Marshfield Clinic

IRB Review of Databases, Registries and Bio-banks

1. SCOPE

1.1. System-Wide

2. DEFINITIONS & EXPLANATIONS OF TERMS

2.1. **Database**:

- Collection of information elements (data) arranged for ease of use and speed of search and retrieval, maintained via paper record systems, or electronically. Examples of databases include:
  - ◊ Set of observations from a research study;
  - ◊ An electronic file of a medical provider's patients
  - ◊ A collection of diagnosis, treatment, or follow-up information from a group of patients;
  - ◊ A file of outcomes information compiled for quality assurance; and
  - ◊ A list of potential research subjects.

2.2. **Engaged in Research**:

- To intervene or interact with human subjects, or obtain individually identifiable private information about human subjects, for purposes of research.

2.3. **Generalizable Knowledge**:

- Investigations designed to develop or contribute to generalizable knowledge are those designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations outside the specific study population), to inform policy, or to provide general, applicable conclusions.

2.4. **Human Subject**:

- A living individual about whom an investigator conducting research obtains: 1) data through intervention or interaction with the individual, or 2) identifiable private information.

2.5. **Registry**:

- A collection of information elements whose organizers:
  - ◊ Receive the information from multiple sources;
  - ◊ Maintain the information over time; and
  - ◊ Control access to, and use of, the information by multiple individuals, and for multiple purposes.

2.6. **Bio-Bank**:

- A collection of biological specimens or human tissue materials whose organizers:
  - ◊ Receive the specimens a single source, or multiple sources;

◊ Maintain the specimens over time; and

◊ Control access to, and use of, the information for research purposes.

2.7. **Research**:

- A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

2.8. **Systematic Investigation**:

- An activity that involves a plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a question.

3. RESOURCE GUIDE BODY

Databases, registries, and bio-banks are used to store data and/or biological specimens over time. They may be created for research, for clinical or quality improvement purposes, or for multiple purposes, and they can be valuable resources to researchers. However, any data or specimen collection effort comes with ethical concerns for the protection of the privacy of individuals and the confidentiality of the data and specimens. The establishment of, and research use of, research databases, registries, and bio-banks is governed by human subjects protection regulations and the HIPAA Privacy Rule. The use or disclosure of individually identifiable data or human specimens for research requires IRB review, approval, and oversight, but the specific requirements depend on how and why the data or specimens are collected, stored, used, and shared.

3.1. Federal Guidance

a. Guidance regarding databases and registries comes from the August 14, 2002 preamble to modifications of the final HIPAA Privacy Rule, and a 2004 guidance document of the Department of Health & Human Services (DHHS), "Research Repositories, Databases and the HIPAA Privacy Rule." The documents state that the creation of databases or data repositories, and the use or disclosure of PHI from them for research purposes, are research activities, and that an authorization or waiver of the authorization requirement is generally required for each. The guidance also affirms that the development of a data repository or database for future research is research as defined in 45 CFR 46, and is not considered review preparatory to research under the HIPAA Privacy Rule.

b. DHHS OHRP guidance entitled "Guidance on Research Involving Coded Private Information or Biological Specimens" (2008) clarifies that the act of obtaining identifiable information or specimens for research purposes constitutes human subjects research. This includes circumstances where private information or specimens will be collected in the future for purposes other than the currently proposed research, such as an ongoing collection of specimens for a bio-bank. However, the document discusses exemption criteria, further outlined below.

c. With regards to bio-banks, the DHHS document, "Research Repositories, Databases and the HIPAA Privacy Rule" states that while biological specimens are not, in and of themselves, individually identifiable health information, they are often labeled with individually identifiable information such as collection dates, which the HIPAA Privacy Rule considers PHI. A covered entity's use or disclosure of such information along with specimens for research purposes is subject to the HIPAA Privacy Rule.

