

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH	Human Research Protection Program Policies & Procedures	
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Title: Informed Consent process	Date Effective 11-23-04	Supercedes P&P dated 9-16-04

Secondary Subjects

Researchers may sometimes seek to obtain *private information* from an individual about other persons. An example might be genetic studies in which the investigator wishes to collect information about the physical or mental health of family members. In this case the family members may be considered secondary research subjects and their consent may be required before the individual is asked to provide information about them that one would reasonably expect to be private. For example, when private information is obtained from a subject about another family member's physical or mental health, *and that person is identified*, the family member may be considered a secondary subject. On the other hand, if the family members' identities were not revealed they would not be considered research subjects.

Examples:

1. If a subject was asked, "*Does anyone in your family experience depression?*" private information *is not* being collected about any an identifiable individual and *the secondary subject would not be considered a human subject.*
2. If a subject was asked, "*Does your mother experience depression?*" private information about an identified individual *is* being collected and *the secondary subject (the mother) would be considered a human subject.*

After determining whether the secondary subject is a human subject, a decision must be made whether informed consent must be obtained from that person. If the information is identifiable and the research is more than minimal risk, written consent should be obtained from the secondary subject unless CHR grants a waiver of informed consent. See the *decision trees*: [Consent and Review Requirements for Research Involving Secondary Subjects](#) and [Waiver or Alteration of Informed Consent](#). The conditions under which CHR may grant a waiver of consent for minimal risk research are described above.

Note: These are provisional guidelines. OHRP has not yet issued formal guidance on consent requirements for secondary research subjects.