Lewis & Clark College
HUMAN SUBJECTS RESEARCH COMMITTEE - HSRC
(Institutional Review Board for Federal Purposes)

Manual for Research Involving Human Subjects

THE PURPOSE OF THIS MANUAL

The manual is intended as a guide for faculty, students, fellows, staff, and any other members of Lewis & Clark College who plan to carry out research, whether funded or unfunded, involving the participation of human subjects. It provides basic information about the materials needed to apply for human subjects approval and how to complete your application.

INTRODUCTION

Research with human subjects that is conducted by any member of the Lewis & Clark College community or anyone using Lewis & Clark facilities, must be reviewed and approved by the Human Subjects Research Committee (referred to hereafter as the HSRC). The purpose of this review is to allow the HSRC to evaluate the "risk-to-benefit ratio" of the research. The HSRC's only interest is in protecting the safety, welfare, privacy and rights of human research subjects. It is not the HSRC's objective to pass judgment on other aspects of the research except as they relate to this ratio. However, the methodology of a research project often pertains to the evaluation of this ratio. To this end, principal investigators shall prepare protocols giving complete descriptions of the proposed research.

The application for review of research involving human subjects must contain specific information. This information allows the HSRC to evaluate the following:

1) Risks to subjects(s)
2) Benefits to subject(s) and /or society
3) Specific nature of subjects' participation including:
    - Recruitment of subjects
    - Voluntary nature of subject participation
    - Informed consent
    - Remuneration (if any) to subject
    - Specific procedures to be followed
    - Confidentiality

In order to submit research for review, investigators must complete the **APPLICATION FOR APPROVAL TO USE HUMAN SUBJECTS IN RESEARCH, AND A SIGNED CONFIDENTIALITY FORM FOR ALL RESEARCHERS, INCLUDING RESEARCH ASSISTANTS.** The most important concerns of the HSRC are to assure subjects' safety, preserve subjects' anonymity and confidentiality, and assure that participation is voluntary. Thus, the application should provide the HSRC with information related to these areas. Another concern is the desire for subjects to be fully informed of the procedures to be employed in the study and of possible adverse effects. Also, the procedures should not influence subjects to continue in a study if they desire to stop participation. In order to facilitate approval of the application for use of human subjects in research, it is necessary for all relevant information to be included in the application. It is of equal importance that the document present a clear and concise explanation of the proposed research project.

Delays in approval by the HSRC are frequently a result of:

1) Insufficient information
2) Relevant information being omitted from the application (or placed in appendices rather than in the text of the application)
3) Presenting information in a manner that is too technical and cannot be understood by HSRC members whose backgrounds and expertise vary greatly
4) The consent document contains grammatical and/or spelling errors or its language is inappropriate to the subject population being targeted

INSTRUCTIONS FOR COMPLETING THE APPLICATION

Important: The application should stand on its own. The application should provide all information necessary for HSRC members unfamiliar with the experimenter's field of research to be able to evaluate the risks to subjects, how subjects will be recruited, the potential benefits, and how informed consent shall be obtained.

Vulnerable Populations: Prisoners, pregnant women, institutionalized individuals, and children are to be studied only under certain conditions, and only if the study could not be undertaken without them. Typically, children are defined as those persons who are under 18 years old and have not obtained the legal age for consent to treatment or procedures involved in the research. Refer to the section "Informed Consent With Minors as Subjects" for details about using children as subjects. If child subjects are being obtained from another institution(s), written permission from an official from the institution(s) authorized to do so must accompany the protocol.

