

**USER'S GUIDE
FOR THE PROTECTION
OF HUMAN RESEARCH PARTICIPANTS
AT SMITH COLLEGE
SCHOOL FOR SOCIAL WORK**

Federal Regulations and Guidelines

Within this Guide, attempts have been made to summarize and interpret a number of Federal regulations and guidelines. These are not to be construed as official versions. Readers are advised to consult the following sources in case of questions: Code of Federal Regulations, Title 45, Public Welfare, Department of Health and Human Services, NIH, Office for Protection from Research Risks, Part 46, *Protection of Human Subjects*; The Belmont Report - *Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, 1997; and the National Association of Social Worker's *Code of Ethic's Ethical Principles in Research and Evaluation*. (WEB addresses added for these resources)

The Office for Human Research Protection maintains an excellent website where all their materials are available: www.hhs.gov/ohrp

NASW Code of Ethics: <http://www.socialworkers.org/pubs/code/code.asp>



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SMITH COLLEGE SCHOOL FOR SOCIAL WORK
NORTHAMPTON, MASSACHUSETTS

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INTRODUCTION: THE VALUES AND ETHICS OF HUMAN SUBJECT RESEARCH

The following is taken from the **Belmont Report**, the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *Ethical Principles and Guidelines for the Protection of Human Subjects of Research*.

The expression "basic ethical principles" refers to those general judgments that serve as a basic justification for the many particular ethical prescriptions and evaluations of human actions. Three basic principles, among those generally accepted in our cultural tradition, are particularly relevant to the ethics of research involving human subjects: the principles of respect for persons, beneficence and justice.

Prior to initiating any research involving human participants (known in the jargon as "subjects"), the investigator should carefully consider the three ethical principles outlined in the Belmont Report and their applicability to the research to be conducted. These principles are

Respect for Persons - This principle is based on two ethical considerations. First, individuals should be treated as autonomous agents, and second, persons with diminished autonomy are entitled to protection. The Belmont Report states that an autonomous person is "an individual capable of deliberation about personal goals and of acting under the direction of such deliberation." To respect autonomy would include not only respecting a person's opinions and choices, but also allowing that person the freedom to act as they choose (as long as that action is not detrimental to others). Human subjects should enter into research voluntarily and with adequate information. Persons with diminished autonomy, who are less capable of self-determination, should be protected.

Beneficence - The investigator should not only respect the autonomy of the person, but should also take measures to secure the person's well-being. Two general rules of beneficence are 1) do not harm and 2) maximize possible benefits and minimize possible harms. Any possible risk to human subjects should be carefully weighed against possible benefits to the individuals and to the improvement of knowledge.

Justice - In research involving human subjects the benefits should at least equal risks to the subjects and most often outweigh the risks. Investigators should especially be careful in the selection of research subjects to be sure that no group of participants is consistently selected or deprived of the opportunity to participate in research.

It is the view of the Smith College School for Social Work that these principles are fully consistent with the values and the ethical positions of the social work profession established in the National Association of Social Worker's (1994) *Code of Ethics*. Social workers value the dignity and worth of the person, the importance of human relationships, seek to pursue social justice, and seek to act with integrity and with competence (Social Work's Ethical Principles, pp. 5-6 of the NASW *Code of Ethics*). Specific ethical standards for research are detailed in Section 5.02 of the NASW *Code of Ethics*, Evaluation and Research.

ALL RESEARCH THAT INVOLVES HUMAN PARTICIPANTS DONE BY ANY MEMBER OF THE SMITH COLLEGE SCHOOL FOR SOCIAL WORK COMMUNITY MUST BE REVIEWED AND APPROVED BY A HUMAN SUBJECTS REVIEW COMMITTEE BEFORE THE RESEARCH IS BEGUN. To gain approval, the research protocols and all of the accompanying materials must conform to requirements laid down by the Federal Government. This User's Guide describes these requirements and includes in the appendices detailed instructions for the various documents.

For Human Subjects Review purposes, research is defined as the collection of information (i.e., data) from or about human beings that is obtained directly from the person or from charts or records kept about the person, with the intention of analyzing the information and producing presentations or publications that will be publicly available.

Research by students in degree and non-degree programs of the SSW, research sponsored by the SSW, research conducted by any SSW employee in connection with his or her SSW responsibilities, research conducted by any SSW employee using SSW or Smith College facilities or properties, or research that involves the use of non-public SSW information to identify or contact subjects must be reviewed.

WHAT IS MEANT BY HUMAN SUBJECTS?

