Mills College

Guidelines for Research and Project Proposals Submitted to the Committee for the Protection of Human Subjects for Summer 2013

These protocol guidelines are based on requirements for research involving human subjects established by the federal government (see 21 CFR 56.101 et seq. and 45 CFR 46.103 et seq.). At Mills, *all faculty members* conducting research with human participants are expected to comply with the protocol guidelines in their own research and *oversight of student research* for two reasons: 1) to carry out their professional and ethical responsibilities as teachers and 2) to comply with federal standards for best research practices. *Mills faculty members and students* understand and accept their duty to protect individuals, respect their right to make informed decisions, avoid institutional forfeiture of research funds, ensure academic reputation, and provide instruction on sound research methods through full and active compliance with these guidelines.

Summer 2013 Chair: Linda Perez, Education

Committee Members:
Bruce Williams, Sociology/Anthropology
Additional Committee Members TBD

Submission: Submit the original directly to Linda Perez, Chair, Human Subjects Committee during summer 2013 (lmperez@mills.edu).

Deadlines for the submission of proposals for review.

Protocols may be submitted at any time. Usually we are able to act on them within a week's time.

Overview

The Committee for the Protection of Human Subjects is required to review all proposals for research by Mills faculty and students that involve human participants and proposals by individuals from other institutions who wish to recruit human participants from the Mills community. Researchers must prepare a written statement following the guidelines stated below. Mills faculty and students should submit their protocol directly to the Chair of the Human Subject's Committee. Individuals from outside of Mills must first submit their protocol to the Provost for consideration. Upon the Provost's approval, these proposals will be forwarded to the committee for review.

Members of the Committee for the Protection of Human Subjects are responsible for reviewing research protocols for potential risks to human participants. The Committee Chair will determine if proposals will receive a short or full review (see below). If full review is required, the Chair will synthesize the questions and concerns raised by Committee members and communicate these concerns directly to the researcher (and faculty advisor if the researcher is a student). The researcher may be asked to respond to questions and concerns before approval is granted. When this occurs, the researcher must address these issues by providing a written response to the Committee before the researcher can receive approval to begin the proposed study. Note that approval of a research proposal is not guaranteed. Final approval to begin the research will be provided to the researcher in writing. Researchers should allow at least two weeks for the full review process. Protocols that require additional information from the researcher will take longer.

Written announcements must also be submitted for approval and may only be distributed or posted if "Human Subjects Approved" is clearly stated. **Only copies of these "approved" announcements may be posted on campus.** All other announcements will be removed.

Information below (1) summarizes the forms of review and (2) addresses frequently asked questions. It then provides (3) instructions for the protocol format, (4) a checklist to help you ensure that your proposal is complete, (5) the title page form required to accompany all submissions, and (6) a copy of the review form that you (and your advisor, if you are an undergraduate or graduate student) will receive if there are questions or problems that need to be addressed.

I. Forms of Review

Proposals will undergo one of the following two forms of review:

A. Short Review: Proposals for research that use questionnaires, do not require descriptions of the research subjects, and recruit subjects from populations that are generally not thought to be at physical, developmental, or psychological risk (see below) will be subject to a short review. A single member of the Committee, the Committee chair or another member designated by the chair, will review these proposals. Note that approval is not automatic and that the proposal may be submitted to full review at the chair's recommendation. Researchers can usually expect a response based on a short review in one week or less.

B. Full Review: Research designed to use open-ended interviews, involve deception, or recruit participants who are minors (i.e., under 18 years of age) or defined as "at risk" will undergo full review by each member of the committee. (Note that some open-ended interviews may be considered for short review, particularly if the participants are not in the “at risk” category.) At risk populations include, but are not limited to, subjects who are identified on the basis of the following criteria or experiences in childhood or adulthood:

1) Psychological or physical trauma, including physical abuse or assault, sexual abuse, molestation, rape, physical injury, or loss through death.
2) Survivors of war, life-threatening illness, or other events that are thought to result in post traumatic stress symptoms.
3) Children and adults who are developmentally disabled or the mentally ill, including populations that are known to have a large representation of mental illness (for example, the homeless).
4) Individuals who are or have been incarcerated or otherwise identified as involved in illegal activities.

