Marshfield Clinic

Sharing and Transfer of Research Data

1. SCOPE

1.1. System-wide: Marshfield Clinic Health System (MCHS), Inc. and its affiliated organizations who adopt this policy including Marshfield Clinic, Inc., Family Health Center of Marshfield, Inc., Security Health Plan of Wisconsin, Inc., Lakeview Medical Center, Inc. of Rice Lake, MCHS Hospitals, Inc., and all facilities owned and/or operated by the aforementioned organizations including all Marshfield Clinic locations, Lakeview Medical Center and Marshfield Clinic Regional Medical Center; MCIS, Inc. and Marshfield Food Safety, LLC.

2. DEFINITIONS & EXPLANATIONS OF TERMS

2.1. Aggregate Research Data

- Data expressed in summary form, and all units of analysis are above the level of individual research subjects and considered to be de-identified.

2.2. Coded Data Set

- A data set that is given a study code or study identification number (SID) to link individual subject records to the source data set. A data set that has no identifiers as defined in Section 2.7. Documents in electronic form are not considered to be coded data by default.

2.3. De-Identified Health Information

- Health information with identifiers removed

2.4. Honest Broker

- An intermediary (person or system) authorized by MCRF to collect and collate pertinent research data replacing identifiers with a code and releasing only coded MCHS information to internal or external third parties, and ensuring documentation of the release in the Accounting for Disclosures database.
- The Honest Broker shall have no responsibilities that directly and significantly affect the design, conduct or reporting of the research.

2.5. Human Subject

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

2.6. Identifiable Research Data / Protected Health Information

- The Privacy Rule protects all "individually identifiable health information" held or transmitted by a covered entity or its business associate, in any form or media, whether electronic, paper, or oral. The Privacy Rule calls this information Protected Health Information (PHI). "Individually identifiable health information" is information, including demographic data, that relates to:

- ◊ the individual's past, present or future physical or mental health or condition,
- ◊ the provision of health care to the individual, or
- ◊ the past, present, or future payment for the provision of health care to the individual,

and that identifies the individual or for which there is a reasonable basis to believe it can be used to identify the individual. Individually identifiable health information includes many common identifiers (e.g., name, address, birth date, Social Security Number).

2.7. Identifiers

- Eighteen (18) identifiers deemed by the HIPAA Privacy Rule to render protected health information (and other data) identifiable when used alone or in combination with other information. These identifiers are:
  - ◊ Names.
  - ◊ All geographic subdivisions smaller than a State (e.g., street address, city, county, precinct, zip code and their equivalent geocodes, except for the initial three digits of a zip code, if according to the currently available data from the Bureau of the Census, the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people. If such geographic units contain 20,000 people or less, then the initial three digits of the zip codes must be changed to 000 and thus treat them as a single geographic area.)
  - ◊ All elements of dates, except year, directly related to an individual including birth date, admission date, discharge date, date of death; and for all ages over 89, all elements of date including year indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
  - ◊ Telephone numbers.
  - ◊ Fax numbers.
  - ◊ Electronic-mail addresses.
  - ◊ Social security numbers.
  - ◊ Medical record numbers.
  - ◊ Health plan beneficiary numbers.
  - ◊ Account numbers.
  - ◊ Certificate/license numbers.
  - ◊ Vehicle identifiers and serial numbers, including license plate numbers.
  - ◊ Device identifiers and serial number
  - ◊ URL
  - ◊ IP address numbers
  - ◊ Biometric identifiers, including finger and voice prints

◊ Full face photographic images and any comparable images

◊ A unique identifying number, characteristic or code (Note: A code is not considered an identifier if it is not derived from or related to information about the individual and is not otherwise capable of being translated so as to identify the individual).

2.8. Limited Data Set

- Protected Health Information that excludes the following direct identifiers of the individual who is the subject of the Protected Health Information or a relative, employer or household member of the individual:

  ◊ Postal address information, other than town or city, state and zip code.

  ◊ Telephone numbers.

  ◊ Fax numbers.

  ◊ Electronic mail address.

  ◊ Social security numbers.

  ◊ Medical record numbers.

  ◊ Health plan beneficiary numbers.

  ◊ Account numbers.

  ◊ Certificate/license numbers.

  ◊ Vehicle identifiers and serial numbers (including license plate numbers).

  ◊ Device identifiers and serial numbers.

  ◊ Web Universal Resource Locators (URLs).

  ◊ Internet Protocol (IP) address numbers.

  ◊ Biometric identifiers (including finger and voice prints).

  ◊ Full face photographic images and any comparable images.

- A Limited Data Set may include zip codes, geo-codes, town, city or state, dates of birth, death or service , and any other identifying code or characteristic not specifically listed above (such as gender or race).