A HUMAN SUBJECT is defined by the Department of Health and Human Services (HHS) as "a living individual about whom an investigator (whether professional or student) conducting research obtains: (1) data through intervention or interaction with the individual, or (2) identifiable private information." This research can include, but is not limited to gathering data through manipulations of the subject or the subject's environment for research purposes, or communication or interpersonal contact between the investigator and the subject."

WHAT HUMAN SUBJECT RESEARCH DOES NOT NEED A REVIEW BY A HUMAN SUBJECTS REVIEW COMMITTEE?

The following may be waived from a review. However, the decision to waive must come from the HSR Committee following a review of the research plan.

- Research conducted in educational settings involving normal educational practices
 - regular and special education strategies
 - effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods
- Research involving the use of educational tests as long as individual participants are not identifiable
- Research involving surveys or interviews -- as long as the participants are not individually identifiable, won't place the subject at risk of criminal or civil liability or be damaging to the participant **and DON'T DEAL WITH POTENTIALLY SENSITIVE ASPECTS OF THE PARTICIPANTS' OWN BEHAVIOR**
- Research involving observation of public behavior (except as noted for research involving surveys and interviews)
- Research involving the collection or study of **EXISTING DATA** including documents, and records, as long as the sources are publicly available and the participants can't be identified directly.

Research with prisoners or children is rarely exempt.

Research being planned by a member of the community but located in another institution which has an IRB may be reviewed and approved by that Institution. The SSW HSR Committee must receive official notification of that review and approval.

HUMAN SUBJECTS RESEARCH AND THE INTERNET

The communication opportunities now made available through the Internet may only be used in the following two ways, and only when approved by the HSR Committee:

Internet aided research when a signed Informed Consent is obtained. The Internet may be used for recruitment. Potential participants may be offered the opportunity to participate and invited to contact the researcher to indicate their interest. An Informed Consent form and Questionnaire can be sent to those who indicate an interest via mail with a return envelope. Questionnaires and Informed Consents can also be sent via Email but must be down-loaded, signed and mailed back with the questionnaire to the researcher.

Internet Research in which the participant remains anonymous. Research may be done through a service that guarantees anonymity and confidentiality. Several services are now available, some at minimal costs, that assist in gathering anonymous surveys and compiling data. If such a service is to be used, you must make sure anonymity is guaranteed and confidentiality is protected. All participants must receive an Informed Consent and must indicate electronically that they have read and agree to the conditions before they are admitted to the research instrument.

If you plan to do anonymous survey research on the Internet please note the following:

1. Anonymity must be protected by using one of the services described above, unless you are doing the research in an institution that has the capacity to encrypt materials.
2. **THE RESEARCH CANNOT DEAL WITH SENSITIVE ASPECTS OF THE PARTICIPANTS' BEHAVIOR.**
3. A screening process must be developed that makes clear the eligibility requirements for participation.
4. It must be made clear that giving electronic consent indicates a willingness to participate. (See examples in Appendix C)
5. **Even if participants are anonymous and a signed Informed Consent will not be returned, the HSR Committee must be assured that the anonymous participants are properly protected.**

WHAT ARE THE RESPONSIBILITIES OF THE RESEARCHER?

PLANNING: Each student is required to submit a Human Subjects Review Planning Form by **OCTOBER 23rd**.

This form informs the HSR Committee of the researcher's plans for their study, whether they will need a Human Subjects Review and whether the SSW Committee or another review board will perform the review. A copy of this form must be sent to the research advisor. **See Appendix A for**

a copy of the HSR Planning Form. If an investigator is seeking a waiver from the review process, this should be done in conjunction with the HSR Planning Form through the submission of a waiver request and a brief study plan. Waivers from the review process must be approved by the HSR Committee.

DOCUMENTS WHICH MUST BE SUBMITTED TO THE HSR COMMITTEE FOR REVIEW

GENERAL INSTRUCTIONS -- While preparing your documents, keep the following general instructions in mind:

- a) **MAKE USE OF THE DETAILED INSTRUCTIONS IN APPENDICES A AND B.**
- b) **DO NOT COPY THE OUTLINE** of the documents from the Appendices into your Application or your Informed Consent.
- c) Include a brief literature review, summarized to a **maximum** of one page.
- d) Keep your audience in mind as you prepare your documents. The Application is for the HSR Committee and the Informed Consent and data collection instruments are for the participants.
- e) Be consistent throughout all of your documents. (If you say the data collection instruments take 45 minutes in the HSR Application, say the same thing in the Informed Consent.)
- f) In so far as possible, avoid technical and professional language, particularly in the Informed Consent. If you need to use a technical term, define it. If appropriate, give an example.
- g) Carefully proofread for spelling, punctuation, grammar, and syntax. Relying on "spell check" alone will not catch everything.
- h) Please use type font of at least 12.
- i) Please think about your own comfort, safety, and privacy as well as your participants'. It is generally wise not to plan to interview participants in their homes. Use your agency address and phone for contact rather than your home address and phone.
- j) If you are a SSW student, all materials must have been reviewed, approved and co-signed by your research advisor before submission to the HSR Committee. The data is shared with the research advisor only after all identifying information has been removed.
- k) Submitted documents must be in final form.