Research Involving Deception: The investigator is justified in withholding information from or giving incomplete or erroneous information to research subjects only when it can be demonstrated that the research cannot be conducted in any other way and that subjects will not be placed at risk. At the earliest possible moment consonant with the validity of the research, the subject should be informed of the actual purpose of the research and procedures must be developed to relieve any distress encountered. **All research involving deception must attach a full description of the debriefing procedure to be used to the application. Address this in application question 4 (Risk-to-Benefit and Levels of Risk).**

Subjects at Risk: "Subjects at risk" are any individuals who may be exposed to the possibility of injury, e.g. physical, psychological, or social injury, as a consequence of participation as a subject in any research or related activity which departs from the application of those established and accepted methods necessary to meet his needs or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service. When reviewing protocols with more than minimal risk to subjects, the HSRC will often delay approval of a protocol and make recommendations to the investigator for alterations in the wording of informed consent documents or for changes in the protocol to further minimize potential risks to subjects.

Applicants Seeking External Funding: Federal regulations require that protocols be "tracked" to grant proposals, although HSRC review and grant proposal preparation are independent activities. The Research & Assessment Office will fill in the internal reference number.

Signatures: Student researchers must obtain the signature of their faculty advisor before the HSRC will consider their application.

Application Questions

1. PURPOSE AND DESIGN OF RESEARCH

The description of your research should be in language that can be understood by non-experts in your field and should be in detail sufficient for the HSRC to make a judgment about the adequacy of the human subjects protections proposed. Such protections are the only concern of the HSRC; judgment about a particular project's validity or feasibility lies within its jurisdiction to the extent that it relates to human subjects protection. Research methodology appraisal is within the HSRC's purview if it determines the need relative to fulfillment of its mission.

2. SELECTION AND RECRUITMENT OF SUBJECTS FOR PARTICIPATION IN RESEARCH

When selecting subjects for research, it is important to consider carefully the category of subjects being chosen. Federal guidelines require a scientific justification if women and/or minorities are to be excluded from a subject population. In addition, vulnerable populations, e.g., prisoners, pregnant women, institutionalized individuals, or children, are to be studied only under certain conditions, and only if the study could not be undertaken without them. When recruiting subjects for research, it is important to follow procedures that will ensure that subject participation is truly voluntary and that no procedures that could be construed as even minimally coercive have been employed. The preferred method of recruitment is to disseminate information about the research study to potential subjects and to instruct them to contact the investigator if they are interested in participating. In the interest of respecting individuals' rights to privacy and confidentiality, recruitment procedures should involve having interested subjects identify themselves to the investigator rather than the investigator obtaining names and addresses from a third party and soliciting participation directly from individuals. Compensation may be offered to participants. However

participants must be assured that they may withdraw from the study at any time and still receive compensation. The type and amount of compensation must be described in the informed consent.

Acceptable means for the selection and recruitment of subjects:

- Placing an advertisement in a newspaper, journal, or other periodical requesting that interested persons who meet relevant criteria contact the investigator
- Posting a sign or placing flyers in a public area or, with permission from the appropriate authority, in a private area (such as a university, store, library, health club, etc.) requesting that interested persons who meet relevant criteria contact the investigator
- Obtaining names from public records, such as telephone directories
- Obtaining names from organization membership or client records to which the investigator has legal access and for which s/he has obtained permission from the appropriate authority

3. FIRST-PERSON SCENARIO AND MATERIALS

Provide a *complete description* of study recruitment and participation *from the respondent's perspective* (e.g., "I was contacted by … to participate in a research project, OR I saw a flyer recruiting subjects for research on… and called the number listed." etc.). Please include all copies of questionnaires and/or interview questions that will be used in the data collection process. If for any reason your project involves experimental or non-standard means of collecting data where standard procedures exist, a justification for the use of the non-standard procedures should be included here.

4. THE RISK-TO-BENEFIT RATIO AND LEVELS OF RISK

In general, the higher the risk involved in the project, the more detailed the explanation, precautions, and informed consent must be. The nature and type of informed consent is determined by the level of risk. Accordingly, the following broad guidelines for degrees of risk may be of assistance in making a necessary determination.

