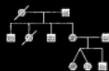




Protecting the Privacy of Family Members in Survey and Pedigree Research

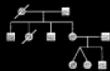
Jeffrey R. Botkin, MD, MPH
University of Utah

The Issues



- When do family members or social contacts of primary subjects become subjects themselves?
- If family members are “secondary subjects”, is informed consent necessary to retain their data?
- Relevant to all research in which data on family members or social contacts is acquired

Human subjects



• 45 CFR 46.102(f)

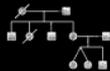
“Human subject means a living individual about whom an investigator ... obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. ... Private information must be individually identifiable (i.e., the identity of the subject is or may be readily ascertained by the investigator ...”

Human Subjects



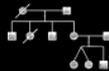
- An individual is a “human subject” for the purposes of federal regulations when:
 - The individual is *readily identifiable* to investigators
- AND**
- The information acquired constitutes *private information*

Human Subjects



- When are family members **NOT** *readily identifiable*?
 - Anonymous primary subject and no unique identifiers on family members
 - Family data is unlinked from identifiable source
 - Family members are identified by family relationship alone to an identifiable subject

Human Subjects



- When are family members *readily identifiable*?
 - When unique identifiers are obtained such as full names and addresses

Human Subjects



- Implications

- Detailed health information can be acquired on family members as long as the information is not linked with unique identifiers

Human Subjects



- What constitutes *private information*?

- Information over which individuals usually want and can maintain control
 - Health information
 - Reproductive history
 - Legal history
- Information available to casual social contacts is not private
 - Age
 - Employment
 - Family structure

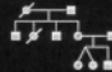
Human Subjects



- Implications

- Family members are **NOT** human subjects if they are identifiable but no private information is retained
- Family members **ARE** human subjects if unique identifiers **AND** private information are retained

Waiver of Consent



- Permitted under 45 CFR 46 if all criteria are met:
 - 1) research involves no more than minimal risk
 - 2) waiver would not adversely affect rights and welfare of the subject
 - 3) research could not be practicably carried out without waiver
 - 4) when appropriate, subjects can be provided with pertinent information after participation

Waiver of Consent



- Minimal risk definition

"Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in an of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

Waiver of Consent



- Does the recording of health information on secondary subjects pose more than minimal risk?
 - Factors in the *magnitude* of harm from a privacy breach
 - Existing health information versus new health information
 - **Highly sensitive** information versus sensitive information
 - Mental health conditions (some but not necessarily all)
 - Sexual orientation
 - Criminal records
 - Substance abuse

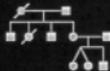
Waiver of Consent



- Does the recording of information on secondary subjects pose more than minimal risk?

- ⇒ Factors in the *probability* of a breach in privacy
 - Quality of data management protocols
 - Training and integrity of interviewers and data management personnel
 - Data security measures

Waiver of Consent



- Recording of existing health information on family members poses minimal risk if:

- ⇒ Health information is not highly sensitive
- ⇒ Careful protocols and strong data security measures are in place

Waiver of Consent



- Practicability of research without waiver

- ⇒ NOT: "Can *this* research project be carried out without a waiver?"
- ⇒ But: "Could *any* project pursuing the same research goals be conducted without a waiver?"
- ⇒ Investigators and funding agencies need to plan for appropriate support for consent when necessary

Conclusions



- I. Are family members human subjects?

- ⇒ Yes if:
 - Unique identifiers are association with individual data
- AND
- Information consists of health status, health history, etc.

Conclusions



- II. If family members are human subjects, can consent be waived?

- ⇒ Yes if:
 - Minimal risk
 - Not highly sensitive data
 - Strong data security
 - Rights and welfare not threatened
 - Not practicality without waiver
 - Information after study

Clarification



- ⇒ Analysis would require consent only from selected family members
- ⇒ Analysis is not relevant to taking a family history in clinical medicine
- ⇒ Some family history data is extremely sensitive, e.g., a history of child sexual abuse. Issues of consent from alleged perpetrators raise special concerns.

Additional Problems



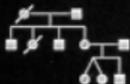
- Temporary retention of private information on subjects before consent is obtained
- When genetic status of family members can be ascertained indirectly from testing of family members
- Deletion of data when subjects decline participation

Additional Ethical Issues



- Can we ask family members to assume some responsibility for guarding the privacy of family members?

Research Strategies



- Development of careful protocols that anticipate privacy issues
- Broad surveys designed to identify a few "interesting families" may not need unique identifiers in the initial stages
- Broad surveys designed to create a database resource for research should avoid highly sensitive questions about secondary subjects whenever possible