# Cerner PowerTrials Standards and Procedures – New Studies Checklist

## Obtain PowerTrials Access*

- ☐ Obtain a Cerner PowerChart/TRACKS account
- ☐ Complete CHEX/In-Person PowerTrials training
- ☐ Administrative manager to submit E-Works request for Patient Protocol Manager (PPM) access
- ☐ Obtain IRB approval to use the Cerner PowerChart function(s) for your clinical trial **(See table below)**

| Participant Management Function | Prescreen Function |
|---|---|
| ☐ Begin entering all active, on-treatment subjects as "Enrolled (on-Study)" within PowerTrials | ☐ Meet with the Bear Institute to build your Prescreening rule and begin using this function |

## Obtain IRB Approval*

Include PowerTrials information in the following sections of the IRBear new study application:

| Participant Management Function | Prescreen Function |
|---|---|
| ☐ Section 2.0 – Required Reviews (Ancillary Reviews) | ☐ Section 2.0 – Required Reviews (Ancillary Reviews) |
| ☐ Section 2.1 – Summary of Research | ☐ Section 2.1 – Summary of Research |
| ☐ Section 7 – Risks and Benefits Assessment | ☐ Section 6 – Study Population |
| ☐ Section 8.1 – Consent Forms & Process of Consent | ☐ Section 8.1 – Consent Forms & Process of Consent |
| ☐ Section 8.4 – Recruitment Methods | ☐ Section 8.4 – Recruitment Methods |
| ☐ Section 9.12 - PHI Identifiers | ☐ Section 9.0 – Data Privacy and Confidentiality |
| | ☐ Section 9.12 – PHI Identifiers |

***Access to PowerTrials and IRB approval can be obtained in parallel. It is recommended to obtain PowerTrials access before your study begins.**

# Cerner PowerTrials Standards and Procedures – New Studies

*Concerning the use of PowerTrials Participant Management functionality and Prescreening functionality for Study Recruitment Purposes*

*Effective Date: [09/02/2014]*

***All access to Children's National information systems is provided based upon specific staff roles and staff need in supporting Children's National Health System's mission. It is the responsibility of every member of the hospital to protect the confidentiality, integrity, and availability of the data, applications, systems, and software through knowledge of, and adherence to, the Children's National Health System Policies that govern Information Systems and Medical Records.***

## OVERVIEW

The PowerTrials Participant Management and Prescreening functions are HIPAA compliant applications that are integrated into the Children's National Medical Center's electronic medical records system (i.e. PowerChart) and used to support the conduct of clinical trials research.

**Participant Management Function**

The PowerTrials Participant Management function is used to efficiently and accurately organize and maintain protocol information, specifically in regard to clinical research enrollment. Its purpose is to promote Children's National patient safety initiatives by actively informing medical providers (e.g. Emergency Department providers, Regional Outpatient Center providers, etc.) that a patient is participating in a research study.

The Children's National PowerTrials team creates a record for each applicable study within PowerTrials. Basic study information is ascertained from the IRB electronic submission system (IRBear) and/or the WIRB Conexus portal. The PowerTrials team may also contact the Investigator/Coordinator to ensure the information is accurate. Once the study record is created, the Investigator/Coordinator accesses PowerTrials Participant Management and adds all active study participants (i.e. study participants that are currently "on treatment" or have completed treatment within a one month period) to the study record.

As the Investigator/Coordinator enrolls each active study participant into the PowerTrials study record, the patient's individual enrollment record is linked to the study. This modifies the patient's PowerChart medical record in real time to display an indicator on the Banner Bar in bold type that reads "Research: On Study." A "Clinical Research" tab also appears on the left-hand menu of the patient's PowerChart record. Clicking on this tab displays the study title, Principal Investigator (PI) name, and PI contact

information for all research studies in which the patient is participating at Children's National. This information allows the medical provider to contact the study PI if warranted (e.g. in the case of a treatment contraindication). When available, the National Clinical Trials (NCT) Registry Number for each study is also shown, giving clinicians access to additional protocol information via the ClinicalTrials.gov website. **A patient's study enrollment ID is <u>not</u> displayed so there is no link in the medical record between the patient and his or her research data.**

As PowerTrials is implemented at Children's National Medical Center, the Participant Management function will become a hospital-wide resource. With certain exceptions, all new or active interventional clinical research studies will be required to be entered into and tracked using PowerTrials.