High Risk: Activities involving medical or behavioral science projects that may induce a potentially harmful altered physical or mental state or condition are forms of personal invasion and, as such, are considered to be in a "high risk" category. (Examples include biopsy procedures; the administration of drugs or radiation; the use of indwelling catheters or electrodes; the requirement of strenuous physical exercise; hypnotism; and subjection to deceit, public embarrassment and humiliation.) In these cases there must be especially careful documentation to show that the benefits outweigh the risks.

Intermediate Risk: Activities involving a wide range of medical, social, and behavioral projects in which there is no immediate physical risk to the subject are considered to be in an "intermediate risk" category. (Examples include personality inventories; interviews; questionnaires; the dissemination of any data or information concerning an identified individual; information gathering activities conducted in classrooms or elsewhere; individual or group therapy sessions; or the use of photographs, taped records, and stored data.) Since some of these types of procedures may involve varying degrees of dignity through the imposition of demeaning or dehumanizing conditions, prior written informed consent is also required. However, since this type of activity does not involve physical invasion but is where voluntary consent on the part of the subject is desirable, a more simplified consent is acceptable.

Low Risk: Certain activities are classified as "low risk" and may not require a written informed consent. (An example is the use of completely anonymous questionnaires.) If a written informed consent is deemed unnecessary or undesirable in a particular instance, there follows an additional responsibility to establish that: 1) the risk to the subject is minimal; 2) obtaining a consent would invalidate objectives of considerable immediate importance; and/or; 3) any reasonable alternative means for attaining the objectives have been thoroughly explored and would be less advantageous to the subject. Low risk involves situations in which there is no conceivable physical or mental discomfort, and the measurements made on subjects can be considered to be reasonably unobtrusive. In these situations written informed consent may be waived.

5. CONFIDENTIALITY AND/OR ANONYMITY

Describe how participant's confidentiality and/or anonymity will be protected. In addition, submit a signed HSRC confidentiality form for all researchers and assistants on your project.

6. DEBRIEFING PROCEDURES/REVELATION OF POTENTIALLY TROUBLESOME SITUATIONS

Describe the debriefing procedure, if applicable. If individuals possessing any special skills or training are to be present during procedures, this should be noted here. Where possible, investigators should provide the HSRC with a list of agencies, hospitals, professionals, etc., to whom they may refer subjects who reveal a need for such assistance.

7. INFORMED CONSENT

The description of the informed consent process and the informed consent form are one of the most important portions of the **APPLICATION FOR APPROVAL TO USE HUMAN SUBJECTS IN RESEARCH**. The form must give a clear and concise explanation of the research to be conducted and the procedures to be employed. The form must be written in language appropriate for the targeted subject population (e.g., English and Spanish versions should be written for a multi-cultural study). An informed consent document ideally should be one or two pages in length. The form should be written in language that is age- and culture-appropriate. The statement should be written clearly enough for the potential participant to understand what involvement in the study entails, so that she or he may make a reasonable, intelligent, and informed decision. The language should be kept simple, and the sentences short. The language of the form should be understandable at the eighth-grade reading level for studies using adult populations. The typeface should be large enough so that even subjects with impaired vision can read it. It is possible that the research may produce psychological difficulties for a subject; therefore, it may be necessary to make arrangements for those difficulties to be dealt with by a professional. For example, in one study of people with chronic illness, the Investigator provided all subjects with a list of mutual-help organizations in the local area. After review of the informed consent document, subjects should have a clear understanding of the procedures that will be followed with regard to their participation. The subject should be able to make an informed decision concerning participation, **free of explicit or perceived** coercion. Potential risks and procedures to minimize such risks must be stated in detail in clear, precise language. A statement should be included in which the subject declares himself/herself fully informed and agrees to participate on a purely voluntary basis. Finally, the subject should be given a copy of the consent form, and/or any information sheets that he/she is required to read. A model consent form is available for study at the end of the *Manual.*

Elements of the informed consent form:

The following elements must be included in the informed consent form:

