

**Policy Number: 27**

**Title: Third Party Subjects (a.k.a., Secondary Subjects)**

**Date of Last Revision: July 5, 2007**

## **I. Introduction**

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 third party subject (a.k.a., secondary subject).

IRB/OPRS review requires consideration of third party human subjects and what consent process may be appropriate for all persons who are determined to be human subjects. Protecting all subjects from a breach of confidentiality or an invasion of privacy, whether they are human subjects or third party subjects, is a key responsibility of investigators and the IRB. Investigators and the IRB/OPRS must ensure that potential risks to the primary and third party subjects are appropriately identified and minimized to the greatest extent possible.

These considerations apply to all three levels of IRB/OPRS review, i.e., exemption, expedited review, and full committee review.

## **II. Definitions**

- A. **Human subject** is defined by 45 CFR 46.102(f) as a living individual about whom an investigator (whether professional or student) conducting research obtains: (1) data through intervention or interaction with the individual, or (2) identifiable private information.
1. **Intervention** includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
  2. **Interaction** includes communication or interpersonal contact between investigator (or his/her research staff) and subject (or the subject's identifiable private information).
  3. **Private information** includes 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 (for example, a medical record). Private information must be ***individually identifiable*** in order for obtaining the information to constitute research involving human subjects.

- B. **Third party subject** is a person about whom researchers obtain personal, identifiable private information from a human subject but who themselves have no interaction with investigators or his/her agent. Persons about whom information is gathered through indirect means (e.g., chart review) are not third party subjects.
- C. **Secondary subject:** See “third party subject”.
- D. **Individually identifiable** means the identity of the subject is or may readily be ascertained by the investigator or associated with the information. Such information might include identifiers such as full name, address and other contact information, social security number, and identifiable photographic images, among others. However, information about familial or social relationships identified only by that association, i.e., spouse, father, mother, sister, friend, social contact, etc., should not usually be considered readily identifiable information.
- D. **Primary subject:** Person with whom the investigator or his/her agent interacts or intervenes, or from whom the investigator or his/her agent obtains identifiable private information.

### **III. Investigator Responsibilities**

- A. 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.
- B. 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 third party 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.
- C. For those components of the research that are not FDA-regulated,<sup>1</sup> investigators may ask the IRB to waive the requirement to obtain informed consent from third party subjects by providing a scientific and ethical justification to explain how the research meets the requirements of 45 CFR 46.116(d), that:

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<sup>1</sup> See [OPRS/IRB Policy 3: Human Subjects Research Determinations](#) for information about when research is FDA-regulated.

1. The research involves no greater than minimal risk to subjects;
2. The waiver will not adversely affect the rights and welfare of the subjects;
3. The research would be impracticable without the waiver; and,
4. If possible and appropriate, the subjects will be informed of the study when it is over.

#### **IV. IRB/OPRS Responsibilities**

- A. The IRB/OPRS, in considering and reviewing research projects and in conducting continuing review, must consider how the research design might focus not only on the identified human subjects, but on other persons.
- B. The IRB/OPRS must determine who is and is not a human subject.
- C. The IRB/OPRS will use the above definitions of “private information” and “individually identifiable” in determining who is and is not a human subject, regardless of whether the information might cause harm or affect rights and welfare.
- D. If the IRB/OPRS determines that a study involves third party subjects, the IRB/OPRS will take the following actions.
  1. The IRB/OPRS must assess investigators’ data security plans in order to ensure that potential risk to both primary and third party subjects from information disclosure is minimized.
  2. The IRB/OPRS must assess the potential risk of information disclosure to primary and third party subjects in order to determine the level of review required. Additional protections must be considered for vulnerable populations, such as those who are socially identifiable.
  3. The IRB/OPRS must determine the appropriate consent process, or waiver of consent, for persons determined to be third party subjects of the research.

#### **References:**

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

<http://www.hhs.gov/ohrp/nhrpac/documents/third.pdf>

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

[http://bioethics.od.nih.gov/nih\\_third\\_party\\_rec.html](http://bioethics.od.nih.gov/nih_third_party_rec.html)

Secretary's Advisory Committee On Genetic Testing (SACGT) letter to the Assistant Secretary of Health, December 12, 2000. <http://www4.od.nih.gov/oba/sacgt/gtsecondary.pdf>

Secretary's Advisory Committee On Genetic Testing (SACGT) letter to the Assistant Secretary of Health, March 4, 2002. [http://www4.od.nih.gov/oba/sacgt/3-4-02\\_secondary.pdf](http://www4.od.nih.gov/oba/sacgt/3-4-02_secondary.pdf)

Letter from the Assistant Secretary of Health to OHRP, March 15, 2002.  
[http://www4.od.nih.gov/oba/sacgt/3-15-02\\_secondary.pdf](http://www4.od.nih.gov/oba/sacgt/3-15-02_secondary.pdf)