***Note: Currently, studies involving an illness of a sensitive nature (e.g. HIV, STDs, and mental health) will not be entered into PowerTrials***

**Prescreening Function**

The PowerTrials Prescreening function enables an Investigator/Coordinator to search the hospital's electronic medical record, PowerChart, for potential research participants using pre-established recruitment criteria. As part of this process the Bear Institute and PowerTrials team will work with the PI/Coordinator to build a Prescreening Rule based upon the research inclusion/exclusion criteria. PowerTrials supports recruitment efforts by identifying the best suited patients within PowerChart for a particular research study.

PowerTrials Prescreening functionality limits study patient Information to IRB approved study users only. Access to PowerTrials Prescreening functionality is also limited strictly to Children's National investigators, healthcare providers, and study nurses/coordinators.

For detailed information on PowerTrials Prescreening functionality, please see **http://www.ctsicn.org/ (For Researchers → Tools & Resources → PowerTrials).**

## Obtaining Access to PowerTrials

*Access to PowerTrials Participant Management functionality and Prescreening functionality is limited strictly to Children's National investigators and study nurses/coordinators.*

Individuals must first obtain a Cerner PowerChart/TRACKS account in order to become users of the PowerTrials Participant Management and/or Prescreening functions (see PowerChart/Tracks Resource Page). Each user must also obtain Citrix XenApp/ThinClient access to the Patient Protocol Manager

(PPM) application. Hospital Providers (i.e. Physicians) automatically have access to the PPM. All others requesting access must complete an in-person training session and brief examination conducted by Bear Institute. Registration information for PPM training can be found in Chex starting July 1st, 2014 (until then please contact Ms. Constance Edwards at CEdwards@childrensnational.org).

Once training has been successfully completed, the potential user's Administrative Manager (i.e. the department Administrator in charge of obtaining IT access for employees) must submit an E-works request for the employee to be given access under one of two possible user categories: Research Nurse or Research View only (for Coordinators, assistants, etc.). *Security account changes and access are requested through the Bear Institute. All access is based on Children's National Health System policy.*

**Account termination requests**

Access to information systems must be revoked in a timely manner following an employee termination or instance in which the user no longer requires access.

1) The user's Administrative Manager requests an account termination by contacting the Bear Institute by phone or e-mail.
2) The Bear Institute Administrator assigned to PowerTrials will terminate the account within a reasonable turn-around time.

**For questions related to PowerChart/PowerTrials training,**
**please contact Ms. Constance Edwards at CEdwards@childrensnational.org**

## IRB Approval for Using PowerTrials

Use of the PowerTrials Participant Management and/or Prescreening functions requires prior IRB approval. Investigators wanting to use these tools as part of a new study must include information about their use in the IRB new study application. Requests to add one or both of these tools to an existing study require the submission and IRB approval of an amendment prior to their implementation (**Please see *IRBear.org website → General Information → Forms and Templates [for related documents]***). Whenever an investigator is proposing to use the Participant Management function, information about the tool must also be included in the Informed Consent/Parental Permission form.

Only studies with IRB approval to use the PowerTrials Participant Management tool will be allowed to enter data into the system. A copy of the IRB approval letter and the IRB-approved informed consent document with applicable language on the use of PowerTrials must be provided to the PowerTrials team in order to have the Participant Management feature activated. Likewise, documentation of IRB

approval to use the Prescreening tool must be included when submitting a request to the Bear Institute to build a Prescreening Rule (inclusion/exclusion criteria) for a clinical trial.

