

Privacy vs. Confidentiality: What is the Difference?



Privacy Applies to the Person

- The way potential participants are identified and contacted
- The setting that potential participants will interact with the researcher team and who is present during research procedures
- The methods used to collect information about participants
- The type of information being collected
- Access to the minimum amount of information necessary to conduct the research

Confidentiality Applies to the Data

- An extension of privacy
- Pertains to identifiable data
- An agreement about maintenance and who has access to identifiable data
- What procedures will be put in place to ensure that only authorized individuals will have access to the information, and
- Limitations (if any) to these confidentiality procedures
- In regards to HIPAA, protection of patients from inappropriate disclosures of Protected Health Information (PHI)

PRIVACY:

Are there adequate provisions to protect the privacy interests of participants?

Privacy refers to an individual's desire to control who has access to him/herself.

The federal regulations define 'private information' as "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 (e.g., a medical or education record)."

In developing strategies for the protection of participants' privacy, consideration should be given to:

- The methods used to identify and contact potential participants.
- The settings in which an individual will be interacting with an investigator. For example, persons may not want to be seen entering a place that might stigmatize them, such as a pregnancy counseling center that is clearly identified as such by signs on the front of the building.
- The appropriateness of all personnel present for research activities.
- The methods used to obtain information about participants.
- The nature of the requested information.
- Information that is obtained about individuals other than the "target participants," and whether such individuals meet the regulatory definition of "human participant" (e.g., a subject provides information about a family member for a survey).
- Privacy guidelines developed by relevant professional associations and scholarly disciplines (e.g., oral history, anthropology, psychology).
- How to access the minimum amount of information necessary to conduct the study.

THE PROTOCOL NARRATIVE ADDRESSES PRIVACY CONSIDERATIONS:

- **Section 3 (Procedures)** – "Describe how the **participant's privacy will be protected** during the research procedures. **Note: This is not the same as confidentiality**
- **Section 5B (Recruitment Procedures)** – "If active recruitment methods will be used (i.e., researchers will make direct contact with participants for the purpose of recruitment), explain how the individual's **privacy will be protected**. **Note: This is not the same as confidentiality**
- **See the Privacy and Confidentiality web page:** <http://www.research.uci.edu/ora/hrpp/privacyAndConfidentiality.htm>

CONFIDENTIALITY:

Are there adequate provisions to maintain the confidentiality of data?

Confidentiality refers to maintenance of the researcher's agreement with the participant about how the participant's identifiable private information will be handled, managed, and disseminated.

While the term 'Confidentiality' is not formally defined in the federal regulations, the regulations make it clear that investigators have an obligation to inform research participants:

- how their data will be used,
- who will have access to it,
- what procedures will be put in place to ensure that only authorized individuals will have access to the information, and
- the limitations (if any) to these confidentiality procedures

Researchers should give consideration to:

- Information obtained preparatory to research. For example, information collected from personal records to determine potential participants. Destroy information obtained about individuals who were not recruited or who refused research participation.
- Methods to shield participants' identity to adequately protect participant privacy (e.g., encryption of data file, Certificate of Confidentiality).
- Whether there is a long-range plan for protecting the confidentiality of research data, including a schedule for destruction of identifiers associated with the data.
- Whether the consent form and other information presented to potential participants adequately and clearly describe confidentiality risks.
- Whether the informed consent process and the informed consent document, and if applicable the HIPAA Research Authorization Form, clearly delineate who will have access to the subject's information and under what circumstances data may be shared (i.e., regulatory agencies, sponsors).

SECTION OF THE PROTOCOL NARRATIVE THAT DESCRIBES MEASURES OF CONFIDENTIALITY:

- **Section 12 addresses the Confidentiality of Research Data** - Researchers describe the methods to be used for collecting, recording, coding and maintaining data, as well as specify who will have access to the data and at what point the subject identifiable data will be de-identified or destroyed.

Certificate of Confidentiality (COC): A COC is issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure (a subpoena). It allows the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. COCs may be granted for studies collecting information that, if disclosed, could have adverse consequences for participants or damage their financial standing, employability, insurability, or reputation.

A COC may be appropriate when research includes sensitive information, such as; establishing a repository that includes genetic information, collecting information about unlawful drug use or other illegal behaviors, collecting information on the participants psychological well being, sexual practices, preferences or attitudes.

Additional Resources Regarding Privacy & Confidentiality:

- HRPP Policies and Procedures: <http://www.research.uci.edu/ora/hrpp/hrppPolicies.htm>
- NIH Certificates of Confidentiality Kiosk: <http://grants.nih.gov/grants/policy/coc/>
- DHHS / Criteria for IRB Approval: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.111>
- FDA/ Criteria for IRB Approval: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?fr=56.111>
- HRP Website: Data Security: <http://www.research.uci.edu/ora/hrpp/dataSecurity.htm#encryption>
- Jan-Feb 2008 HRP News Brief: Articles on Privacy vs. Confidentiality & Data Security: http://www.research.uci.edu/ora/hrpp/newsarchive/HRPP_NewsBrief_08JanFeb.pdf