II. Frequently Asked Questions

What is the Committee for the Protection of Human Subjects and why does a committee need to review projects that involve human participants?

The Committee for the Protection of Human Subjects is charged by Mills College to oversee the health and welfare of human participants involved in research or projects that involve systematic contact (see below). The committee follows guidelines established by federal and state regulations. It is important to understand also that although the federal guidelines are primarily established to protect the human participant, the process of review and informed consent also serves to protect the researcher and the College.

What constitutes "research" that needs to be reviewed by the Committee for the Protection of Human Subjects?

Here are some guidelines to help you decide if your work needs human subjects review.

Research is defined as systematic investigation, interaction (communication and interpersonal contact), intervention (data gathering and manipulations of the individual's environment), examination (testing, evaluation), or the gathering of identifiable personal information (information about behavior or opinions in the absence of formal observation or data recording that potentially identifies a particular individual) that is designed to contribute to generalized knowledge. Demonstration, service, and creative or artistic projects that involve systematic contact with human participants with the goal of contributing to generalizable knowledge are considered "research." These projects often include the use of video or interview material. All "research" projects that are being funded by external or internal sources (e.g., Barrett undergraduate research grants) must be submitted for review.

As a rule of thumb, research projects that require review typically result in some form of systematic or formal presentation, including a senior thesis or senior project, conference presentation (including the Mills Undergraduate Research Conference), publication, community video presentation, etc. Interaction or the observation of human participants that is carried out within the context of a single class assignment and is under faculty supervision is not subject to human subjects review. Faculty who utilize this forms of "research" as a consistent pedagogical technique in their courses may wish to submit for review a generic proposal that covers these instructional "research" activities. Individual service learning projects as typically organized at Mills are not subject to review. These projects usually involve, in addition to the actual hours of service, (1) student participation in a Mills Cares seminar, (2) student participation in an already approved faculty project, or (3) written service learning response papers. If service learning is being used to, however, to contribute to generalized knowledge through a semester long group project that is systematic and draws together the work all of the students in a class, the committee recommends that the faculty member in charge of this project submit either a proposal specific to that project or a generic proposal as described above.

It can be difficult to determine if a demonstration, service project, or creative/artistic project is subject to review. Here are two key elements to consider in determining if your project needs to be reviewed. One element is how you select the human participants. If you are selecting a group of participants by approaching them (by letter, announcement, internet, or in person) and asking them if they wish to participate in your work (random selection, or based on a set of participation requirements, e.g., females between 18 and 24 years of age), then you may indeed be doing "research." The other element to consider is whether or not the goal of your project is to contribute to generalized knowledge. If your goal is to contribute to the understanding of a phenomenon (e.g., why do individuals wear clothing with sports logos) then you are contributing to generalized knowledge. Creative projects traditionally in the arts and

journalism are not considered research. Note though that video arts projects are often artistic research projects and may be subject to review.

As of October 2003, oral history projects are exempt from human subjects review. Oral history is defined as interviews that are designed to explain a particular past. The individuals who are interviewed are selected because of their unique relationship to and perspective on the topic under pursuit.

Above all, if you are uncertain about whether or not your project needs to be reviewed, get more information. Students should contact their advisors. The committee Chair can also answer questions.

May I get started on my research before I have received approval from the human subjects committee?

No. Review is the first step in "research" projects; **recruiting and interaction with human participants may not begin until the project has been approved**. The researcher is notified in writing when the approval process has been completed. Be sure to keep this letter on file, as you may be asked to provide evidence of approval (e.g., when applying for funding or when approaching other institutions for permission to recruit participants).

What is a consent form and are some projects exempt using written consent forms?

Informed consent is key to the process of protecting human participants. Informed consent is typically documented through the use of a written signed consent form that describes the nature of the project and what the participant should expect to experience. It also establishes in writing that the participant has the discretion to withdraw from the project at any time without ill consequence. The consent form should be written in a language that is understood by the participant. If reading is a problem, the consent form should be read to the participant. The participant should be allowed to ask questions about the project prior to signing the consent form. The consent form must be signed by both the researcher and the participant, or his/her legal representative (e.g., a child's parent or guardian). A copy of the signed consent form must be provided to the person signing the form.

