Marshfield Clinic

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Policy Title: Ownership, Management, and Sharing of Research Data and Materials

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1. SCOPE

1.1. System Wide

2. DEFINITIONS & EXPLANATIONS OF TERMS

2.1. Institutional Officials

- For purposes of this document, the Director of Medical Research and the MCRF Deputy Director.

2.2. Protected Health Information (PHI)

- Individually identifiable health information transmitted or maintained in electronic media, or other form or medium.
  - ◊ Individually identifiable information is health information that includes demographic information collected from a person, and
    - For purposes of this policy, is created or received by Marshfield Clinic or Security Health Plan; and
    - Relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual; and

      That identifies the individual; or

      There is a reasonable basis to believe the information can be used to identify the individual.

2.3. Research

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

2.4. Research data and materials

- For purposes of this document, includes all of the following:
  - ◊ Data recorded for research purposes, regardless of their form or the media on which they may be recorded, and are commonly accepted in the scientific community as necessary to reconstruct and evaluate research findings. Such research data may be observational, experimental, or computational, and may be raw, preliminary, or final. Data includes, but is not limited to, technical data, digitally recorded data, laboratory worksheets and instruments, memoranda, interpretations and analysis, printouts, tables, charts, slides, surveys, statistics, samples, photographs, computer files, notes resulting from observation and field activities. For clinical investigations, data also includes case history records and the study protocol.
  - ◊ Materials, which are tangible research products or items, including compositions, biologics, materials, specimens, samples, prototypes, devices, synthetic compounds, organisms, cell lines, viruses, cell products, illustrations and drawings, and equipment.

2.5. Sponsor

- The organization or entity funding a grant or contract under which research is conducted.

3. POLICY BODY

All individuals engaged in research at Marshfield Clinic have responsibilities with respect to research data and materials. Maintaining proper ownership, management, and sharing of research data and materials serves to uphold the scientific integrity of research, protects the privacy and confidentiality rights of research participants, ensures compliance with laws, regulations, and contractual agreements with sponsors or government entities, makes the resources available for future collaborative research and review, and protects intellectual property rights.

3.1. Federal Guidance

a. Health Insurance Portability and Accountability Act of 1996 (HIPAA)

- The Privacy Rule, specifically at 45 CFR 164.530, requires Marshfield Clinic, a covered entity, to retain documentation required by the Privacy Rule for six years from the date of its creation, or the date when it was last in effect, whichever is later. This includes all Authorizations, accountings for disclosures of PHI, data use agreements, and all other required documentation.
- The Privacy Rule also has implications for access and transfer of research data and materials, set forth in the institutional documents, "Use and Disclosure of Protected Health Information in Research" and "Sharing and Transferring Research Data and Materials."

b. National Institutes of Health (NIH)

- NIH Guidelines for Research Involving Recombinant DNA Molecules set forth requirements for safe handling, usage, and containment of recombinant DNA materials.
- NIH encourages the timely release and sharing of results from NIH-supported research. It has published guidelines for obtaining and disseminating research data for NIH, including Final NIH Statement on Sharing Research Data (February 2003).

c. National Science Foundation (NSF)

- In Important Notice 106 (1989), NSF encourages open sharing of primary data, samples, and physical collections, or other supporting data and materials, created or gathered in the course of research.

d. The Office of Management and Budget

- Circular A-110 states that financial records, supporting documents, statistical records, and all other records pertinent to an award shall be retained for three years.

e. Department of Health and Human Services, Public Health Service (PHS)

- According to the Final Rule on Public Health Service Policies on Research Misconduct (June 2005), institutions must keep copies of all records that may be relevant to allegations of research misconduct, including research data (see 42 CFR 93.317(c)). Investigations into research misconduct allegations

are normally limited to that which allegedly occurred within six years before the allegation was made, with few exceptions (see 42 CFR 93.105).

3.2. Ownership of Research Data and Materials

a. Marshfield Clinic owns all research data and materials collected, generated, or produced as part of research conducted at Marshfield Clinic, or by its employees in the scope of their employment. Its ownership rights stem from its responsibility to produce research data and materials to federal funding agencies for certain purposes, including to support scientific findings, and during research misconduct investigations. Marshfield Clinic may elect not to claim ownership rights only by way of a term or condition of an award, through an authorized agreement, or by law or regulation.