ONGOING RESPONSIBILITIES OF THE RESEARCHER

- a) Any changes to the protocol requires prior approval by the HSR Committee.
- b) If a project lasts more than one year, approval must be renewed.
- c) Any unanticipated problems involving risks to subjects or others must be reported immediately to the HSR Committee.
- d) Any noncompliance with the approval conditions must be reported promptly to the Committee.

1. THE HUMAN SUBJECTS REVIEW APPLICATION FORM

This form describes the total project and all of the portions that have particular relevance to the protection of human subjects. When you do this fully and carefully, the rest of the documentation will fall into place. **See Appendix B for an outline of the Human Subjects Review Application form.**

2. THE INFORMED CONSENT

All participants must have the opportunity to give informed consent. This crucial document insures that all participants (and/or their guardians in the case of a minor or a person unable to understand or sign the document) understand the study, their role in it and that they consent to participate. **See Appendix C for an outline of the Informed Consent.**

3. A COPY OF THE CONFIDENTIALITY AGREEMENT

This document is required when someone besides the investigator will be transcribing tapes, doing data analysis, or otherwise having access to the CONFIDENTIAL material. The agreement is signed by handlers of the data, committing them to hold all information in confidence. **See Appendix D for a model Confidentiality form.** It will have to be slightly edited for anyone but a transcriber. Members of the SSW faculty and Administrative staff are not required to sign a confidentiality agreement.

4. COPIES OF ALL DATA COLLECTION INSTRUMENTS

This includes interview protocols, standardized or newly constructed tests, lists of questions which will guide an interview, demographic questionnaires, etc. All data collection instruments that are submitted to the Committee must be in the final form that will be used in the study. **(Be sure to include full attribution for any instrument created, published, or copyrighted by another.)**

5. A LIST OF REFERRAL SOURCES

Include, when required, a variety of resources appropriate and accessible for your participants. Include agency and or clinic resources with sliding scales or insurance eligibility. Check out internet and telephone sources before listing. A list of referrals is not required for mental health professionals.

6. COPIES OF ALL RECRUITMENT MATERIALS

This may include advertisements, recruitment letters, posters, fliers, internet postings, talking points for recruitment presentations, questions for telephone screening, etc.

7. COPIES OF REQUIRED LETTERS FROM AGENCIES OR INSTITUTIONS

- a) If you are doing the research within an agency or institution with people who are employees or clients of that institution or agency and that organization does not have a Human Subjects Review Board, you must attach a letter giving permission for the research to take place and requesting that the SSW HSR Committee do the review. **(See Appendix E for a model Agency or Institution Approval Letter)**
- b) If you are recruiting through agency or institution employees or posting or distributing recruitment materials in an agency or institution you must obtain permission from that agency or institution to do so.

WHAT IS THE PROCESS FOR SUBMISSION TO THE HSR COMMITTEE?

It is the responsibility of the investigator to submit the above documents to the Chair of the Human Subjects Review Committee at the School for Social Work. Materials may be sent by post, email, or FAX. Before students submit the materials to the HSR Committee, the HSR Application and accompanying materials must be reviewed, approved and signed off on by the research advisor. Some advisors feel it is in the best interest of the student to have a draft of the Human Subjects Review materials prepared for discussion by the time of the first research advisor-student meeting. Verification of approval by the research advisor is required and may be submitted to the HSR Committee by Email or as a hard copy. **A minimum of three to four weeks is required for review. Usually, some revisions or corrections are required before approval, which then requires additional time for review. Investigators should factor the review period into the project time line and plan accordingly.**

WHEN REVISING MATERIALS, HIGHLIGHT OR PRINT IN COLOR ANY CHANGES YOU SEND TO THE HUMAN SUBJECTS REVIEW COMMITTEE. Any revisions, changes, modifications or supplements to existing, approved protocols should also be submitted to the Chair of the Human Subjects Review Committee for review. Be sure to identify revisions for easy review.

WHAT ARE THE REQUIREMENTS FOR DOCUMENTATION AND RECORD KEEPING?

❖ **Requirements for Investigators**

Investigators must store all research materials including the data, tapes, analysis, and signed consent documents in a secure location in a way to insure confidentiality of participants for three [3] years after completion. After three years, the materials must be destroyed or kept in a secure location as long as they are needed. When materials are no longer needed, they must be destroyed. Electronically stored data must be protected, generally through the use of a password that limits access. Different word processing systems give instructions on how this may be done.

