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# Yale University Institutional Review Boards

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## IRB Policy 400 Privacy and Confidentiality of Human Research Information

Responsible Office	Office of Research Administration	Effective Date	12/1/09
Responsible Official	Institutional Review Board Director	Last Revision	9/18/09

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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.

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### Policy Statement

Yale respects the rights of individuals to control access to their personal information and the need protect the confidentiality of personal information obtained in the course of University research. The 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.

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### Reason for the Policy

Public trust necessitates that researchers respect the privacy and confidentiality of information regarding current or prospective research participants. Privacy principals 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, including psychological distress, loss of insurance, loss of employment, or damage to social standing, that could occur as the result of an invasion of privacy or a breach of confidentiality.

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### 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 investigator in accordance with the IRB-approved protocol.

#### Confidentiality

The maintenance of information in keeping with the 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 becomes part of the agreement between the researcher and the research participant, described in the consent form, and is detailed during the consent process.

## **Certificate of Confidentiality**

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 U.S.C. §241(d). It does not protect against voluntary disclosures by the researcher, and as such anticipated disclosures must be specified in the informed consent and HIPAA Research Authorization forms (RAFs). A researcher may not rely on the CoC to withhold data if the participant consents in writing to the disclosure.

## **Privacy**

An individual's right to control access to personal information about him or herself.

## **Private Information**

Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

## **Sensitive Information at Risk of Subpoena**

Any information which could be of interest to the court in civil, criminal or other judicial proceedings. Most commonly this includes the use of alcohol, illegal drugs or addictive products and illegal behavior. Other examples which may in some instances be of interest to the court include information regarding HIV, AIDS, and other STDs; sexual practices or preferences; the participant's psychological state or mental health; information that can be linked to a participant's financial standing, employability or reputation within the community or that might lead to social disgrace or prejudice; genetic information or identifiable biological samples and corresponding data that may be used to demonstrate predisposition to disease or disputes in paternity; or information regarding behavioral interventions.

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## **Policy Sections**

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### **400.1 Privacy Requirements**

The IRB will approve research that does not unreasonably invade the privacy of research participants. Investigators and the IRB must consider the necessity of accessing private information without participant consent and will only do so 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 minimize the amount of information which is gathered without the participants' knowledge or consent in any phase of the research including recruitment and screening.

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### **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 which necessitates confidentiality protection will require that the Investigator implement security and confidentiality measures commensurate with the risk assessment, and which must be approved by the IRB. The IRB requires the investigator to explain in the protocol how privacy and 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 privacy and 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

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.

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#### **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, such that their clinical significance should be further investigated, then the investigator should notify the subject of such findings. (See IRB Policy 720 Findings with Possible Health and Safety Significance for Research Participants).

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#### **400.4 Unauthorized Release of Information**

Investigators must inform the IRB immediately in the event of an unauthorized release or loss of subjects' private or confidential information. The IRB Compliance Manager will assist the research team in investigating the incident and determining whether a protocol violation or other non-compliance has occurred, and report findings to the IRB for further consideration if necessary.

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#### **400.5 Additional Protection: The Certificate of Confidentiality**

Any investigator engaged in research that will collect and/or retain personally identifiable sensitive information which 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 an 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 to warrant 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.

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### **Related Information.**

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

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

## Contacts

Subject	Contact	Phone
Unauthorized Release of Information	IRB Compliance Manager	203-785-4688
Certificate of Confidentiality in Biomedical Research	Human Investigation Committee	203.785.4688 ysmhic@yale.edu
Certificate of Confidentiality in Social and Behavioral Research	Human Subjects Committee	203.436.3650 human.subjects@yale.edu
Subpoenas	Office of the General Counsel	203-432-4949

## Roles and Responsibilities

### [Human Investigation Committee:](#)

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](#)

The HSC is responsible for the review and oversight of social and behavioral research involving human participants.

### **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