INSTRUCTIONS AND GUIDELINES FOR PREPARATION OF PROTOCOLS FOR SOCIAL AND BEHAVIORAL RESEARCH INVOLVING HUMAN SUBJECTS

This document is intended to be a concrete set of instructions for preparing protocols for submission to the Social and Behavioral Sciences Committee of the University of Miami's Institutional Review Board (IRB). As a "how-to" document, it includes specific warnings about how a number of issues should be dealt with in preparing protocols. The IRB members will assume you have attended carefully to those issues in preparing your protocol. This "how-to" description, however, does not substitute for an understanding of the principles involved. In addition to this document, you should refer to the **Policies and Procedures for the Protection of Human Subjects in Research** when preparing your protocol submission.

I. General Information

A. Completeness of Project Description

The University of Miami's IRB does not review projects for which the researcher provides only an "in principle" description with the intent of establishing actual procedures later on. It is expected that every protocol submitted contains sufficient detail to permit an evaluation as to whether the rights of participants are being safeguarded. If the researcher later decides to change the procedure, this may be done either by submitting a new protocol or by submitting an amendment form requesting changes in the original protocol.

B. Deadlines

The Social and Behavioral Sciences Committee typically meets on the first and third Thursdays of each month at 3:00 p.m. on the Coral Gables campus. However, the material dealt with by the committee must be processed (at the Medical Campus) prior to that meeting. Please contact the Human Subjects Office to obtain a list of the submission deadline dates. Failure to meet that deadline will cause the protocol to be deferred until the following meeting. Note that this provision applies to all proposed research, including grant proposals.

C. Where to Submit

We are now accepting new protocol submissions only through the e-prost system. Please visit our website at hsro.med.miami.edu and request an account to enter the e-prost system. Please refer to the eProst: User Guide for Investigators under the e-Prost link in Investigator's Resources for guidance in using the system.

If you are sending your submission by Interoffice Mail, direct it to "Human Subjects Research Office (SBSC), Locator Code M-809, Medical Campus." If you are mailing it through the U.S. Mail, send it to "Human Subjects Research Office (SBSC), P.O. Box 016960 (M-809), Miami Florida, 33101". If you would like to deliver your submission by hand, the office is located at Jackson Medical Towers, East, 1500 NW 12th avenue, 33136, 10th floor, room 1000. If you have any questions about how to get your submission to the Committee, contact Jennifer Garcia de Osuna, IRB Administrator, at (305) 243-2079.

D. Appeals

If a protocol is acceptable except for small details, the Committee may approve the study pending required changes. If a protocol is judged not to be acceptable as written, and not easily amended, it may be disapproved. In either case, the investigator may appeal the decision and is welcome to attend the next regularly scheduled meeting of the Committee to discuss the matter further. If you wish to do so, please notify the SBS IRB administrator of your intent. If you anticipate that objections may be raised to your protocol, contact the SBS IRB administrator, and she will recommend a committee member with whom you can discuss the problem. This is particularly important if you are under time pressure (e.g., to submit a grant proposal).

II. Submitting a Protocol

A. What to Submit (only when using the "paper" version. If you are using e-prost, you do not need to submit any copies)

- 17 copies of the protocol form (the protocol form with the original signatures must be included)
- 17 copies of all consent/assent forms. Copies of recruitment flyers/advertisements must also be submitted.
- 17 copies of all questionnaires, instruments, and interview questions.
- 3 copies of the grant proposal (if a the study bears on a grant proposal)
- 3 copies of the thesis or dissertation proposal (if student research)

The forms are available on our website at **hsro.med.miami.edu**

B. Protocol Format

Many protocols submitted to the committee are missing one important element or more. The committee will disapprove these protocols and the projects will be needlessly delayed. To minimize this problem, a list of what needs to be in the protocol is provided below.