3.3. Stewardship

a. Marshfield Clinic Principal Investigators ("PIs") are designated as the primary stewards of all research data and materials. For each study, the PI is responsible for ensuring that all data and materials are appropriately collected, recorded, stored, and retained in proper form. PIs must also ensure that the data and materials can be accessed for review and possible reuse, and that only authorized persons or entities have access, or receive the data and/or materials via sharing or transfer. PI responsibilities are discussed in further detail below.

b. Stewardship duties over financial, administrative, or regulatory data relating to research activities are designated to the appropriate departments or offices within Marshfield Clinic, including within the Marshfield Clinic Research Foundation (MCRF). Such data are collected, recorded, stored, and retained at the departmental or office level.

3.4. Collection and Recording

a. A PI is the person primarily responsible for proper collection and recording of research data and materials in a study. PIs, and when appropriate, study management, must know and understand the industry and regulatory standards for proper collection and recording. They are obligated to discuss the standards with the research team to ensure that each member complies with them.

b. Data and materials should be collected and recorded in forms that are readily interpretable by qualified practitioners in the field.

3.5. Storage

a. A PI is the person primarily responsible for proper storage of research data and materials. PIs, and when appropriate, study management, must know and understand the industry and regulatory standards for proper storage, and discuss the standards with the research team to ensure that each member complies with them.

b. In most circumstances, research data and materials will be securely stored in the center or office in which they were collected, generated, and/or recorded.

c. Investigators may have to consult a MCRF regulatory body, including the MCRF Institutional Review Board (IRB) or Biosafety Committee, to determine the degree of security required for storage of research data and materials. Storage methods should safeguard against not only deliberate tampering, damage, or unauthorized access, but also system failures, natural disasters, and other accidents that could occur. Investigators should consult National Cancer

Institute's *Best Practices for Biospecimen Resources*, as well as the institutional document, "Privacy and Security in Genetic Research," which sets forth the security standards for genetic data and materials.

d. PIs are responsible for knowing and adhering to any storage requirements set forth in an applicable agreement with a sponsor of the research.

3.6. Retention

a. All research data and materials collected, generated, and/or recorded as part of research conducted at Marshfield Clinic, or by its employees, must be retained for a minimum period of SIX (6) years after the submission of the final research report, or the publication of research results, whichever is later. Longer periods of retention may be required in the following circumstances:

- If an agreement with a sponsor or collaborator specifies a longer retention period;
- If the data must be kept longer to protect any intellectual property resulting from the work, for instance, at least through the life of a patent;
- When data or materials are linked to litigation, inquiries, or investigations, such as regarding allegations of scientific misconduct or conflict of interest, they should be retained until charges are fully resolved; and
- If the researcher believes the data and materials should be retained for a longer period because of a reasonable need to refer to them in the future.

b. If the research involves the use or disclosure of Protected Health Information (PHI), the PI must retain the Authorizations allowing for the use or disclosure of PHI for SIX (6) years beyond the expiration date of the Authorizations. See the institutional document, "Use or Disclosure of PHI In Research."

c. A PI is the person primarily responsible for proper retention of research data and materials. PIs, and when appropriate, study management, must know and understand the industry and regulatory standards for proper retention, and discuss the standards with the research team to ensure that each member complies with them.

d. When the qualities of the research data or materials prohibits retention for the requisite period, such as biological materials not capable of being stored for a long period, the PI must ensure that the characteristics of the data or materials are documented, and the reasons for non-retention or destruction are fully stated in the research record.

e. In most circumstances, research data and materials are to be retained by the center or office in which they were collected, generated, and/or recorded.

f. After the required retention period has passed, the destruction of research data and materials is at the discretion of the PI, subject to permission of sponsor(s) or collaborator(s), if required, and the appropriate Marshfield Clinic center or office retaining the research data and materials.

3.7. Access

a. During research, internal use of research data or materials by staff members is subject to the reasonable control of the PI.

b. The PI is responsible for ensuring that research data and materials can be accessed in the future. Institutional officials or bodies, and representatives of

sponsors, government officials, and regulatory agencies may require access. PIs may also be required to give institutional officials physical custody of data and materials under certain circumstances, such as when the scientific integrity of the research is in question.

3.8. Transfer and Sharing

a. The procedure, "Sharing and Transferring Research Data and Materials" is the primary document that outlines the steps for transferring and sharing research data and materials outside Marshfield Clinic, including when departing scientists wish to receive or view research data and/or material after their departure.

4. ADDITIONAL RESOURCES

4.1. References:

- *Data Sharing for Genome-Wide Association Studies (GWAS)*
- *Privacy and Security in Genetic Research*
- *Transferring and Sharing Research Data and Materials*
- *Use and Disclosure of Protected Health Information in Research*

4.2. Supporting documents available:

- *Request to Transfer Data or Materials*

5. DOCUMENT HISTORY

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.0	6/1/01: New Document