Informed Consent

Smith College School for Social Work
Lilly Hall
Northampton, Massachusetts 01063

James W. Drisko, PhD, LICSW

Protecting Human Research Participants: An Introduction

This material is largely drawn from the U.S. National Institute of Health's Human Participant Protections Education for Research Team's Web Site http://cme.nci.nih.gov/ About half of this document is directly quoted from this excellent interactive learning site. I have also added information on several topics, attempting to make the information more useful to social work researchers. Also very useful is the DHHS Office for Human Research Protection's IRB Guidebook.

To Whom does Human Subjects Review Apply: Any living person about whom a researcher obtains either (1) data through intervention or interaction with the individual, or (2) identifiable private information.

Note, too: If you use another researcher's existing data base, you will need to verify the original informed consent specifically told the original participants that their data might be used for purposes beyond the original study. Researchers can not assume such consent was given unless they can document it. In a thesis or dissertation, students should include both a copy of the original consent form in the report, as well as a letter from the original researcher authorizing your use of their collected data. However, some data sets are "fair use" information. Census data is such a data set. Consent forms and letters are not needed in such instances.

In What Types of Research? Any where bodily materials (cells, blood, hair, nail clippings, etc - even if you did not originally collect these materials); residual diagnostic specimens (even if they would otherwise have been discarded) or private information that can be readily identified with individuals (even if the information was not specifically collected for the study in question). Most social work research falls into the latter category.

Why is it Important? Research is ethically necessary to improve practice and services. Yet is must also be done in a manner that protects and promotes the safety and well being of human participants in research, adheres to the ethical values and principles underlying research, is both ethical and scientifically valid

research, and addresses concerns of the general public about the responsible conduct of research.

Abuses of research such as Nazi experimentation on prisoners led to the first principles for ethical principles to protect the interests of research participants. These principles are still vital and important today. The Tuskeegee syphilis study and later research on developmentally delayed children in the Willowbrook School showed further standards were needed. These include the Belmont Report http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm and the United States government's Department of Health and Human Services (HHS) regulations for Protection of Human Research Subjects (45 CFR 46, as amended) http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm and the National Association of Social Worker's Code of Ethics http://www.naswdc.org/Code/ethics.htm

Who's Responsible? Researchers are ultimately responsible for their work. Agencies such as the National Institutes of Health (NIH) provide policies and guidelines concerning participant protections for research. Funding agencies and other sponsors such as educational institutions are responsible by ensuring that grantees, faculty and students adhere to the federal regulations. Scientific peer review groups, institutional review boards review research and oversee humanparticipant protections at different stages in the research process. Through all these steps, the researcher has responsibility to know the regulations and to take several steps to insure their work adheres to the HSR policies and procedures.

The Researcher's Responsibilities: The researcher is specifically responsible for assuring that the study is properly designed and should yield valid results; that participants meet selection and eligibility requirements; that the study is approved by the IRB and conducted according to the approved protocol; that the informed consent is appropriately obtained and documented; that changes in the research protocol and adverse events are reported; that the rights and welfare of participants are monitored throughout the trial; and that all members of the research team are qualified: trained in research methods and human participant protections.

Stating and Explaining What the Study is About. The researcher(s) must briefly explain the overall purpose of the study, may include a brief statement of what it seeks to find out (perhaps including a brief statement of what's already known and what's new in this study). The uses of the data or materials must also be clearly specified. (For example: This data will be used for my MSW Thesis at Smith College School for Social Work, as well as for later scientific publications and presentations). Note that this statement does not permit use of the data by other researchers. If this is a potential or planned used, a statement to this effect must be explicit to allow later secondary use for different purposes.

Stating and Explaining What the Participant will Do. Researchers must clearly detail, in everyday language, what the participant will have to do as a research participant. This includes how long participation will take and any other relevant information. (For example, complete a brief pencil and paper survey about yourself and your use of clinical social work services followed by a separately scheduled one hour long interview about what you found helpful and found unhelpful about these services).

