Systematic Pediatric Assessment of Rome Criteria (SPARC)

Principal Investigator: William Bennett MD

IRB Protocol # 1811325201

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#1811325201 - Systematic Pediatric Assessment of Rome Criteria (SPARC)

Protocol Information

Review Type
Expedited

Status
Approved

Approval Date
Sep 10, 2024

Continuing Review Date
Dec 05, 2020

Expiration Date
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Initial Approval Date
Dec 05, 2018

Initial Review Type
Expedited

Feedback

Approval Comment

Amendment A017 This research is approved under the following expedited categories: - Category 5 - Category 7

Protocol Amendment Form

Amendment Request
4000

Select your Protocol Type

Expedited/Full Board
4012

Amendment Number

A017
4001

Select the types of changes being made.

Personnel update
4002

Does this amendment include a change in PI?

No

General Information

Principal Investigator

Bennett, William

Lead Unit

IN-PGAS - PED-GASTROINTESTINAL DISEASES

Protocol Title

Systematic Pediatric Assessment of Rome Criteria (SPARC)

Personnel

Person

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Email Address

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Researcher Role

Principal Investigator (PI)

Home Unit

IN-PGAS - PED-GASTROINTESTINAL DISEASES

Contact Roles

Permissions

Full Access

Affiliation Type

IU

Training

- Biomedical Researcher - Stage 4 - CITI
- 08/07/20 - 08/06/25

Status: Approved

Personnel Attachments

Protocol Type

Select Protocol Type

Expedited

Participant Type

Participant Information

Participant Type

Children

Participant Number
10000

Participant Type
Economically/Educationally Disadvantaged
Participant Number
600

Participant Type
Total
Participant Number
10600

Organizations

Organizations List

Organization
ESKENAZI HEALTH CENTER

Organization
INDIANA UNIVERSITY

Funding

Will the study be funded, fully or partly by, any of the following sources (this includes pass through funding)? Select all that apply.

Federal funding

Funding Sources

Funding Source
NATIONAL INSTITUTE OF DIABETES, DIGESTIVE & KIDNEY

Conflicts of Interest

q134

Are any of the investigators listed in the personnel section aware of an institutional conflict of interest which could affect or be affected by this research?

No

q24901

Do any of the investigators listed in the Personnel section (or their immediate family members) have a significant financial interest which could affect this research?

No

q24905

Does the Principal Investigator affirm all investigators listed as personnel on this protocol have agreed to participate in this project, are aware of their status and role, and have been adequately trained to participate in the project?

Yes

A-Level of Review

q720

Does any research activity in this study present more than minimal risk to human subjects?

No.The research may qualify for Expedited review if all research procedures fall into one of the categories below.

q721

Check all category(ies) which apply to this research.

Category 5 - Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes

Category 7 - Research on individual or group characteristics or behavior, or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies

q724

Will the researchers be using a data collection form?

No

q725

List all data points that will be recorded or collected.

FGID Module: Data points collected for participation in the retrospective review of FGID module data include date(s) of visit, physician name, patient vitals and demographics, contact information, patient/parent answers to GI questions, who is answering the questions (parent or patient or both), and physician notes about GI diagnoses, treatments, and recommendations. Tool Usability Questionnaire: Data points collected in the Gastrointestinal Symptom Survey Tool and FGID Module (as above) Survey (online and phone): In addition to the FGID Module data points above, we will use parent and patient answers to the phone survey, along with parent-reported demographics. Baseline retrospective review: DOB, date/diagnosis (ICD

codes), Eskenazi clinic(s) of care Health care utilization retrospective review: • The presence of outpatient sick visits within the Eskenazi system clinic for any complaint • The presence of outpatient sick visits within the Eskenazi system clinic with an associated GI billing code • The presence of visits to statewide providers, including inpatient hospital stays, outpatient clinic visits, and emergency room visits. • The occurrence of any GI-related testing and procedures – specifically radiologic, laboratory testing, endoscopy, and surgical procedures related to GI diagnoses • The use of any medications prescribed to treat Rome IV diagnoses – specifically acid-suppressants, antispasmodics, antidepressants, stool softeners and laxatives, and pro-motility agents.

q23340

Would identification of subjects and/or their responses reasonably place them at risk for any of the following (check any that apply):

None

B-Lay Summary Research Design

q22122

Describe the purpose of this study in lay terms, including research question(s) and hypothesis.

Functional gastrointestinal disorders (FGIDs) are extremely common in children and adolescents, and represent a wide range of disorders that are apparently related to the gastrointestinal tract, but which have no clear structural, anatomic, or histopathologic cause. FGIDs represent an enormous burden on patients and families, and patients with these functional disorders have much higher health care utilization and related costs. FGIDs are diagnosed according to the symptom-based Rome criteria. The Rome criteria have been developed by experts in pediatric functional disease through literature review and a consensus process. Unfortunately, FGIDs are often diagnosed incorrectly by primary care providers and patients often wait months to years before a correct diagnosis is made, and effective treatment is begun. Furthermore, primary care providers are often unaware of recent guideline changes or the evidence base for children with FGIDs, leading to overuse of testing, inappropriate or ineffective treatment, and increased costs. Given this information, it is essential that we develop interventions that target pediatric primary care providers to improve their care for children with FGIDs. We propose that using a Clinical Decision Support System (CDSS) that incorporates the Rome IV criteria for diagnosis and evidence-based care for FGIDs will improve the (1) accuracy of diagnosis and (2) effectiveness of clinical care, thereby improving clinical outcomes and reducing the economic burden of FGIDs in children. Once a FGID screening and care module within Epic is developed and tested, when a patient is scheduled to see

or presents to any primary care clinics in the Eskenazi health system which support general pediatric care, the patient (and/or parent) will be asked to complete FGID screening questions prior their provider visit as part of standard care. Rules have been established within EPIC to determine how often patients receive the FGID questionnaire to avoid redundancy, inappropriate use, and/or burden to the patient. Screening results will be available to physicians immediately, and physicians in the intervention clinics will have access to specific guidance for the diagnosis and treatment/management of the FGID, as well as information to share with families. Physicians may chose to document their FGID assessments and plans in the patient's EMR via EPIC. We hypothesize that automation of screening, diagnosis, and management of FGIDs will result in improved resolution of FGIDs (primary outcome), as well as decreased utilization of medical services (secondary outcomes). We propose to test this hypothesis using the following specific aims: Aim 1: Develop computer-based decision support system, to screen children 0 to 18 years of age for functional gastrointestinal disorders (FGIDs) using the Rome IV criteria, and provide guidance regarding diagnosis and management of probable FGIDs. (Please note that Aim 1 does not involve the use of human subjects/PHI.) Aim 2: Demonstrate the feasibility and effectiveness of thie FGID Module to improve clinical care measures (e.g., resolution of Rome IV criteria) and reduce utilization of healthcare services (e.g. repeat outpatient visits, ED visits).

q22123

List and describe all research interactions and/or interventions, including the frequency and duration of procedures, and length of participation for individual subjects.

In order to determine the effect of the FGID decision support module, we will complete the following study procedures: FGID module (data review): There is no contact with subjects for this portion of the study; this is a retrospective and prospective review of data. We will pull retrospective and prospective patient data from the EMR for FGID screening, diagnosis, and treatment in order to analyze module process and outcome data, including any difference in physician behavior at control vs. intervention clinics in the diagnosis, treatment, and symptom resolution of FGIDs. Control verses intervention clinic will be determined by cluster randomization at the clinic site level. A002: In order to determine the usability, "patient-friendliness" of this module, we will collect qualitative feedback about of the user's experience from a subset of 50 families who completed it. This one time questionnaire will be administered by REDCap survey. A003:Tool usability questionnaire: Expand enrollment aim to 50 to 100 participants. Survey (online and

