

## APPENDIX M

### Obtaining Prospectively the Written Informed Consent of Family Members When Research Involves the Collection of Their Private Information

University of Pittsburgh IRB Guidelines (02/22/01)

The federal regulations governing human research subject protections define a “*human subject*” as “*a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.*” In accordance with this definition, the collection (e.g., in conjunction with obtaining a medical or pedigree history) of private information about family members of research subjects may require that the written informed consent of the family member be obtained prior to collecting this information.

Note that the federal regulations define “*private information*” as including “*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 (for example, medical record information)*”. Private information must be individually “*identifiable*” (i.e., “*the identity of the subject is or may readily be ascertained by the investigator or associated with the information*”) in order for obtaining the information to constitute research involving human subjects.

Written informed consent of the family members is not required if 1) the recorded information about family members is not of a private nature (e.g., readily observable traits such as baldness or obesity), or 2) the recorded private information is not linked to the specific identity of the family member or to identifiers (e.g., social security number, hospital record number) wherein the identity of the family member could be readily ascertained.

#### Guidelines:

1. If private information about family members of the research subject (i.e., the proband) will be recorded to include linkage with the family member’s name, social security number, hospital record number, address, or telephone number; written informed consent of the family member must be obtained prior to collecting and recording such information unless the IRB has granted a waiver of the requirement to obtain written informed consent of the family members for this research activity.
  - a. In order to obtain IRB approval of a waiver of the requirement to obtain informed consent of the family members for this research activity, the principal investigator must submit a request for such a waiver to the IRB (i.e., for full board review). In this waiver request the principal investigator

must address and justify each of the following regulatory criteria (45 CFR 46.116 (d)) for granting such a waiver:

- i. the research activity (i.e., the recording of identifiable private information) involves no more than minimal risk to the subject;

The primary risk associated with the recording of identifiable private information about family members would be potential harm associated with a breach of the confidentiality of this information. To address this risk, the principal investigator should describe the specific procedures that will be employed to protect the confidentiality of the recorded data. It is recommended that the recorded data be coded and personal identifiers removed. Information linking the data codes with the family members' identities should be stored separate from the recorded data. All research data and linkage information should be stored in a secure manner with access limited only to the study investigators. If the recorded family member information is especially sensitive in nature (e.g., information related to sexual attitudes, preferences or practices; the use of alcohol or illicit drugs; illegal activities; mental health conditions; or any other information wherein disclosure may lead to social stigmatization or discrimination) the principal investigator should consider obtaining a Federal Certificate of Confidentiality which is intended to protect the research records from subpoena by the courts.

- ii. the waiver of consent will not adversely affect the rights and welfare of the family members;

A major concern associated with the recording of identifiable private information about family members without obtaining their prior consent includes the possible invasion of the family members' privacy and the confidentiality of their private information. To address this criterion, the principal investigator should clearly delineate the specific information that will be requested about the family member and the relevance of obtaining this information to achieving the goals of the research study. It is important that the principal investigator certify that the scope of the family member information to be obtained will be limited to this specific relevant information. It is recommended that a script or text of the family member questions that will be posed to the proband be included with the waiver request.

Another issue that must be addressed in justifying this criterion is the right of family members to divulge private information about themselves to other family members with the expectation that such information will remain confidential within the family. Investigator-initiated questioning directed at obtaining identifiable, private information about family members without their prior consent may be considered an invasion of the family members'

privacy and the confidentiality of their private information. This also applies to information about a certain family member that other family members may have, but which has not been explicitly divulged by the involved family member.

Note that the issues to be addressed under this criterion (i.e., whether a waiver of consent will adversely affect the rights and welfare of the family members) are not the same as the level of risk addressed under the first criterion. The level of risk is related to the potential for a breach of confidentiality of the research data once such has been collected.

It is important to recognize that research studies are subject to different (stricter) regulatory oversight than clinical practice. That certain medical information about identified family members is routinely obtained without their consent in a clinical setting does not constitute an appropriate justification for a waiver of informed consent for the collection of such information as part of a research study.