Stating and Explaining the Participant's Rights. These include clear and explicit statements of the research purposes, a description of participation, a statement of rights, a statement of risks and benefits as well as:

contact information and credentials for the researcher(s),
clear indication they are making a choice to participate or to decline,
an explicit statements regarding if, and if, how, participating or declining will impact on current and future services with the researcher and the host institutions or agencies,
opportunities to ask questions about the research, participation and participant rights before during and after participation,
a specific option to withdraw later (often limited by a set date), and
a clear statement that by signing the informed consent form they are making a decision to participate.

The Risk/Benefit Ratio. Research always includes some element of risk. It should also include some element of benefit, either directly to the participant or for others the participant chooses to help with knowledge or information.

Risk/benefit categories. Risk/benefit categories include:

a) not involving greater than minimal risk to the participant,

b) involving greater than minimal risk but presenting the prospect of direct benefit to the participant,

c) involving greater than minimal risk and no prospect of direct benefit to the participant, but likely to yield knowledge about the participant's disease, disorder or experience, and

d) studies not otherwise approved which present an opportunity to understand, prevent, or alleviate a serious problem for others in the same or a similar situation.

Reducing risks. Precautions, safeguards, and alternatives should be incorporated into the protocol to reduce the probability of harm or to limit its severity or duration.

Stating and Explaining Risks and Benefits: Researchers should include separate paragraphs in the consent form on both the potential risks of participation and on the potential benefits of participation. Risks relate to what the process and content of participation may evoke in the participant, given their personal and societal history. Risks may be psychological, social, physical or economic in nature.

They also include real or potential costs of participation (time, travel, potential loss of privacy). Even minimal risks must be stated (embarrassment, painful self-reflection on your actions). What appear to be "obvious" risks -- that a study on trauma might re-evoke this painful experience -- must also be explicitly stated so the participant can make an informed choice to participate or not.

Privacy violations are another risk, usually addressed a yet another separate paragraph. Being potentially identifiable -- even with some disguise -- is a real risks. A description of how the researcher will protect privacy in collecting, maintaining and storing the data and in the research report is needed. (Detail is clear to the participant, simply making a claim is not acceptable.)

In some research, researchers may also be mandated reporters of abuse or neglect they uncover in children, the elderly, or in other legally protected groups. (This varies state by state.) Researchers must state this risk, and allow potential participants to make an informed choice taking it into account.

Researchers must be careful not to give the impression of establishing dual roles. That is, researchers must keep clear (to participants) that they are doing research. Debriefing may be a useful way to reduce risk, but to serve as both researcher and follow-up clinician is not appropriate. (See dual relationships below.)

Benefits of participating in research run a spectrum from immediate and personal to rather abstract and altruistic. One can learn about themselves, reflect on a situation or status, or offer information that will improve practice procedures, build theory or change policy to impact others who share some characteristics.

Compensation is another benefit. Payment in cash or vouchers for goods or services are appropriate to offset cost of participation. These should be stated explicitly in consent materials.

return to top

Dual Relationships: The NASW *Code of Ethics* states that social workers should not engage in dual or multiple relationships with clients due to the potential for exploitation and harm. To be a service provider and a researcher may make both roles unclear to the participant/client. However, research on one's practice can be ethical, so long as the client/participant understands from the start that the work will be examined and published or presented. Information for informed consent for

both the service and the research should be provided at the start of services. Opportunities for clients to change their minds and later withdraw from the research must be part of the informed consent process.

Researchers need to keep clear role boundaries. It is appropriate to end a research interview or questionnaire with items that allow the participant to "wind down" from stressful or emotionally charged material. It is also appropriate to offer to provide referral information for participants who wish them as a result of participating in the research. However, the researcher should not provide, or appear to offer to provide, such follow-up services to avoid creating a dual relationship (or the appearance of one).