**Completing the IRBear SmartForm application**

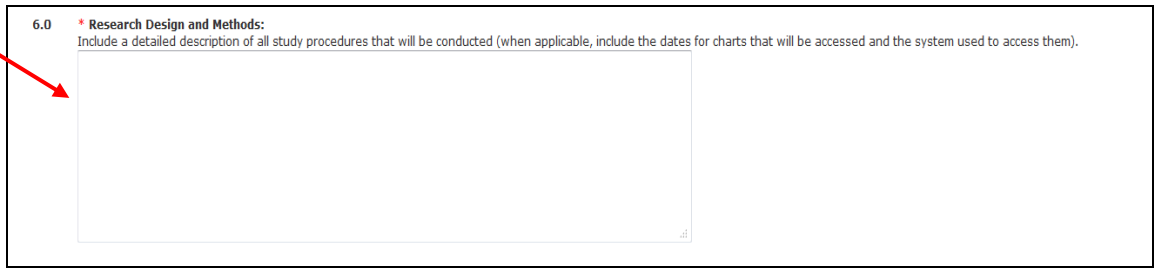
Investigators proposing to use the PowerTrials Participant Management and/or Prescreening functions as part of a new study submission to the IRB must describe the tools and their use in a number of specific sections of the IRBear SmartForm application. These sections are listed below. The PowerTrials function for which each section applies is indicated, along with suggested text when applicable.

Section 2.0 **Required Reviews** **Participant Management and Prescreening functions**

- Item 3.0 "Ancillary Reviews" – Select "Medical Records" as a required Ancillary Review in addition to any other Ancillary Reviews required for your study.

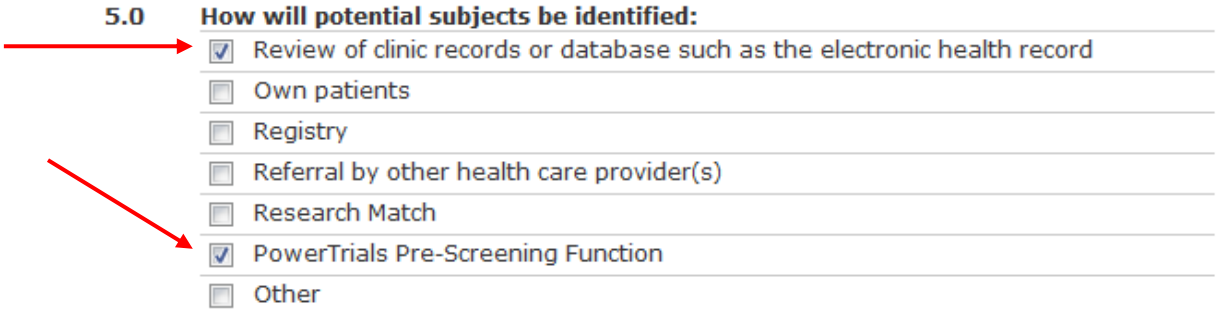
Section 2.1 **Summary of the Research** **Participant Management and Prescreening functions**

- Item 6.0 "Research Design and Methods" – In addition to what you would normally enter in this section, add a description of PowerTrials, including the tool's background and function.
  - Prescreening example: "Potential research participants will be identified using the PowerTrials Prescreening function. PowerTrials is a HIPAA-compliant application that is integrated into the Children's National Cerner electronic medical records system (PowerChart). Study inclusion and exclusion criteria will be used to create a Prescreening Rule. A screening engine in PowerChart will compare the criteria to patient data within the medical records system, and a list of potential study subjects will be generated.
    [Continue by describing how identified patients will be approached and recruited.]
  - Participant Management example: "The PowerTrials Participant Management function will provide an additional safety measure for participants by alerting Children's National medical providers when one of their patients is enrolled in this study. PowerTrials is a HIPAA-compliant application that is integrated into the Children's National Cerner electronic medical records system (PowerChart). As each patient is enrolled in the study, the investigator or coordinator will enter their information in the Participant Management function. This will link the patient's medical record to the study and identify them in their record as a research participant along with the protocol number, PI name, and PI contact information. This will allow the medical provider to contact the PI if warranted (e.g. in the case of a treatment contraindication)."



