
Utilization of IHI UBMD Database for Participant Recruitment in Clinical Research Studies

Category: Research

Responsible Office: Institute of HealthCare Informatics (IHI)

Responsible Executive: Vice President for Research and Economic Development and Vice President for Health Sciences

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Summary

This policy provides guidelines and procedures for utilizing the UBMD patient data stored with IHI for conducting feasibility assessments and patient recruitment using i2b2.

Policy

POLICY STATEMENT

This policy describes the procedures to be followed by UB researchers and research staff in using i2b2 to query the IHI UBMD database. Included are guidelines and processes to access the IHI database, IRB requirements, training requirements, and contact with potential participants. This policy covers both feasibility and recruitment activities. Use of this query process to determine feasibility of finding adequate numbers of potential participants in a study can be conducted prior to IRB approval of the research study. Only the number of patients in the database that meet the query criteria are provided and no personal health information (PHI) is released. Use of this query process is only permitted after the study is IRB approved, at which stage the potential participants PHI is released to the investigator/staff on their request. They can then proceed to contact the patients following the process outlined in the policy. Protection of this released PHI is the investigator/staff responsibility.

BACKGROUND

The University at Buffalo (UB, university) recognizes recruitment is a major challenge in clinical research studies. Innovative **software tools that extracts information using natural language processing** from electronic health records (EHR) have been developed and are being widely used for scanning EHR to identify potential participants for research studies. One such tool is i2b2. The Institute of Healthcare Informatics is a core research facility at UB, which is a secure computing center — compliant with the Health Insurance Portability and Accountability Act (HIPAA) — that stores, aggregates and innovatively analyzes health care data. All UBMD practice plan patient data is currently stored at IHI. The IHI has developed the capability of using i2b2 to query this UBMD database for research purposes. This capability can now be assessed by all UB researchers and research staff.

APPLICABILITY

This policy applies to all researchers and research staff at UB who want to use the IHI UBMD patient database for clinical research purposes. This policy does not apply to queries for research purposes of UB affiliated institutions EHR databases, such as those at ECMC, Kaleida or Roswell Park.

RESPONSIBILITY

Institute of Healthcare Informatics

- Provide Investigators/Research Staff with appropriate UB credentials access to the IHI database for running queries.
- Train and assist these Investigators/Research Staff in running queries of the IHI database.
- When asked to query for recruitment, verify that the study has been IRB approved, and that the approval included the use of the IHI UBMD database as a recruitment tool.
- Provide Investigators/Research staff the list of potential participants identified by their queries in a HIPPA compliant manner on request.

Investigator / Research staff

- Apply for access the IHI database for running queries.
- Run feasibility queries on the IHI database as needed.
- Ensure their IRB application includes the use of IHI database for recruitment if so desired.
- Provide to IHI documentation of IRB approval of study and the use of IHI as a recruitment tool.
- Submit request to IHI for release of list of potential participants from their query by the IHI.
- Handle this data in a HIPPA compliant manner and ensure patients PHI is protected.
- If the investigator is not the treating physician for a potential participant, request permission from the treating physician using the attached template (appendix 1) in a HIPPA compliant manner.
- On obtaining permission from the treating physician, contact the potential participant using the procedure below and the attached templates (appendix 2 letter template, appendix 3 phone call template) in a HIPPA compliant manner.

PROCEDURE

- 1) Investigator/ Research Staff apply for IHI database access at IHireq@buffalo.edu
- 2) Upon receiving access, they can run feasibility queries for studies in the planning or preparatory phase.
- 3) If they want use the IHI database for recruitment, the investigator/staff include within the IRB submission details of how the IHI based recruitment will be conducted, as well as partial HIPPA waiver for such use. As the process has been pre-defined, templates for such submission are available through the Clinical research Facilitators.
- 4) Investigator/staff submit the request for the list of potential participants to IHI, along with the IRB approval.
- 5) IHI verifies the IRB approval and sends the list to the investigator/staff in a in a HIPPA compliant manner.
- 6) Investigator/staff examine the EHR of provided list of participants to further identify those that meet the inclusion and exclusion criteria of the study.

- 7) If the investigator is the treating physician (for the condition under study), this step can be skipped. If not, the investigator will ask that patient's treating physician (for the condition under study) if the treating physician has any objection to requesting the patient's participation in the research as a subject. This communication will use the template in Appendix 1 and will be done in a HIPPA compliant manner. The treating physician will have seven days from the receipt of the request to reply. If no reply is received at the end of the seven days, the researcher may contact the patient to request participation. If the treating physician objects to the recruitment of the patient into the study, the Investigator will ensure the patient is not contacted.
- 8) If the patient is not recruited while being seen during an appointment with a UBMD healthcare provider, the patient must be initially recruited by letter. The template for the letter (with all UBMD Practice Plans listed on the letterhead) is provided in Appendix 2. If the patient does not respond to the initial letter, the researcher may attempt to contact the patient by telephone one time with one follow up call if the patient does not respond. The template for the phone calls is in Appendix 3. If the patient expresses his or her desire to not be a research subject at any time, no follow-up is permitted.