Protection of Privacy Interest and Maintenance of Confidentiality of Data of Research Subjects Policy

Scope

Applies to personnel in the Mayo Clinic Human Research Protection Program and other entities/organizations for which the Mayo Clinic Institutional Review Board (IRB) is the Reviewing.

Purpose

To describe the measures used to ensure protection of privacy interests of participants in proposed research and to assess the maintenance of confidentiality of their data in research at Mayo Clinic and those entities for which Mayo Clinic is the Reviewing.

Policy

In order to approve research covered by Health and Human Services (HHS) regulation 45 CFR 46.111(a) (7), the Mayo Clinic Office for Human Research Protection - IRB will review a research project application to ensure adequate provisions exist to protect the privacy of subjects and to maintain the confidentiality of data during and following completion of a research project.

Mayo Clinic has specific policies in place to guard against release of private information without the subject's permission during and after research. The IRB requires any disclosure plans by the investigator to a third party, be described in the informed consent materials. Mayo Clinic investigators should refer to the policy Release of Human Subject Identifiers for Research Purposes for additional information.

When Mayo Clinic collects data from subjects who are in the European Economic Area (EEA), and the European Union (EU), General Data Protection Regulation (GDPR) may apply. Refer to Mayo Clinic's General Data Protection Regulation Compliance Policy.

Investigator Responsibilities

In the IRB application and, when applicable, the informed consent materials, the investigator describes plans to protect the private information subjects choose to disclose **throughout the research process**, including maintaining confidentiality of subject records after the study is completed. The investigator also discloses the existence of a Certificate of Confidentiality, when applicable.

IRB Responsibility

The IRB assesses privacy protections through review of the IRB application including the protocol, informed consent materials, and all relevant documentation submitted by the investigator.

Certificate of Confidentiality

A Certificate of Confidentiality (CoC) helps investigators protect the privacy of human research subjects enrolled in research in which identifiable, sensitive information is collected or used. The CoC policy and 42 U.S. Code §241(d) defines identifiable, sensitive information as information that is about an individual and that is gathered or used during the course of research and: a) through which an individual is identified; or b) for which there is at least a very small risk, that some combination of the information,

a request for the information, and other available data sources could be used to deduce the identity of an individual.

The IRB has the authority to require a CoC prior to initiation of the research.

Investigator Responsibilities

When research is covered by a CoC:

- Investigators must inform subjects (for example, in the consent document) of the protections and limitations of CoC:
    - For studies that were previously issued a Certificate, and subjects were notified of the protections provided by that Certificate, NIH does not expect subjects to be notified that the protections afforded by the Certificate have changed, although IRBs may determine whether it is appropriate to inform subjects.
    - If part of the study cohort was recruited prior to issuance of the Certificate, but are no longer actively participating in the study, NIH does not expect subjects consented prior to the change in authority, or prior to the issuance of a Certificate, to be notified that the protections afforded by the Certificate have changed, or that subjects who were previously consented to be re-contacted to be informed of the Certificate, although IRBs may determine whether it is appropriate to inform subjects.
- Investigators conducting NIH- supported research covered by a certificate of confidentiality must ensure that if identifiable, sensitive information is provided to other investigators or organizations, regardless of whether or not the research is federally funded, the other investigator or organization must comply with applicable requirements when research is covered by a certificate of confidentiality.

When research is covered by a CoC, researchers:

- May not disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- May not disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.
- May disclose information only when:
    - Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding.

    - Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;
    - Made with the consent of the individual to whom the information, document, or biospecimen pertains; or
    - Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human participants in research.