❖ **Requirements for the Human Subjects Committee**

The School for Social Work will prepare and maintain documentation of Human Subjects Review Committee activities. This documentation will be kept on file in the Office for at least three [3] years after completion of the research and will include:

1. Copies of all research protocols reviewed, evaluations, approved sample consent documents, progress reports, and reports of injuries to subjects
2. Minutes of Human Subjects Review Committee meetings
3. Copies of HSR Committee correspondence
4. A list of Human Subjects Review Committee members
5. Copies of policies and guidelines.

WHAT ARE THE RESPONSIBILITIES OF RESEARCH ADVISORS?

Research Advisors will

- Provide consultation on research questions and methods
- Provide consultation on and review all materials prepared for human subjects review
- Sign off on all materials before submission to the HSR Committee.

WHAT ARE THE RESPONSIBILITIES OF THE HUMAN SUBJECTS REVIEW COMMITTEE?

The HSR Committee will

- Offer consultation on issues of informed consent and human subjects review
- Review and approve or disapprove HSR Applications and accompanying materials involving human subjects
- Provide initial and continuing review of research protocols and research activities involving human subjects.

WHAT IS THE HUMAN SUBJECTS REVIEW PROCESS?

The Chair of the Human Subjects Review Committee reviews each submission to determine if there should be a full committee or an expedited review. Any Committee member can also refer an application for full committee review.

▪ **Full Committee Review**

Full committee reviews are required when the participants are vulnerable, in need of special protections or when the research may be particularly stressful. Vulnerable populations include minors, people who are incarcerated, people who are unable to give informed consent because of cognitive or psychiatric limitations. Full HSR Committee reviews are scheduled biweekly from October through April.

▪ **Expedited Review**

The Human Subjects Review Committee may review submissions through an expedited review procedure if the participants are not vulnerable, if the proposed research activity involves no more than minimal risk to the participant and if the only involvement of human subjects will be in one or more of the following categories:

- Voice or video recordings
- Research on individual or group behavior, where the investigator does not manipulate participant's behavior **and** the research **will not involve more than minimal stress to participants**
- Study of existing data, documents, or records.

Under an expedited review procedure, the submission is reviewed by two members of the Human Subjects Review Committee who send their feedback to the HSR Chair, who sends a report of the findings to the applicant (and the research advisor if the researcher is a student). Expedited reviews are reported to all members of the HSR Committee.

Criteria For Evaluating All Submissions

All submissions are evaluated to determine that all of the following requirements are satisfied:

- Risks to participants are minimized
- Risks to participants are reasonable in relation to anticipated benefits to participants and the importance of the knowledge that may reasonably be expected to result.
- Selection of participants is equitable
- Informed consent will be sought from each prospective participant or the participant's legally authorized representative and will be appropriately documented. In the case of anonymous research as described above, the electronic indication of consent is sufficient documentation.
- Adequate provision is made for monitoring the data collected to insure the safety of participants
- Adequate provisions have been made to protect the privacy of participants and to maintain the confidentiality of data
- Additional safeguards have been included in the study to protect the rights and welfare of "vulnerable" participants.

Following all reviews, the Human Subjects Review Chair will send a written report of the findings of the Committee to the Applicant, giving approval or requesting that additions, corrections or revisions be made. The HSR Chair, or designated Committee member in case of the HSR Chair's absence, will have the authority to approve or require modifications to the research protocol. However, a research protocol can only be finally disapproved after it is reviewed by the majority of Committee members at a convened meeting. This occurs only when the Committee feels that even extensive modification would not bring the study into compliance.

The Chair of the Committee reviews revised submissions to be certain that all requested changes have been made, and if they have been satisfactorily completed, sends a final letter of approval.

Minor changes in previously approved research protocols may also be reviewed and approved by the Chair of the Committee. Major changes must be returned for the review process.

Appendix A
Human Subjects Review Planning Form

Student _____ Date _____

Advisor _____

NOTE: If your project fits 1, 2, 3, or 4a, you will need to include letters documenting both the original Human Subjects Review and the authorization of your use of the data as appendices in your thesis. **All students: please indicate below whether or not your thesis project will require a Human Subjects Review.**

1. My project is based upon existing (but not publicly available) data with a Human Subjects Review completed by the party giving me access to the data. I have indicated below the name of the researcher or administrator giving me this access and the name and address of the agency which granted the Human Subjects Review approval:

a) Name of person authorizing the use of the data:

b) The name and address of the agency that gave the Human Subjects Review approval:

2. My project will require an agency Human Subjects Review. I have indicated below the name of the agency and the name of the Chair of its Human Subjects Review Board:

a) Name and address of agency doing the Human Subjects Review:

b) The name of the agency Human Subjects Review Board Chairperson:

3. My project will require a Smith College School for Social Work Human Subjects Review.

4. My project will not require a HSR Committee review.

- a. I am requesting a waiver from the Human Subjects Review process. Attached is a brief plan of my study for the Committee's approval.
- b. My project will not involve collection of original data from human subjects. (This includes use of publicly available "canned" data sets.)