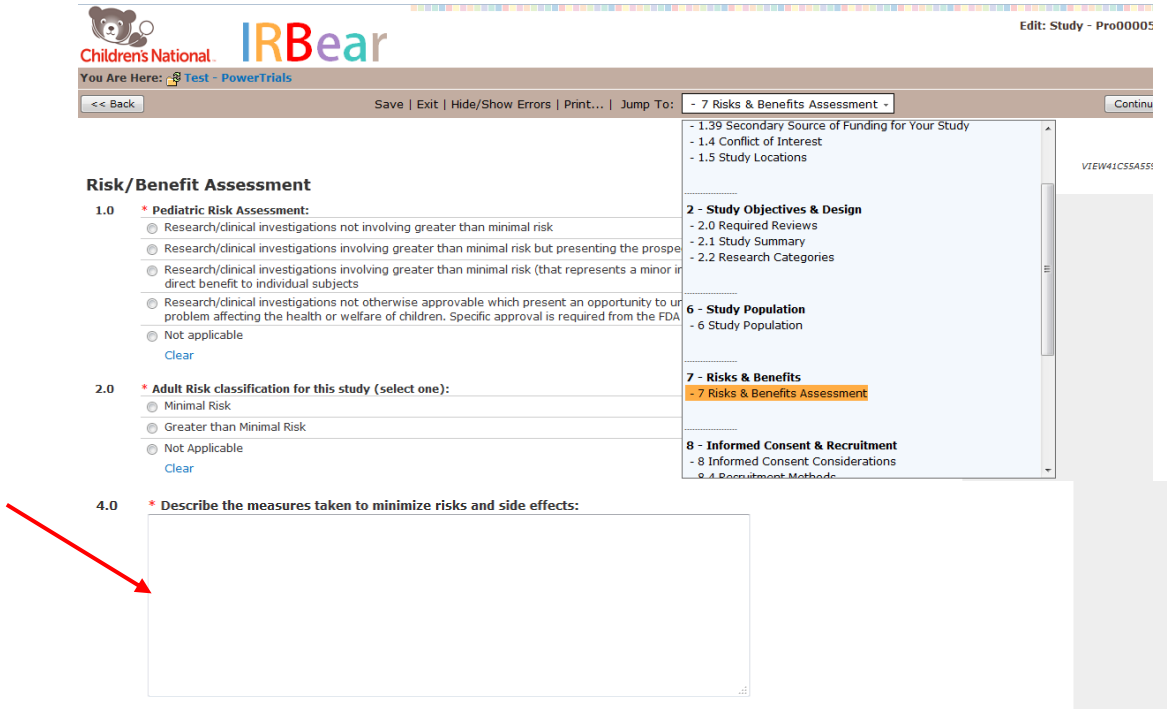

Section 6 **Study Population** **Prescreening function**

- Item 5.0 "How will subjects be identified?" – In addition to any other methods you will be using to identify subjects also check the following options: 1) Review of clinic records or database such as the electronic health record and 2) PowerTrials Prescreening Function.



Section 7 **Risks & Benefits Assessment** **Participant Management function**

- Item 4.0 – Describe the measures taken to minimize risks and side effects:
  - Example – "The PowerTrials Participant Management function actively informs Children's National medical providers (e.g. Emergency Department providers, or Regional Outpatient Center providers) that a patient is participating in a research study. The PI's contact information will also be included in the medical record. If the patient seeks treatment for a condition unrelated to the research, the provider can contact the PI for additional information if there is a concern that a procedure or treatment may be contraindicated due to the patent's participation in the clinical trial. This could prevent the patient/participant from experiencing an adverse event.