- A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental. If the purpose of the research cannot be fully revealed to subjects, describe exactly what subjects will be told, the justification for any deception of subjects, and plans to debrief subjects after their participation in the research.
- A description of any reasonably foreseeable risks or discomforts (both physical and mental) that could reasonably be anticipated. This includes any potential financial risks or burden that could ensue such as who has responsibility for any costs or expenses that might arise from the study.
- A description of any benefits to the subject or to others that may reasonably be expected from the research. In most research, expected results are tenuous, at best. If no direct benefits due to participation are foreseen, it is appropriate to state this.
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. If the participant has been promised financial compensation, but chooses to withdraw, state that a pro-rated portion of the fee will be paid up to the point of withdrawal.
- A statement describing how anonymity and confidentiality will be maintained as well as the extent, if any, to which confidentiality of records identifying the subject will be maintained which should include how records will be kept confidential, (e.g., locked cabinet, erasing of tapes, etc.). If audiotaping is to occur, indicate who will hear the tapes, where they will be stored, and how and when they will be disposed. If videotaping is to occur, indicate to whom the tapes are to be shown and where they will be stored.
- The Principal Investigator(s) name(s) and affiliation(s).
- The informed consent form must have a line for the subject's and researcher's signatures, and the date of consent. If the participation must be anonymous and the form is to be signed with an X, then the signature of a witness must also be obtained. The Investigator should retain a copy of the signed consent form and provide a copy to the subject.

- An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of research-related injury to the subject. The informed consent form should include a phrase such as: If you have any questions regarding this research, you can call Professor _____ at (area code) TELEPHONE.

A Note on Language Style:

The language used in the consent form must be appropriate to the subject's level of education and understanding. Exculpatory language through which the subject is made to waive his/her legal rights or releases or appears to release the institution from liability for negligence may not be included. When applicable, a consent form should be translated into the subjects' first language. The consent form, and any materials used to recruit subjects should be submitted to the HSRC at the time application for human subjects approval is made. If these materials are written in a foreign language, both the forms to be used and their English translations are to be submitted.

Informed Consent With Minors As Subjects:

Participants under age 18 are considered legally unable to give informed consent. As human subjects, children are especially vulnerable. The following definitions are important for research with minors: (a) “Children” are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted, (b) “Assent” means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent, (c) “Permission” means the agreement of parent(s) or guardian to the participation of their child or ward in research, (d) “Parent” means a child's biological or adoptive parent, (e) “Guardian” means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care. The HSRC has decided that written assent should be obtained from children aged 12 and older; verbal assent should be obtained from children under 12 years of age. Assent from a child should be requested only after the child's parents or guardians have agreed that the child may participate. In most cases, the signature of one parent or guardian is sufficient. However, in studies involving greater than minimal risk, signatures from both parents or guardians may be required. Information provided during the procedure to obtain consent or assent from children should be presented in a form understandable by the children selected for the study. We encourage researchers to consider alternatives to the conventional consent form used with adults. Appropriate alternatives include: a checklist, pictures, role playing and audiovisual methods (slides, videos, cassettes). The basic information about procedures, purpose, selection, risks, benefits and willingness of the researcher to answer questions should be provided to children serving as research subjects.

Oral Consent:

In certain cases, the Principal Investigator may determine that oral consent is more appropriate and more adequately safeguards the subject. Oral consent shall consist of a written consent document presented orally to the subjects (or his/her legally authorized representative). The HSRC shall approve the written text of what is said to the subject or representatives. A copy of the information that is read to the subject should be given to the subject or the representative to keep. There should be a witness to the oral presentation who can attest that the information was given as stated.