phone): We will also conduct surveys with a subset of parents of patients and patients with a positive FGID screen to assess symptoms, parental concern, and parent satisfaction. With the parent's permission, patients ages 10-17 will also be invited to participate in the phone survey about their symptoms and satisfaction. The surveys will be conducted over various time points: approximately 1, 3, 6, and 12 months after the positive screen for a FGID. (We anticipate conducting surveys with a maximum of 600 parents/legal guardians and older patients.) Survey responses can be obtained from the parent, parent and child, or child only (age 10-17). Determination as to who completeness the questionnaire at each time point will be influenced by family availability and desire to not place burden. All participants will be offered the option to complete surveys online or by phone to accommodate their changing needs at the designated timepoints. The patient facing online surveys will be bilingual (English and Spanish) and will include the same data elements as the instruments designated for the demographics and the diagnosis specific follow up questionnaires . The survey version will include participant instructions/prompts to guide independent completion. A012: To offer potential participants two different channels for participation, enrollment and surveys will be offered electronically and by phone. Online enrollment will be deployed in 2 phases. Phase 1 (A012) will be for English and the Phase 2 for Spanish. Future amendment will be submitted to initiate Phase 2. For those who read the E-Consent but opt to not consent/participate, the person reading the consent will be asked one additional question in an effort to better understand the decision not to participate. This question is voluntary and included in the REDCap E-Consent draft. A014: To remain in compliance with University and IU Health Policies, we will inform participants that personal email is not a secure means of communication and obtain their permission to use email for communications. Baseline retrospective review: We will submit a query to the Indiana Health Information Exchange at the Regenstrief Institute for FGID diagnosis data to determine the prevalence for each functional GI disorder diagnosed by the primary care provider prior to the implementation of the FGIDs Modules. Health care utilization retrospective review: We will query Epic, and Indiana Network for Patient Care (INPC) via RMRS for data to assess health care utilization including outpatient visits, inpatient hospital stays, emergency room visits, and the use of GI-related testing and procedures and any medications prescribed to treat Rome IV diagnoses. A003: Reference: Where FGID screening module, patient facing questionnaire is "Gastrointestinal (GI) Symptom Survey". Where tool usability questionnaire, patient facing questionnaire is "Gastrointestinal Symptom Survey Tool: Usability and Qualitative Data Survey" with 2 versions for age

q23358

Will any non-English study documents be uploaded?

Yes

q23359

The PI affirms that translated versions are complete and accurate translations which do not contain information not presented within the context of the English version(s).

Yes

q24919

Is this research funded by, or has a funding application been submitted to, a federal agency? This includes federal pass-through funding.

Yes

q25019

Provide the name of the federal funding agency.

q23234

List inclusion criteria - eligibility criteria for subjects.

FGID module: Any child between the ages of 0 through 18 who is a pediatric primary care clinic in the Eskenazi health system and the PCP/physician who sees them A002 Tool usability questionnaire: A subset of patients who completed the FGID module between age 0 and 17 Survey (online and phone): A subset of patients with a positive screen for a FGID and their parents between age 0-17 Baseline retrospective review: Any patient ages 0-18 who presented to a a pediatric primary care clinic in the Eskenazi health system prior to the implementation of the FGID module Health care utilization retrospective review: Any patient ages 0-18 who presents to a pediatric primary care clinic in the Eskenazi health system after the implementation of the FGID module

q23235

List exclusion criteria (any criteria which would exclude otherwise acceptable subjects).

FGID module, retrospective reviews: none A002 Tool usability questionnaire: does not meet inclusion for FGID module and did not complete the module Survey (online

and phone): Parent and patient be able to provide consent/assent in English or Spanish. We do not currently have the resources to include participants who speak a language other than English and Spanish.

q23346

Will subjects be paid for their participation in the study? Payment includes reimbursement of expenses (other than compensation for injury).

Yes

q23347b

Describe the payment arrangement, including amount and timing of disbursement.

FGID module, retrospective reviews: none (no patient interaction) Survey participation (online and phone): Patients and parents/legal guardians will receive a $25 gift card for completing enrollment and the 1 mo survey. They will receive a $10 gift card for each phone survey they complete thereafter. Requested timepoints are 3, 6, and 12 months. For those that complete all time points, they will receive a $20 bonus after completing the 12 month phone survey. All gift cards will be sent electronically unless a physical card is requested by the participant. In those circumstances, the study team will work to make an accommodations where can. A002 Tool usability questionnaire: Patients will receive a $20 e gift card for after completing the survey

q23348

Justify the proposed payment arrangement described above, specifically why payment does not provide undue influence for subject participation.

Survey participation (online and phone): We do not believe that the payments described above provide undue influence because the time requested. Time required to enroll is approx. 20 minutes and each phone call approx. 10 minutes. A002 Tool usability questionnaire: Participation is voluntary. Payment of $20 is a thank you for the time dedicated to completing the questions. This is a minimal risk study and the amount offered should not coerce or create undue influence to participate.

q23349

Will partial payment be provided if the subject withdraws prior to completion of the study?

No

q23350

Explain why failure to offer partial payment will not unduly influence subjects to complete the study.

Survey participation (online and phone): Each data collection point will offer a payment so even participants who chose to withdraw will receive payment for their time. A002 Tool usability questionnaire: Only completed surveys will be compensated. If the participant feels uncomfortable answering questions or for other reason chooses not to complete the questionnaires, compensation at this level should not unduly influence subject to proceed.

q23352

Does this research involve (choose all that apply):

- the STUDY of any of the following products (regardless of FDA approval status). "The study of" means at least one objective of the study is related to obtaining data about the product
- USE of any of the following products which have not been cleared or approved by the FDA for use in the US
- USE of any of the following products for open label extension, treatment, or compassionate use

NONE

q23454a

This research involves (check all that apply):

None of the Above

q25049a

Is this research considered a prospective clinical study?

Yes - This study may require entry in OnCore.

q30000a

Is this community-engaged research?

No

C-Sites and Collaborations

q700

Are there additional locations of research, not already listed?

No

q704

Are you requesting that IU provide IRB approval for any researchers who are NOT IU affiliates?

No

q710a

Is this a multi-center study or multi-site clinical trial?

No

D-Recruitment Methods

q23236

Describe how potential subjects will be initially identified.

Potential subjects will be identified via the following: FGID module: child age 0 through 18 year old who is patient of a pediatric primary care clinic in the Eskenazi health system via age/DOB and all physicians at these clinics A002 Tool usability questionnaire: patient completed FGID module, age 0-17 years Survey (online and phone): patients with a positive FGID screen per the module, age 0-17 years Baseline retrospective review: query of RMRS for FGID diagnoses in pediatric primary care clinic in the Eskenazi health system Health care utilization retrospective review: patients with a positive FGID screen via the module

q30002

Check any of the following sources of information which will be used to identify potential subjects.

Medical records or clinic schedules

q30003

Describe how potential subjects will be initially contacted.

FGID module, retrospective/prospective reviews: There is no contact with subjects for this part of the study as it is retrospective and prospective data review. Before

the FGID module launches in clinic, physicians at both control and intervention clinics will be informed about the module and its respective functions. Phone survey: Study staff will contact parents and patients via phone and will use the verbal script (included in survey) to present the study to the potential subject. If phone attempt is unsuccessful, RA may send a follow up email if they deem this to be beneficial and not intrusive. Email script in Notes and Attachments. Expanded recruitment option for phone surveys: For patients who completed a FGID screening module with a positive result, patients may receive a MyChart message that will introduce this study opportunity prior to receiving a call from study team. A012: The MyChart message will include the option for online enrollment for English speakers (phase 1). The MyChart message for patients with Spanish as the preferred language, will remain unchanged from A011. The online enrollment option will be added for Spanish speakers in a later amendment (phase 2). A002 Tool usability questionnaire: After the parent, parent/ patient dyad, or patient has completed the FGID module, they will receive electronic communication [via EPIC MyChart (preferred) or email] on behalf of the study team offering the opportunity to provide voluntary feedback.

q23237

Check any of the following recruitment materials which will be used to contact potential subjects.

Direct Mail/Email
Verbal Scripts
Other

q23237C7Text

Explain the Other recruitment material(s) which will be used to contact potential subjects.

EPIC MyChart

q25426b

Select any of the following circumstances which apply to this research.

None of the above.

q23245

Would participation in this study preclude subjects from participating in other research studies?

No

E-Risks Benefits Protections

q23296

List and describe (in lay terms) the potential risks to which subjects may be exposed as a result of their participation in the research.

FGID module, retrospective/prospective reviews: minimal risk of loss of confidentiality A002 Tool usability questionnaire: As with phone surveys, minimal risk of loss of confidentiality and possible discomfort answering questions Survey (online and phone): minimal risk of loss of confidentiality and possible discomfort answering questions

q23297

Describe procedures for protecting against, or minimizing, the potential risks listed above. Include any procedures that are already being performed on subjects for diagnostic, treatment, or standard purposes.

All procedures: Study team personnel have been trained in human subjects' research practices and HIPAA regulations (i.e. confidentiality, privacy and security practices). Furthermore, all data will be securely transferred and stored on fire-walled, encrypted and password-protected hard drives and databases, and locked file cabinets will be used to store any confidential paper study materials. Tool Usability Questionnaire: If participants do not feel comfortable completing the questionnaire they have the right to discontinue their participation right and end the session.

q23299

Explain how research data will be protected so that only approved persons have access to subjects' identifiable data (i.e. confidentiality of data).

