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 research for which the Mayo Clinic Institutional Review Board (IRB) is the IRB of Record.

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 IRB of Record.

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 researcher describes how he/she 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.

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

For studies in which informed consent is sought, investigators shall inform research participants of the protections and the limits to protections provided by a CoC.

- **National Institutes of Health (NIH) Funded Research**
  - Per Section 2012 of the [21st Century Cures Act](https://www.nih.gov) as implemented in the [2017 NIH Certificates of Confidentiality Policy](https://www.nih.gov), 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](https://www.nih.gov). 

Policy Notes

N/A

Related Procedures

N/A

Related Documents


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)](https://irb.mayo.edu/irb/print/DOCMAN-0000047851)

**Owner**

[Tammy S. Neseth, M.A.](mailto:Owner) on behalf of the Office for Human Research Protections

**Contact**

[Michelle K. Daiss](mailto:Contact) and [Heidi M. Hanf](mailto:Contact)

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<td>Scheduled review. Moved content to the policy template.</td>
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