Third Party Research

Summary/Purpose: Definition of third party research and determination of need for informed consent of third parties.

Definitions:

Third party research: Information provided by a human subject about someone else (i.e., a third party) who has no interaction with the researchers.

Human subject: When the information is private and the third party can be readily identified by the information, he/she is considered a human subject and must give informed consent to participate.

Private information: “…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 (45 CFR 46.102).”

Identifiable information: “…the identity of the subject is or may readily be ascertained by the investigator or associated with the information (45 CFR 46.102),” e.g., social security number, identifiable photographic images, etc. Familial or social relationships alone, i.e. mother, father, etc., are not considered identifiable information.

Procedure:

The IRB determines who is a human subject (and thus must give informed consent) by considering the following four factors (among others):

- The quantity of information collected about the third party;
- The nature of the information collected, including the sensitivity of the information and the possibility that it might harm the third party;
- The ability of investigators to record information on third parties in a manner that protects the identity of those parties; and
- The possibility that classification of a third party as a human subject may have an impact on the rights or welfare of the originally designated human subject, which obligates the IRB to protect the interests of both the original human subject and the third party.

*See also: Protection of Third Party Information in Research: Recommendations of the National Institutes of Health to the Office for Human Research Protections (http://www.nih.gov/sigs/bioethics/.nih_third_party_rec.html)