- National Institutes of Health (NIH) Funded Research
    - Per Section 2012 of the 21st Century Cures Act as implemented in the 2017 NIH Certificates of Confidentiality Policy, all ongoing or new research funded by the National Institutes of Health (NIH) as of December 13, 2016, that is collecting or using identifiable, sensitive information is automatically issued a CoC. Compliance requirements are outlined in the NIH Grants Policy Statement, which is a term and condition of all NIH awards.
- Other HHS Agencies (non-NIH)
    - Several non-NIH HHS agencies, including CDC, FDA, HRSA, and SAMHSA, issue Certificates of Confidentiality (CoCs). Investigators conducting research funded by one of these agencies or operating under the authority of the FDA, are advised to contact the Certificate Coordinators at the funding agency to determine how to obtain a CoC.
- Non-HHS Agencies and Non-Federal Funders
    - Investigators may request a CoC from the National Institutes of Health (NIH) for research funded by a non-HSS Federal Agency or research that is not federally funded. Issuance of a CoC is at the discretion of the NIH.

Additional information about the NIH policy for issuing CoCs, the purpose, scope and applicability, disclosure requirements, and responsibilities of CoC recipients is available at NIH Website: Certificates of Confidentiality.

Special considerations for studies sponsored by the Department of Defense (DoD)

- Data or information acquired by the DoD component under a pledge of confidentiality for exclusively statistical purposes must be used exclusively for statistical purposes and may not be disclosed in identifiable form for any other purpose, except with the informed consent of the respondent.
- All studies involving large scale genomic data collected on/from DoD-affiliated personnel will apply an DHHS Certificate of Confidentiality.

Policy Notes

N/A

Related Procedures

N/A

Related Documents

General Data Protection Regulation Compliance Policy

Release of Human Subject Identifiers for Research Policy

Definitions

Confidentiality: Confidentiality refers to the researcher's agreement with the subject about how the subject's identifiable private information will be handled, managed, and disseminated.

Privacy versus Confidentiality: Privacy is about people and their choice to share personal information. It is a right in health care and research. Confidentiality is about data. It is the investigator's obligation to protect subjects' information.

Private Information: Includes information about behavior that occurs in a setting in which an individual can reasonably expect that no observation or recording is taking place. It includes information, which has been provided for specific purposes by an individual, and the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable in order to be considered information to constitute research involving human subjects. This may include identifiable private information obtained from a primary subject about a third party.

References

NIH Website: Certificates of Confidentiality (CoC)

42 US Code 241

DoDI 3216.02

Owner

Michelle Daiss on behalf of the Office for Human Research Protections

Contact

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Revision History

Date	Synopsis of Change
12/27/2023	Per AAHRPP recommendation, added definitions and additional investigator responsibilities when research is covered by a CoC. Updated owner and contacts.
12/11/2020	Updated Owner and Contact. Updated NIH CoC policy and process information. Added General Data Protection Regulation information. Minor edits.
12/29/2017	Scheduled review. Moved content to the policy template.
01/14/2016	Scheduled Review.
03/14/2014	Scheduled Review
07/01/2012	Scheduled Review

01/03/2012	Scheduled Review
04/28/2010	Approval for need to establish document: Office of Human Research Protection

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Applicable Sites

Arizona Sites:
Arizona

Florida Sites:
Florida

Rochester Sites:
Kasson, Litchfield, Little Falls, Minneapolis, Northfield, Rochester, Superior

NW WI Region:
Barron, Bloomer, Chetek, Chippewa Falls, Eau Claire, Glenwood City, Menomonie, Mondovi, Osseo, Rice Lake

SE MN Region:
Adams, Albert Lea, Austin, Cannon Falls, Ellsworth, Faribault, Lake City, Lake Mills, New Richland, Owatonna, Plainview, Red Wing, Wells, Zumbrota

SW MN Region:
Belle Plaine, Fairmont, Janesville, Le Sueur, Mankato, Montgomery, New Prague, St. James, St. Peter, Waseca, Waterville

SW WI Region:
Arcadia, Caledonia, Holmen, La Crosse, Onalaska, Prairie du Chien, Sparta, Tomah

Reviewer(s):

Approver(s):

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