TITLE OF PROJECT	Title of the project.
PRINCIPAL INVESTIGATOR & COLLABORATORS	For purpose of this committee, the P.I. must be a University of Miami faculty member who has completed the IRB certification course. Students are to be listed as collaborators, even if the research is for a dissertation. The faculty member named will be held responsible for the content of the protocol. For student research, all additional committee members need to be listed as collaborators. The department, phone number and email address for the P.I. and each collaborator must be listed. All key personnel must be IRB certified (see Policies and Procedures for the Protection of Human Subjects in Research).
PERFORMANCE SITE	Approval must be obtained from the performance sites before the study can be initiated. A copy of the approval letter must be submitted to the Human Subjects Office.
PROPOSED START DATE	Please do not indicate in the protocol that you are going to start data collection on July 5 if the protocol is submitted August 1. Your protocol may not be approved if the committee is concerned that you may have started the project before obtaining approval.
FUNDING AGENCY	If the protocol pertains to a grant proposal, include the full address of the agency to which the grant has been or will be submitted (If not funded, write "not applicable").
PROJECT OBJECTIVES	Give a brief, clear description of what you are trying to find out. Do not go on endlessly about

	subtle theoretical points or use too much jargon. Be concrete.
RECRUITMENT PROCEDURES	Include a step-by-step description of how you are recruiting participants. For example, if participants are medical patients, medical staff should contact them, indicate that you are conducting research, and ask if they are willing to talk with you. If you are a staff member on their ward, on the other hand, you can contact participants directly. If you are using a sample that is at all sensitive, spell out this procedure clearly. If it is not clear, your protocol may not be approved. If you are going to use a flyer to solicit participants, please submit the flyer with the protocol.
METHODS AND PROCEDURES	Describe your data collection procedures in a concrete, step-by-step fashion. Be clear about what you are going to ask people to do. Include enough detail to allow us to evaluate potential stress and risk. Do not go on endlessly, however. Note: Referring the Committee to an "attached" method section of a dissertation or grant proposal is not acceptable.
PARTICIPANTS	Indicate what specific populations participants are drawn from.
WOMEN/MINORITIES/MINORS	Federal regulations have established guidelines for the inclusion of women, minorities, and children (NIH defines children as 21 and under) in research involving human participants, whether or not it is supported by NIH funds. You need to indicate those participants that will be enrolled in your study. If you are not enrolling any of these participants you need to state why. If you are enrolling only a specific population, please provide the rationale.
NUMBER OF PARTICIPANTS TO BE RECRUITED	Indicate the total number of participants that will be enrolled in this study, their age range, and their sex. **If you recruit more participants than listed here, you will need to submit an amendment.**
RECORD MAINTENANCE	Indicate where the files of the project will be maintained.
CONFIDENTIALITY	State if the data are anonymous or confidential. Anonymous means that names or other identifiers will not be collected and individual participants cannot be linked to their data. If this is not the case, indicate what procedures you will use to enhance confidentiality. For example, common procedures are the following: "Data will be coded by a special number, rather than by name." "Results will be published as group averages only." "Once all data have been collected, the list that identifies what person has been assigned

	what code number will be destroyed." Make sure that the statement in this part of the protocol is consistent with what you say in the informed consent form and what you actually tell participants.
DECEPTION	If the study involves no deception, say so. If deception is involved, describe what it will be.
EVALUATION OF POTENTIAL PHYSICAL, PSYCHOLOGICAL, OR SOCIAL RISK TO THE PARTICIPANT	Give your own evaluation of the source of any potential risk and/or harm and the severity of risk and/or harm.
INFORMED CONSENT PROCEDURES	An Informed Consent Form Checklist has been developed to assist investigators in writing an informed consent. Take care to ensure that your consent statement is complete; incomplete consent information is the reason for disapproval of many protocols. If your study entails no risk, you may choose to obtain verbal consent or consent participants by using a throw-away cover letter. If you are obtaining verbal consent, a paper copy of this statement must be provided to participants and to the IRB. If you are studying children between the ages of 7-17, note that you must include both a parental consent form and an assent form suitable for the child's age. The consent form, cover letter, and/or assent form must be written in the participant's primary language.
STUDY RESULTS	Describe the procedure that will be used to inform the participants of the results of the study.
MEDICAL FACET	If the answer given is yes, someone in the IRB office will check to make sure the protocol has also gone to the Medical Sciences Committee.
ASSURANCES AND SIGNATURES	This is a sequence of promises: that you won't make important changes in procedure without prior approval of the committee, that you will prepare annual and final reports as needed, that you have a copy of these Instructions and Guidelines for Preparation of Social and Behavioral Protocols and of the Policies and Procedures for the Protection of Human Subjects in Research and that you agree to

C. IRB Certification

All key personnel must be IRB-certified before they can conduct human subjects' research. Key personnel are defined as those individuals participating in the design, conduct or analysis of research studies involving human subjects, whether or not they receive compensation from the grant supporting that project. UM key personnel must take the Collaborative IRB Training Initiative (CITI) online for certification or receive certification by other means approved by the Assistant Provost for Human Subjects

Research. Re-certification of key personnel is required annually. Go to http://www.miami.edu/bb/citireg/ to register for the CITI certification and re-certification courses. All key personnel must be IRB certified no later than December 31, 2002.