**Appendix B
Human Subjects Review Application**

Investigator Name: _____

Project Title: _____

Contact Address: _____

Contact Phone: _____ E-mail Address: _____

Please do not copy the outline into your Application. Just use the appropriate topic headings that are in bold.

Project Purpose and Design

- a) Describe the project, the research questions, and the research methods to be used.
- b) Discuss the background and justification for the study, including a brief review of the salient literature.
- c) Describe the potential usefulness or value of the findings.
- d) State specifically how the research will be used. (That is for the MSW Thesis, presentation, and publication. Do not say "submitted in partial fulfillment...")
- e) Determine and state whether your research involves prisoners or any participants who are likely to become prisoners during the research. (see note below for definition of prisoner)
- f) Determine and state whether your research involves women who are pregnant or likely to become pregnant during the research or if your research involves neonates.

The Characteristics of the Participants

This may include race or ethnic group, age range, etc.; affiliation of participants, e.g., institution, agency, etc.; participants' general state of health or vulnerability.

- a) List specific inclusion criteria.
- b) List specific exclusion criteria.
- c) State sample size desired.

The Recruitment Process

- a) DESCRIBE EVERY STEP OF THE RECRUITMENT PROCESS from the initial identification of a potential participant to the moment the data gathering process begins. Be sure to include the screening process.
- b) Include information about where recruitment will take place.
- c) Describe efforts to achieve diversity or state why you will not recruit for diversity.
- d) Attach copies of all recruitment materials.

Note: Prisoner means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. 45 C.F.R. 46.303(c)

The Nature of Participation

- a) Describe the nature of the participation. Exactly what will the participants do?
- b) List all procedures to be used. Be sure these procedures relate to your research questions. Do not pursue gratuitous information.
- c) If you are collecting demographic data, say so.
- d) If there are interviews or other personal contact, state where this will take place.
- e) Estimate how long the participation will take. Always consider the extent of the burden to be placed on the participant. Keep demands as small as possible while enough to meet the needs of the project.
- f) Describe how you will gather and process your data. If you are audio or video tape recording, say so and say who will do the transcription.

Risks of Participation

- a) Put yourself in the place of the participant and try to think how each step of the process might be experienced.
- b) Describe but try not to either exaggerate or minimize the risks to the participant of participating in the research.
- c) State that you will distribute a list of referral sources to all participants with the exception of social workers or other mental health professionals. It is often useful to attach these to the Informed Consent.
- d) Make it clear that all identifying information will be held in confidence, but if it will not be possible to keep confidential the fact that a person is participating in the study, make a statement to this effect.

Benefits of Participation

- a) Describe the personal benefits that the participant might gain from being involved in the research (for example, gaining a new perspective, having an opportunity to share experience).
- b) Describe the benefits that the participants could gain in participating in the development of knowledge that might be helpful to others or increase understanding.
- c) If there is a tangible benefit (money, material goods, expenses, course credit), explain this. Do not use such a benefit coercively. If there is a tangible benefit, participants must be rewarded even if they withdraw or fail to complete the participation.

Informed Consent Procedures

- a) **Describe every step of obtaining the Informed Consent.**
- b) If the participant is a minor, describe how parental or guardian consents will be obtained BEFORE THE MINOR IS APPROACHED.
- c) Address a minor's right to refuse to participate.
- d) In the case of participants under eighteen, state that you will provide an Informed Consent in age appropriate language or a verbal discussion of rights and expectations, so that minors are fully informed. Most children age ten and over should have an opportunity to sign an Informed Consent.
- e) If your participants do not read English, state that the Informed Consent will be translated into the participant's native language and describe how you will obtain the Informed Consent. Attach a copy of the translated Informed Consent.

Precautions Taken to Safeguard Confidentiality and Identifiable Information

- a) Describe the steps that will be taken to safeguard identifiable information (for example removing names, using code numbers, keeping signed Informed Consents separate from completed instruments or tapes).
- b) State that anyone transcribing tapes or analyzing data in which participants could be identified will sign a confidentiality agreement.
- c) Differentiate between anonymity and confidentiality. In many studies, it is not possible to guarantee anonymity, while it is possible to promise confidentiality, for example when a questionnaire is administered in a group.

