8.22.2013

Use of PowerTrials Screener for Study Recruitment Purposes

Effective Date:

OVERVIEW

All access to information and systems is provided based on business need in support of the Georgia Regents University (GRU) mission. It is the responsibility of every member of the university and health system to protect the confidentiality, integrity, and availability of the data, applications, systems, and software through knowledge of, and adherence to, the GRU Policies that govern Information Systems.

PowerTrials Screener is an online HIPAA compliant application that enables investigators to obtain a list of potential study subjects from PowerChart, the hospital electronic medical record. For detailed information on PowerTrials Screener, see the OCIS website at www.gru.edu/OCIS.

To use PowerTrials Screener as a method of study subject recruitment follow the process outlined below.

POWERTRIALS SCREENER REQUESTS AND USE

The PowerTrials Administrator requests PowerTrials accounts for faculty, staff, and students. Security account changes and access are requested through the GRU AccessIS system. All access is based on GRU policy. (MCG Health, Inc. Policy Number 12.54 Information Systems Security)

To ensure proper access control, all PowerTrials Screener access is contingent on prior IRB approval for each user on a specific study. PowerTrials Screener limits study patient Information to IRB approved study users only. Access is limited to the user’s IRB approved role on the study. Access to PowerTrials Screener is limited to GRU investigators, study recruiters and study coordinators.

For studies that use an Internal IRB:

PowerTrials Screener is a recruitment method. When creating a new study or modifying an existing study, in eIRB section 8.4 Recruit Methods, 1.0, select “Medical records or other institutional sources involving patients under the care of the study investigators,” and “Medical records or other institutional sources involving patients NOT under the care of the study investigator”. In addition, check “Other methods(s)” and indicate PowerTrials Screener.

In section 8.4 Recruitment Methods, 2.0, indicate by which means you will contact potential subjects based on PowerTrials Screener results (i.e., letter, brochure, phone call). The corresponding advertising material must be uploaded for IRB review/approval. In addition, a “Waiver of HIPAA Authorization” must be requested. In section 8.4 Recruitment Methods, 2.0, page 9.1, select and complete the Smart Form entitled “Waiver of HIPAA Authorization”. Justification for requesting Waiver of HIPAA Authorization could include:

- Critical to obtain the number of patients required by the study
- PowerTrials Screener is a more focused method of identifying potential subjects versus manual review of medical records
- Reduces the risk to patient privacy by only targeting specific groups of patients who may potentially qualify based on protocol inclusion/exclusion criteria

In eIRB on page 1.0 under Study Personnel, select the person who will use PowerTrials Screener. Under Responsibilities, select “Other” and type in PowerTrials Screener.
For studies that use an External IRB:
Screener is a recruitment method. When creating a new study or modifying an existing study in
CIRBI: Under Recruit Methods, 1.0, check “Database/Chart Review,”. Check “Other” and indicate
PowerTrials Screener. In the section entitled “Recruitment through Database/Chart Review”, check
“Electronic Database,” and “Medical records/charts/paper records.” Answer all subsequent questions
on the Smart Form.

In the section “Site Documentation Attachment Summary”, indicate by which means you will contact
potential subjects based on PowerTrials Screener results (i.e., letter, brochure, phone call). The
corresponding advertising material must be uploaded for IRB review/approval. In addition, a “Waiver
of HIPAA Authorization” must be requested. In the section “Site Documentation Attachment
Summary”, create and upload a document entitled “Waiver of HIPAA Authorization – PowerTrials
Screener.” The document should indicate the reason for requesting Waiver of HIPAA Authorization,
which includes:

- Critical to get the number of patients required by the study
- PowerTrials screener is a more focused method of identifying potential subjects versus
  manual review of medical records
- Reduces the risk of patient privacy by only targeting specific groups of patients who may
  potentially qualify based on protocol inclusion/exclusion criteria

ACCESS APPROVALS

1. When a study is IRB approved, the person approved to use the Screener tool completes an online
  Screener Request form located on the OCIS website: www.gru.edu/OCIS
2. The PowerTrials Administrator reviews the request to ensure complete compliance with all applicable
   regulations and policies. The PowerTrials Administrator verifies that the request is IRB approved and
   consistent with the user’s job description and role on the study.
3. The PowerTrials Administrator submits PowerTrials access requests via the online AccessIS.
4. The Information Security Administrator (ISA) grants the user minimum access necessary to screen for the
   major inclusion and exclusion criteria required by the study.
5. Access is terminated when the study is closed with the IRB or the user is no longer associated with the
   study. It is the Principal Investigator’s responsibility to inform the PowerTrials Administrator of these
   changes.

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 PowerTrials Administrator requests an account termination via the GRU AccessIS system.
2) The Information Security Administrator assigned to PowerTrials terminates the account with a turn-
   around time of no later than two days upon receipt of request.