USE OF ELECTRONIC HEALTHCARE DATA FOR RESEARCH RECRUITMENT PURPOSES

OVERVIEW

Electronic healthcare data encompasses a broad range of data sources including: Electronic Health Records (EHRs), claims (medical, dental, pharmacy), prescriptions, clinical research, drug review applications, and patient registries (clinical and population health). The opportunity to use these data to support research could be lost or limited without timely introduction of a means to access this data through the development of electronic databases and search engines such as PowerTrials Screener and i2b2. 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 and i2b2 pull from the same pool of patients – GRMC patients who have accepted the Notice of Privacy Practices.

PowerTrials Screener is an online HIPAA compliant application that enables investigators to screen for a list of potential study subjects from PowerChart, the hospital electronic medical record.

The i2b2 database allows investigators to query a limited, de-identified dataset from GRU’s electronic medical records while maintaining the capability to re-identify patient data at a later date. Researchers can run queries and perform simple data analysis on the limited data for the purposes of cohort identification and hypothesis generation. IRB approval is not required for de-identified datasets.

To obtain identified patient data from PowerTrials Screener and/or i2b2, the researcher must receive study-specific IRB approval to use these tools as a recruitment method.

REQUESTING IRB APPROVAL

For studies that use an Internal IRB (IRB A, B, or C)

Screener and i2b2 are recruitment methods. When creating a new study or modifying an existing study in eIRB:

1. **In section 1.0 Study Identification**, select the person who will use electronic database tools. Under “Responsibilities,” select “Other” and enter “Electronic Healthcare Database tools.”
2. **In section 8.4 Recruitment Methods, 1.0**, indicate by which means you will develop potential subjects’ information for studies.
3. Under the “Other” field add: EHR secured data applications.”
4. **In section 8.4 Recruitment Methods, 2.0**, indicate by which means you will recruit potential subjects defined by PowerTrials Screener, i2b2, or chart review results (i.e., letter, brochure, phone script).
5. The corresponding advertising/recruitment material must be uploaded for IRB review/approval.
6. Create and upload a document entitled “Electronic Healthcare Date for Recruitment Purposes” in section 2.0. This will ensure the recruitment method is listed on the IRB approval letter.

A “Waiver of HIPAA Authorization” is required.

7. **In section 8.4 Recruitment Methods, 2.0, 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 and i2b2 offer a more focused method of identifying potential subjects versus mass manual review of medical records. A specified chart review that is created from the electronic database tools.

Reduces the risk of abusing patient privacy by only targeting specific groups of patients who may potentially qualify based on protocol inclusion/exclusion criteria as defined by the study.

For studies that use an External IRB (Chesapeake Research Review, Inc., National Cancer Institute):

Screener and i2b2 are recruitment methods. When creating a new study or modifying an existing study in CIRBI:

1. In section Recruit Methods, 1.0, check “Database/Chart Review.”

2. In section “Recruitment Through Database/Chart Review,” check “Electronic Database,” and “Medical records/charts/paper records.” Answer all subsequent questions on the Smart Form.

3. In section 2.0, create and upload a document entitled “Electronic Healthcare Date for Recruitment Purposes” along with any other recruitment material that will be used to contact potential participants. This will ensure the recruitment method is listed on the IRB approval letter.

A “Waiver of HIPAA Authorization” is required.

4. In section “Site Documentation Attachment Summary,” create and upload a document entitled “Waiver of HIPAA Authorization.” The document should indicate the reason for requesting Waiver of HIPAA Authorization, which includes:

Critical to obtain the number of patients required by the study.

PowerTrials Screener and i2b2 offer a more focused method of identifying potential subjects versus mass manual review of medical records. A specified chart review that is created from the electronic database tools.

Reduces the risk of abusing patient privacy by only targeting specific groups of patients who may potentially qualify based on protocol inclusion/exclusion criteria as defined by the study.

REQUESTING IDENTIFIED DATA

1. Send an email to OCIS (OCIS@gru.edu) with “Screener Request and/or i2b2” in the subject line and provide:

- Study short name
- IRB number
- Study contact information (including phone numbers) and name of the Principal Investigator
- IRB approval letter indicating electronic healthcare database as a recruitment tool
- Diagnosis codes (ICD9) or CPT codes, and constraints (age, gender, ethnicity, dates) or de-identified query name for i2b2
2. For **Screener**, the PowerTrials Administrator will schedule an appointment with study staff member. The appointment for Screener will include:

- Training on the use of the Screener application and chart review training to supplement results. (Classes will be individual working sessions.)
- Determination and confirmation of inclusion/exclusion criteria to be used for the study. This is to be defined by the requestor and may include diagnosis codes, age, gender, or other requirements.
- Completing a Service Request for IS to build the inclusion/exclusion criteria for the study (if needed).
- How to check the status of Service Requests.

3. If a Service Request is required for more complex requests the designated investigator or study coordinator can run the Screener tool for the study after it is completed.

4. The list of potential subjects and subject status is maintained in PowerTrials application within the specific study folder.

5. For **i2b2**-identified records, researchers will be able to run queries and perform simple data analysis on the limited data for the purposes of cohort identification. If an investigator identifies a suitable cohort or a promising avenue of researcher, they can request access to the fully identified records of those patients by contacting the administrator **OCIS@gru.edu** (see above). Users also have the ability to work directly with the i2b2 administrator to meet their data needs. All i2b2-identified results will be stored on the study’s R Drive.

   **For questions and information, email OCIS at OCIS@gru.edu.**

   **For detailed information on PowerTrials Screener and i2b2, see the OCIS website at [http://www.gru.edu/research-admin/ocis/](http://www.gru.edu/research-admin/ocis/).**