



Guidance: Secondary Subjects (last updated June 17, 2011)

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Overview

Research activities often include procedures wherein the primary subject is asked by an investigator to provide potentially sensitive information, such as personal health and family history information, about family members or other social contacts. If the information provided about the family member or other social contact is private, individually identifiable information, that person becomes a secondary subject (a.k.a., third party subject).

Both the researchers and the IRB need to consider appropriate protections for secondary subjects as well as primary subjects. This guidance discusses those protections. These considerations apply to all three levels of IRB review, i.e., exemption, expedited review, and full committee review. Additional protections may be considered for vulnerable populations, such as those who are socially identifiable.

Privacy & Confidentiality

Investigators, in designing and proposing research projects, must consider how the research design might focus not only on the identified human subjects, but on other persons.

Investigators must develop appropriate plans for [data security](#) in order to minimize a breach of confidentiality or an invasion of privacy to both primary and secondary subjects from information disclosure. The specific measures used to protect the data should take into account the sensitivity of the information collected, the risks associated with a breach of confidentiality, and include additional protections for vulnerable populations, such as those who are socially identifiable.

The IRB/OHRPP will assess investigators' data security plans in order to ensure that potential risk to both primary and secondary subjects from information disclosure is minimized.

Informed Consent

Investigators may ask the IRB to waive the requirement to obtain informed consent from secondary subjects by providing a scientific and ethical justification to explain how the research meets the requirements of [45 CFR 46.116\(d\)](#), that:

- The research involves no greater than minimal risk to the secondary subjects;

- The waiver will not adversely affect the rights and welfare of the secondary subjects;
- The research would be impracticable without the waiver; and,
- If possible and appropriate, the secondary subjects will be informed of the study when it is over.

Important note: If research is FDA regulated, this guidance will probably not apply. Please contact the OHRPP Director or MIRB Administrator at (310) 825-5344.

References

National Human Research Protections Advisory Committee (NHRPAC), [Clarification of the Status of Third Parties When Referenced by Human Subjects in Research, April 2002.](#)

[Protection of Third Party Information in Research: Recommendations of the National Institutes of Health to the Office for Human Research Protections, December 7, 2001.](#)

Secretary's Advisory Committee On Genetic Testing (SACGT) [letter to the Assistant Secretary of Health, December 12, 2000.](#)

Secretary's Advisory Committee On Genetic Testing (SACGT) [letter to the Assistant Secretary of Health, March 4, 2002.](#)

[Letter from the Assistant Secretary of Health to OHRP, March 15, 2002.](#)