D. Continuing/Final Reports

The University of Miami requires that follow-up reports be made concerning all research approved by the committee. Accordingly, a follow-up report will be requested at least annually after initial approval of a protocol is granted. When the data collection and analysis have been completed and no link remains between participants and the data, this will constitute a Final Report. If the research is still on-going, it will represent a Continuing Report and another report will be due in most cases a year later. As a courtesy reminder, forms requesting follow-up report reminders will be sent to the investigator by the Human Subjects Office. You can also obtain the continuing/final report form from our website at http://www.miami.edu/research-irb.

E. Amendments

Any and all modifications (amendments) to the protocol and consent form must be submitted to and approved by the IRB before implementation. Investigators must not initiate any changes in the protocol or consent forms prior to IRB approval. Seventeen copies of the Amendment form and 17 copies of all revised materials must be submitted to the Human Subjects Research Office for review. The Administrator reviews the proposed modification(s) in accordance with 45 CFR 46.110(b) and 21 CFR 56.110(b). If the submission does not fulfill these requirements for expedited review, it is submitted by the Administrator for full IRB review. The full IRB is notified of those protocols which have had modifications approved by expedited review.

III. Guidelines

A. Participant Rights

All participants in research have the right to know several things about their participation: that this is for research, what they are being asked to do, roughly how much time is involved, that their participation is voluntary, that they may decline or discontinue participation with no negative consequences, what steps will be taken to ensure confidentiality, and how they can obtain answers to questions they may have.

Consideration of the rights of the research participant should begin even before the person is contacted for possible participation in the project. In particular, contact with people should not be initiated in a manner that is intrusive, presumptuous, or embarrassing to the participant.

This issue becomes particularly salient when you want to study a sample that is vulnerable or sensitive (e.g., families of mental patients, or persons who are inpatients or outpatients in treatment for some specific disorder). Contact with members of such groups should be initiated by someone with whom they already interact. For example, in research on a patient sample, it is ordinarily expected that some staff professional (e.g., physician or a nurse) should mention the research project to the potential subject and ask whether he or she is willing to discuss possible participation with a member of the

research team. If the researcher already interacts with the patient as a member of the hospital staff, the researcher may contact the potential subject directly.

Recruitment of participants should also take place in a manner that is not coercive or pushy or does not overstate the benefits of the project. For example, newspaper ads that might be purchased to induce potential subjects to contact the research team should not use language that emphasizes either how important the project is or how people should feel a duty to participate.

These rights must be acknowledged explicitly and communicated to the potential participant in language that he or she can comprehend.

B. Tape-Recordings

If you are going to audiotape or videotape subjects, tell them so in the consent form. You should also tell them what will be done with the recordings after the study has been completed (e.g., will the tapes be coded and erased, kept indefinitely for [state purpose]). You may choose to use a separate audio/video consent form if you'd like.

C. Medical Facet to Research

Some studies incorporate both behavioral components and medical components. This is the case, for example, whenever a behavioral study also involves instituting or removing medication of any kind. The study may also be regarded as having a medical facet if the proposed behavioral events might plausibly be expected to interact with medications currently taken by subjects or an unusual physical condition that the subjects are known to have (e.g., heart disease, epilepsy). If the study has a behavioral component, it must satisfy the guidelines of the Behavioral Sciences Committee. If the study also has a medical component, such as described above, it must also satisfy the requirements of the Medical Sciences Committee. Any such protocol must be reviewed separately by both committees. For information about special issues that arise in medical research contact the Medical Sciences Committee.

D. Deception of Subjects

Though deception of research subjects should not be undertaken gratuitously, sometimes it is necessary to deceive subjects in the course of a research procedure. Deception per se does not necessarily create any risk for subjects. Deception is, however, often used as a vehicle for presenting subjects with experimental manipulations that are unpleasant or stressful and which may in extreme circumstances place subjects at risk. Note the separation of issues: deception does not necessarily imply risk and risk does not necessarily presume that there has been deception. (Researchers conducting deceptive research in which there is any question of possible risk to subjects should carefully examine section E as well as this section.)