Some projects do not require written signed consent. These projects include interaction with adult participants where failure to provide consent is clearly interpreted from the individual's nonparticipation (e.g., failure to return an anonymous survey; internet surveys), where the researcher is a "participant observer" (a technique that is popular, for example, in anthropological studies), or some naturalistic observation projects that involve no intervention or interaction with human participants.

How long does it take to complete the review process?

The initial review process may take about two weeks but the committee tries to keep the time as short as possible. For the purpose of planning it is important to remember that if the committee requests modifications or responses from you regarding your proposal, review will continue beyond the initial period until it is complete.

If I am a student, can the review process begin before my faculty advisor has read the proposal and signed the title page?

No. Student projects must be reviewed first by faculty advisors prior to submitting the protocol to the committee. Overview by your faculty advisor is advantageous as faculty can help you submit a thorough protocol and, thus, decrease the amount of time your proposal is under committee review. The committee will not initiate the review process if title the page is incomplete. Be sure to get your faculty advisor's signature prior to submitting your proposal.

May I recruit participants by posting or distributing announcements on campus?

Yes. Recruitment advertisements may be posted on campus or you may recruit participants through course or e-mail news announcements. All advertisements posted on the Mills Campus must have the Human Subjects Committee approval designation on them or they will be removed. If you are recruiting participants through e-mail or course announcements, be sure to indicate that your project has been approved by human subjects. A copy of the "approved" announcement will be returned to you with your approval letter. You may request to pick up the "approved" announcement directly from the Committee Chair or your faculty advisor (for students).

How do I recruit participants from agencies or institutions off campus?

Mills approval does not extend to other institutions. If you plan to recruit participants from locations off campus, you first must complete the Mills College human subjects review process. Upon approval of your project, you may then contact other institutions for permission to recruit participants. If the institution has its own human subjects review board, you will need to submit your protocol to this board. If you are recruiting participants using class announcements at other educational institutions (including elementary and high schools), be sure to check with the school principal or dean to find out more about that institution's specific recruitment rules. Classroom teachers often do not know these rules, so be prepared to speak with the institution's administrators.

What do I do if my proposal has already been approved but I want to change my study or project?

Let the committee know the status of your project. There are occasions when a project has already been approved but you wish to change or add to the data collection procedures or the manner by which you contact, interview, or interact with your participants. Simple additions or changes do not required full submission of another research protocol. Rather, submit in writing to the committee chair information about the revisions you propose. These revisions will be reviewed; once approved, they are added to your original proposal. As with the original proposal, **(1) documents submitted for project changes are not reviewed during academic breaks and (2) revisions cannot be implemented until you have received written approval of the changes**.

Some individuals find that their original research or project ideas do not work out and that they must develop new projects. New projects are treated in the same way as first time submissions. This means that a new proposal must be submitted to the committee for review. Approval of a different project under your name or the names of others in your group does not constitute approval for new projects that have different goals and methods of interacting with human participants.

III. Protocol Format

Human Subjects protocols must include a description of the information provided below. Submission of a research summary or pages of one's proposal and a consent form alone are not sufficient.

Title Page – Basic Information

Please fill out the proposal information sheet provided with this document and use it as your cover sheet for submission to the Committee. The faculty advisor must sign student proposals. Please be sure that all written information is legible (especially name and contact information).

Description of Research

Describe precisely:

1) The goal(s) of this research.
2) The scholarly background that provides the framework for this research.
   The purpose of the scholarly background section is to provide evidence to the committee that your project is worthy and makes a contribution to your field. Be sure to include reference citations and a bibliography. Remember that it is unlikely that the committee members who review your protocol are familiar with your area of interest, so this section must be sufficiently complete to establish the importance of your project. It is not sufficient to prepare a few paragraphs stating your ideas are important as evidenced by a list of references.

Benefits of the Research to Human Subjects

Specify the benefits of this research to the subjects, and to scientific and human knowledge. The researcher must not assume that actual participation in your project is indeed a benefit, nor is providing a format or context for discussing or engaging in dialogue regarding certain issues necessarily a benefit (unless your project is a form of psychotherapy intervention). The researcher must also take care here not to assume that he or she will provide feedback about his or her own experience as a benefit to the participant (unless this is specifically a form of your intervention study and design).