2.9. Research

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

2.10. Research Data

- For purposes of this document, Research Data includes the following: Data collected, generated and recorded for research purposes, regardless of form or media that are commonly accepted in the scientific community as necessary to validate 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 instrument readings, memoranda, interpretations and analysis, printouts, tables, charts, slides, surveys, statistics, samples,

photographs, computer files, and notes resulting from observation and field activities. For clinical investigations data also includes case records and the study protocol.

3. PROCEDURE BODY

Marshfield Clinic Health System (MCHS) owns all research data collected, generated, or produced as part of research conducted at MCHS, or by its employees in the scope of their employment. The exception is data generated in the conduct of a research protocol under contract. MCHS recognizes the value of sharing research data within the scientific community, which includes any non-MCHS third parties. MCHS strives to balance potential for scientific advancement with the obligation to protect the privacy and confidentiality of research subjects and to fulfill contracted agreements to sponsors and collaborators while remaining in compliance with applicable laws and regulations.

3.1. Data Transfer Agreement

a. A determination will be made whether a Data Transfer Agreement (DTA) is required to govern the sharing or transfer of the data to any non-MCHS external parties. Such agreements define the rights and responsibilities of MCHS and the recipient individual or institution. With the exceptions of sharing aggregate research data, or disclosure of research data to public health authorities for specific purposes (see HIPAA Privacy Rule45 CFR 164.512(b) (i)), an agreement is typically required.

- Marshfield Clinic Research Foundation (MCRF) Office of Research Integrity & Protections (ORIP) coordinates the development and review of DTAs. DTAs are crafted with focus on human subject protection, HIPAA Privacy and Security Rule requirements, safeguards for privacy and confidentiality of subjects, intellectual property issues, and attendant resource costs.
- Legal Services review is required if the standard MCRF DTA template is changed in any way.

3.2. De-identified Data

a. If de-identified data is required, the Principal Investigator (PI) will work with the honest broker who is responsible to: de-identify data sets to the extent required to meet IRB, MCHS policy, and HIPAA requirements; maintain the confidentiality and security of Study IDs, and links between Study ID and identifiers; ensure secure and compliant transfer of data; and document the disclosure in the Accounting for Disclosures database, see Section 3.8.b.

b. De-identified Research Data Sharing or Transfer

- No DTA is typically required for the sharing or transfer of aggregate data.
- All of the following conditions must be met:
  - The data must be de-identified; and
  - The data will be shared and/or transferred to: a non-profit institution, public or private academic institution, or government agency, for research or education purposes only; and

- The PI has approved the sharing and/or transfer. See Section 3.6 for IRB considerations when sharing and transferring research data.

 If any one or more of the above conditions are not met, the PI must submit a "Request to Transfer Research Data or Materials" Form (hereafter "Transfer Request Form") to ORIP. The PI may contact ORIP to discuss the required DTA. Data transfer approval by the PI, Center Administrator/Director and any assisting department is documented by signature on the Transfer Request Form.

- If the transfer agreement for data with indirect identifiers varies from the standard MCRF template, Legal Services must review and approve, per the MCRF Honest Broker policy.

3.3. Coded or Limited Data Set

a. DTAs are required for Coded or Limited Sets of research data. Although the purpose and recipient for Coded or Limited Set research data sharing/transfer may vary, the procedure remains the same.

b. The PI must submit the "Transfer Request Form" to ORIP. ORIP, in cooperation with Legal Services, and the MCRF Executive Director as needed, will coordinate the development of any necessary agreements. Data transfer approval by the PI, Center Administrator/Director and any assisting department is documented by signature on the Transfer Request Form.

 This applies to non-aggregate research data sharing and/or transfer to:

- Non-Profit Organizations;
- For-Profit Organizations;
- Public or Private Academic Institutions;
- Government Agencies For Research or Education Purposes;
- Corporations For Research, Education, or Other Purposes.

 If the transfer agreement for data with indirect identifiers varies from the standard MCRF template, Legal Services must review and approve, per the MCRF Honest Broker policy.

3.4. Identifiable Research Data / Protected Health Information

a. DTAs are required for sharing or transferring identifiable research data per written authorization, institutional policies, state laws and regulations.

b. The PI must submit the "Transfer Request Form" to ORIP. ORIP, in cooperation with Legal Services, and the MCRF Executive Director as needed, will coordinate the development of necessary agreements. Data transfer approval by the PI, Center Administrator/Director and any assisting department is documented by signature on the Transfer Request Form.

 This applies to identifiable research data sharing and/or transfer to:

- Non-Profit Organizations;
- For-Profit Organizations;
- Public or Private Academic Institutions;

- Government Agencies For Research or Education Purposes;
- Corporations For Research, Education, or Other Purposes.

c. Legal Services must approve the transfer of data with direct identifiers.