FGID module: The EPIC system runs on a server in the Eskenazi Health network. This server resides behind the Eskenazi firewall and is accessible only to Eskenazi IT staff. Study data pulls are handled by faculty and staff with appropriate IRB approvals and HIPAA compliance training. Identifiable data is secured in transit via SSL encryption or via encrypted files in the case of data pulls for data analysis. A002 Tool usability questionnaire: Responses will be securely stored in a REDCap database with access limited to the study team members. Survey(online and phone): All survey data will be securely stored in a REDCap database with access limited to the study team members. Baseline retrospective review: All data will be securely access, transferred,

and stored for analysis and only accessible to members of the study team. Health care utilization retrospective review: see above

q23300

Explain how subjects' physical privacy will be protected, both during recruitment/screening and during participation in the research.

FGID module, retrospective/prospective reviews: There is no contact with patients for this portion of the study; this is a retrospective and prospective review of data. Physicians will document any FGID assessments/plans in an environment deemed appropriate by the provider to document usual clinical care. Survey(online and phone): Phone: The verbal consent, authorization, assent (if applicable) and surveys will take place with study personnel completing the procedures in a private space. Online: The questionnaire will be completed in a space deemed appropriate by the participant who is filling out the questionnaire independently. A002 Tool usability questionnaire: The questionnaire will be completed in a space deemed appropriate by the participant who is filling out the questionnaire independently.

q23301

Is there a potential for subjects to benefit directly from participation in the study?

Yes

q23302

Describe the potential benefits to be gained by the individual SUBJECT. Please note that payment for participation is not considered a benefit.

FGID module, retrospective/prospective reviews: There are no potential benefit to patients for being part of a data review. Physicians at intervention clinics may benefit from knowledge gained via the automated guidance for diagnosing and managing FGIDs. A002 Tool usability questionnaire: Obtaining user feedback is a means to ensure the tool provides optimal user experience. The user may not directly benefit from this encounter but may benefit from the information learned if/when they complete this module again in future visits to their care provider. Survey(online and phone): no potential benefit

q23303

State the potential benefits or information which may accrue to SCIENCE or SOCIETY in general as a result of this work.

There is a significant benefit to society at large as the results of this research allow us to substantially improve the care of patients with functional GI disoders by standardizing health information technology-based interventions that can then be used in a variety of settings to accomplish transition. The lessons we learn from this intervention could then be used at a health system and national level.

F-Data Safety Monitoring

q23304

Describe the provisions for monitoring the data to ensure the safety of subjects.

All procedures: Oversight for the conduct of the study will be provided by the principal investigator. Adverse events are not anticipated, but any occurring will be documented and reported according to Human Research Protection Program (HRPP) at Indiana University policies and procedures. The PI will take primary responsibility for data collection and verification, and review of cumulative adverse events. Any cumulative adverse events and study progress summary will be communicated to the IRB at the time of continuing review.

G1-Children

q22116

Select the category below which best applies.

45 CFR 46.404: Research not involving greater than minimal risk to children.

q23199

Will you be enrolling foster children or children who are considered wards (i.e. who have been placed in the legal custody of the State or other agency, institution per local, state, or federal law)?

No

H-Informed Consent

q901

Will all or some subjects consent to participate in the research?

Some subjects (or their legally authorized representative) will consent to participate in the research, and some subjects will not.

q902

Explain which subjects will consent to the research, and which subjects will not.

FGID module, retrospective/prospective reviews: No consent will be obtained for using the prospective and retrospective data reviews. A002 Tool usability questionnaire: If the individual agrees to participate by voluntarily proceeding to questionnaire, consent is implied. Survey(online and phone): Phone: verbal consent/assent will be obtained. Online: electronic signature will be obtained Subjects who age up to 18 while on study, whose parents will continue to answer the phone survey on their behalf, will not be consented.

q909

For those subjects who will consent to participate, explain how subjects (or subjects' legally authorized representative) will be presented with the information needed to decide to participate, including all elements of informed consent.

Survey(online and phone): Phone: The RA will verbally review the Study Information Sheet/Auth over the phone with the parent/legal guardian and, when appropriate, with the patient, and answer any questions before obtaining verbal consent from the parent for both his/her own parental participation as well as the participation of the minor/patient. A copy of the study SIS/Auth will be sent to participants done electronically where able after receiving consent to send email to the participant. Online: A MyChart message will be sent to the patient/patient proxy to introduce the study opportunity. This introduction will include the SIS/Auth. The English version will include a time limited participant specific link to the REDCap e-consent. (Patient communication uploaded in Notes and Attachments). Recognizing that the MyChart account for patients 14-17 may not have a parent proxy assigned, a statement is added to the introduction requesting interested teens share this study information with a parent/legal guardian for full consideration and consent. A002 Tool usability questionnaire: After the parent, parent/ patient dyad, or patient (add A003 "or patient") has completed the FGID module, they will receive communication offering opportunity to provide voluntary feedback. If interested in providing feedback, they will be presented with the electronic SIS (in Notes and Attachments) for them to read independently.

q903

Describe any informed consent tools which will be used to present information to potential subjects (i.e. consent documents, videos, brochure, drug/device information, etc) and how they will be used.

Survey(online and phone): SIS/Auth form A002 Tool usability questionnaire: SIS

q925

Describe the timing of the informed consent process, including how you will ensure potential subjects have sufficient opportunity to discuss and consider participation before agreeing to participate in the research.

Survey(online and phone): Phone: The informed consent process for phone surveys will take place over the phone when the patient and parent indicate their interest and availability. Any participants wishing more time to consider will be called back at a different time. Online: After reviewing the MyChart recruitment message, the potential participant will be able to advance directly to the online enrollment process when they desire. A002 Tool usability questionnaire: After the parent, parent/ patient dyad, or patient has completed the FGID module, expressed interest in providing feedback, read the SIS, and implied consent by voluntarily proceeding to the questionnaire.

q30127a

Will you include all required elements of consent in your consent process?

Yes

q921

Indicate in what language(s) the consent conversation will be conducted.

English

q926

Explain how you will ensure potential subjects understand the information you have presented to them before they agree to participate in the study.

Survey(online and phone): Phone: An RA will ask participants if they have any questions (and provide the answers to those questions) before the subject agrees to

participate. Online: The e-consent instrument will contain instructions for completion. Within those instructions will be PResNet contact information for questions. If participants proceed without asking questions, it is implied that the content was understood. A002 Tool usability questionnaire: Participants will voluntarily agree to fill out questionnaire before being presented with the survey. If they do not understand the content or choose not to participate, they are given the option to decline participation.

q929

Briefly describe any training provided to investigators who are obtaining informed consent.

Phone surveys: PResNet Research Assistants have been trained in obtaining informed consent (and assent) through online CITI training, university-sponsored training, and internal training and QA programs.

q931

Does the research include any minimal risk procedures to which subjects will not consent?

Yes

q932

A waiver of consent for those procedures is required. List the procedures and explain how they involve no more than minimal risk to the subject.

FGID module, retrospective/prospective reviews: We are requesting a waiver of consent for this part of the research. Patients and parents will be asked (but not required) to respond to yes/no questions about GI symptoms as part of standard care. No part of this research presents more than a minimal risk to subjects. Study team personnel have been trained in human subjects' research practices and HIPAA regulations (i.e. confidentiality, privacy and security practices). Furthermore, all data will be securely transferred and stored on fire-walled, encrypted and password-protected hard drives and databases, and locked file cabinets will be used to store any confidential paper study materials.

q933

Explain how the waiver will not adversely affect the rights and welfare of subjects.

FGID module, retrospective/prospective reviews: The waiver will not adversely affect the rights and welfare of subjects as we are only (securely) accessing and using data generated in a clinical setting under standard care.

q905

Explain how the research could not be practicably carried out if informed consent were required.

FGID module, retrospective/prospective reviews: If informed consent were required, we could not practicably obtain consent from the patients who answer module questions or whose data is used in the retrospective reviews as there are no study staff present in clinics.

q30004b

Explain why the research could not be practicably carried out without identifiers.

FGID module, retrospective/prospective reviews: Without identifiers, we could not conduct the research because we need to link patient encounter data to past and prospective health data to look at patient outcomes.

q914

Explain how subjects will be informed of pertinent results at the conclusion of the study, if appropriate. If subjects will not be informed, enter N/A.

N/A

q23678a

For those subjects who will consent to participate, choose whether the consent process will be documented by a written signature from subjects.

Some subjects will provide a written signature as documentation of consent, and some subjects will not.

q30129a

Will subjects participate in any study activity prior to physically signing a consent document?

No

q939a

Explain which subjects will provide a written signature as documentation of consent, and which subjects will not.

Survey participants who enroll online will be asked for a printed (typed) signature.

q940b

Explain the process for obtaining a written signature from subjects.