Description of the Participants

Specify exactly who the participants in this research will be and approximately how many participants will be included in your project. Be sure to include information about age, sex, and physical, psychological, experiential, social, or any other demographic characteristics that will be used to determine who will be considered a potential participant in this research.

Procedures and Methods

Describe the procedures for recruitment and the data collection settings and measures/methods that will be used with the participants in this study. Be sure to specify what, if any, data will be in video or audiotaped form. Copies of all measures, including interview protocols, must be submitted in an appendix. Procedures also include the steps you take to contact agencies or authorities that need to be informed or approve your project beyond the Mills community. Be sure also to include, where applicable, (1) the statement, advertisement, or recruitment flyer that will be used to recruit participants and (2) copies of letters you will use to introduce your project to other institutions (e.g., letters to school principals, child care agencies, jail administrators, battered women's shelters, etc.). If you are contacting participants through other institutions (e.g.,

schools, shelters, jails), the names of these institutions should be specified in this section of your proposal.

Potential Risks and Discomforts to Subjects

Identify and discuss all the potential risks and discomforts to participants in regard to the data collection procedures identified above. This discussion should be thorough and careful. The researcher should not assume that there are no potential risks or discomforts to participants, even if the project appears to the researcher to be benign or potentially beneficial to participants. It is particularly important to discuss 1) issues of confidentiality and 2) special characteristics of the population being studied.

Means Taken to Minimize Risk and Discomfort

Describe thoroughly the steps the researcher will take to minimize the potential risks and discomforts to the participants identified above. Be sure also to describe how written, video, and audio data will be stored and exactly who will have access to data that have not been made confidential (e.g., by eliminating personal identifying information).

Informed Consent (See attached sample consent form below)

Provide the Committee with a copy of the consent form to be used with this research. Be sure the consent form includes:

1) A title.
2) A brief but honest description of what the research participant will experience or should expect during the course of the study, including setting where participation will occur and length of time and/or number of contacts.
3) An explanation that participation is voluntary and that the participant may withdraw from the study at any time without penalty.
4) A description of who will see the participant's data and how the data will be stored.
5) In some studies, the researcher may wish to use an individual participant's data in a venue beyond this project. For example, the researcher may wish to show a videotape recording in a class or at a professional conference, or to describe a participant in a media interview. If this form of use is anticipated, the consent form should list potential venues and the participant should initial the venues for which he or she provides consent. The researcher should think this through carefully for without this consent, data that might identify the individual participant can never be used in these other settings.
6) Signature of the participant. If the participant is a minor, state the minor's name and the signature of a parent or legal guardian.
7) Date.
8) Signature of the researcher.

Researchers must provide a copy of the consent form to the participant and keep a copy for one's own records.

Mills College Human Subjects Protocol
Sample Informed Consent Form

"Title of Project"
Informed Consent

I, [NAME OF PARTICIPANT], state that I am over 18 years of age and that I voluntarily agree to participate in a research project conducted by [NAME OF PRINCIPAL INVESTIGATOR, TITLE, INSTITUTIONAL AFFILIATION].

The research is being conducted in order to [BRIEF DESCRIPTION OF THE GOALS OF THE RESEARCH]. The specific task I will perform requires [DETAILS OF THE RESEARCH TASK INCLUDING INFORMATION ABOUT THE DURATION OF PARTICIPANT'S INVOLVEMENT. ANY POSSIBLE DISCOMFORT TO PARTICIPANT MUST ALSO BE DESCRIBED.]

I acknowledge that [NAME(S) OF PRINCIPAL INVESTIGATOR OR RESEARCH ASSISTANT(S)] has (have) explained the task to me fully; has informed me that I may withdraw from participation at any time without prejudice or penalty; has offered to answer any questions that I might have concerning the research procedure; has assured me that any information that I give will be used for research purposes only and will be kept confidential. [PROCEDURE FOR PROTECTING CONFIDENTIALITY OF RESPONSES SHOULD BE EXPLAINED.] [IF THIS PROJECT INCLUDES DATA THAT IS IDENTIFIABLE IN ANY WAY, SUCH AS VIDEO, AUDIO TAPE, PHOTOGRAPHS ETC., INCLUDE THE FOLLOWING: I understand that any use of the [VIDEO, AUDIO TAPE, ETC.] that result from my participation in this study will not be used for purposes that are not directly related to research venues, such as presentation in meetings or conferences open to the public or press, without my further written consent. I understand that individuals associated with this research may request now or at some time in the future an extension of the permissions for the use of this information that I consent to here.]