Section 8.1 **Consent Forms & Process of Consent** **Prescreening function**

- Item 2.0 – In addition to your general process for consenting, also provide a description addressing the following statement:

  *"Once subjects are identified through PowerTrials please indicate how subjects will be approached and enrolled into a study by the Study Team."*

  **Note:** Patients who are identified through PowerTrials should not be contacted directly unless they initiate the contact or give their permission to be contacted by the study team.

See the section on page 11 titled “Contacting Potential Participants Identified through PowerTrials Prescreening.”

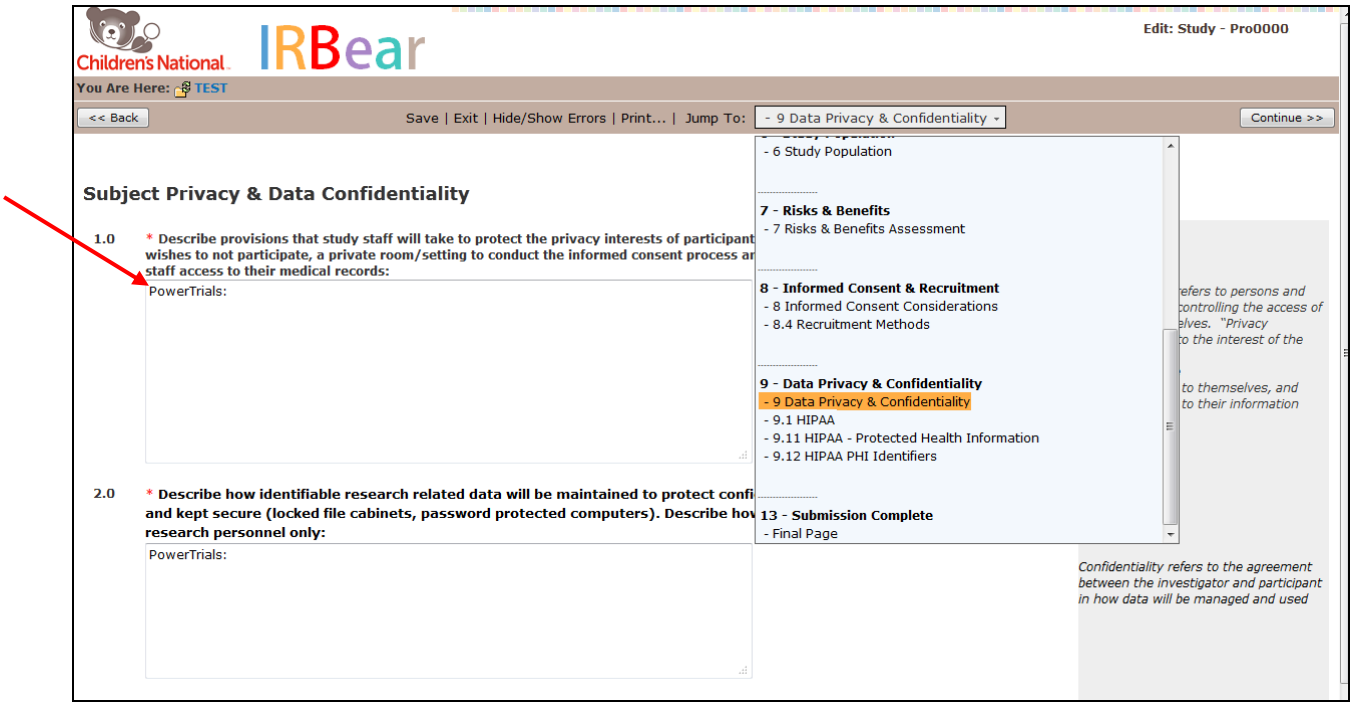
Section 8.4 **Recruitment Methods  Prescreening function**

