PRIVACY AND CONFIDENTIALITY

Unit: Human Research Protections Program (HRPP), Office of Research

Applies to: Institutional Review Board Committees

PURPOSE:
The MCW Institutional Review Board (IRB) must review, evaluate and require that all reasonable measures be taken to protect the privacy of research subjects and the confidentiality of information relating to research subjects prior to granting IRB approval.

The MCW IRB also serves as the privacy board for MCW, Froedtert Health (FH), Versiti and Children's Wisconsin (CW). The MCW IRB is charged with review of human subject research submissions to ensure protection of the research subjects and prospective research subjects privacy and confidentiality of the research data in accordance with federal regulations and that the requirements of the HIPAA Privacy Rule are met.

DEFINITIONS:
Confidentiality: refers to the treatment that must be afforded to individually identifiable information about research subjects or potential research subjects. Confidential treatment of information in the context of research is required for all non-public information that has been disclosed by or about research subjects to researchers with the expectation that it will not be disclosed to others without permission.

Covered Entity: *Per MCW Corporate SOP: HIPAA Privacy Definitions (AD.HP.010*) a covered entity is a health plan, or a health care clearinghouse, or a health care provider who transmits any health information in electronic form in connection with a transaction covered by the provisions of the Privacy Regulation.

HIPAA: the acronym for the federal law called the Health Insurance Portability and Accountability Act. This federal law regulates, among other things, the disclosure of protected health information ("PHI") about patients treated by most health care providers and organizations in the United States ("Covered Entities"). In the context of human subject research, HIPAA establishes a federal standard for the manner in which the confidentiality of **PHI** will be maintained by Covered Entities and prescribes a process through which researchers can obtain **PHI** about patients who are sought by researchers to be research subjects or potential research subjects.

Individually Identifiable Information (health care): *Per MCW Corporate SOP: HIPAA Privacy Definitions (AD.HP.010*), this is information that is a subset of health information, including demographic information collected from an individual, and:

1. Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and
2. 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
    a. That identifies the individual; or
    b. With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

Privacy: an individual's right to be free from unauthorized or unreasonable intrusion into their private life and the right to control access to individually identifiable information about themselves.

Privacy Board: defined by the Department of Health and Human Services as “A review body that may be established to act upon requests for a waiver or an alteration of the Authorization requirement under the Privacy Rule for uses and disclosures of PHI for a particular research project3.8-.0034 Tw(themselves.)TjTb from an in14.5543 0 TD-.0001 Tc.gw[and disclosures

a. **Certificates of Confidentiality (COC)**: NIH funded researchers are automatically issued a COC through their award for research that is collecting or using identifiable, sensitive information. Other Department of Health and Human Services (HHS) agencies issue COCs to researchers they fund. Researchers not funded by HHS can continue to apply to NIH or the FDA as appropriate to request a COC for the research. The use of a COC allows the investigator to withhold the names of research subjects from all persons not connected with the performance of the research. Investigators who have a COC generally cannot be compelled to identify research subjects in any Federal, State, or local civil, criminal, administrative, or legislative proceedings.
b. **If a Certificate of Confidentiality (COC) is not available:** The research subject should be informed of the possibility of disclosure or a breach of confidentiality in the

d. Under a privacy certificate, researchers and research staff do not have to report child abuse unless the subject signs another consent form to allow child abuse reporting.

2. For research conducted with the Bureau of Prisons:
   a. A non-employee of the Bureau may receive records in a form not individually identifiable when advance adequate written assurance that the record will be used solely as a statistical research or reporting record is provided to the agency.
   b. Except as noted in the consent statement to the subject, the researcher must not provide research information that identif

MCW Corporate Policy: HIPAA Privacy Definitions (AD.HP.010)
MCW Corporate Policy: Business Purchases, Payments and Reimbursements (BF.PA.010)
MCW Corporate Policy: External Sharing and Privacy of Research Data (RS.GN.080)
MCW Corporate Policy: Ownership, Access and Integrity of Research Data (RS.GN.070)
MCW Corporate Policy: Research Involving Human Subjects and/or their Private Identifiable Information (RS.HS.010)
Office of Research SOP: Subject Payments for Research Participation
IRB Member SOP: Advertisements, Recruitment Methods and Compensation
MCW Informed Consent Templates

Effective Date:	07/01/2023
Version number:	4.0
Previous Version/date:	3.0; 04/28/2023

Resp TwmyoDr16e0TwmyoDr16e0TwmyoDr1iDβ6r-.0007 TP