I also acknowledge that the benefits derived from, or rewards given for, my participation have been fully explained to me-as well as alternative methods, if available, for earning these rewards-and that I have been promised, upon completion of the research task, a brief description of the role my specific performance plays in this project. [THE EXACT NATURE OF ANY COMMITMENTS MADE BY THE RESEARCHER, SUCH AS THE AMOUNT OF MONEY TO BE PAID TO INDIVIDUALS FOR PARTICIPATION, SHOULD BE SPECIFIED HERE.] I understand that I may contact [NAME OF PRINCIPAL RESEARCHER, PHONE NUMBER, STUDENT'S ADVISOR IF THE RESEARCHER IS A STUDENT, AND MILLS COLLEGE DEPARTMENT AND PHONE NUMBER] if I have questions about this study at a time following my participation.

_____	_____
(Signature of researcher)	(Signature of participant)
_____	_____
(Date signed)	(Date signed)

IV. Protocol Submission Checklist

Have you completed the following?

___ Undergraduate and graduate students: Advisor has reviewed protocol thoroughly.
___ Undergraduate and graduate students: Advisor's signature

Protocol includes:

___ Title Page
___ Description of Research:
    ___ Goal of research
    ___ Scholarly background (sufficient explanation)
___ Benefits of the Research to Human Subjects
___ Description of the Participants
___ Procedures and Methods
___ Potential Risks and Discomforts to Subjects
___ Means Taken to Minimize Risk and Discomfort
___ Informed Consent
    ___ Project title at top of consent form
___ Appendix
    ___ Copies of data collection methods and interview protocols
    ___ Letters or materials introducing study to other agencies or institutions (if applicable)
    ___ Announcements to be posted
    ___ Newspaper advertisement
    ___ Telephone or personal recruitment scripts

V. Title Page: Committee for the Protection of Human Subjects
Proposal Information

Name of Project: _____

_____

Submission Date: _____ Sponsoring Department: _____

Anticipated completion date or project due date: _____

Researcher Information (print):

Name: _____

Address: _____

_____

_____

Phone: _____ email: _____

Researcher's Signature: _____
Date: _____

For student projects (print)

Project Advisor's Name: _____ email: _____
(Print)

Project Advisor's
Signature: _____ Date: _____

VI. Committee for the Protection of Human Subjects Protocol Revision Checklist

Name _____ Date _____
Project Title: _____
Program/Department _____ Advisor _____

The committee has received your protocol and the sections checked below need to be revised. Students should consult with their advisors to help them with revisions. Please submit your revised protocol to Linda Perez, Chair, Human Subjects Committee during summer 2013 (lmperez@mills.edu). You do not need to resubmit the original title page. Indicate in a written cover letter that you are resubmitting your protocol and how you have addressed the problems or questions raised. *Protocol revision received after the deadline will be reviewed* _____.

___ Title page with appropriate signatures

___ Description of Research

___ Inadequate description of research goal

___ Inadequate summary of background research

___ Reference citations and/or references omitted from summary

____ Benefit of Research to Human Subjects: Inadequate description of what research in this area will contribute to the field

___ Description of Subjects: Inadequate description of the pool of human participants proposed for your study.

___ Procedures: Inadequate description of procedures. Be sure to describe exactly what proposed involvement with human participants is, including what surveys, questionnaires, videotapes, interventions, etc. will be used.

___ Assessments have not been appended to the protocol. Add as appendices copies of all proposed interviews, surveys, questionnaires, written recruitment announcements, script for telephone participant recruitment, letters/materials introducing your study to other institutions/agencies, etc.

___ Potential Risks and Discomforts to Subjects: Inadequate description of the distress or discomfort a human participant may experience by participating in your research or project.

___ Means Taken to Minimize Risk and Discomfort: Inadequate description of the means taken and/or resources provided to human participants who might experience distress or discomfort a human participant may experience by participating in your research or project. Psychological or social services resources should be named if applicable.

___ Consent Form