When it Might be Appropriate to Omit Use of Consent Form:

As a general rule, the HSRC believes informed consent should be obtained from all research subjects. However, if the Principal Investigator believes that obtaining a signed consent form would be inappropriate, such a request must be justified according to the following criteria:

1) The only record linking the subject and the research would be the consent form and the principal risk would be potential harm resulting from a breach of confidentiality.
2) The research presents no more than minimal risk and involves no procedures for which written consent is normally required outside the research context. For example, in a sample survey of volunteers, investigators would describe the nature of the interview to the subjects. Rather than seek written approval, participation here is regarded as de facto consent.
3) Tacit Consent. When participation entails only the completion of anonymous written questionnaires, consent may be considered to be tacit. Provided that responses can in no way be used to identify subjects, written consent is not necessary. (To ensure that participation is voluntary, the investigator should not be present when subjects are filling out the instruments and subjects must not be required to hand back their responses directly to the investigator.)

When the use of a consent form is waived, the HSRC requires the Principal Investigator to provide subjects with a written statement regarding the research.

FREQUENT OVERSIGHTS IN APPLICATION MATERIALS AND CONSENT FORMS

1) The language in the consent form must be understandable to the population being addressed (e.g., children). In the event that consent forms may be best understood in another language, that version must be submitted along with an English translation.
2) The name and status of the investigator, as well as the College, school and department identifiers should be incorporated into the consent form text. The address and telephone number where the researcher can be reached should questions arise also must be included; where appropriate, the name of and telephone number of a faculty advisor should be included as well.
3) When cooperating institutions are involved, a letter of cooperation from an authorized official should be included. If a letter is not available at the time of application, it must be submitted before research may begin.
4) Methods for maintaining confidentiality of the data should be described in detail (i.e., coding procedures, who has access to the files, where files are kept, and how anonymity is protected).
5) When treatment or services are involved, an affirmation should be included indicating that an individual's decision not to participate will in no way affect the availability of services to which individuals are entitled.
6) When students are involved, an affirmation should be included indicating that non-participation will in no way affect academic standing.
7) When children are involved, both parental permission and children's consent or assent are required.
8) When audio or videotaping is involved, an opportunity to review the completed tape must be given so that subjects may ask that it not be used (either in whole or in part).
9) Requests to have proposals classified as exempt must be accompanied by a supporting statement, detailing which category of exemption is being claimed, and why the researcher believes the activity falls into this category. In the case of minors (individuals under 18 who are participants in research), exemptions are limited to the following categories of research:
    - studies that constitute normal educational practices in educational settings
    - educational tests, where identifiers are not recorded
    - collection or study of existing data, documents, records, pathological or diagnostic specimens, if these sources are publicly available, or if the information is recorded so that subjects cannot be identified
    - observation (as opposed to participation) by the principal investigator of public behavior where identifiers are not recorded by the principal investigator and there is neither a risk of harm to subjects nor observation of sensitive aspects of the subjects' own behavior

Reporting Unanticipated Problems and Changes in Protocol:

Any unanticipated problems involving risks to subjects or others participating in a research study or proposed changes to a previously approved application must be promptly reported in written memorandum to the HSRC. This includes changes in the (approved) consent form, sample composition, sample recruitment, or study procedures.

ACKNOWLEDGEMENTS

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IRB/HSRC MODEL CONSENT FORM

One copy of the consent form must be kept for your records and one copy must be given to the subject. Please include all of the elements described below in the submitted consent document, unless the review board explicitly waives one or more of the required elements. Informed consent documents should contain these elements:

A. Purpose & Procedures: A fair explanation of the study's purpose and procedures.
B. Risks: A description of any possible discomforts and risk reasonably expected.
C. Voluntary: Clear instructions that the subject is free to withdraw or discontinue participation at anytime without prejudice or penalty. Subjects must receive any promised compensation even if they discontinue their participation.
D. Questions: An offer to answer any inquiries concerning the goals of the research or the research procedures and to provide a summary of results upon a request. A contact person and phone number should be provided.
E. Confidential: A statement that the data collected is confidential and that the subject will not be identified by name in writing or orally.
F. Data Management: Provide itemized explanation of how the data will be managed, stored, and protected.
G. Video and/or Audio: When utilizing video and/or audio recordings, clearly receive confirmation from participant, explain how the researcher will use session video and/or audio recordings, who will have access to the recordings, and length of time stored.
H. Participant Compensation: Explain that there will be no compensation or if compensation is given, explain that the participant may voluntarily withdraw with compensation promised.
I. Researcher's contact information.
J. Confirmation that the subject is over 18.
K. Restatement of voluntary participation.