Using the REDCap e consent platform parents/guardians will type their name in a signature box

q934a

Since some subjects will not provide a written signature as documentation of consent, a waiver of documentation of consent is required. Choose the option which most appropriately applies to your study.

The research presents no more than minimal risk of harm to subjects AND involves no procedures for which written consent is normally required outside of the research context.

q23764

Since some subjects will not consent to participation in the research, a waiver of consent is required. Choose the appropriate reason for waiving consent.

Research is minimal risk and obtaining consent is not practicable.

q904b

Explain how the research involves no more than minimal risk to the subjects.

FGID module, retrospective/prospective reviews: No part of this research presents more than a minimal risk to subjects. Study team personnel have been trained in human subjects' research practices and HIPAA regulations (i.e. confidentiality, privacy and security practices). Furthermore, all data will be securely transferred and stored on fire-walled, encrypted and password-protected hard drives and databases, and locked file cabinets will be used to store any confidential paper study materials. Survey(online and phone): : N/A - Parents and older patients will verbally or electronically consent (for those who agree to receive emails) to participate. A002 Tool usability questionnaire: There is a minimal risk for loss of confidentiality. The

questions capture information about the user's interaction with the module. A005, regarding new waiver for child subjects who age up while on the study: The study activity will remain unchanged. Patients and/or parent will continue to answer of short phone surveys at defined timepoints.

q906b

Explain how the waiver will not adversely affect the rights and welfare of subjects.

FGID module, retrospective/prospective reviews: The waiver will not adversely affect the rights and welfare of subjects as we are only (securely) accessing and using data generated in a clinical setting under standard care. A005, regarding new waiver for child subjects who age up while on the study: The study activity will remain unchanged and is minimal risk. Patients and/or parent will continue to answer of short phone surveys at defined timepoints. Participants can opt to withdraw from study at any time.

q907b

Explain how the research could not be practicably carried out if informed consent were required.

FGID module, retrospective/prospective reviews: If informed consent were required, we could not practicably obtain consent from the patients who answer module questions or whose data is used in the retrospective reviews as there are no study staff present in clinics. A005, regarding new waiver for child subjects who age up while on the study: Intent is to limit any barriers to ongoing participation. In the event that the parent has been the main source of information for the phone surveys (for teen age 17), we wanted to minimize any disruptions.

q30004d

Explain why the research could not be practicably carried out without identifiers.

FGID module, retrospective/prospective reviews: Without identifiers, we could not conduct the research because we need to link patient encounter data to past and prospective health data to look at patient outcomes. Survey(online and phone): The research could not be practicably carried out without identifiers because we are contacting patients who screened positive in clinic. A002 Tool usability questionnaire: The research could not be practicably carried out without identifiers because we are only surveying family who have completed the module and meet our inclusion age and setting

q908b

Explain how subjects will be informed of pertinent results at the conclusion of the study, if appropriate. If subjects will not be informed, enter N/A.

N/A

J-Child Assent Parent Consent

q23808

Can children provide legal consent for themselves to participate in this study?

No children can provide legal consent for themselves.

q936

Will consent be obtained from subjects' parents/guardians? Select both options if consent will be obtained from some parents but not all.

Yes

No. I am requesting a waiver of parental consent.

q23779

Explain how parents/guardians will be presented with the information needed to decide to allow their children to participate, including all elements of informed consent.

FGID module, retrospective/prospective reviews: N/A - We will not obtain parental consent for the inclusion of their children's data in the data reviews. We are seeking a waiver of parental consent for this portion of the research. A002 Tool usability questionnaire: The potential participant will have no interaction with a research team member at the point the questionnaire opportunity is introduced. We will inform prospective subjects about the research opportunity via a SIS. It is not practical to obtain signed consent. If the individual agrees to participate by voluntarily proceeding to questionnaire, consent is implied. A003 Tool usability questionnaire:The 14-17 year old will assent for self, parental consent deemed not feasible and waiver parental consent requested for this age group. For patients 14-17year old, the parent has limited permissions to access the patient''s MyChart account. This age group will complete the FGID module independently or with assist if they choose. We request a waiver of parental consent since the 14-17 year old has their own account and thus getting parental consent is not feasible. Survey(online and phone): Phone: For the phone surveys, we will seek verbal consent from the parent for the child's participation. The RA will verbally review the SIS/Auth form

over the phone and answer any questions before obtaining verbal consent and auth from the parent the participation of the minor/patient if age 10-17 years old. Online: A MyChart message will be sent to the patient/patient proxy to introduce the study opportunity. This introduction will include the SIS/Auth and a time limited participant specific link to the REDCap e-consent. (Patient communication uploaded in Notes and Attachments). Recognizing that the MyChart account for patients 14-17 may not have a parent proxy assigned, a statement is added to the introduction requesting interested teens share this study information with a parent/legal guardian for consideration and consent.

q23780

Describe any informed consent tools which will be used to present information (i.e. consent documents, videos, brochure, drug/device information, etc) and how they will be used.

FGID module, retrospective/prospective reviews: N/A Survey(online and phone): SIS/Auth form A002 Tool usability questionnaire: Study Information Sheet

q23784

Describe the timing of the informed consent process, including how you will ensure parents/guardians have sufficient opportunity to discuss and consider their children’s participation before agreeing to allow their children to participate in the research.

FGID module, retrospective/prospective reviews: N/A Survey(online and phone): Phone: The informed consent process for phone surveys will take place over the phone when the patient and parent indicate their interest and availability. Any participants wishing more time to consider will be called back at a different time. Online: After reviewing the MyChart recruitment message, the potential participant will be able to advance directly to the online enrollment process when they desire. A002 Tool usability questionnaire: After the parent, parent/patient dyad, or patient (add A003 "or patient") has completed the FGID module, expressed interest in providing feedback, read the SIS, and implied consent by voluntarily proceeding to the questionnaire.

q30127c

Will you include all required elements of consent in your consent process?

Yes

q23789

Indicate in what language(s) the consent conversation will be conducted.

English

q23793

Explain how you will ensure parents/guardians understand the information you have presented to them before they agree to allow their children to participate in the research.

FGID module, retrospective/prospective reviews: N/A Survey(online and phone): Phone: An RA will ask participants if they have any questions (and provide the answers to those questions) before the subject agrees to participate. Online: The e-consent instrument will contain instructions for completion. Within those instructions will be PResNet contact information for questions. If participants proceed without asking questions, it is implied that the content was understood. A002 Tool usability questionnaire: Participants will voluntarily agree to fill out questionnaire before being presented with the survey. If they do not understand the content or choose not to participate, they are given the option to decline participation.

q23798

Briefly describe any training provided to investigators who are obtaining informed consent.

Phone surveys: Research Assistants have been trained in obtaining informed consent (and assent) through online CITI training, university-sponsored training, and internal training and QA programs.

q23800

Does the research include any minimal risk procedures to which parents/guardians will not consent for their children to participate?

No

q30330

For those parents/guardians who will consent to allow their children to participate, choose whether the consent process will be documented by a written signature.

Some parents/guardians will provide a written signature as documentation of consent, and some will not.

q30331

Will subjects participate in any study activity prior to parents/guardians physically signing a consent document?

No

q30334

Explain which parents/guardians will provide written signature as documentation of consent, and which will not.

Survey participants who enroll online will be asked for a printed (typed) signature.

q30333b

Explain the process for obtaining a written signature from parents/guardians.

Using the REDCap e consent platform parents/guardians will type their name in a signature box

q30335

Since some parents/guardians will not provide a written signature as documentation of consent, a waiver of documentation of parental/guardian consent is required. Choose the option which most appropriately applies to your study.

The research presents no more than minimal risk of harm to subjects AND involves no procedures for which written consent is normally required outside of the research

q942

Choose the option which most appropriately applies to your study.

Parental/guardian consent cannot be practicably obtained.

q943

Explain how the research involves no more than minimal risk to the subject.

FGID module, retrospective/prospective reviews: For the data reviews, parental consent cannot be practicably obtained as there are no study staff in clinic and attempting to reach each parents of so many patients is not feasible. There is a

minimal risk for loss of confidentiality but not beyond the risk of a routine clinic visit. No part of this research presents more than a minimal risk to subjects. Study team personnel have been trained in human subjects' research practices and HIPAA regulations (i.e. confidentiality, privacy and security practices). Furthermore, all data will be securely transferred and stored on fire-walled, encrypted and password-protected hard drives and databases, and locked file cabinets will be used to store any confidential paper study materials.

q944

Explain how the waiver will not adversely affect the rights and welfare of subjects.