1. Consent

In obtaining informed consent for participation, whether verbally or in writing (if a written consent is necessary), nothing in the description of the procedures of the study may be overtly deceptive. The information given for a deception study will necessarily be less than fully informative to the subject. However, it is this

Committee's position that a general--if less than thoroughly informative--description of the events to which the subject will be exposed is ethically more justifiable than a statement that actively misleads subjects about what their experiences will be.

2. Debriefing of Deception

When subjects have been deceived, there should be a debriefing session immediately upon the conclusion of the experimental session. This debriefing should include a description of the nature of the deception, an explanation of the reasons for the use of deception, and--when the deception has been at all stressful--an opportunity for subjects to vent their feelings about having participated in the research (see Section E 2 below).

3. A Special Kind of Deception: Surreptitious Recordings

Researchers occasionally can justify the need to videotape or audiotape subjects without their prior knowledge. The researcher should be aware, however, that as presently written the Florida wiretap law makes surreptitious recording a third-degree felony except under certain conditions. Obviously, given these legal constraints it would be preferable to find an alternative way to obtain the data you need. If you are uncertain about how this statute applies to your research, you should consult with the IRB personally at a regularly scheduled meeting before preparing a protocol.

E. Physical, Psychological, and Social Risks to Participants

When research participants are exposed to stresses that are outside the range of normal day-to-day experience, they are said to be "at risk." Risk may be physical, such as exposure to noises of sufficient intensity to induce temporary hearing loss. Risk may also be psychological. For example, if a questionnaire asking about employment practices is given to employees of an organization in a form in which it is possible to identify individual respondents, it might thereby be possible to punish a specific employee (through unfavorable evaluations) for responses made to the questionnaire. Such a possibility would constitute risk. As another example, a researcher once set about systemically delivering bogus feedback to subjects indicating that they had homosexual tendencies. Confronting and dealing with that information, however temporarily, doubtlessly caused psychological stress.

There is also a third category of risk, which is more vague and difficult to pin down: social risk. This is the risk that participation in the research may be detrimental to some group of people. This category of risk appears to have been conceptualized first in terms of risk to minority groups. That is, if a study were to reveal that some minority group was deficient or deviant in some important way, that group might be held up to public ridicule. There are other ways, however, for social risk to be incurred. For example, if a study were to find (hypothetically) that most students at the University of Miami were racists, the finding might cause students at the University of Miami to be ridiculed. It is arguable that such a study creates social risk.

It is often quite difficult to determine where the "normal" range of experience ends and "risk" begins. The mild embarrassment associated with having been deceived by an experimenter does not constitute risk. The arousal of mild emotional states does not usually constitute risk. But if the emotional states are extreme, risk may be entailed.

The sub-sections below deal with three issues. The first two apply whenever the subject may be at risk. The third deals with the gray area where it is not clear that risk is present, nor is it clear that risk is absent.

1. When the Participant is at Risk: Written Informed Consent

Any time a human subject is placed at either physical or psychological risk the informed consent procedure should make use of a written informed consent form (ICF). In addition, the ICF must describe, as accurately as possible, what sort of stresses the subject may experience as a result of participation in the research. In essence, this form provides a warning to potential subjects that their experiences while participating in the experiment may not be pleasant.

When the study involves risk without deception, the description of possible stresses will be quite explicit. For example, subjecting participants to loud noises may entail risk of temporary headaches or ringing in the ears, and there is no obvious reason why potential participants should not know this before deciding whether to participate. If the study involves deception, however, the subject in many cases cannot be fully informed about potential stresses. For example, research studying responses to the experience of failure--which may or may not involve risk, depending on the magnitude of the failure--requires that the subject experience the event as a failure. Subjects obviously cannot be told that they will be caused to fail at a task. In most such cases, the ICF should indicate in general terms to the subject that some people find the experiences that are involved in the experiment to be aversive, stressful, or unpleasant.

When there is more than minimal risk of physical injury, the ICF should also indicate whether medical treatment is available if such an injury should occur, and if so, what that treatment would be. Information should also be given concerning where to obtain further information about such treatment and whom to contact in the event of such injury. The ICF should indicate whether any compensation is available if such an injury should occur. When there is more than minimal psychological risk, it may under certain circumstances be advisable to include in the ICF a statement about the availability of psychological treatment, including information about whom to contact for such treatment.