Sample Participant Consent Form

Please acknowledge that you have read and agree to each paragraph by checking each box.

A. Explanation of Procedure.

Study Purpose – *(Create a clear and specific description of the study purpose and procedure)*
□ I consent to participate in this study concerning the relationship between life events and journal writing. I understand that I will be expected to write in a journal three times, as well as complete some tasks on the computer. I understand that there are three phases too this study, two of which require my presence at the laboratory. Sessions at the laboratory will not exceed sixty minutes and my commitment outside of the lab will be limited to a fifteen-minute period.

B. Identification of Risks.

Risk Mitigation - *(Describe any risks to participants and include community-based services available to support participants. If participants are LC students LC services may be listed)*
□ I understand that aspects of the study may ask me to reflect on life events that might elicit negative feelings initially, but that these feelings should dissipate over time. If these feelings do not dissipate, I understand that there are services available to assist me and I can contact these services if I feel I need assistance. I am aware that if I would like to utilize the services of a mental health expert, I can contact the Lewis & Clark Counseling Center at (503) 768-7160 or the Lewis & Clark College Health Center at (503) 768-7165. I also understand that I will be given a list of contact numbers for these services.

C. Freedom to Withdraw.

Voluntary Participation
□ I understand that I may terminate my involvement in the study for any reason without penalty or loss of compensation. I understand that I may decline to answer any question asked of me, and that by doing so I will not be required to terminate my involvement in the study.

D. Offer to Answer Inquiries.

Questions
□ I understand that the researcher is willing to answer any questions I might have after I have participated in the study. The researcher reserves the right to answer questions regarding the findings of the study until after the project has been completed.

E. Statement of Confidentiality and/or Anonymity.

Confidentiality
□ I understand that no individual data will be reported and that the researcher will not share my individual results with me either during or after the project. Subject codes will be used to maintain confidentiality. I permit publication of the results of the study with the agreement that appropriate steps are taken to maintain participant confidentiality.

F. Data Management

Data Management
□ I understand that data from this study will be kept no longer than five years after the study is complete.

□ I understand that data may be collected in written or digital form and the data will be stored under password protection.

□ I understand that data collected in this study belong to the researcher.

□ I may request to review my interview transcript and offer additional comments after the interview is complete

□ I permit publication of the results of the study with the agreement that appropriate steps are taken to maintain participant confidentiality.

G. Video and Audio Recordings

H. Compensation Information

I. Contact Information.

J. Age Confirmation.

K. Restatement of Freedom to Withdraw.

Video and Audio
□ I understand that the researcher will be utilizing (audio and/or video) to record the session(s). The recordings will only be used for (purpose). Only (researcher & other assistants names) will have access to the recordings. The recordings will be kept for (time range) in accordance with the studies Data Management agreement.

Compensation
□ I understand there will be no compensation for participation in this study. OR I understand that if I withdraw for any reason, I will not lose compensation for my participation.

Contact Information
□ I understand that matters relating to this study can be directed to (researcher) at (phone and email), or the faculty advisor at (phone and email). If I have additional questions or concerns about this study, I can contact the Lewis & Clark College Human Subjects Research Committee at irb@lclark.edu.

Age to Consent
□ I acknowledge that I am eighteen years of age or older, and that I have read and understand the above explanations.

Voluntary
□ Again, I understand that my participation in this study is voluntary and that I have the ability to withdraw at any point without penalty or loss of compensation.

_____

Participant's Name (Print) Participant's Signature Date

I have presented this information to the participant and obtained his/her voluntary consent.

_____

Researcher's Signature Date

The extra copy of the consent form is for you to keep.