FGID module, retrospective/prospective data reviews: There is a minimal risk for loss of confidentiality but not beyond the risk of a routine clinic visit. The subjects will continue to receive care as normal, waiver will not affect care provided. No part of this research presents more than a minimal risk to subjects. Study team personnel have been trained in human subjects' research practices and HIPAA regulations (i.e. confidentiality, privacy and security practices). Furthermore, all data will be securely transferred and stored on fire-walled, encrypted and password-protected hard drives and databases, and locked file cabinets will be used to store any confidential paper study materials.

q945

Explain how the research could not be practicably carried out if informed consent were required.

FGID module, retrospective/prospective reviews: The research could not be practicably carried out if informed consent of patients at clinic visits were required because there are no study staff on site to conduct the consent process. (Research staff are not based in the study clinics.) Additionally, informing patients that they are part of a study involving GI disorders may bias the results given to the clinician, and in turn, to the FGID module.

q30004i

Explain why the research could not be practicably carried out without identifiers.

FGID module: The research could not be practicably carried out without identifiers because GI screening questions are based on patient DOB/age. Survey(online and phone): The research could not be practicably carried out without identifiers because we are contacting patients who screened positive in clinic. A002 Tool usability

questionnaire: The research could not be practicably carried out without identifiers because we are only surveying family who have completed the module and meet our inclusion age and setting

q946

Explain how subjects will be informed of pertinent results at the conclusion of the study, if appropriate. If subjects will not be informed, enter N/A.

N/A

q950

In order to describe the process for obtaining assent from children, check all that apply.

Some/all children are not capable of providing assent.
Some/all children will not provide assent even though they are otherwise capable. A waiver of assent will be requested.
Some/all children will provide assent.

q951

Explain why children are not capable of providing assent. Consider age, maturity, and psychological state, and situations where capability is so limited that they cannot reasonably be consulted.

This research will include patients ages 0 through 17 and children age 0-6 are typically not considered mature enough to provide assent.

q952

Choose the option which most appropriately applies to your study.

Assent cannot be practicably obtained.

q953

Explain how the research involves no more than minimal risk to the subject.

FGID module: In clinic, patients and parents will be asked (but not required) to respond to yes/no questions about GI symptoms as part of standard care. There is a minimal risk for loss of confidentiality but not beyond the risk of a routine clinic visit. Phone surveys: N/A - will get verbal assent from older patients Retrospective reviews: There is only a minimal risk of loss of confidentiality as all data will be

securely accessed, transferred, and analyzed. A002 Tool usability questionnaire: There is a minimal risk for loss of confidentiality. The questions capture information about the user's interaction with the module.

q954

Explain how the waiver will not adversely affect the rights and welfare of subjects.

FGID module, retrospective/prospective reviews:There is a minimal risk for loss of confidentiality for the retrospective and prospective review of data but not beyond the risk of a routine clinic visit. Phone surveys: N/A (verbal consent/assent) A002 Tool usability questionnaire: Consent implied through agreement to participate

q955

Explain how the research could not be practicably carried out if child assent were required.

FGID module, retrospective/prospective reviews:: The research could not be practicably carried out if informed assent of patients at clinic visits were required because there are no study staff on site to conduct the consent process. (Research staff are not based in the study clinics.) Additionally, informing patients that they are part of a study involving GI disorders may bias the results given to the clinician, and in turn, to CHICA. Phone survey: N/A (verbal consent/assent) A002 Tool usability questionnaire: The parent, parent/child dyad, or patient (add A003 "or patient") who filled out the tool will be presented with the SIS. The SIS will serve as a consent and assent tool, the questionnaire is targeted to the individual or individuals who completed the module.

q30004j

Explain why the research could not be practicably carried out without identifiers.

FGID module, retrospective/prospective reviews:: The research could not be practicably carried out without identifiers because GI screening questions and are based on patient DOB/age. Retrospective reviews are based on patient DOB, symptoms, and diagnoses. Phone survey: The research could not be practicably carried out without identifiers because we are contacting patients who screened positive in clinic. A002 Tool usability questionnaire: The research could not be practicably carried out without identifiers because we are only surveying family who have completed the module and meet our inclusion age and setting

q956

Explain how subjects will be informed of pertinent results at the conclusion of the study, if appropriate. If subjects will not be informed, enter N/A.

N/A

q958

Describe the timing of the assent process, including how you will ensure children have sufficient opportunity to discuss and consider participation before agreeing to participate in the research.

Surveys Phone enrollment: After getting permission from the parent/LG to speak with the patient ages 10 through 17, the RA will verbally review the SIS/Auth with the youth at the same time it is reviewed with the parent, answer any questions, and call back later if s/he would like more time to consider participation. Online enrollment: In a brief introduction to the online consent process on the E-consent page, it is asked that the child age 10 and older review the online consent document with the parent. During the recruitment phone contact or online enrollment: If the parent has the desire to complete enrollment and the youth is unavailable, enrollment will proceed without assent to decrease burden on family and barrier to enrollment. A002 Tool usability questionnaire: After the parent, parent/patient dyad, or patient (add A003 "or patient") has completed the FGID module, they will receive communication offering the opportunity to provide voluntary feedback. If interested in providing feedback, they will be presented with the electronic SIS (in Notes and Attachments)

q959

Describe any assent tools which will be used to present information to potential subjects (i.e. assent document, study information sheet, videos, brochure, drug/device information, etc) and how they will be used.

Phone surveys: SIS/Auth form will be used for assent of patients 10 years and older. Will not seek assent for child < 10. Assent tool will be used for those 10-13 and consent form will be used for ages 14-17. Only verbal assent will be obtained. A002 Tool usability questionnaire: electronic SIS (in Notes and Attachments)

q996

Will children indicate their consent with a signature on an assent or consent statement?

Subjects will not provide a signature

K-HIPAA

q23253

Are you part of a covered entity (health care provider that transmits health information electronically) or are you receiving information from a covered entity as part of your research?

Yes

q23254

Will protected health information be utilized, accessed, collected, or generated as part of the study?

Yes

q30347a

Select the electronic systems to be used for the collection and/or storage of protected health information (ePHI). Choose all that apply.

REDCap

IU Box Health Data Account

q23257

Will you be accessing or collecting protected health information for RECRUITMENT purposes?

Yes

q23258

Choose all that apply to the recruitment plans.

Review of medical records by the study team

q23259

Will review of medical records for recruitment purposes be conducted by an investigator who is NOT a part of the potential subject's care team?

No

q23277

HIPAA applies to your study, and requires that you obtain authorization for PARTICIPATION in research, or that you request a waiver. Check all that apply.

I will obtain written, signed authorization from subjects prior to their participation
I will obtain authorization from subjects prior to their participation but subjects will not physically sign a document
I will not obtain authorization prior to their participation

q23650

List all data elements to be used or disclosed (do not refer to an attachment).

FGID Module: Data points collected for participation in the retrospective review of FGID module data include date(s) of visit, physician name, patient vitals and demographics, contact information, patient/parent answers to GI questions, who is answering the questions (parent or patient or both), and physician notes about GI diagnoses, treatments, and recommendations. Phone survey: In addition to the FGID data points above, we will use parent and patient answers to the phone survey along with parent-reported demographics. Baseline retrospective review: DOB, date/diagnosis (ICD codes), Eskenazi clinic(s) of care Health care utilization retrospective review: • The presence of outpatient sick visits within the CHICA system clinic for any complaint • The presence of outpatient sick visits within the CHICA system clinic with an associated GI billing code • The presence of visits to statewide providers, including inpatient hospital stays, outpatient clinic visits, and emergency room visits. • The occurrence of any GI-related testing and procedures – specifically radiologic, laboratory testing,endoscopy, and surgical procedures related to GI diagnoses • The use of any medications prescribed to treat Rome IV diagnoses – specifically acid-suppressants, antispasmodics, antidepressants, stool softeners and laxatives, and pro-motility agents. A005, regarding child subjects who age up to 18 while on the study, whose parents will continue to answer the phone survey on their behalf: Will proceed with the same data collection as prior to birthday. Will as before, collect responses from the FGID Module, phone survey responses and parent reported demographics for self (where applicable).

q23651

A waiver of the requirement for a written signature must be approved by the IRB. Explain how this research involves no more than minimal risk of loss of confidentiality to the subject.

No part of this research presents more than a minimal risk of loss of confidentiality to subjects. Study team personnel have been trained in human subjects' research practices and HIPAA regulations (i.e. confidentiality, privacy and security practices).

q23652

Describe the plan for protecting identifiers from improper use and disclosure.

All data will be securely transferred and stored on fire-walled, encrypted and password-protected hard drives and databases, and locked file cabinets will be used to store any confidential paper study materials.

q23653

Describe the plan to destroy identifiers at the earliest opportunity appropriate for the research, considering the purpose of the research and local data retention requirements.