- iii. the research could not practicably be carried out without the waiver;

The principal investigator must address why the research study, or this step in the conduct of the research study, requires the collection and recording of identifiable private information about the family members of the proband. A sound argument must be presented for why this research objective requires that the identity of the family members be linked with the recorded private information rather than recording such information in an anonymous manner or linked only to general relationship information (e.g., “mother”, “father”, “sister”, “brother”, etc.).

If the recording of identifiable private information about the family members is required, the principal investigator must clearly address why it is not possible to obtain the consent (written or verbal) of the family members prior to obtaining their identifiable private information. Note: principal investigators are advised against using time constraints or costs as a justification for not obtaining prospectively the consent of family members for the collection of their identifiable private information.

- iv. whenever appropriate, the family members will be provided with additional pertinent information after participation.

The principal investigator should clearly address at what stage in the research study identified family members of the proband will be contacted and their consent obtained for validation of their previously collected identifiable private information and their participation in other aspects of

the research study. (Note: the linkage of family member identities with private information obtained from the proband cannot be justified if there is no intention to contact the family members for validation of their identifiable private information and/or their participation in other aspects of the research study.) The principal investigator should also address whether any pertinent, new information obtained as a result of the research study will be conveyed to the identified family members following study completion.

2. If private information about family members of the research subject (i.e., the proband) will be recorded to include linkage with the general relationship of the family member to the research subject (e.g., “father”, “mother”, “brother”, “sister”, “grandmother”, “aunt”, etc.); obtaining written informed consent of the family member prior to collecting and recording such information is not required. However, the principal investigator of the research study must include written certification within the respective IRB research protocol submission that none of the involved study investigators will attempt to identify or contact specific family members based on the relationship information.
  - a. An exception to this policy exists where other requirements associated with the conduct of the research study result in the disclosure, to the investigators, of the specific identity of the related family member about whom the private information was obtained. E.g., questioning a child about private information concerning his/her parents wherein the required parental signatures on the child consent form would disclose the parents’ identities.
  - b. For parents of the proband, private information may be recorded to include linkage only with relationship information (i.e., “father”, “mother”).
  - c. For other family members of the proband, private information may be recorded to include linkage with relationship information (e.g., “brother”, “sister”) and either year of birth/birth order or initials.
3. If family members of the research subject (i.e., the proband) will be contacted to obtain consent for the collection of their identifiable private information (i.e., the private information is recorded to include linkage with the family member’s name, social security number, or hospital record number) or for their participation in other research activities, the research study should be first introduced to the family members by the research subject (i.e., the proband). With notification of the family member’s verbal or written permission obtained either from the proband or directly from the family member, the family member may be subsequently contacted by the study investigators.
  - a. Following contact with the family member, the recording of his/her

identifiable private information is subject to obtaining prospectively the written informed consent of the family member for the collection of such information. The recording of identifiable private information about the family member may proceed with verbal consent of the family member only if the IRB has granted a waiver of the requirement to obtain a written, signed consent form for this research activity.

(Note that a request for a waiver to document (i.e., to obtain a signed consent form) is different and involves different criteria than a request for a waiver of the consent process, in general.)

- b. In order to obtain IRB approval of a waiver of the requirement to obtain a written, signed consent form for the recording of identifiable private information about the contacted family member, the principal investigator must submit a request for such a waiver to the IRB. In this waiver request the investigator must address and justify the following regulatory criteria (45 CFR 46.117 (c) (2)) for granting such a waiver:
  - i. the research activity (i.e., the recording of identifiable private information) involves no more than minimal risk of harm to the family member; and See previous comments under item 1, waiver of consent criterion #1.
  - ii. the research activity (i.e., the recording of identifiable private information) involves no procedures for which written consent is required outside of the research context.
- c. It is possible that this latter criterion may be justified by relating the proposed research collection of family medical information to the routine practice of obtaining, without their prior consent, medical history information about identified family members for medical care purposes.
- d. The request for a waiver to document consent (i.e., obtain a signed consent form) should also include a script of the information that will be provided to the family members in obtaining their verbal consent for the collection and recording of their identifiable private information. This verbal consent process should include all of the basic and applicable, additional elements, of informed consent that would normally be required with a written signed consent form. In addition, the waiver request should address the mechanism that will be used by the investigators to document that verbal consent of the family member has, in fact, been obtained.