Participant Selection: In selecting participants, researchers are responsible to ensure that selection is equitable. No individual or group should be overburdened without the acquisition of potential benefits. (This is the "Principle of Justice" in research). The researcher must consider the nature of population from which the sample is drawn, feasibility, and that the recruitment procedures to ensure an equitable distribution across the population. In large scale research, NIH guidelines require the inclusion of women and minorities as participants in research

"so that the research findings can be of benefit to all persons at risk of the disease, disorder, or condition under study." If a proposed study includes a population in which women and minorities are not appropriately represented, the researcher must provide "a clear compelling rationale for their exclusion or inadequate representation." This clearly allows for small scale projects which purposefully address the needs of specific groups, whether white or person of color, female or male.

Vulnerable Populations: Vulnerable research participants are persons who are relatively or absolutely incapable of protecting their own interests. The researcher must be cognizant of the special problems of research involving vulnerable populations, justify the proposed involvement of these populations in the research, and include additional safeguards for their safety and welfare. These populations include (but are not limited to) children, individuals with questionable capacity to consent, prisoners, pregnant women, terminally ill people, and students or employees. In clinical social work, persons with significant mental disorders, abuse or other trauma histories are also vulnerable populations requiring additional safeguards.

Legal Ability to Give Informed Consent.
Children lack the legal authority to give consent for themselves. Parents or guardians must give consent for them. Some adults with mental retardation or profound organic illness may also be determined by a court to be unable to give informed consent. In high risk situations, an additional court review may be needed, guardians may be unable to give consent on their own (such as for

administration of psychotropic medications). However, in some states children in special circumstances may be able to give informed consent for some purposes. For example, in Massachusetts, it appears that adolescents may consent to participate in a survey about services for Gay and Lesbian youth without parental consent (which itself may be a risk). Details of such exceptions must be determine on a state by state basis.

Capacity to Give Informed Consent. Individuals in a wide variety of situations may have impaired decision making capacity. For example, impairment may occur at times of great stress. Impaired capacity is not limited to individuals with neurologic, psychiatric, or substance abuse problems. Conversely, individuals with neurologic, psychiatric, or substance abuse problems should not be presumed to be decisionally impaired.

return to top

Privacy. Privacy ma y be defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, emotionally or intellectually) with others. When participants in research give information about themselves to the research team or institution, they expect, and trust, that the information will be shared only as necessary.

Protecting Privacy and Confidentiality. Confidentiality can be defined as the treatment of information that an person has disclosed in a specific relationship of trust. One expects that this information will be divulged only in ways for which permission has been freely given. One also expects that no information will be divulged without permission in ways that are inconsistent with the understanding of the original disclosure. (Note that violation of confidentiality is a potential risk of participating in research.)

Researchers ordinarily use information that participants have disclosed or provided voluntarily (i.e., with their informed consent) for research purposes. Under these circumstances a key privacy issues remains: assuring that appropriate confidentiality of research data is maintained.

Anonymity differs from confidentiality in that the identity of the participant is never disclosed or associated with the data. It may be possible to do an anonymous survey, such as if a customer satisfaction survey is given to all clients of a mental health center who may return them without disclosing any information that can be used to identify them. These include names, code numbers, addresses as well as the name of their therapist, and potentially diagnoses and many other personal details.

Studies which involve contact with participants via a list of names linked to telephone numbers, addresses, work places, **OR** which involve any direct contact with the participant (such as an interview or an observation) are not anonymous.

However, they may be structured to keep confidentiality -- which is usually sufficient.

Be thoughtful regarding where, how and when data is collected. The location and timing of interviews or other research activities should not publicly identify participants as research participants. Privacy may be violated by holding an interview in the common room of a nursing home.

Steps to protect confidentiality of collected data and in research reports. Typically a set of procedures is specified to protect confidentiality. The research participant is informed of these procedures in detail before participation as part of the informed consent process. Steps to protect confidentiality include (but are not limited to):

substitute codes for names and other identifiers,

removal of addresses and names that specify a location or setting,

the encryption of identifiable data,

removal of "face sheets" (containing identifiers such as names and addresses) from instruments containing data,

properly dispose of computer sheets and other papers,

limiting access to identifiable data,

educating staff on the importance of confidentiality,

store paper research records in locked cabinets, and

provide security codes for computerized records.