We will destroy identifiers in the database (and any paper records) at the earliest opportunity appropriate for the research and allowable by law.

q23654

Confirm that the study team will assure identifiable PHI will not be re-used or disclosed to individuals outside the study team, except as required by law.

PHI will not be re-used or disclosed to individuals outside the study team, except as required by law.

q23655

Explain how the research could not be practicably conducted without waiver of authorization or alteration of authorization requirements.

The research could not be practicably carried out if authorization for the use of PHI were required because there are no study staff on site to conduct the informed authorization process. (Research staff are not based in the study clinics.) Regarding new waiver for child subjects who age up while on the study: Intent is to limit any

barriers to ongoing participation. In the event that the parent has been the main source of information for the phone surveys (for teen age 17), we wanted to minimize any disruptions.

q23656

Explain how the research could not be practicably conducted without access to and use of identifiable PHI.

The research could not be practicably conducted without access to PHI because we are identifying patients based on health information (FGIDs) and their connecting data across sources.

q23278

Will you be collecting information from subjects' medical records?

Yes, I have uploaded an Authorization template to the Attachments section.

q23693

Explain which subjects will sign a written authorization form and which subjects will not.

Surveys Phone enrollment: Parents will provide verbal authorization for use of their child's PHI via phone. (No one will provide written/signed authorization.) Online enrollment: Parents will provide electronic signature on the the REDCap E-consent to document consent and authorization to participate

q23694

Explain how the elements of authorization will be presented to potential subjects, including a description of any tools used.

The elements of authorization will be presented to parents via phone by review of the Authorization form. (Parents may also choose to receive a copy via mail with their gift card.)

Attachments

Attachment Type
Data Collection Instrument
Attachment
FGID Algorithm Tool Usability and Qualitative Survey - Ages 0-13 - with SUS and demographics_4.9.20 MF.docx
Name
Gastrointestinal Symptom Survey Tool – Usability and Qualitative Data Survey Ages 0 to 13 Years

Comments

Attachment Type
Data Collection Instrument
Attachment
FGID Algorithm Tool Usability and Qualitative Survey - Ages 14-17 - with SUS and demographics_4.9.20 MF.docx
Name
Gastrointestinal Symptom Survey Tool – Usability and Qualitative Data Survey Ages 14 to 17 Years
Comments

Attachment Type
Data Collection Instrument
Attachment
FollowUpFunctionalDyspepsiaEpi.pdf
Name
Functional Dyspepsia- Epigastric Pain Syndrome Subtype 8yr to 18 yr Phone Survey Draft
Comments

Attachment Type
Data Collection Instrument
Attachment
FollowUpIrritableBowelSyndrome.pdf
Name
Irritable Bowel Syndrome 8yr to 18 yr Phone Survey Draft
Comments

Attachment Type
Data Collection Instrument
Attachment
FollowUpAbdominalPainOtherwise.pdf
Name
Abdominal Pain-Otherwise not specified 8yr to 18 yr Phone Survey Draft
Comments

Attachment Type
Data Collection Instrument
Attachment
FollowUpAbdominalMigraine8yrTo.pdf
Name

Abdominal Migraine 8yr to 18 yr Phone Survey Draft
Comments

Attachment Type
Data Collection Instrument
Attachment
FollowUpInfantRegurgitation012-2.pdf
Name
Infant Regurgitation 0-12mo Phone Survey Draft
Comments

Attachment Type
Data Collection Instrument
Attachment
FollowUpInfantColic06mo_System.pdf
Name
Infant Colic 0-6mo Phone Survey Draft
Comments

Attachment Type
Data Collection Instrument
Attachment
FollowUpInfantDyschezia012mont.pdf
Name
Infant Dyschezia 0-12months Phone Survey Draft
Comments

Attachment Type
Data Collection Instrument
Attachment
FollowUpAerophagiaAllAges0mo18.pdf
Name
Aerophagia all ages 0mo-18yrs Phone Survey Draft
Comments

Attachment Type
Data Collection Instrument
Attachment
FollowUpInfantRuminationSyndro.pdf
Name
Infant Rumination Syndrome 0-12mo Phone Survey Draft
Comments

Attachment Type
Data Collection Instrument
Attachment
FollowUpRumination4yrsTo18yrs_.pdf
Name
Rumination 4yrs to 18yrs
Comments

Attachment Type
Data Collection Instrument
Attachment
FollowUpFunctionalConstipation.pdf
Name
Funct Constipation 0-12 mo Phone Survey Draft
Comments

Attachment Type
Data Collection Instrument
Attachment
FollowUpFunctionalConstipation.pdf
Name
Funct Constipation 12 mo to 18yrs Phone Survey Draft
Comments

Attachment Type
Data Collection Instrument
Attachment
FollowUpCyclicVomitingSyndrome-2.pdf
Name
Cyclic Vomiting Syn 0-18yrs Phone Survey Draft
Comments

Attachment Type
Data Collection Instrument
Attachment
FollowUpFunctionalDiarrhea6moT.pdf
Name
Functional Diarrhea 6mo to 8 yrs Phone Survey Draft
Comments

Attachment Type
Data Collection Instrument

Attachment
FollowUpNonRetentiveFecalIncon.pdf
Name
Non Retentive Fecal Incontinence 4yr to 18 yr Phone Survey Draft
Comments

Attachment Type
Data Collection Instrument
Attachment
FollowUpFunctionalVomiting8yrT.pdf
Name
Functional Vomiting 8yr to 18 yr Phone Survey Draft
Comments

Attachment Type
Data Collection Instrument
Attachment
FollowUpFunctionalNausea8yrTo1.pdf
Name
Functional Nausea 8yr to 18 yr Phone Survey Draft
Comments

Attachment Type
Data Collection Instrument
Attachment
FollowUpFunctionalDyspepsiaPos.pdf
Name
Functional Dyspepsia- Postprandial Distress Subtype 8yr to 18 yr Phone Survey Draft
Comments

Attachment Type
Other
Attachment
MyChart%20Msg_FGID%20module%20pilot_6.11.20.docx
Name
MyChart script (for batch messaging) to patient introduce FGID module for pilot testing
Comments

Attachment Type
Recruitment Materials
Attachment

SIS Usability Questionnaire _recruitment Intro_4.17.20.docx
Name
Introduction to SIS For Tool Usability Survey (questionnaire)
Comments
A002: Version 1.27.20 A003:4.17.20 Draft of email communication to introduce SIS for tool usability questionnaire.

Attachment Type
Recruitment Materials
Attachment
A012_MyChart Intro to Phone Surveys.docx
Name
Phone Survey Recruitment: MyChart Introduction
Comments
A012 replaced A008 version

Attachment Type
Recruitment Materials
Attachment
A014_Verbal Intro _Phone Contact_Parent_Patient.docx
Name
Phone Surveys PResNet Intro Script
Comments
Replaces: A011_Verbal Intro _Phone Contact_Parent_Patient.docx

Attachment Type
Study Information Sheet
Attachment
1811325201A002_SIS Usability survey__4.17.20 .docx
Name
SIS for Tool Usability Survey
Comments
A002: Version 1.27.20 A003: Version 4.17.20

Attachment Type
Study Information Sheet
Attachment
1811325201A014 - Bennett, W - SIS and Auth Phone or Online Survey - Oct 2023.docx
Name
Phone Survey SIS

Comments
A011: Version 2.15.23 A012: Version 5.30.23 A013: Version 7.18.2023

Attachment Type
Recruitment Materials
Attachment
A011_Email Script_Phone Survey Recruitment.docx
Name
Comments
A014: Cease use of this document. With updated requirements, will not send email communication to potential participants without attaining their consent to send.

Attachment Type
Recruitment Materials
Attachment
A012.1_MyChart Intro to Phone Surveys-1_Spanish rev.docx
Name
Comments
replaced A008 version

Attachment Type
Recruitment Materials
Attachment
A014_Verbal Intro _Phone Contact_Parent_Patient_Spanish rev.docx
Name
Comments
Replaces: A011_Verbal Intro _Phone Contact_Parent_Patient_Spanish rev.docx

Attachment Type
Study Information Sheet
Attachment
1811325201A014- Bennett, W - SIS and Auth Phone Survey - Oct 2023_Spanish rev-2.docx
Name
Phone Survey SIS - Spanish
Comments

Attachment Type
Recruitment Materials
Attachment
A011_Email Script_Phone Survey Recruitment_Spanish rev.docx
Name

Comments
A014: Cease use of this document. With updated requirements, will not send email communication to potential participants without attaining their consent to send.

Attachment Type
Other
Attachment
A015- Draft E-Consent.docx
Name
Comments
New: For the online enrollment of survey participants. Same language as SIS/Auth placed in RC E-consent framework. A015 replaced A013.