3.2. Assessing Purpose of Databases, Registries, and Bio-Banks

a. Requirements relating to databases, registries, or bio-banks vary depending on the intent and use of them. In order to assess whether efforts to collect data or specimens require IRB review, the purpose of the collection effort must first be determined.

b. Databases, Registries, and Bio-Banks for Research

- If the purpose of establishing or maintaining a database, registry, or bio-bank is to conduct research, then IRB review of the proposed collection effort needs to take place prior to establishment. Any addition of data elements to the database or registry, or any change to, or addition of, biological specimens in a bio-bank, must be reviewed by the IRB as amendments prior to their initiation. Informed consent and HIPAA authorizations must also be obtained from participants, unless the IRB waives those requirements.
- Individual research projects to be conducted with the data or samples from the collection must have separate IRB review and approval prior to initiation.

c. Non-Research Databases, Registries, and Bio-Banks

- If the purpose of establishing or maintaining a database, registry, or bio-bank is a non-research purpose, such as to make clinical, quality improvement and process, or operational decisions, then no IRB review is necessary.
  - Examples of non-research databases would be those for treatment or payment purposes, disease-specific registries mandated for public health purposes, or outcomes data that a physician maintains on his or her own surgical cases.

d. Clinical Operations Primary, Research Secondary

- There are instances when a database, registry, or bio-bank is established primarily for clinical or operational purposes, without a research project in mind, but with the intent to conduct research if the opportunity presents itself. In these cases, the database, repository, or bio-bank is subject to IRB review at its establishment. Informed consent and HIPAA authorization must also be obtained, or the requirements waived by the IRB. If the data or specimens are needed foremost for clinical purposes, a waiver of informed consent and authorization may be justified.
- If the database, registry, or bio-bank is used to conduct research, each individual research project must also receive IRB review and approval, or verification of exemption, prior to initiation. The requirements for informed consent and HIPAA authorization must also be considered by the IRB for each project, but in many cases, a waiver can be justified if the requirement for informed consent and authorization were waived at the establishment of the database, registry, or bio-bank.

e. Research Intent after Establishment

- If a database, registry, or bio-bank was established for non-research purposes, and there was no initial intent for the data or specimens to be used for research, but later, an individual wishes to utilize the data or specimens to conduct research or answer a research question, the individual must obtain IRB approval or verification of exemption prior to using the data or specimens. An IRB Application – New Research must be submitted. The need for informed consent and HIPAA Authorization will be considered by the IRB for each project.

f. Marshfield Clinic Contribution to a National or International Data or Specimen Collection Effort

- Local IRB review is required when the purpose of Marshfield Clinic's involvement in a national or international data or specimen collection effort is to contribute clinical patient data or materials, or research subject data or materials, to a research project.
- IRB review is not necessary when Marshfield Clinic's involvement is for purposes of quality improvement, organizational and practice comparisons, administrative planning, or developing clinical guidelines.
- If the data or specimens in a national or international database, registry, or bio-bank is utilized by individuals not on staff at Marshfield Clinic for research purposes, IRB review should be conducted at that individual's site, but will not be required by MCRF IRB unless a Marshfield Clinic researcher is also involved in the research effort, such as being involved in the interpretation or analysis of data or a co-author of a publication.

g. Investigator Transferring Data or Specimens to Marshfield Clinic

- Investigators coming to Marshfield Clinic with data and/or specimens collected and maintained as a research database, registry, or bio-bank at his or her other institution must contact the Office of Research Integrity & Protections (ORIP) to determine whether IRB approval is required to transfer the data or material to Marshfield Clinic.

3.3. Exemption from IRB Review

a. Although rare, a data or specimen collection effort meeting the definition of research may be exempt from IRB review. To be exempt, criteria noted in the federal regulations must be met, and an IRB Exemption Request must be filed with the IRB office. See the document, "Exempt Projects, Review of" for reference.

b. ORIP must verify the exemption status.

3.4. Informed Consent and HIPAA Authorization

a. If the data or specimen collection effort requires IRB review, informed consent must be sought and documented, or the requirement to do so must be waived by the IRB. If the database, registry, or bio-bank requires IRB review and involves the use or disclosure of protected health information (PHI), authorization must also be obtained from subjects, or the requirement must be waived by the IRB.

b. The necessity of informed consent and authorization must be considered, both at the time of initial IRB approval of a database/data repository, as well as for each project initiated using the collected data or specimens.

4. ADDITIONAL RESOURCES

4.1. IRB Forms for submission: (located in the Policy Handbook Library [FORMS])

- IRB Application – New Research (appendix creation of a Research Bio Bank, Creation of a Research Database)

4.2. References

- Exempt Projects, Review of
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5. DOCUMENT HISTORY

Version No.	Revision Description
1.0	New Document in Document Control system transferred from Policy & Handbook Library - #780.7 (no changes made)
2.0	Add Hyperlinks to IRB form and other applicable polices referenced in this document.

6. DOCUMENT PROPERTIES

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