Though clarity of communication is always a potential problem, it is particularly likely to be so when the communication is in a written rather than spoken form. All of the elements of a written ICF must be presented in a form and vocabulary that will be intelligible to the potential subjects. For example, subjects with limited education may require a simpler consent than subjects with a college education. You should not patronize subjects, but neither should you confuse them. If you intend to use subjects who are not fluent in English, you must submit ICFs in the subject's principal language (as well as in English, for the committee).

2. When the Participant is at Risk: Debriefing

When participation has entailed risk, debriefing must be immediate and thorough. It should include a full description of the reasons for subjecting the person to risk in the

research and (to as great a degree as possible) an amelioration of the stress associated with the risk. In addition, if any deception was involved, debriefing should include a full explanation of the deception and the reasons for deception (See D2 above).

As an example, if the stressor has been a failure experience, it should be explained to the subjects that the failure was not a product of their own inadequacy but that it had instead been arbitrarily determined that they would experience failure. An opportunity for subjects to discuss the experience and to vent their feelings about the experience should also be provided. As another example, research involving interpersonal provocation to induce anger often ends by assuring the subject and the confederate with assurances that the provocation was conducted solely for the benefit of the research project.

When a study entails risk there must also be back-up procedures for dealing with possible participant stress. In the event of any unusual reaction, the person conducting the study should take the participant to the faculty member in charge of the project, or to whatever facility is available near-by for dealing with stress (e.g., the University Counseling Center). The person conducting the study must also record full details of the unusual reaction. These details must be presented as part of the continuing report for that research project.

3. Research Entailing Intermediate Levels of Risk

A vast gray area exists in which some observers would view participants as being at risk, whereas other observers would see no risk. It is the position of this committee that where there is doubt, the researcher is advised to assume the presence of risk. Disagreements with this recommendation are likely to occur and are likely to revolve around such matters as including in the ICF words such as "stressful," "unpleasant," "aversive," or the like. A researcher who suspects that there will be mixed views among Committee members on these questions should either justify his or her position thoroughly in the submitted protocol or plan to be present at the meeting where the protocol is to be discussed.

F. Research Involving Children

1. General

Participation in a research project by a minor (anyone under the age of 18) or any other dependent requires the permission of a parent or legal guardian. NOTE: Florida statute prohibits guardians to consent for research studies unless the guardian obtains permission from the courts to do so.

If the participant will be a child between the ages of 7 and 17, the investigator must also obtain the child's "assent" to participate (the term assent is used when the participant is not legally empowered to give consent). The assent statement should have the same elements as are used for adult research participants, but in language suitable for the child's comprehension (consider having a child you know who is the age of your intended subjects read your assent to determine if the language is age-

appropriate). Please see the Assent Form Checklist for the required elements of the assent form.

2. Research involving deception of children

When deception is used with children, the informed consent statement presented to the parent must specify the nature and reason for the deception and must specify what debriefing information will be presented to the child. The child's assent need not specify the deception, but it must be prepared in a manner consistent with Section D1 above.

3. Research involving risk

All of the restrictions that apply to adult research (Section E above) apply to research with dependents. If the research involves risk and no direct benefit to the child, written consent must be obtained from both parents and a written assent form must be obtained from the child.

G. Wards

If wards of the state are to be included in a study, approval to approach the ward must first be obtained from the judge overseeing that particular ward's case and then from the ward's primary guardian. Then the ward may be approached for assent/consent.

H. Research on Drug Abuse and Other Illegal Activities

Research on illegal activities creates a problem of confidentiality. If you know that you cannot promise participants complete confidentiality, you have an ethical dilemma if you ask them to inform you about illegal actions they have taken. One way to resolve this dilemma is to ensure that data collection is truly anonymous. This, of course, cannot always be done.

An alternative would be to obtain a Certificate of Confidentiality. Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect the privacy of research subjects by preventing investigators and institutions from being compelled to release information that could be used to identify subjects in a research project. They allow the investigator and others who have access to research records to refuse to disclose identifying information in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. "Identifying information" is broadly defined as any item or combination of items in the research data that could lead directly or indirectly to the identification of a research subject.

By protecting researchers and institutions from being compelled to disclose information that would identify research participants, Certificates of Confidentiality help achieve the research objectives and promote participation in studies by assuring privacy to subjects. For more information about Certificates of Confidentiality go to http://grants1.nih.gov/grants/policy/coc/index.htm

If the research deals with illegal activities to which this waiver does not apply, it is clear that participation in the research puts participants at risk. Accordingly, the nature and extent of that risk must be specified prior to participation.

