

**PRIVACY AND CONFIDENTIALITY****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 research participant'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 methods used to protect privacy and confidentiality. Researchers will be asked to inform the IRB about the precautions and procedures employed to protect privacy and confidentiality with regard to his/her specific project. 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.

**Examples of Privacy Protections:**

- Interviewing participants about sensitive topics individually instead of in front of a group.
- Interviewing the participant in their home or a private office instead of a public place.
- Providing a private exam room for study procedures.
- De-identifying photos, audio tapes, or video tapes of the participant that will be made during the study.
- Allowing for anonymous submission of surveys and questionnaires.

**Examples of Confidentiality Protections:**

- Storing research data on password protected computers or in locked cabinets or offices.
- Limiting access to study data to only a few members of the study team.
- Using only encrypted systems for storing research data on laptops.
- De-identifying study data.
- Using a code number instead of the participant's real name on study data and blood/tissue samples.
- Destroying photos, audio tapes, or video tapes at the end of the study.

**Breaches of Confidentiality**

Investigators are responsible for the confidentiality of participant information collected during the course of a study, including how this information will be stored and shared. A breach of confidentiality is an unanticipated problem that must be reported to the IRB. Additional requirements apply if the breach involves Protected Health Information (PHI)

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covered under HIPAA regulations. For examples of data breaches and for a description of how to report breaches of confidentiality, please refer to the IRB website under Breaches of Confidentiality.

### Additional Considerations

- If the research involves observation or intrusion in situations where the participants have a reasonable expectation of privacy, investigators should examine the design of the research to determine whether the intrusion can be avoided or reduced.
- If the investigators want to review existing records to select subjects for further study, the investigator must follow the University of Illinois Urbana-Champaign recruitment guidelines and abide by any applicable HIPAA requirements. Please see additional IRB guidance on this topic on the IRB website.
- If investigators are collecting sensitive information about individuals, adequate provisions must be made for protecting the confidentiality of the data through methods that are appropriate to the study. For example, if the information obtained about subjects might interest law enforcement or other government agencies to the extent that they might demand personally identifiable information, the investigator may want to obtain a Certificate of Confidentiality to protect the research data and the identity of the participants, as applicable.
  - *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
  - *Reportable Diseases*: Other reportable diseases include Hepatitis A, Syphilis, Tuberculosis, etc. If during the course of research procedures any reportable disease is discovered, participant confidentiality 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.
  - *Tissue/Specimen Use and Repositories*: The IRB expects a detailed description of the privacy and confidentiality protections for research proposals that include tissue/specimen use be provided.

**For additional guidance on the above-mentioned topics please refer to the following:** Research Guidance Documents on Recruitment Methods, Certificates of Confidentiality, Genetic Research, and HIV Antibody Testing. Also, see the IRB Guidance on Tissue/Specimen Use and Repositories.

### Points to Address

#### New Study Application:

1. **Data Monitoring Page, Privacy Protections:** Please describe what precautions will be used to ensure subject privacy is protected.
2. **Data Monitoring Page, Confidentiality Precautions:** Please describe what precautions will be used to maintain the confidentiality of identifiable information.

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**Consent Document:**

1. **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.

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