In studies of participants with sensitive, stigmatizing or illegal personal information e.g., persons who have sexually abused children, tested positive for HIV, or who have sought treatment in a drug abuse program), keeping the identity of participants confidential may be as or more important than keeping the data obtained about the participants confidential. In such cases, any written record linking participants to the study can create a threat to confidentiality. Having the participants in these studies sign consent forms may increase the risk of a breach of confidentiality, because the consent form itself constitutes a record, complete with signature, that identifies particular individuals. The federal policy allows the IRB to waive the requirement for the researcher to obtain a signed consent form in cases where it will be the only record linking participants to the research, and where a breach of confidentiality presents the principal risk of harm that might result from the research.

In certain circumstances researchers may obtain a certificate of confidentiality, which protects them from legal action to share research data. Such needs are rare but may pertain to studies of substance using/abusing populations and studies of some sexual practices -- which may be important to insuring public health.

return to top

In **survey research**, complete information is included in a cover letter format, which may, or may not, be signed and returned by the participant. In many instances, return of the survey instrument is understood as implied consent by the participant (an implication which should be clearly stated in the cover letter). This allows anonymous responses even where a known mailing list defined the study's sampling frame. However, in some situations, researchers may elect to ask that survey participants return a signed consent form. Numerical codes are often used as the means of limiting personal identifiers in survey research, but they do not create anonymity (as the researcher typically knows what number has been assigned to each participants -- usually to allow follow up mailing if the participant does not respond within a given time period).

Protecting Rights Research participants have the right to 1) ask questions about the study, 2) their participation in it, and 3) their rights as participants. This means they may ask questions and expect answers about the purpose(s) of the study, its design and the qualifications of the researchers. (Some forms of deception about the exact purpose of the study may be approved by an IRB in some circumstances.) Participants must be informed about, and free to ask questions about, what they will have to do for the research, how long it will take and about real and potential risks and benefits. Finally, the must be informed about the steps the researcher will take to protect their rights, as well as to ask questions about their rights and to whom they may make complaints (both the researchers institution and the human subjects review committee or IRB).

All research participants should be given explicit notice that they may stop participating at any time if it is stressful or too uncomfortable.

Using concrete examples of how privacy will be protected is helpful. (In the report, data will be reported mainly in the aggregate, with some quotes that are not connected to identifying information about you or other participants.) Claims without examples are not persuasive (even if they are accurate).

Documentation: A signed consent form (or a returned, completed survey) documents that consent was given voluntarily by the participant. Both participant and researcher sign the form and date it. One copy of the signed consent form is given directly to the research participant to keep (which may be the cover letter of a mailed survey). Another copy is kept by the researcher.

The consent form should specify that the potential participant was give information and a chance to ask questions about a) the study (which includes the researcher), about b) their participation in it (what they will do, how long it will take, risks and benefits and privacy protections) and c) and their rights as a participant. All these areas must be detailed in the consent form.

A clear statement that a) signing the consent form or b) returning the survey reflects a voluntary decision by the participant must be included.

Consent forms and original collected data must be kept by the researcher for three years. (See below).

Asking Questions and Withdrawal The consent form should include a clear process for 1) asking questions that occur before, during and after participating, and 2) withdrawing from the study after participating. This requires the participant have the researcher's accurate contact information (which can be tricky for students who move!) A date for final withdrawal from the study should also be given. It may not be possible to delete information about a single participant from a published study, so the final withdrawal date should be realistic to the timetable of the study and its presentation or publication.

return to top

An IRB May Make Additional Requirements of Researchers. If the IRB deems that additional requirements would add to the protection of the participants' rights and welfare, it is within its authority to impose additional safeguards.

Cultural Differences These requirements are located in a particular cultural and legal context which assumes that have information provided clearly and directly to the participant in detail is (generally) a cultural good. This form of providing information to an individual directly may appear to be dystonic or even culturally insensitive to some groups. However, it is the law of the United States and is consistent with the democratic ideal of individual choice and responsibility.

