



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

Content Applies To

Mayo Clinic Human Research Protection Program

Research for which the Mayo Clinic IRB is the IRB of Record

Purpose

The purpose of this policy is to describe 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.

Key Terms

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.

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.

Policy

In order to approve research covered by HHS regulation 45 CFR 46.111(a) (7), the Mayo Clinic Office for Human Research Protection - Institutional Review Board (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 consent documents. Mayo Clinic investigators should refer to the policy *Release of Human Subject Identifiers for Research Purposes* for additional information.

Investigator Responsibilities

In the IRB application and informed consent document, 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 document, and all relevant documentation submitted by the investigator.

Certificate of Confidentiality

A Certificate of Confidentiality helps investigators protect the privacy of human research subjects enrolled in biomedical, behavioral, or other forms of sensitive research. Investigators may voluntarily obtain Certificate of Confidentiality from the National Institutes of Health (NIH). The Certificate of Confidentiality prevents involuntary disclosure of research subject information by the investigator.

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

The following list includes, but is not limited to research topics that may require a Certificate of Confidentiality, i.e. information obtained from a research subject pertaining to:

- HIV status, AIDS related complications, or other sexually transmitted diseases (STDs);
- Sexual attitudes, preferences, or practices;
- Use of alcohol, drugs or other addictive products;
- Illegal conduct,
- Information potentially damaging to an individual's financial standing, employability, or reputation within the community, or with the potential to cause social stigmatization or discrimination;
- Psychological well-being or mental health;
- Genetic information.

To obtain a Certificate of Confidentiality, access [NIH Website: Certificates of Confidentiality](#).

Related Documents

[Release of Human Subject Identifiers for Research](#)

References

NIH Website: Certificates of Confidentiality (CoC) Kiosk
<http://grants.nih.gov/grants/policy/coc/>

Effective Date

January 14, 2016

Revision History

Date	Synopsis of Change
12/30/15	Scheduled Review.