

In many instances, an individual's status as a human subject is clear: through interaction, intervention, or identifiable private information, the individual provides personal or contextual details about his or her own life for research purposes. But research participants might also make reference to the lives, circumstances, perceptions, or histories of others. When human subjects provide information about individuals who are not involved in the study at hand and with whom the research team has no interaction, we call these individuals *third parties*. References to third parties, or even the recording of third-party information in research records, does not automatically suggest that third parties must be regarded as research subjects. The IRB must make this determination and, in making it, should consider

- whether third-party information is private or sensitive  
*and*
- whether the third party can be identified through the research data

When third-party information is sensitive, and the associated risk cannot be mitigated by confidentiality procedures, it may be necessary to obtain informed consent from third parties. Researchers may request and IRBs may decide to grant a waiver of informed consent for third parties, provided that

- the research presents no more than minimal risk to subjects
- the waiver will not adversely affect third parties' rights and welfare
- the research could be practicably be conducted without the waiver  
*and*
- whenever applicable, subjects will be provided with additional pertinent information after their participation

IRBs may suggest strategies to mitigate the risks associated with collection of third-party information. For example, researchers might avoid collecting identifiable information about third parties, such as their names or relationships to primary subjects, or they might be able to record information in a manner that protects the third party's identity. If the data contain no identifiable private information, there are no third-party human subjects involved.

Given the ethics and privacy issues associated with third-party data collection, IRBs should consider the possibility that classifying a third party as a study subject may impact the primary subject's rights or welfare. In addition, HIPAA provisions may apply, which govern the access, use, and disclosure of protected health information.

Contact the IRB for more information about third parties in human subjects research.

*Posted: 10/2/2013*