- d) Students should state that their research advisors will have access to the data after identifying information has been removed.
- e) Describe how you will prepare presentations and publications in such a way that participants will not be identified. (Present data about participants as a group. Disguise illustrative vignettes and quoted comments.)
- f) Describe how you will store data in a secure place. Electronically stored data must be protected. State that all data and tapes will be kept secure for three years as required by Federal regulations and that after that time, they will be destroyed or continue to be kept secured as long as you need them. When no longer needed, data will be destroyed.

The Voluntary Nature of Participation

- a) State that participation is voluntary and that participants may refuse to answer any question.
- b) State the conditions under which they may withdraw from the study should they wish to do so and how they withdraw. Include the date after which they cannot withdraw.
- c) Say you will immediately destroy all materials related to them should they withdraw or, if the protocol makes identification and destruction of their material impossible (eg. a focus group), explain that.
- d) Explain to anonymous participants that it will be impossible to withdraw once their materials have been submitted as it would not be possible to identify it.

Procedures for Administering an Anonymous Research Project

- a) Potential participants may be recruited in a variety of ways including email postings, the distribution or posting of fliers, etc.
- b) The communication should briefly describe the project and invite the potential participant to sign on to an email address which will take them to your project.
- c) They should be greeted by a “welcome page” which thanks them for their interest and asks them in a yes or no format the questions which determine eligibility.
- d) If they say “no,” they should be thanked and informed that they are not eligible for the study. If they say “yes,” they are automatically sent to the Informed Consent.
- e) At the end of the Informed Consent, after the Statement of Agreement, they can check an “I agree” box. If they agree, they are automatically sent to the research instrument.
- f) The list of referrals should be attached to the Informed Consent so that when the Consent is printed, the referral list will accompany it.

Investigator’s Signature: _____ Date: _____

Advisor's Signature (if applicable): _____ Date: _____
(Required for all students)

Appendix C

Format of an Informed Consent Form

General Instructions

- 1) Use the first person. This is a "letter" addressed by you to your potential participant. Maintain this consistently throughout the Consent.
- 2) BE AS BRIEF AND SUCCINCT AS POSSIBLE. Don't burden your potential participants with unneeded detail.
- 3) Avoid the use of technical or professional language. Make the Consent "reader friendly."
- 4) If you have fully and carefully filled out the Application, it will guide you in writing the Informed Consent. Although you will alter the language, as this is for a different audience, keep the Consent basically consistent with the Application.
- 5) If this Informed Consent is for a parent or guardian, make the appropriate language changes, saying "your child" or "your ward" when you refer to the participant.

Salutation, such as, "Dear Participant"

First Paragraph

- Introduce yourself and describe who you are and your affiliation.
- Include a statement that this study involves research.
- Give a brief statement/explanation of the focus and purposes of the research.
- Include a statement about the specific uses of the data (MSW thesis, dissertation, publications, presentation.) Do NOT say "submitted in partial fulfillment."

Second Paragraph

- Describe the participant's involvement in the research in concrete terms.
- Include a statement of inclusion and exclusion criteria for participation.
- Provide the approximate length of time for participation in this research.
- Briefly describe the procedures to be followed, for example, audio or video taping, a survey, etc. and say who will do the transcription. (e.g. yourself or a professional transcriber) and add that if a transcriber is used, he or she will sign a confidentiality pledge.

Third Paragraph

- Describe but do not exaggerate the possible risks associated with involvement in this research, including any emotional discomfort or stress that may occur.
- Inform participants that you will provide them with a list of referral resources. Generally, a list of referral sources will not be provided to social workers and other mental health professionals as they would be aware of appropriate resources.
- Describe any benefits to the participants and to society associated with involvement in this research.
- Include a statement about whether or not compensation will be provided for participation in this study and describe the compensation.

Fourth Paragraph

- Describe the confidentiality that can reasonably be provided in this research.
- Inform participants of those who will have access to the data – such as advisors.
- Describe how confidentiality will be maintained to the extent possible in the research.
- Describe how confidentiality will be maintained with additional data handlers, such as transcribers, data analysts, etc. Include the fact that should a transcriber aside from you transcribe the tapes, they will sign a confidentiality pledge.
- State that in publications or presentations, the data will be presented as a whole and that when brief illustrative quotes or vignettes are used, they will be carefully disguised.
- Include a statement that all data (notes, tapes, transcripts, questionnaires, etc.) will be kept in a secure location for a period of three years as required by Federal guidelines and that data stored electronically will be protected.
- State that should you need the materials beyond the three year period, they will continue to be kept in a secure location and will be destroyed when no longer needed.

