IRB Policy 400 Privacy and Confidentiality of Human Research Information

Responsible Office: Office of Research Administration
Responsible Official: Executive Chair, Institutional Review Boards
Effective Date: 12/1/09
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Scope

This policy describes requirements related to protecting the privacy and confidentiality of human research data and applies to all investigators conducting human research, as well as to all authorized individuals who interact with participants and/or access participant records.

Policy Statement

Yale respects the rights of individuals to control access to their personal information and the need to protect the confidentiality of personal information obtained in the course of University research. The Institutional Review Board (IRB) will only approve research projects which indicate reasonable and appropriate plans to maintain the privacy and confidentiality of personal information accessed, created, used and/or maintained during the recruitment, screening, conduct and data analysis of human research, in accordance with this policy (45 CFR §46.111(7); 21 CFR §56.111 (7)).

Reason for the Policy

Public trust necessitates that researchers respect the privacy and confidentiality of information regarding current or prospective research participants. Privacy principles dictate that individuals have authority to restrict access to information about them. Similarly, individuals may only be willing to share information for research purposes with an understanding that the information will remain confidential. This policy and related procedures describe the privacy and confidentiality requirements for research access, creation, use and disclosure of identifiable private information so that research participants are adequately protected from a variety of potential harms, such as psychological distress, loss of insurance, loss of employment, or damage to social standing, that could occur as a result of an invasion of privacy or a breach of confidentiality.

Definitions

Confidential Data
Data which is collected and maintained in such a way that research participants may be identified but which will be protected from further release by the Principal Investigator and his/her study team in accordance with the IRB-approved protocol.

Confidentiality
The maintenance of information in keeping with the Principal Investigator’s agreement with the research participant regarding how the participant's involvement in research and their identifiable private information will be handled, managed, disseminated and protected from release or access by others. Confidentiality is part of the agreement between the researcher and the research participant, is described in the consent form, and is detailed during the consent process.

Certificate of Confidentiality (CoC)
Authorizations granted by agencies within the Department of Health and Human Services (DHHS) such as the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), or the National Institutes of Health (NIH) to withhold the names or other identifying characteristics of individuals participating in research from any person or authority not connected with the conduct of such research including any Federal, State or local civil, criminal, administrative, legislative, or other proceedings. This protection is afforded by the Public Health Service Act §301(d), 42
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Section 400.1 Privacy Requirements

The IRB will approve research that does not unreasonably invade the privacy of research participants. Research studies must comply with all relevant privacy regulations, (e.g., HIPAA, FERPA, etc.) Principal Investigators and the IRB must consider the necessity of accessing private information without participant consent and the IRB will permit such to occur only if the activity meets the criteria for a waiver of consent in IRB Policy 200, and, if applicable, waiver of authorization under HIPAA Policy 5032. Studies must be designed to gather only the minimum necessary information to accomplish the intended purpose of the use, disclosure, or request without the participants’ knowledge or consent in any phase of the research including recruitment and screening.

The Principal Investigator must describe in the protocol application the provisions that will be made to protect the privacy of the participants, including the setting(s) for recruitment and consent. If the study involves observation of or interaction with subjects in a normally private setting, justification for this must be included in the application.

In reviewing the protocol application, the IRB will consider whether the intrusion is justifiable, what information will be provided to the participant, (either beforehand or afterwards), and whether there are protocol design alternatives that would yield study results while minimizing intrusion.

Section 400.2 Confidentiality Requirements

The IRB will approve research protocols that adequately protect the confidentiality of research data commensurate with risks associated with disclosure, legal obligations related to confidentiality and the
confidentiality commitment made to research participants. Particular attention must be given to the need to collect sensitive information and whether or not the research could reasonably be conducted without such information.

Information collected in the course of research that necessitates confidentiality protection requires that the Principal Investigator implement security and confidentiality measures commensurate with the risk assessment. These must be approved by the IRB. The IRB requires the Principal Investigator to describe in the protocol how confidentiality of information obtained during the recruitment, screening and conduct of the research will be maintained. To determine the adequacy of confidentiality protections, the IRB will consider the nature, probability, and magnitude of harms that would be likely to result from an unauthorized release of a participant’s participation or their personal information. Acceptable measures taken to protect the confidentiality of the data obtained during a study are varied and depend on whether the data is identifiable, the sensitivity of the data, and the potential harm to the participant should the data mistakenly be released or lost.

Principal Investigators have an obligation to inform research participants whether or not their information will be held as confidential, as well as:

(a) which persons will know of their participation in research,
(b) how their data will be used,
(c) whether the data collected will be retained, and, if so, for what purpose, what period of time, or whether and when data will be de-identified and destroyed,
(d) who will have access to their data,
(e) what procedures will be put in place to ensure confidentiality and that unauthorized individuals will not have access to this information, and
(f) the limitations (if any) to these confidentiality procedures, such as inspection of medical records by the IRB or agents of the FDA and the industrial sponsor in studies involving investigational drugs and devices; or legal reporting requirements such as in the case of suspected child or elder abuse.

