

Privacy vs. Confidentiality What's the Difference?

The IRB is responsible for systematically evaluating proposed research for adequate provisions which protect the privacy interests of participants and to maintain the confidentiality of identifiable data. The federal regulations differentiate between privacy and confidentiality, and it is important to understand the difference to determine whether these regulatory criteria for approval of human subject research are appropriately met.

Privacy

Privacy refers to a person's desire to control the access of others to themselves. 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. Privacy concerns people, whereas confidentiality concerns data. The research proposal should outline strategies to protect privacy including how the investigator will access information from or about participants.

In developing strategies for the protection of subjects' 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.
- 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 complete the study.

Regulatory and Guidance References

- [45 CFR 46.111\(a\)\(7\)](#)
- [21 CFR 56.111\(a\)\(7\)](#)

Confidentiality

Confidentiality refers to the researcher's agreement with the participant about how the participant's identifiable private information will be handled, managed, and disseminated. The research proposal should outline strategies to maintain confidentiality of identifiable data, including controls on storage, handling, and sharing of data. When appropriate, certificates of confidentiality could be used to maintain the confidentiality of identifiable data (for more information on Certificates of Confidentiality, see ORI's "[Certificate of Confidentiality Summary Sheet](#)" in the online [IRB Survival Handbook](#) under topic *Confidentiality/Certificate of Confidentiality*:).

When the IRB evaluates research proposals for strategies for maintaining confidentiality, where appropriate, consideration will be given as to whether:

- Methods to shield participants' identity adequately protect participant privacy.
- There is a long-range plan for protecting the confidentiality of research data, including a schedule for destruction of identifiers associated with the data.
- The consent form and other information presented to potential research participants adequately and clearly describe confidentiality risks.
- The informed consent process and the informed consent document (and, if applicable, the HIPAA Authorization section), clearly delineate who will have access to the subject's information and under what circumstances data may be shared (i.e., with government agencies, sponsors).

Regulatory and Guidance References

- [45 CFR 46.111\(a\)\(7\)](#)
- [21 CFR 56.111\(a\)\(7\)](#)

*Organizations subject to the HIPAA Privacy Rule should comply with the provisions applicable to research.

Sections of this handout adapted from the Association for the Accreditation of Human Research Protections (AAHRPP)
Evaluation Instrument
Update based on OHRP Recent Compliance Oversight Determinations [2/4/09]

University of Kentucky
TG-4/11/18
CW-8/28/18

J:\Master Outreach Documents\Survival Handbook\D - Guidance-Policy-Educational\32-Privacy-vs-Confidentiality.doc