3.5. Unique Circumstances of Disclosure

a. Sharing Research Data with External Researchers Visiting MCHS

- Research staff who request that researchers not affiliated with MCHS be allowed to view research data, even while on site at Marshfield Clinic and supervised by MCHS staff, must contact ORIP before sharing occurs to discuss what agreement must be in place. Since law restricts disclosing medical records to even affiliated researchers, a collaborative agreement is typically required.
- If medical records need to be accessed by the visiting researcher, security requirements must be met. The research staff who requests that a visiting researcher be allowed to access medical records must complete an access request (CARS), which is available at the Self Service Help Desk.
- Health Information Management (HIM) can directly monitor the record access while it occurs, and if appropriate, tokens will be placed by HIM to restrict access to certain records.

b. Transfer of Research Data to Departing Researchers

- Researchers leaving MCHS may wish to have research data transferred to their new institutions or to themselves directly, in order to continue research. As MCHS owns the data, an agreement must be in place before the data transfer can occur.
  - The PI must submit a transfer request form to ORIP and verify that any grant or collaborative agreements allow for the transfer. Some agreements may require consent from a sponsor or collaborating institution, or may prohibit any transfer.
  - MCHS will retain the original research data whenever possible. Institutional Officials must approve any request to transfer original research data material elsewhere, and will only do so when it is not feasible for MCHS to retain the data. Institutional Officials will require a complete copy of transferred original data to be retained by the departing investigator's office or center, and may still require that MCHS be allowed access to the original data.

c. Transfer of Research Data for Independent Replication of Published Research

- Subject to the approval by the Institutional Officials, researchers who publish their research may assist other researchers interested in independent replication by providing certain requested raw research data.
  - Unless privacy or proprietary restrictions apply, research data will normally be made available after publication to requesting scientists. The requester must have a well-articulated justification for reexamining the raw data, and experience in the scientific specialty in question, or in examining closely related problems in the field. The data requested also

must directly underlie a scientific conclusion being questioned. Requesting scientists are responsible for all costs incurred.

d. Genetic Research Data

- Any sharing or transfer of MCHS genetic research data must adhere to the requirements in the institutional document, "Privacy and Security in Genetic Research." PMRP genetic and clinical data must be free of any identifiers.

3.6. IRB Considerations

a. Transfer of Data with Direct Identifiers

- The IRB must approve the transfer of data with direct identifiers as part of its review, considering the nature of the transfer, as well as the necessity of additional informed consent or validity of a previously- granted waiver of the informed consent requirement.

b. Transfer of Deidentified Data

- If the data were not collected for the currently proposed research through an interaction or intervention with living individuals, the data may be rendered unidentifiable, therefore no IRB approval of the transfer is needed. However, it is required to:
  - Document an agreement between MCHS and the proposed recipient prohibiting exchange of any identifiable data or key to the coded data.

3.7. Initiation, Maintenance and Function of Data Transfer Agreements

a. ORIP maintains all letter agreements and data transfer agreements as documentation of data transfer.

- Deidentified Data
  - If deidentified data is to be shared or transferred, a letter agreement between the investigator and external party is sufficient.
- Identifiable Data
  - If data with direct identifiers is to be shared or transferred, this will require a formal Data Transfer Agreement to be in place.
- All grant and contract requirements will be taken into consideration when determining how to document the transfer.
- Once ORIP determines that all regulatory requirements are met, and that any requested agreements are fully executed, ORIP will notify the PI that the transfer may occur.

3.8. Handlers of Research Data

a. No MCHS staff will transfer research data to any non-MCHS third parties before obtaining documentation that the transfer has been approved, and that any required agreement is in place.

- However, staff may prepare data sets while waiting for documentation of approval and that the required data transfer agreement is in place.

b. Any staff member preparing data for transmission must work with a MCRF honest broker. A MCRF honest broker will assist with the transfer of research data to any approved non-MCHS third parties, and document all disclosures of participant data whether identifiable, partially identifiable, or de-identified by entering it in the Accounting for Disclosures database.

4. ADDITIONAL RESOURCES

4.1. References:

- Data Sharing for Genome-Wide Association Studies (GWAS)
- Ownership, Management, and Sharing of Research Data and Materials
- Uses and Disclosures of Protected Health Information for Research

4.2. Supporting documents available:

- Privacy and Security in Genetic Research
- Request to Transfer Research Data or Materials
- Uses and Disclosures of De-Identified Health Information
- Uses and Disclosures of Protected Health Information for Research
- Uses and Disclosures of Protected Health Info for Which an Authorization or Opportunity to Agree or Object is Not Required

5. DOCUMENT HISTORY

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6. DOCUMENT PROPERTIES

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