Attachment Type
Other
Attachment
A014 _RA phone script re communicating with Research Participants by Email.docx
Name
Comments
A014: Script for RA to discuss email communication with existing participants

Attachment Type
Data Collection Instrument
Attachment
Demographics RC Draft.docx
Name
Comments

Attachment Type
Data Collection Instrument
Attachment
Payment language RC Draft.docx
Name
Comments
language added to the end of follow up questionnaires completed online

End of Protocol Form

KC IRB History

approvalDate
December 5, 2018

FOR HSO OFFICE USE ONLY

Action History

Description
Expedited Approval
Date
December 18, 2020
Action Date
December 18, 2020
Comments
Amendment-005: Approved
Updated By
kwcrain
Update Time
2020-12-18T12:00:00.000Z

Description
Assigned to Agenda
Date
December 18, 2020
Action Date
December 18, 2020
Comments
Amendment-005:
Updated By
kwcrain
Update Time
2020-12-18T12:00:00.000Z

Description
Submitted to IRB
Date
December 17, 2020
Action Date
December 17, 2020
Comments
Amendment-005: Submitted to IRB
Updated By
ashlmeye
Update Time

2020-12-17T12:00:00.000Z

Description
Returned To PI
Date
December 17, 2020
Action Date
December 17, 2020
Comments
Amendment-005: Open to revise Amendment QU and KC QUs.
Updated By
ashlmeye
Update Time
2020-12-17T12:00:00.000Z

Description
Submitted to IRB
Date
December 16, 2020
Action Date
December 16, 2020
Comments
Amendment-005: Submitted to IRB
Updated By
ashlmeye
Update Time
2020-12-16T12:00:00.000Z

Description
Returned To PI
Date
December 16, 2020
Action Date
December 16, 2020
Comments
Amendment-005: Open to upload final versions of study documents to notes and attachments.
Updated By
ashlmeye
Update Time

2020-12-16T12:00:00.000Z

Description
Submitted to IRB
Date
December 11, 2020
Action Date
December 11, 2020
Comments
Amendment-005: Submitted to IRB
Updated By
stasulli
Update Time
2020-12-11T12:00:00.000Z

Description
Returned To PI
Date
December 10, 2020
Action Date
December 10, 2020
Comments
Amendment-005: Open to edit Amendment and KC Questionnaires, and upload final version of study docs to notes and attachments.
Updated By
ashlmeye
Update Time
2020-12-10T12:00:00.000Z

Description
Submitted to IRB
Date
December 8, 2020
Action Date
December 8, 2020
Comments
Amendment-005: Submitted to IRB
Updated By
stasulli
Update Time

2020-12-08T12:00:00.000Z

Description
Returned To PI
Date
December 5, 2020
Action Date
December 5, 2020
Comments
Amendment-005: Sending pre-review to study team.
Updated By
ashlmeye
Update Time
2020-12-05T12:00:00.000Z

Description
Annual Reminder Generated - Expedited or Full Board
Date
December 5, 2020
Action Date
December 5, 2020
Comments
Annual Reminder
Updated By
kc
Update Time
2020-12-05T12:00:00.000Z

Description
Submitted to IRB
Date
November 24, 2020
Action Date
November 24, 2020
Comments
Amendment-005: Submitted to IRB
Updated By
stasulli
Update Time
2020-11-24T12:00:00.000Z

Description
Amendment Created
Date
September 8, 2020
Action Date
September 8, 2020
Comments
Amendment-005: Created
Updated By
stasulli
Update Time
2020-09-08T12:00:00.000Z

Description
Expedited Approval
Date
July 29, 2020
Action Date
July 29, 2020
Comments
Amendment-004: Approved
Updated By
khersber
Update Time
2020-07-29T12:00:00.000Z

Description
Assigned to Agenda
Date
July 29, 2020
Action Date
July 29, 2020
Comments
Amendment-004:
Updated By
khersber
Update Time
2020-07-29T12:00:00.000Z

Description

Submitted to IRB
Date
July 29, 2020
Action Date
July 29, 2020
Comments
Amendment-004: Submitted to IRB
Updated By
khersber
Update Time
2020-07-29T12:00:00.000Z

Description
Returned To PI
Date
July 29, 2020
Action Date
July 29, 2020
Comments
Amendment-004: open to prepare for approval
Updated By
khersber
Update Time
2020-07-29T12:00:00.000Z

Description
Submitted to IRB
Date
July 29, 2020
Action Date
July 29, 2020
Comments
Amendment-004: Submitted to IRB
Updated By
stasulli
Update Time
2020-07-29T12:00:00.000Z

Description
Amendment Created

Date
July 26, 2020
Action Date
July 26, 2020
Comments
Amendment-004: Created
Updated By
stasulli
Update Time
2020-07-26T12:00:00.000Z

Description
Expedited Approval
Date
April 21, 2020
Action Date
April 21, 2020
Comments
Amendment-003: Approved
Updated By
khersber
Update Time
2020-04-21T12:00:00.000Z

Description
Assigned to Agenda
Date
April 21, 2020
Action Date
April 21, 2020
Comments
Amendment-003:
Updated By
khersber
Update Time
2020-04-21T12:00:00.000Z

Description
Submitted to IRB
Date

April 21, 2020
Action Date
April 21, 2020
Comments
Amendment-003: Submitted to IRB
Updated By
khersber
Update Time
2020-04-21T12:00:00.000Z

Description
Returned To PI
Date
April 21, 2020
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April 21, 2020
Comments
Amendment-003: open to prepare for approval
Updated By
khersber
Update Time
2020-04-21T12:00:00.000Z

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April 17, 2020
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April 17, 2020
Comments
Amendment-003: Submitted to IRB
Updated By
stasulli
Update Time
2020-04-17T12:00:00.000Z

Description
Amendment Created
Date
April 3, 2020

Action Date
April 3, 2020
Comments
Amendment-003: Created
Updated By
stasulli
Update Time
2020-04-03T12:00:00.000Z

Description
Expedited Approval
Date
January 30, 2020
Action Date
January 30, 2020
Comments
Amendment-002: Approved
Updated By
khersber
Update Time
2020-01-30T12:00:00.000Z

Description
Assigned to Agenda
Date
January 30, 2020
Action Date
January 30, 2020
Comments
Amendment-002:
Updated By
khersber
Update Time
2020-01-30T12:00:00.000Z

Description
Submitted to IRB
Date
January 30, 2020
Action Date

January 30, 2020
Comments
Amendment-002: Submitted to IRB
Updated By
khersber
Update Time
2020-01-30T12:00:00.000Z

Description
Returned To PI
Date
January 30, 2020
Action Date
January 30, 2020
Comments
Amendment-002: open to ensure study is on most current version of questionnaires
Updated By
khersber
Update Time
2020-01-30T12:00:00.000Z

Description
Submitted to IRB
Date
January 27, 2020
Action Date
January 27, 2020
Comments
Amendment-002: Submitted to IRB
Updated By
stasulli
Update Time
2020-01-27T12:00:00.000Z

Description
Amendment Created
Date
December 18, 2019
Action Date
December 18, 2019

Comments
Amendment-002: Created
Updated By
stasulli
Update Time
2019-12-18T12:00:00.000Z

Description
Annual Reminder Generated - Expedited or Full Board
Date
December 5, 2019
Action Date
December 5, 2019
Comments
Annual Reminder
Updated By
kc
Update Time
2019-12-05T12:00:00.000Z

Description
Expedited Approval
Date
May 29, 2019
Action Date
May 29, 2019
Comments
Amendment-001: Approved
Updated By
slbenken
Update Time
2019-05-29T12:00:00.000Z

Description
Assigned to Agenda
Date
May 29, 2019
Action Date
May 29, 2019
Comments

Amendment-001:
Updated By
slbenken
Update Time
2019-05-29T12:00:00.000Z

Description
Submitted to IRB
Date
May 29, 2019
Action Date
May 29, 2019
Comments
Amendment-001: Submitted to IRB
Updated By
williaud
Update Time
2019-05-29T12:00:00.000Z

Description
Returned To PI
Date
May 29, 2019
Action Date
May 29, 2019
Comments
Amendment-001: Comments from reviewer
Updated By
williaud
Update Time
2019-05-29T12:00:00.000Z

Description
Submitted to IRB
Date
May 28, 2019
Action Date
May 28, 2019
Comments
Amendment-001: Submitted to IRB

Updated By
williaud
Update Time
2019-05-28T12:00:00.000Z

Description
Returned To PI
Date
May 28, 2019
Action Date
May 28, 2019
Comments
Amendment-001: Pre-Review
Updated By
williaud
Update Time
2019-05-28T12:00:00.000Z

