

Investigator Guidance Series

University of Utah Institutional Review Board

PRIVACY & CONFIDENTIALITY

Definitions

Privacy is defined as the quality or condition of being secluded from the presence or view of others. The state of being free from unsanctioned intrusion, e.g. a person's right to privacy. It is control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

Confidentiality is discretion in keeping secret information; the ethical principle or legal right that a physician or other health professional will hold secret all information relating to a patient, unless the patient gives consent permitting disclosure.

Description

When thinking about privacy and confidentiality in the research context, distinctions should be made between the two issues.

Privacy refers to persons and to their interest in controlling access of others to themselves. Privacy can be thought in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

Confidentiality is an extension of the concept of privacy, but it refers to the subject's understanding of (and agreement to) the ways that their identifiable information will be stored and shared. Identifiable information can include printed information, electronic data or media, or visual information (photographs, video records, etc.).

The bottom line: Privacy refers to **people**; Confidentiality refers to **data** about people.

The following are examples of descriptions used by researchers to inform the IRB about the precautions and procedures employed to address these issues:

Privacy Protections Example:

"Patients will be consented in a private room out of earshot of other patients in the office. They will have the opportunity to discuss the consent form in the private room with their family members if they so choose. The procedures will be done in a private clinical setting, and if at anytime the participant feels embarrassed or uncomfortable, they will have the option to withdraw from the study."

Confidentiality Protections Example:

"Only the Principal Investigator and appropriate members of the research staff as designated in the Protocol Summary will have access to participants' Protected Health Information (PHI). All PHI and study data will be maintained on a password-protected computer and a locked filing cabinet in a locked office."

Different levels of protection are appropriate for different studies; the researcher should assume the IRB will require the highest level of protection for the most vulnerable population included in the study.

Points to Consider:

- Does the research involve observation or intrusion in situations where the subjects have a reasonable expectation of privacy? Would reasonable people be offended by such an

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- intrusion? Can the research be redesigned to avoid the intrusion?
- If privacy is to be invaded, does the importance of the research objective justify the intrusion? What if anything, will the subject be told later?
 - If the investigators want to review existing records to select subjects for further study, whose permission should be sought for access to those records (the physician, the institution maintaining the records, the subjects)? How should the subjects be approached (through their physician, the medical records department, the institution)?
 - Will the investigator(s) be collecting sensitive information about individuals? If so, have they made adequate provisions for protecting the confidentiality of the data through coding, destruction of identifying information, limiting access to the data, or whatever methods that may be appropriate to the study? If the information obtained about subjects might interest law enforcement or other government agencies to the extent that they might demand personally identifiable information, can a grant of confidentiality be sought from a federal or state agency to protect the research data and the identity of the subjects from subpoena or other legal process?
 - *HIV Antibody Testing:* If the study involves HIV testing, investigators are cautioned that a discovery or diagnosis of HIV or AIDS in a patient must be reported to the State Health Department. A positive diagnosis may have serious legal and financial consequences for research subjects. Please see additional IRB guidance on this topic on the IRB website.
 - *Reportable Diseases:* Other reportable diseases include Hepatitis A, Syphilis, Tuberculosis, etc. If during the course of research procedures any reportable disease is discovered, participant privacy may be limited by state reporting laws.
 - *Genetic Testing:* Investigators must establish a method to secure information related to genetic testing in a highly secure and confidential manner, and communicate this method in a manner satisfactory to the IRB. Identifiable results cannot be disclosed to the subject or anyone else except in compliance with an approved protocol for contacting subjects and/or family members. If there is a potential risk to the patient's insurability or employability as a result of participation in the study, the consent document should disclose this. Please see additional IRB guidance on this topic on the IRB website.
 - *Tissue Banking/Registries:* In some of these studies, it is not clear what results the future testing on banked tissue or registered data will yield, so it is essential that participants be fully informed about their subsequent knowledge of research results. If identifiers are removed from the test results (data) or the banked specimens, it should be clear to participants that they will not be informed of future results because their data/specimens cannot be linked back to them. Please see additional IRB guidance on this topic on the IRB website.
 - Are the investigator's disclosures to subjects about confidentiality adequate? Should documentation of consent be waived in order to protect confidentiality?

See also: IRB Guidance on Certificates of Confidentiality, Genetic Testing, Tissue Banking, HIV Antibody Testing, etc.

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Points to Address

New Study Application:	<ol style="list-style-type: none">1. Section 6.5, Privacy Protections: Please describe what precautions will be used to ensure subject privacy is protected.2. Section 6.6, Confidentiality Precautions: Please describe what precautions will be used to maintain the confidentiality of identifiable information.
Protocol Summary:	<ol style="list-style-type: none">1. Administrative Responsibilities: Detailed descriptions of the measures taken to protect participant privacy and confidentiality should be included in this section.
Consent Document:	<ol style="list-style-type: none">1. Study Procedures: Please include descriptions in this section of the precautions that will be taken to ensure subject privacy while study procedures are being performed.2. Confidentiality: Describe the procedures used to maintain the confidentiality of the records and data pertaining to the participant, how the participant's confidentiality will be protected, and who may inspect the records. If a Certificate of Confidentiality has been acquired for this study, this should be stated in this section.

References & Links

*IRB Guidance on
Certificates of
Confidentiality*

<http://www.research.utah.edu/irb/guidelines/pdf/Certificates%20of%20Confidentiality%20A1108.pdf>

*IRB Consent Document
Template*

http://www.research.utah.edu/irb/forms/hipaa/word/biomed_consent-32.doc

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