jennifer Schurman	PI	Ph.D.	No	Yes	
Kristi Williams	Co-I	M.D.	No	Yes	
Mark Connelly	Co-I	Ph.D.	No	Yes	
Rebecca Johnson	Co-I	Ph.D.	No	Yes	
Jolynn Parker	Co-I	RN	No	Yes	
Kevin Mroczka	Co-I	Other	No	Yes	
Keith Mann	Co-I	M.D.	No	Yes	
Steve DeLurgio	Co-I	Ph.D.	No	Yes	
KaMara White	Co-I	Other	No	Yes	
Nancy Lathrom	Study Coordinator	None	No	Yes	
Dustin Wallace	Co-I	Ph.D.	No	Yes	
Amanda Drews	Co-I	Ph.D.	No	Yes	
Lynn Anson	Co-I	RN	No	Yes	
Carol Garrison	Co-I	M.D.	No	Yes	
Chelsea Waller	Co-I	LPN	No	Yes	
Emily Kessler	Co-I	MA	No	Yes	

***** IRBEC Requirements:** Persons who are not ìengagedî in research but who are listed on a research application where the CMH Pediatric IRB is the IRB of record do not have to complete on-site CMH research training (i.e. IRBECs). The following are persons ìnot engaged in researchî:

a. A non-CMH employee investigator who is not actively participating in the implementation of research procedures or obtaining individually identifiable private data about CMH patients for research purposes. Example: A collaborator at another institution aiding in analysis of de-identified data only. Please label these persons as ìOff-site Investigator.î

b. A person 1) whose services performed are clinical trial-related medical services and are typically provided by the person for clinical purposes and would constitute standard of care, 2) who does not enroll subjects or obtain the informed consent of any subject for participation in the research; and 3) who does not administer any study intervention being tested or evaluated under the protocol. This would also include a Lab technician or biostatician, regardless of employee status, who is not actively participating in the implementation of research procedures, but performing services in line with his/her everyday job functions. Example: A qualified laboratory personnel who performs routine serum chemistry analysis of blood samples for an investigator as a service. A radiology clinic whose employees perform x-rays and send the results to investigators as a service. Please label these persons as ìservice provider.î

c. Persons who 1) inform prospective subjects about the availability of the research or provide prospective subjects with written information about the research but do not explain the study, obtain subjects' consent for the research, or act as representatives of the investigators; provide prospective subjects with information about contacting investigators for information or enrollment; and/or seek or obtain the prospective subjects' permission for investigators to contact them. An example of this would be a clinician who provides patients with literature about a research study at another institution, including a copy of the informed consent document, and obtains permission from

the patient to provide the patient's name and telephone number to investigators. These persons do not need to be listed on the protocol, but should be described in the recruitment plan for subjects.

d. Persons who give to CMH investigators information or biological specimens pertaining to the subjects of the research. Note that in some cases the institution releasing identifiable private information or identifiable biological specimens may have institutional requirements that would need to be satisfied before the information or specimens may be released, and/or may need to comply with other applicable regulations or laws. Please label these persons as ìProvider of materials.î Example: An outside collaborator provides a cell culture with some PHI on the donor to a CMH investigator under a Data Use Agreement for use in the study.

e. Consultants are persons, regardless of employee status, who may provide technical input or advice but play no ongoing and active role in the research design, research project implementation, or data analysis. They must not enroll subjects, obtain informed consent or administer any study intervention. Example: a mentor in study design providing general and limited advice on the protocol but not actively performing ongoing work on the project.

CONFLICT OF INTEREST DECLARATION PAGE

Policy: Proposals for Research (sponsored or not sponsored) involving any of the following arrangements shall be disclosed by each Investigator who intends to participate in the research project and:
1. Will receive, or anticipate receiving, anything of monetary value (including payments, salary, equity interest, and intellectual property rights) that represent a Financial Interest which are made by the study sponsor to an investigator or to CMH to support activities of the investigator (ex: grants to support investigator-initiated research, payments for educational activities and/or staff development, equipment, and consultancy or honoraria payments) that are external to the costs of conducting a sponsor-initiated clinical trial or
2. Has professionally-related activities (such as consulting, speaking engagements and/or speaker's bureaus, advisory board services, and review panel participation) related to study sponsor.

Instructions: Declaration of Conflicts: Answer yes in page 2 if:
1. You (including spouse or dependent children) have any financial interest such as royalty, equity or any payments (e.g., consulting, salary, etc) in the sponsor or other entities having a financial interest in intellectual property, product, or service which is the subject of the proposed research or
2. There are other circumstances, relationship, or situation (other than financial), which might be considered as a conflict of interest (e.g., member of board of directors, consultant, partnerships, employment relationship, etc.).

This page should be completed and submitted to the IRB when an investigator proposes a project and there is a member who declares a conflict on page 2. Contact April Smith, Conflicts of Interest, at extension 44572 for advice regarding COI. A conflict of interest management plan will have to be received from April Smith before the IRB can approve your project.

L. Declaration of Conflicts	
Name of research team member	**Indicate the nature of the conflict to disclose**

M. Investigator Attestation to Conflict of Interest Declarations

By signing below, you certify and attest that:

- I certify that declarations have been obtained by each research team member and the information in this application is complete and correct to the best of my abilities.
- I certify that no similar proposal has been disapproved by another IRB.
- I agree to comply with all CMH policies and procedures, as well as with all applicable federal, state, and local laws regarding conflicts of interest.

Signature: .

PI printed name: **Jennifer V. Schurman, PhD.**	Date

N. Statement of Support and Signature of Department Manager or Section Chief	
This is to certify that I have read the protocol and believe that there is value in asking and answering these research questions using the approach described in this application. To the best of my knowledge, the researcher(s) have the time, facilities, and expertise to conduct this study. My signature below signifies my support of this study as presented in this document.	
Signature:	Date:
Dept. Manager or Section Chief printed name: **Michele Kilo, MD.**	Name of Department/Section: **Section of Developmental & Behavioral Sciences.**

O. Investigator Checklist: Exempt Studies	
Protocol Title:	
Instructions: This page is to aid you in ensuring all parts to the submission are provided. You may use the checkboxes to the far left as a checklist for documents that need to be received. Submit two copies of the investigator checklist. One copy will be stamped as received by ORI office staff and returned to you as an acknowledgement of receipt. The other copy will remain with the protocol submission form as an IRB record. Submissions will be returned if any of the following documents are missing in your submission without IRB review.	
Investigator Checkbox	**IRB received submission stamp**
☐ 1. Request for Exemption Determination Form and completely filled out. Submission will be returned to sender without IRB review if the submission is incomplete.	
☐ 2. If claiming exemption (b)(4) (Existing Data, Documents and Specimens), data collection sheet showing what data is being recorded.	
☐ 3. If you answered under HIPAA "yes" to "Project contains HIPAA defined identifiers and therefore HIPAA must be addressed" (Ques. 23), then include a Request for HIPAA Waiver or HIPAA Authorization Form (see Authorization for Use or Disclosure of Medical Information for Database Submission) you will be using.	