Description
Submitted to IRB
Date
May 24, 2019
Action Date
May 24, 2019
Comments
Amendment-001: Submitted to IRB
Updated By
elinder
Update Time
2019-05-24T12:00:00.000Z

Description
Returned To PI
Date
May 23, 2019
Action Date
May 23, 2019
Comments
Amendment-001: Pre-Review
Updated By

williaud
Update Time
2019-05-23T12:00:00.000Z

Description
Submitted to IRB
Date
May 22, 2019
Action Date
May 22, 2019
Comments
Amendment-001: Submitted to IRB
Updated By
elinder
Update Time
2019-05-22T12:00:00.000Z

Description
Amendment Created
Date
May 17, 2019
Action Date
May 17, 2019
Comments
Amendment-001: Created
Updated By
elinder
Update Time
2019-05-17T12:00:00.000Z

Description
Expedited Approval
Date
December 5, 2018
Action Date
December 5, 2018
Comments
A Certificate of Confidentiality has been issued for this study. Subjects' identifiable sensitive research information must be protected in accordance with the terms of the certificate.; Research complies with and is subject to 45 CFR 46 effective January

21, 2019 (i.e. Revised Common Rule or 2018 Requirements).; Waiver of informed consent per IU HRPP Policies; Waiver of documentation of informed consent per IU HRPP Policies; Waiver of authorization under 45 CFR 164.512(i); The PHI to be used or disclosed is determined to be necessary; The explanation of how this research involves no more than minimal risk of loss of privacy to the subject is sufficient; There exists an adequate plan to protect the identifiers from improper use and disclosure; There exists an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research; There exist adequate written assurances that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the requested information would be permitted by the Privacy Rule; The explanation of how this research could not be practicably conducted without waiver of authorization is adequate; The explanation of how this research could not be practicably conducted without access to and use of the individually identifiable health information is appropriate; Plan for soliciting the assent of the children and/or the parent/guardian permission is appropriate.; Child Category 404: not greater than minimal risk to the children; Waiver of assent for children per IU HRPP Policies; Waiver of parental/guardian permission approved per IU HRPP Policies; Waiver of documentation of parental/guardian permission per IU HRPP Policies
Updated By
droessin
Update Time
2018-12-05T12:00:00.000Z

Description
Assigned to Agenda
Date
December 5, 2018
Action Date
December 5, 2018
Comments
A Certificate of Confidentiality has been issued for this study. Subjects' identifiable sensitive research information must be protected in accordance with the terms of the certificate.; Research complies with and is subject to 45 CFR 46 effective January 21, 2019 (i.e. Revised Common Rule or 2018 Requirements).; Waiver of informed consent per IU HRPP Policies; Waiver of documentation of informed consent per IU HRPP Policies; Waiver of authorization under 45 CFR 164.512(i); The PHI to be used or disclosed is determined to be necessary; The explanation of how this research

involves no more than minimal risk of loss of privacy to the subject is sufficient; There exists an adequate plan to protect the identifiers from improper use and disclosure; There exists an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research; There exist adequate written assurances that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the requested information would be permitted by the Privacy Rule; The explanation of how this research could not be practicably conducted without waiver of authorization is adequate; The explanation of how this research could not be practicably conducted without access to and use of the individually identifiable health information is appropriate; Plan for soliciting the assent of the children and/or the parent/guardian permission is appropriate.; Child Category 404: not greater than minimal risk to the children; Waiver of assent for children per IU HRPP Policies; Waiver of parental/guardian permission approved per IU HRPP Policies; Waiver of documentation of parental/guardian permission per IU HRPP Policies
Updated By
droessin
Update Time
2018-12-05T12:00:00.000Z

Description
Submitted to IRB
Date
December 5, 2018
Action Date
December 5, 2018
Comments
Submitted to IRB
Updated By
pattonle
Update Time
2018-12-05T12:00:00.000Z

Description
Returned To PI
Date
December 5, 2018
Action Date
December 5, 2018

Comments
Updated By
pattonle
Update Time
2018-12-05T12:00:00.000Z

Description
Submitted to IRB
Date
December 5, 2018
Action Date
December 5, 2018
Comments
Submitted to IRB
Updated By
elinder
Update Time
2018-12-05T12:00:00.000Z

Description
Returned To PI
Date
December 4, 2018
Action Date
December 4, 2018
Comments
Updated By
pattonle
Update Time
2018-12-04T12:00:00.000Z

Description
Submitted to IRB
Date
December 3, 2018
Action Date
December 3, 2018
Comments
Submitted to IRB
Updated By

elinder
Update Time
2018-12-03T12:00:00.000Z

Description
Returned To PI
Date
November 26, 2018
Action Date
November 26, 2018
Comments
Updated By
pattonle
Update Time
2018-11-26T12:00:00.000Z

Description
Submitted to IRB
Date
November 21, 2018
Action Date
November 21, 2018
Comments
Submitted to IRB
Updated By
elinder
Update Time
2018-11-21T12:00:00.000Z

Description
Protocol Created
Date
November 13, 2018
Action Date
November 13, 2018
Comments
Protocol created
Updated By
elinder
Update Time

2018-11-13T12:00:00.000Z

Administrative Details Form

Protocol Details

9031

Protocol Type

Expedited

Billing Account #

Study Status

Submission Details

9000

Submission Review Level

Expedited

9030

Expedited Category.

Category 5: Data or specimens that have been or will be collected for nonresearch purposes

Category 7: Survey, interview, focus groups, human factor, group behavior or characteristics

9002

Criteria for Approval. Select to confirm.

Approved: The criteria for approval of the research are satisfied in accordance with IU HRPP Policies, and applicable federal regulations.

Protocol Determinations

9003

Protocol Level of Risk.

Minimal risk

9020

Is renewal required for this research?

No

9004

Check all determinations that need to be made.

Informed Consent Waiver

HIPAA Waiver

Vulnerable Population

Certificate of Confidentiality

9005

Informed Consent Waivers

Waiver of informed consent granted in accordance with IU HRPP Policies
Waiver of documentation of informed consent granted in accordance with IU HRPP Policies.

9006
HIPAA Waivers
Participation
9010
Brief description of PHI - Participation
FGID Module: Data points collected for participation in the retrospective review of FGID module data include date(s) of visit, physician name, patient vitals and demographics, contact information, patient/parent answers to GI questions, who is answering the questions (parent or patient or both), and physician notes about GI diagnoses, treatments, and recommendations. Survey (online and phone): In addition to the FGID data points above, we will use parent and patient answers to the phone survey along with parent-reported demographics. Baseline retrospective review: DOB, date/diagnosis (ICD codes), Eskenazi clinic(s) of care Health care utilization retrospective review: The presence of outpatient sick visits within the CHICA system clinic for any complaint; The presence of outpatient sick visits within the CHICA system clinic with an associated GI billing code; The presence of visits to statewide providers, including inpatient hospital stays, outpatient clinic visits, and emergency room visits.; The occurrence of any GI-related testing and procedures – specifically radiologic, laboratory testing, endoscopy, and surgical procedures related to GI diagnoses; The use of any medications prescribed to treat Rome IV diagnoses – specifically acid-suppressants, antispasmodics, antidepressants, stool softeners and laxatives, and pro-motility agents.
9009
Participation HIPAA Waiver
Alteration of authorization criteria satisfied in accordance with 45 CFR 164.512(i)(2)(ii). Alteration of authorization approved in accordance with 45 CFR 164.512(i).
Waiver of authorization criteria satisfied in accordance with 45 CFR 164.512(i)(2)(ii).
Waiver of authorization approved in accordance with 45 CFR 164.512(i).

9011
Identify population(s) involved in this research.
Children
9012
Involvement of Children: Select to confirm.
The involvement of children in the research is appropriate in accordance with IU HRPP Policies.

9013

Children Category.

The involvement of children in the research satisfies the conditions of Category 404 in accordance with IU HRPP Policies.

9014

Parental Consent/Waivers. Choose all that apply.

The plan for soliciting parental/guardian permission is appropriate in accordance with IU HRPP Policies.

Waiver of parental/guardian permission granted in accordance with IU HRPP Policies.

Waiver of documentation of parental/guardian permission granted in accordance with IU HRPP Policies.

9015

Child Assent. Choose all that apply.

The plan for soliciting and documenting assent from children is appropriate in accordance with IU HRPP Policies.

Waiver of assent from children who are otherwise capable of providing assent granted in accordance with IU HRPP Policies.

9025

Certificate of Confidentiality.

The research is subject to the NIH Policy for Issuing Certificates of Confidentiality and therefore has been issued a Certificate.

9028

Other Determinations.