I. Child Abuse/Neglect

Research involving the potential for discovery of child abuse/neglect raises additional concerns because Florida law requires the investigator to report to authorities any suspected instance of child abuse/neglect. It follows that participating in a study of parent-child interaction may under some circumstances put subjects at risk of being reported to authorities as abusers.

This problem impinges on the issue of the degree of confidentiality that the researcher can provide. The question becomes how or whether to communicate the fact that suspected abuse/neglect may have to be reported. We have found no real way around this dilemma. Our current stance is that the investigator should specify clearly to potential participants that the nature of the behaviors to be investigated will be protected "to the extent permitted by law." Under current Florida Law and according to the Committee's understanding of the implications of the law, research that is explicitly aimed at studying subjects who are at very high risk of being identified as abusers--in situations in which evidence of abuse is relatively likely to be obtained--can be conducted only under the following conditions: potential participants must be informed of the risk that they assume by being involved in the research--specifically that they may be reported for child abuse/neglect.

J. Research Concerning AIDS

Research on AIDS presents a different ethical dilemma. Two kinds of participants may be put at risk by participating in the research: those who do not know whether they have been infected by HIV and will find out in the course of participation and those who know they have been infected but who do not acknowledge it publicly. In each case, there is risk that other people will find out the participants' exposure status, which can have vast social and economic repercussions.

One issue here is confidentiality: the need to inform the subject clearly to what degree confidentiality can be maintained and the procedures by which that will be done. A second issue is alerting the potential subject to the fact that if confidentiality is somehow inadvertently breached there are potential adverse consequences.

In addition to these potential risks, some participants may discover for the first time that they have been exposed to HIV. The stress this may produce may represent another risk that should be addressed in the consent statement. If the participants will be tested for HIV exposure as part of the study, the provisions of Florida Statute Section 381.609 must be carefully followed. A copy of the relevant portions of this statute can be obtained from the Human Subjects Office.

K. Web-Based Research

OHRP has recommended using encrypted servers to increase the security of responses gathered via the web. Verisign provides UM with an encrypted server to guarantee that transmissions are secure (the same security as secure credit card servers). All investigators collecting or transferring data via the web must use this server which encrypts data the moment they are entered and only a computer with the certificate key can decrypt them. This server can be used at no cost to the investigator, who provides access to the site by https://etc, instead of http://etc. The https:// site, which is on the central university server and can be used by any member of the university community to create a site, is secure.

Please contact Wendy Dibean, the University Webmaster, at 305-284-1102 for further information.

L. International Research

The Office for Human Research Protections (OHRP) has strengthened mechanisms for the protection of international research subjects. Because UM holds a Federal Wide Assurance (FWA) the proposed research site(s) will most likely need to file for their own FWA. If the research is funded by a department or agency of the United States government, it is probable that the institution will need to file for their own FWA (the investigator can confirm this with the funding officer). In many cases, it is required that a local IRB in the country where the study is to be conducted review the proposal first. If there is no local IRB, our FWA requires the institution to name a designated IRB. If UM is designated by the local institution to be solely responsible for reviewing the protocol, the UM IRB will need to determine if it has the appropriate level of local knowledge pertaining to the proposed international study sites to do so.

M. Research Conducted with Other Institutions

If your study involves research activities with an institution outside of UM that is "engaged" in human subjects' research that is nonexempt, that institution must obtain its own Federal Wide Assurance (FWA) before IRB approval here can be granted. An institution is considered to be "engaged" when its employees or agents (1) intervene or interact with living individuals for research purposes; or (2) obtain individually identifiable private information for research purposes. This includes obtaining informed consent, collecting data, and performing actions dictated in the protocol.

N. Secondary Subjects

When questions asked of a subject in a study elicit private, identifiable information about a living person that can be readily associated with the identity of that person through data management or publication, that other person becomes a secondary subject. If any questions identify secondary subjects, informed consent must be obtained from the secondary subject before the participant can answer these questions (except in very unusual circumstances). Examples of "private information" are questions that could cause criminal liability ("Has your son ever shot anyone?"), economic disadvantage ("Does your mother lie about her income to get Medicaid?"), and embarrassment ("Does your wife have genital herpes?").