Fifth Paragraph

- Include a statement that participation in the study is voluntary.
- State that they may withdraw from the study at any time during the data collection process and that they may refuse to answer any question. If it is possible to withdraw from the study, say so and describe how they may do that and specify the final withdrawal date. Add that all materials pertaining to them will be immediately destroyed should they choose to withdraw. If their data cannot be withdrawn, say so and explain why, for example in anonymous studies and focus groups.
- Include information about how to contact the researcher in case the participant has additional questions or wishes to withdraw.
- State that should they have any concerns about their rights or about any aspect of the study, they are encouraged to call you (give contact information) or the Chair of the Smith College School for Social Work Human Subjects Review Committee at (413) 585-7974.

Sixth Paragraph

Include the standard phrase:

YOUR SIGNATURE INDICATES THAT YOU HAVE READ AND UNDERSTAND THE ABOVE INFORMATION AND THAT YOU HAVE HAD THE OPPORTUNITY TO ASK QUESTIONS ABOUT THE STUDY, YOUR PARTICIPATION, AND YOUR RIGHTS AND THAT YOU AGREE TO PARTICIPATE IN THE STUDY.

- Include signature and date lines for the participant and the researcher.
- Often a researcher includes her/his contact address, phone or email at this point. It is generally wise not to use your home phone number or address.

- Indicate that the participant should keep a copy of this form that you have provided for her/his records.
- Thank the participant for her/his participation.

MODIFICATION FOR INFORMED CONSENTS SIGNED BY PARENTS OR GUARDIANS:

YOUR SIGNATURE INDICATES THAT YOU HAVE READ AND UNDERSTAND THE ABOVE INFORMATION AND THAT YOU HAVE HAD THE OPPORTUNITY TO ASK QUESTIONS ABOUT THE STUDY, YOUR AND/OR YOUR CHILD'S (OR WARD'S) PARTICIPATION, AND YOUR AND YOUR CHILD'S (OR WARD'S) RIGHTS AND THAT YOU AGREE TO PARTICIPATE AND TO ALLOW YOUR CHILD (OR WARD) TO PARTICIPATE IN THE STUDY.

MODIFICATIONS FOR MAILED QUESTIONNAIRES:

Mailed questionnaires will be sent with an accompanying Consent form. The signed Consent form must be returned, with the mailed questionnaire. A coding system may be used in which a code number is placed on the Consent and the Questionnaire, obviating the need for a signature on the questionnaire. The Consents and the questionnaires should then be kept secure and separate to protect confidentiality. It is generally wise and tends to increase participation if you send a stamped, addressed envelope in which your participants can return their materials.

MODIFICATIONS FOR ANONYMOUS RESEARCH PROJECTS:

When the Informed Consent is handled electronically, it is still essential that the participant be clear about his or her rights and that he/she has consented to participate. We recommend that the Informed Consent letter which describes the project end with the following statement, or one that makes the same points:

BY CHECKING "I AGREE" BELOW (OR INSERT ANOTHER MEANS OF INDICATING CONSENT) YOU ARE INDICATING THAT YOU HAVE READ AND UNDERSTAND THE INFORMATION ABOVE AND THAT YOU HAVE HAD AN OPPORTUNITY TO ASK QUESTIONS ABOUT THE STUDY, YOUR PARTICIPATION, AND YOUR RIGHTS AND THAT YOU AGREE TO PARTICIPATE IN THE STUDY.

Appendix D

Example of Volunteer or Professional Transcriber's Assurance of Research Confidentiality

This thesis project is firmly committed to the principle that research confidentiality must be protected and to all of the ethics, values, and practical requirements for participant protection laid down by federal guidelines and by the Smith College School for Social Work Human Subjects Review Committee. In the service of this commitment:

- All volunteer and professional transcribers for this project shall sign this assurance of confidentiality.
- A volunteer, or professional transcriber should be aware that the identity of participants in research studies is confidential information, as are identifying information about participants and individual responses to questions. The organizations participating in the study, the geographical location of the study, the method of participant recruitment, the subject matter of the study, and the hypotheses being tested are also be confidential information. Specific research findings and conclusions are also usually confidential until they have been published or presented in public.
- The researcher for this project, - *insert name of researcher* - shall be responsible for ensuring that all volunteer or professional transcribers handling data are instructed on procedures for keeping the data secure and maintaining all of the information in and about the study in confidence, and that that they have signed this pledge. At the end of the project, all materials shall be returned to the investigator for secure storage in accordance with federal guidelines .

