



Cerner PowerTrials Standards and Procedures – Study Amendment Checklist

| <u>Obtain PowerTrials Access*</u> | |
|--|---|
| <input type="checkbox"/> Obtain a Cerner PowerChart/TRACKS account <input type="checkbox"/> Complete CHEX/In-Person PowerTrials training <input type="checkbox"/> Administrative manager to submit E-Works request for Patient Protocol Manager (PPM) access <input type="checkbox"/> Obtain IRB approval to use the Cerner PowerChart function(s) for your clinical trial (See table below) | |
| <p><u>Participant Management Function</u></p> <input type="checkbox"/> Begin entering all active, on-treatment subjects as “Enrolled (on-Study)” within PowerTrials | <p><u>Prescreen Function</u></p> <input type="checkbox"/> Meet with the Bear Institute to build your Prescreening rule and begin using this function |

| <u>Obtain IRB Approval*</u> | |
|---|---|
| <p>Include PowerTrials information in the following sections of the IRBear study amendment application:</p> | |
| <p><u>Participant Management Function</u></p> <input type="checkbox"/> Complete the Amendment Cover Sheet <input type="checkbox"/> Complete the Detailed Description of Changes section <input type="checkbox"/> Complete the Protocol Changes section <input type="checkbox"/> Open the SmartForm and modify all IRBear sections noted in the “Cerner PowerTrials Standards and Procedures – New Studies” document for Participant Management functionality <input type="checkbox"/> Modify the Informed Consent document | <p><u>Prescreen Function</u></p> <input type="checkbox"/> Complete the Amendment Cover Sheet <input type="checkbox"/> Complete the Detailed Description of Changes section <input type="checkbox"/> Complete the Protocol Changes section <input type="checkbox"/> Open the SmartForm and modify all IRBear sections noted in the “Cerner PowerTrials Standards and Procedures – New Studies” document for Prescreening functionality |

*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 – Study Amendment

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 IRB protocol number, 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 not 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.ctsicc.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 for an existing IRB- approved study must submit a protocol amendment and receive IRB approval prior to their implementation. If one or both of these tools are to be used in a new study, the IRB application form must include information about their use. 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.

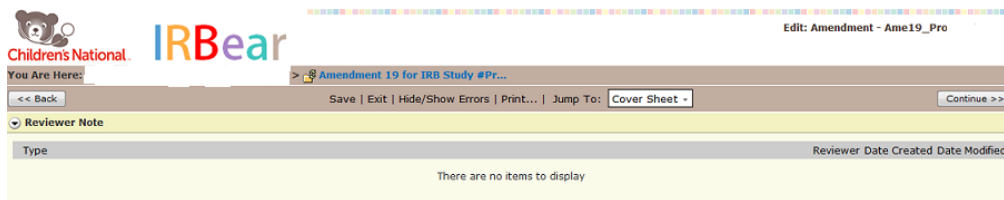
Only studies with IRB approval to use the PowerTrials Participant Management tool will be allowed to enter data into the system. A copy of the IRB approval letter and the IRB-approved informed consent document with applicable language on the use of PowerTrials must be provided to the PowerTrials team 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 Study Amendment application

Investigators submitting an amendment for the use of the PowerTrials Participant Management and/or Prescreening functions for an existing study must describe the tools and their use in a number of specific sections of the IRBear Amendment form. These sections are listed below. The PowerTrials function for which each section applies is indicated, along with suggested text when applicable.

Section: **Coversheet** **Participant Management and Prescreening functions**

- Item 1.0 “Type of Change this amendment is making” – Select “PowerTrials Participant Management” and/or “PowerTrials Pre-Screening Function”
 - If for **Participant Management**, also select “Changes to Consent Form(s)” and “Changes to Protocol Document(s).”
 - If for **Prescreening**, also select “Changes to Protocol Document(s)” and “Changes to Procedures.”



Amendment Request

- An amendment request includes two parts: the Amendment form and modifications to the Study form
- Only one amendment request is allowed at any given time, i.e: amendment 1 must be approved, denied or withdrawn before amendment 2 can be created

1.0 * Type of change this amendment is making (check all that apply):

- Changes to Consent Form(s)
- Changes to Protocol Document(s)
- Changes to Advertisements
- Change of Principal Investigator
- Changes to Risks
- Changes to Procedures
- Closed to Enrollment
- Reopen Study Enrollment
- Changes to Investigator Brochure
- Changes to DSMB Report
- Changes to Grant
- Administrative
- Approved Industry Contract (Clinical Trials Agreement)
- Notification of New information
- Inclusion/Exclusion
- PowerTrials Participant Management
- PowerTrials Pre-Screening Function
- Conflict of Interest
- Other changes



Section: **Detailed Description of Changes** **Participant Management and Prescreening functions**

- Item 1.0 to 5.0 - Complete all sections to reflect your request for PowerTrials approval for your specific study. Summarize how PowerTrials will change the protocol and add a description of PowerTrials, including the tool's background and function.

Note: If you are seeking approval for the Prescreening function, part of your summary should also describe the specific parameters you have requested for you Prescreening rule (i.e. list the exact criteria that are being used to build your Prescreening rule).

- 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).”
- 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.]

Note: Summary of Changes and Risk and Benefit Information concerning PowerTrials may be found in the “Cerner PowerTrials Standards and Procedures – New Studies” document. See “Section 2.1 Summary of Research” and “Section 7.0 Risk & Benefit Assessment.”

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Reviewer Note

| Type | Reviewer | Date Created | Date |
|-------------------------------|----------|--------------|------|
| There are no items to display | | | |

Detailed Description of Changes

- 1.0 * Provide a summary of the changes, including the rationale and justification for the proposed changes:
- 2.0 * Describe how the changes alter what the IRB last approved:
- 3.0 * Do the changes alter the risks and benefits of the study? Yes No
- 4.0 If no, state why the changes do not alter the study risks and benefits:
- 5.0 If yes, provide a description of how the risks and benefits have changed:

Section: Protocol Changes Participant Management and Prescreening functions

- Item 1.0 and 2.0 - Summarize how PowerTrials will change the protocol and add a description of PowerTrials, including the tool's background and function.
- *Note: If you are seeking approval for the Prescreening function, part of your summary should also describe the specific parameters you have requested for you Prescreening rule (i.e. list the exact criteria that are being used to build your Prescreening rule).*
 - 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)."
 - 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.]

Section: **Summary of Changes** **Participant Management and Prescreening functions**

- Item 2.0 "SmartForm" – Open and update each section noted above, as well as those noted in the "Cerner PowerTrials Standards and Procedures – New Studies" document.

- Participant Management - Please complete the following sections within the SmartForm:

Section 2.0 – Required Reviews (Ancillary Reviews)

Section 2.1 – Summary of Research

Section 7 – Risks and Benefits Assessment

Section 8.1 – Consent Forms & Process of Consent

Section 8.4 – Recruitment Methods

Section 9.12 - PHI Identifiers

- Prescreening - Please complete the following sections within the SmartForm:

Section 2.0 – Required Reviews (Ancillary Reviews)

Section 2.1 – Summary of Research

Section 6 – Study Population

Section 8.1 – Consent Forms & Process of Consent

Section 8.4 – Recruitment Methods*

Section 9.0 – Data Privacy and Confidentiality

Section 9.12 – PHI Identifiers

***For Item 2 "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).



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 Jurrán Wilson at x2196**

Wishing you great success with your enrollment and recruitment efforts,

The Children's National PowerTrials Team