- Item 1.0 – Select ”PowerTrials”
- Ancillary review of recruitment materials (e.g. brochures, leaflets, phone scripts, etc.) by the Children’s National PR and Marketing Department is required as part of the IRB application process. If your study is using such materials to help in the recruitment of patients identified through the PowerTrials prescreening or if you intend to give potential study participants that you have identified via PowerTrials any recruitment materials, you must:
  1) Upload those materials in the Documents section of the application; and
  2) Select “PR & Marketing” as a required Ancillary Review in Section 2.0, **Required Reviews**, Item 3.0.
- Item 2.0 – “please describe” – Describe the specific parameters you have requested for your Prescreening rule (i.e. list the exact criteria that are being used to build your Prescreening rule).

Section 9.0 **Privacy and Confidentiality** **Prescreening function**

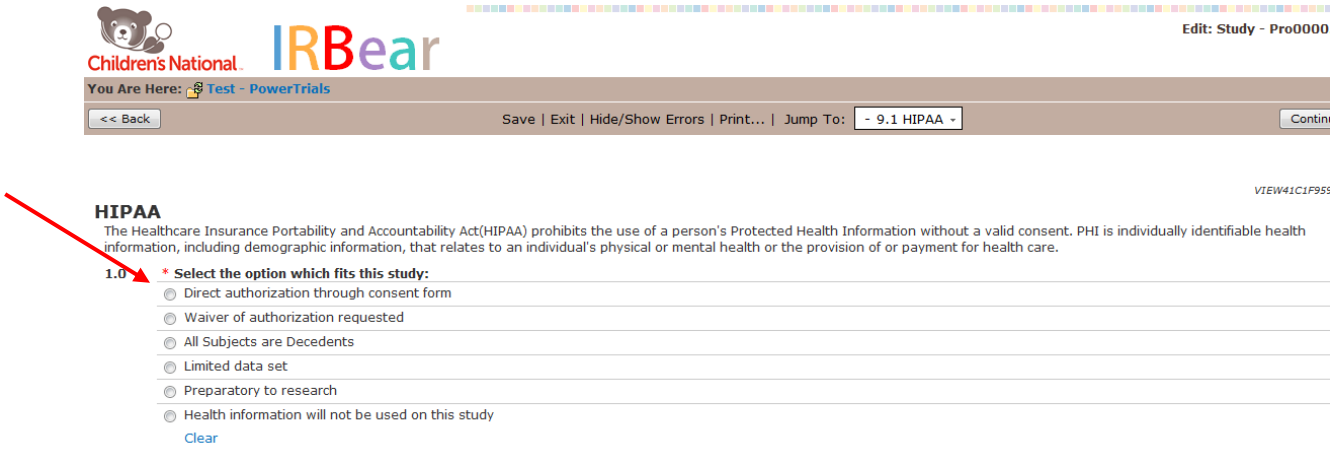
- Item 1.0 – In addition to the other information you would normally enter, be sure to include language describing how the study team will maintain patients' privacy when using PowerTrials. For example:
  - How will the list of potential participants be stored, and when and how will it be destroyed?
  - Who on the study team (identified by name) will have access to PHI, and what procedures are in place to ensure that only authorized personnel have access to PHI in PowerTrials? How will potential study participants identified through PowerTrials be approached and how you will maintain their privacy?
  - What will be done with information on potential subjects who decline to participate?

  **Note:** Patients who are identified through PowerTrials should not be contacted directly unless they initiate the contact or give their permission to be contacted by the study team. See the section on page 11 titled "Contacting Potential Participants Identified through PowerTrials Prescreening."




Section 9.1 **HIPAA** **Prescreening function**

- Item 1.0 – Choose the option (i.e., direct authorization through consent form; waiver of authorization requested) that applies to the protocol overall. **If you plan to use the PowerTrials Prescreening function to identify potential participants, you must also complete a [HIPAA/IRB Authorization for Preparatory to Research form]** (document can also be found on **IRBear.org website → *General Information* → *Forms and Templates***) and upload it in the Documents section of the IRBear application.




