

## Clarification of the Status of Third Parties When Referenced by Human Subjects in Research

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The National Human Research Protections Advisory Committee (NHRPAC) agreed to the following statement clarifying the status of third parties as human subjects at the January 28-29, 2002 Committee meeting.

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These recommendations are meant to clarify issues specifically dealing with information provided by a human subject about someone else (i.e. a third party). They are not meant to address situations where information about a research subject is gathered through indirect means (e.g. chart review), as these situations are already covered in the existing regulation, Title 45 CFR, Part 46.

In regard to considering third parties in research, parties whose roles and interests must be considered include:

1. investigators or their agents,
2. human subjects who interact personally with investigators, and
3. third parties, about whom researchers obtain information from human subjects but who themselves have no interaction with investigators or their agents.

The determination of who is and is not a human subject rests with the IRB. The requirement of informed consent, or waiver of consent, pertains only to those deemed to be human subjects by IRBs.

In most instances, the identity of human subjects of research is clear. Whether through interaction, intervention, or identifiable private information, persons are human subjects when they provide personal or contextual information about their own lives, circumstances, perceptions, or histories even when they make reference to others.

Neither reference to a third party in a research design, nor the recording of information about a third party in research records suggests that a third party must be regarded as a research subject. Nevertheless, investigators, in designing and proposing research projects, and IRBs, in considering and reviewing research projects and in conducting continuing review, should consider how the research design might focus not only on the identified human subjects, but on other persons. In cases in which a research project's design requires the collection of information about third parties, the investigator and IRB should consider the following factors (among others) in considering whether the information is private and whether the third party is identifiable (and thus, by definition, a human subject):

- 1.the quantity of information collected about the third party;
2. the nature of the information collected, including the sensitivity of the information and the possibility that it might cause harm to the third party;
3. the ability of investigators to record information on third parties in a manner that protects the identity of those parties; and
4. 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; this requires the IRB to protect the interests of both the original human subject and the third party.