A special situation arises for video or taped data and photographs (when not used for transcription purposes) since these media provide additional potential means for participant identification. Investigators must secure participant consent explicitly mentioning these practices.

400.3 Limits to Confidentiality
When participants will be tested for reportable diseases, such as HIV or hepatitis, the consent form must clearly reflect limits to confidentiality (see also IRB Policy 200 Informed Consent and Guidance 100 GD7 Select State and Federal Laws and Regulations Applicable to Human Research). For example, a consent form for participants who are tested for HIV should state, “The requirements for reporting infectious disease to the Connecticut Department of Public Health includes positive HIV results. The report must include the subject’s name or a coded version of the name.”

Similarly, individuals who are mandated to report child or elder abuse must indicate in the consent that such information would be reported if warranted.

Certain study procedures may reveal information about a study participant that is unexpected for that particular individual but which would necessitate follow-up to mitigate risks to participants. Should this occur, Investigators must be prepared to act in this situation with sensitivity and discretion. When incidental findings appear in, for example, MRI, x-Ray or CT-scans, or blood tests or urinalysis, indicating their clinical significance should be further investigated, the investigator should notify the subject of such findings. (See IRB Policy 720 Findings with Possible Health and Safety Significance for Research Participants).

400.4 Unauthorized Release of Information
Investigators must inform the IRB immediately in the event of an unauthorized release or loss of participants’ private or confidential information. The Human Research Protection Program (HRPP) Compliance Manager will assist the research team in investigating the incident and determining whether a protocol violation or other non-compliance has occurred, whether a HIPAA or other regulatory violation has occurred, and will report findings to the IRB for further consideration if necessary.
Incidents of unauthorized access to or disclosure of protected health information are also subject to immediate reporting requirements to the HIPAA Privacy Office in accordance with University Policy 5005 Reporting Incidents Involving the Security or Privacy of Protected Health Information: Breach Notification

400.5 Additional Protection: The Certificate of Confidentiality

Any investigator engaged in research that will collect and/or retain personally identifiable sensitive information that has the potential to be sought under a judicial subpoena research (e.g., involving drug or alcohol abuse, genetic studies, or human cell repository specimens and data) must consider the targeted research population and determine whether a Certificate of Confidentiality (CoC) will further protect the data from being involuntarily disclosed for civil, criminal or other judicial proceedings. The IRB will require a Principal Investigator to apply for, or obtain, a CoC prior to approving the enrollment of participants into the research protocol when it believes that the data collected from research participants is of the sensitivity warranting additional protection.

Researchers must obtain a CoC promptly when an approved protocol indicates that a CoC will be used to enhance the confidentiality of subjects. Failure to obtain a CoC in a timely manner may result in the temporary suspension of enrollment. When a significant change in the research project is proposed after a CoC is issued, the Principal Investigator must obtain IRB approval for the change and inform the Certificate Coordinator of the Institute or agency issuing the CoC.

A CoC does not authorize researchers to refuse to disclose information about participants if authorized Department of Health and Human Service (DHHS) personnel request such information for an audit or program evaluation. Neither can researchers refuse to disclose such information if it is required to be disclosed by the Federal Food, Drug, and Cosmetic Act.

National Institutes of Health (NIH) documents stress that a CoC does not take the place of good data security procedures, which are essential to the protection of research participants’ participation and data. Researchers should take appropriate steps to safeguard research data and findings against access by unauthorized individuals.

Related Information.

HIPAA Policy 5032: Statement of Policy on Use and Disclosure of Protected Health Information for Research Purposes

University Policy 5005 Reporting Incidents Involving the Security or Privacy of Protected Health Information: Breach Notification
IRB Policy 200: Informed Consent for Research Involving Human Participants
IRB Policy 720: Findings with Possible Health and Safety Significance for Research Participants

400 PR 1: Protecting Participants’ Research Data

400 PR 2: Certificate of Confidentiality

400 GD 1: Use of Investigational Genetic Tests in Research

100 GD 7: Select State and Federal Laws and Regulations Applicable to Human Research

NIH Certificate of Confidentiality Instructions: http://www.yale.edu/hrpp/resources/docs/NIHCOCInstructions5-11-10.pdf

FDA Certificate of Confidentiality Instructions: http://www.yale.edu/hrpp/resources/docs/FDACOCINSTRUCTIONS5-12-10.pdf

Contacts
Roles and Responsibilities

**Human Investigation Committee (HIC)**
The HIC I, HIC II, HIC III and HIC IV serve as the four Institutional Review Boards or IRBs for biomedical human research conducted at Yale University.

**Human Subjects Committee (HSC)**
The HSC serves as the Institutional Review Board for social, behavioral, or education research at Yale University.

**Office of General Counsel**
Interprets human subjects protection regulations and assists in ensuring that agreements between Yale and parties external to the University, which involve human subjects, require the ethical conduct of human subject research.

Revision History
Original 9/18/09 revised 12/1/09; 10/31/12, 1/19/2013, 11Dec2017