Section 9.12 **PHI Identifiers** **Prescreening function**

- Item 1.0 "Identify the types of PHI collected" – If you have not done so already, select "Hospital or Medical Records," as PowerTrials uses PowerChart, the Children's National medical record system. Please also be sure to select any other types of PHI that will be collected during the study.

**Informed Consent/Parental Permission Form considerations**

For studies using the PowerTrials Participant Management function, the Informed Consent/Parental Permission form must disclose that a person's participation in research will be entered into their electronic medical record.

- The following text is recommended as part of the Informed Consent/Parental Permission form when the Participant Management function will be used. It should appear under "Confidentiality" (section I) of the Children's National consent form.

  "Information that you are participating in this study will be entered into your electronic medical record. This information will be seen by any medical provider caring for you at Children's National and its affiliated institutions. In the uncommon event that you are treated outside of this research study by a medical provider affiliated with Children's National, there is a possibility that the medical provider may contact the Principal

Investigator regarding your participation in this research study. This could be necessary for your safety if the experimental treatment used in this study might interfere with a treatment being considered by the provider. The Principal Investigator will carefully decide on the type and amount of information he/she gives to the medical provider and will maintain your privacy and the confidentiality of the information to the extent possible."

## Building the Prescreening Function

Once the PowerTrials Prescreening function for a study is IRB approved, the Investigator approved to use the Prescreening functionality tool must complete an online Prescreening functionality request via the Cerner Enhancement Request Form. Instructions for this process can be found on the intranet by searching for the "PowerTrials Pre-Screening Submission Process" document.

Once the form is reviewed by the Bear Institute, a member of the PowerTrials team will schedule a development meeting to discuss the inclusion/exclusion criteria used to build the Prescreening Rule. Once designed and built, the study team will have the ability to test the Prescreening rule. After testing, a *Go Live* date for the Prescreening Rule will be provided and the study team will then be able to search for potential research participants using the rule immediately.

## Contacting Potential Participants Identified through PowerTrials Prescreening

Once IRB approval has been obtained and potential participants are identified using the inclusion/exclusion criteria created in the PowerTrials prescreening rule, the principal investigator/study team must approach the medical provider caring for each identified patient during that visit and ascertain if the provider knows of any reason the patient should not be invited to participate in the research. If, in the medical care provider's opinion, it would not be appropriate for the patient to be approached about the research, the study team will update the patient's status in PowerTrials as "Declined by Physician." That patient will not be contacted by the study team for that particular study. If the medical care provider agrees that it is appropriate to inform the patient about the research, the study team may proceed with the recruitment process.

There are two acceptable methods of recruiting potential participants identified using the PowerTrials Prescreening function:

1. The clinician caring for the patient introduces the study (either in person or through a letter) and gives the participant/family information on how to contact the study team if they are

interested in learning more. (The letter to potential participants may be co-signed by the PI of the study and must be approved by the IRB.)

2. The clinician caring for the patient introduces the study (either in person or through a letter) and asks the participant/family for permission for the study team to contact them directly. (The letter to potential participants may be co-signed by the PI of the study and must be approved by the IRB.)

The study team may not contact potential participants unless the patient/family initiates the contact or gives their permission to be contacted by the study team. The IRB does not consider "cold calling" an acceptable recruitment practice because it infringes on individuals' privacy.

When a patient agrees to take part in the research, the participant's informed consent/parental permission and assent will be obtained and documented by the study team as per the IRB-approved protocol and consent forms.

**For questions related to IRB approval, please contact the Children's National IRB at x3472 or (301) 565-8452.**

**For technical questions related to PowerTrials, please contact the Bear Institute at x6119.**

**For any other questions related to PowerTrials, please contact Jurran Wilson at x2196**

**Wishing you great success with your enrollment and recruitment efforts,**

**The Children's National PowerTrials Team**