



IRB Toolbox

Privacy and Confidentiality in Human Subject Research

Inherent in the ethical principle of respect for persons is the need to consider the privacy of the human participants and the confidentiality requirements for the information collected about them. The federal regulations governing human subject research also require, when appropriate, that the research include adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. To adequately design your research to address these requirements it is important to understand the differences between the two.

Privacy refers to a person's interest in controlling the access of others to themselves and can include personal, cultural and physical resources or actions. Persons of different ethnic or cultural groups or even of different ages may have differing concepts of privacy. The description of the research submitted to the IRB should provide information on strategies to protect the privacy of participants when accessing information from or about them. When developing these strategies, the investigator should consider the following:

- How the investigator will identify and contact the participants
- Where interactions with the participants will take place and who will be present
- The methods used to obtain information about participants.
- The nature of the requested information
- How to access the minimum amount of information
- Whether information 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).

Confidentiality refers to how the participants' private information/data are handled, managed and disseminated. Information on how the investigator will control access to the data must be included in the IRB application and most importantly in the informed consent agreement. The participant is then able to consent to participate in the research with the full knowledge of these conditions.

When appropriate, certificates of confidentiality can be used to maintain the confidentiality of sensitive identifiable data. More information on certificates of confidentiality can be found on the IRB website at <http://compliance.vpr.okstate.edu/hsp/confidentiality-cert.htm>.

Confidentiality issues are not pertinent to all human subject research. In some studies, the consent agreement establishes that research participants neither seek nor want confidentiality (i.e., oral histories). In circumstances where a promise of confidentiality is not a part of an informed consent agreement, the IRB application must make clear to the IRB the nature of the consent agreement and why biographical anonymity and confidentiality of the are not sought.



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

- The 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, clearly state who will have access to the subject's information and under what circumstances

Please do not hesitate to contact the OSU IRB Manager at 405-744-5700 or dawnett.watkins@okstate.edu if you have questions.

References:

Privacy vs. Confidentiality, What's the Difference?, University of Kentucky Office of Research Integrity website <http://www.research.uky.edu/ori/ORIForms/32-Privacy-vs-Confidentiality.pdf>.

Sieber, J. E., Summary of Human Subjects Protection Issues Related to Large Sample Surveys, U.S. Dept. of Justice, NCJ