If the Study is Amended these requirements may also be applicable:

Amendments: If you wish to change any aspect of the study (such as design, procedures, consent forms, or subject population), you must submit these changes to the Committee.

If the Data Collection Extends Beyond One Year Researchers are required to apply for renewal of approval every year for as long as the study is active. [This requirement applies to some post-residency masters students and to many doctoral students.]

return to top

Researcher Responsibilities Continue After the Data is Collected!

Maintaining Documents: Federal regulations require that the researcher maintain certain documents after the data is collected.

a) Consent Forms: Researchers must retain signed consent documents for at least three (3) years past completion of the research activity.

b) Maintaining Data: Researchers must retain the original collected data (tapes, instruments, etc) for at least three (3) years past completion of the research activity.

Notification of Completion of Data Collection: Researchers are required by federal regulations to notify the Chair of the Human Subject's Review Committee when your study is completed (data collection finished). [For Smith College SSW Masters students only -- this requirement is met by completion of the thesis project during the Third summer which documents completion of the project as a whole.]

More information online at **www.drisko.net** then follow links to Informed Consent

Thanks to Mary Beth Averill, PhD LICSW who has reviewed the first draft of this piece and offered very helpful comments, and to Mary Beth Averill, Joanne Corbin, Jerome Sachs and Monica Green who have worked hard with me this year on Smith College School for Social Work's IRB. Together we have learned a lot and struggled to define our work, which includes reviewing over 60 MSW theses proposals, as well as Doctoral dissertation proposals and Faculty research proposals.

References

National Association of Social Worker's (1996/1999). Code of Ethics. Washington, DC: Author. online at http://www.naswdc.org/pubs/code/standard5.htm

Office of Human Research Protections. (1993). IRB Guidebook. Retrieved from the World Wide Web March 29, 2001: http://ohrp.osophs.dhhs.gov/irb/irb_guidebook.htm

return to top

Appendix A Clinical Trials

Many medical or pharmaceutical studies involve potentially substantial risks to human participants. They often involve work on issues affecting social work clients in HIV+, cancer care and treatment of psychotic disorders. For example, when a drug company develops a new medication, test tube and animal studies are done first to show promise of results in humans. When such tests, posing potentially substantial risks, are done on human, a multiphase strategy is employed. The "phases" have different purposes and strategies.

Phase I trails. Phase I trials are done to determine if the new treatment is safe. It is very risky as they unknowns are substantial. Volunteers are used to determine safe dosages or procedures and likely effective treatment dosage ranges or procedures. Phase I trials are usually short in duration and involve few participants.

Phase II trials. Phase II trials seek to determine if the treatment works. There is moderate risk as some safety information about the drug or treatment are known (but individual differences which make people more or less sensitive or responsive are not fully clear). They are of medium duration -- up to a year. About 100 participants are involved in Phase II trials.

Phase III trials. Phase II trials seek to determine the long-term results in a large number of people. They pose the lowest risk of the three phases as more information about safety and effectiveness is known from prior trials. Phase III trials are the longest -- perhaps 2 or 3 years. Several hundred participants are involved in Phase III trials.

Sometimes Phase II and Phase III are combined. In some circumstances, an Expanded Access program may be run, involving individuals who will not benefit from existing medications or treatments (perhaps due to certain contraindications to their use, or their limited effectiveness). Safety and effectiveness information is then collected on all participants.

Phase IV trials. Medications and treatments are usually approved (or disapproved) by the FDA or other organizations after Phase III trails. Phase IV trials involve thousands of participants to determine more safety information, such as rare or long-term side effects or contraindications.

Benefits for participants in clinical trials include increased care and monitoring of the condition, helping others (altruism), and possible access to new, as yet unapproved medications and procedures. Risks include potentially harmful and unpleasant side effects and the obligation of stopping any current medication or treatment regime to participate in the new study. Stopping current treatments could cause faster progression of the individual's disorder

or regression in functioning. There is no guarantee the new treatment will be effective for any individual participant. Individual differences in sensitivity or responsiveness to medication or procedures may risk death or loss of function. However, these risks are generally rare. Time to participate and discomfort are also risks.