PLEDGE

I hereby certify that I will maintain the confidentiality of all of the information from all studies with which I have involvement. I will not discuss, disclose, disseminate, or provide access to such information, except directly to the researcher, - *insert name of researcher* - for this project. I understand that violation of this pledge is sufficient grounds for disciplinary action, including termination of professional or volunteer services with the project, and may make me subject to criminal or civil penalties. I give my personal pledge that I shall abide by this assurance of confidentiality.

Signature

Date

Insert name of researcher

Date

Appendix E

Example of an Agency or Institution Approval Letter

AGENCY LETTERHEAD MIGHT BE PLACED HERE

Date

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

To Whom It May Concern:

(Agency or Institution Name) gives permission for **(Student Name)** to locate his/her research in this agency (institution). We do not have a Human Subjects Review Board and, therefore, request that Smith College School for Social Work's (SSW) Human Subject Review Committee (HSR) perform a review of the research proposed by a **(Student Name)**. **(Agency or Institution Name)** will abide by the standards related to the protection of all participants in the research approved by SSW HSR Committee.

Sincerely,

Signature
(Agency or Institution Director)
(Name of program, if applicable)

Appendix F

Responsibilities of the Smith College School for Social Work

The Smith College School for Social Work will

- Protect the rights and welfare of human subjects
- Comply with federal, state and local laws as they relate to research involving human subjects
- Be responsible for research involving human subjects, as approved by the Human Subjects Committee. Provide written assurance to the Secretary of Health and Human Services that SSW will comply with the requirements of HHS regulations
- Establish and maintain an Institutional Review Board (The Human Subjects Review Committee)
- Provide meeting space for the Human Subjects Review Committee
- Provide sufficient staff to support protocol review
- Provide sufficient staff to support record keeping duties
- Encourage and support constructive communication of all relevant parties to maintain a high level of awareness regarding safeguarding the rights and welfare of subjects
- Maintain documentation of Human Subjects Review Committee activities
- Provide administrative overview

Appendix G

The Human Subjects Review Committee

The SSW has established and will maintain an Institutional Review Board (IRB) in compliance with HHS regulations (45 CFR 46, as amended). The Human Subjects Review Committee will act as the Institutional Review Board for Smith College SSW. The Dean of the SSW will insure appointment or election of the Committee members, which will consist of at least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the SSW. One member of the Committee must be a scientist. One must be an unaffiliated member of the community. The Committee will not entirely consist of women, or entirely of men, or entirely of members of one profession and will represent reasonable racial and cultural diversity. The Committee may, in its discretion, invite other individuals with competence in special areas to assist in the review of complex issues which require expertise beyond, or in addition to, that available on the Committee. These individuals may not vote with the Committee. Members will recuse themselves from reviewing any project in which they have a conflicting interest.

The Human Subjects Review Committee will follow written procedures as detailed in the assurance to the Department of Health and Human Services Expanded Guide for the Protection of Human Research Subjects. Except when an expedited review procedure is used, the Committee will review research protocols at convened meetings at which a majority of the members are present, including at least one member whose primary concerns are in non-scientific areas. Research protocols must be complete and must include documentation regarding planned research activities and participant informed consent. The Committee has the authority to approve, require modifications in (to secure approval), or disapprove research protocols. All non-expedited protocols must receive the approval of the majority of those members present at the meeting in order to be approved. The Chair of the Human Subjects Review Committee will provide written notification to investigators regarding the decision of the Committee to approve or disapprove the research protocol, or of modifications required to secure Committee approval of the research activity. If the Committee disapproves or requires modifications to a protocol, the written notification will include a written statement regarding the reasons for its decision. The investigator must respond to the notification.

- The Human Subjects Review Committee may waive the requirement for a review (see page 2) or waive the requirement for a signed, returned Informed Consent under certain conditions. (see page 3 of this document)
- The Human Subjects Review Committee has the authority to disapprove a project or to suspend or terminate approval of research that is not being conducted in accordance with the Committee's requirements or that has been associated with unexpected serious harm to subjects. The Committee will notify the investigator and the SSW Dean in writing of the disapproval, suspension or termination of approval including a statement of reasons for the action.

Appendix H

Availability of the Human Subjects User's Guide

Copies of these guidelines will be distributed to the following:

- ❖ Investigators involved in research with human subjects
- ❖ Sequence and program (masters and doctoral) Chairs
- ❖ Senior administrative staff
- ❖ All full- and part-time faculty with research, teaching or advising assignments
- ❖ Members of the Human Subjects Review Committee
- ❖ The Dean and Associate Dean of SSW, the Provost of Smith College and other Smith College administrators at the direction of the Provost

A copy will also be on file in the Office of the Dean of the Smith College School for Social Work.