**Protocol Packet for Institutional Review Board (IRB) for the**

**Protection of Human Subjects**

**Lake Superior State University**

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# PROTOCOL PACKET

# INSTSTUTIONAL REVIEW BOARD FOR THE PROTECTI0N OF HUMAN SUBJECTS

Since your research will involve human subjects, your project will require review to determine if adequate measures are employed to protect those individuals involved in your study. Lake Superior State University reviews all research proposals involving human subjects regardless of the funding source.

The box below contain Lake Superior State University policy statement for implementation of federal regulations concerning institutional Review Board (IRB) governance of research involving human subjects.

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| The Office of the President has published regulations governing institutional Review Board (IRB) policies LSSU adheres to these regulations and has adopted the Piedmont Report [April 18, 1979, (which provides ethical principles and guidelines for the protection of human subjects of research)]. Anyone intending to use human subjects in research should reed these two publications. These publications are available in the Kenneth Shouldice Library Reserve Desk.  For the purpose of IRB Review, research is defined in the Federal Register [June 19,1991, Vol. 56, No. 117] as:  a systematic investigation., including research development; testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this recognition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some ‘demonstration‘ and ‘service' programs may include research activities. |

The attached pages include guidelines and instructions to assist you in preparing a protocol to be submitted to the IRB. The brief synopsis-on pages 5-6 will help you determine which parts of the protocol to complete and will give an explanation of the review process. If your research will be done at another facility that has NIH Assurance for IRB review, please have the other facility's IRB approve your protocol bringing it before the LSSU Institutional Review Board for review. Once you have approval format the other facility, please submit to the IRB office e copy of your approved protocol, LSSU cover sheet, and a copy of the letter stating that your protocol has been approved by that facility's IRB, which includes' their assurance number. There will be no need to revise your protocol packet, as long as ‘the original protocol covers all the points that must be addressed under LSSU protocol review. Any additional information that is required should be submitted with your original protocol. If you have any additional questions regarding completion of the protocol or the federal regulations, please contact the Chair of the Human Subjects Committee.

RESEARCH WHICH IS "EXEMPT" FROM REVIEW

EVEN THOUGH AN INDIVIDUAL RESEARCHER MAY, DETERMINE THAT AN INVESTIGATION FALLS WlTHIN THE CATEGORIES OF EXEMPT RESEARCH, IT IS NECESSARY TO FILE THE COVERSHEET AND A ONE-PAGE DESCRIPTION OF THE PROJECT WITH THE REVIEW COMMITTEE. The one-page description of the project must include the reason for the exemption and be written lay persons terminology.

**EXEMPTIONS DO NOT APPLY TO RESEARCH INVOLVING PRISONERS, FETUSES, PREGNANT WOMEN, OR HUMAN IN VITRO FERTILIZATION.**

Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from IRB review:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular' and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. (Applies to research with minors.)
2. Research involving the use of educational tests 1 (cognitive, diagnostic, aptitude, achievement), survey procedures 2, interview procedures 2, or observation of public behavior 3 unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; Any disclosure of the human subjects’ responses outside the research could reasonably piece the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation.

1 Applies to minors

2 Does not apply to research with minors.

3 Applies to research with minors only when the investigator(s) does not participate in the activities observed.

1. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not already exempt under #2, if:

(i) The human subjects are elected or appointed public officials or candidates for public office; or

(ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

1. Research involving the collection or study of existing data, documents, records, pathological, specimens, or diagnostic specimens, if those sources are publicly available or if the information is recorded by the investigator in such at manner that subjects cannot be identified, directly or through identifiers linked to the subjects. (Applies to research with minors.)
2. Research and demonstration projects which are conducted by or subject to the approval of [federal] department or agency heads and which are designed to study, evaluate, or otherwise examine:

(i) Public benefit or service programs;

(ii) procedures for obtaining benefits or services under these programs;

(iii) possible changes in or alternatives' to those programs or procedures; or

(iv) possible changes in methods- or revels of payment for benefits under those programs.

1. Taste and food quality evaluation and consumer acceptance studies,

(i) if wholesome foods without additives are consumed or

(ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level' found to be safe, by the Food and Drug Administration, or approved by the Environmental Protection Agency or the Food Safety and inspection Service of the U.S. Department of Agriculture.

Submission of Exempt Project Proposals

|  |  |
| --- | --- |
| **Determination of Exempt Status and Submission of Materials** | **Review of Exempt Research** |
| Read through the exempt categories. Note: these exemptions do not apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization. If it is exempt, your protocol packet should consist of:   * A Coversheet which is provided in the protocol packet. * Be sure to indicate the appropriate exemption numbers. * Completed Questionnaire. * A one-page project summary/abstract in lay persons terminology which includes the reason(s) your project qualifies for exempt status. * Any instruments used for your research project * An affiliation letter - if applicable (see instructions) * An informed consent | Send the materials to the Human Subjects Chair, CR 236E where your protocol will be reviewed by the committee. When your project is approved for exemption, the Human Research Subjects Chair will send you a letter stating that determination. Otherwise, your project must be submitted for Expedited or Full Review. |

Submission of Minimal Risks Expedited Review Projects

|  |  |
| --- | --- |
| **Determination of Minimal Risk Status and Submission of Materials** | **Review of Minimal Risk Research** |
| If your project is not 'exempt' and the risk of harm anticipated in the research is not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during he performance of routine physical or psychological examinations or tests, your project may be classified **minimal risk** and qualify for expedited review. In this case your submission should  consist of:   * A Coversheet which is provided in the protocol packet. * Completed questionnaire. * Complete CITI Human Subjects Research course, either Biomedical Basic, or Social-Behavioral-Educational Basic, Web course. * A one-page project summary/abstract in lay persons terminology which includes the reason(s) your project qualifies for minimal risk status and Expedited Review. * A summary-of your project using the outline format in Part Two of the protocol packet. * Any instruments used for your research project. * An affiliation letter if applicable (see instructions) * An informed consent form (see instructions) | You must submit your protocol to the Human Subjects  Committee. Send the materials to the Human Subjects Committee, CRW236E. Your materials will reviewed by two members of the Committee, as determined by the Chair. If the designated members concur that the proposed work qualifies for Expedited review, they may approve or call for review by the full Committee at the next meeting. One week before the meeting, the Human Subjects Chair will send you a letter stating the time and place for protocol review. Your attendance at this meeting is encouraged, as further clarification of the protocol may be needed. If you do not attend, there is a higher risk of your proposal being disapproved or tabled (e.g., due to insufficient information, concern about the protocol) at this meeting.  After the meeting, you will receive a letter indicating the status of your protocol. If conditions need to be fulfilled you must submit materials to fulfill the conditions to receive a one year approval. Once you have met the conditions, you will receive a condition fulfillment indication an approval period. **Note: An approval letter will not be sent to funding agencies until all concerns are met and the protocol is approved.** A request for renewal will be sent to you two months before the end of the approval period. If there are any modifications to the protocol during the approval period, these must be submitted Human Subjects Committee for further review. |

LAKE SUPERIOR STATE UNIVERSITY

HUMAN SUBJECTS REVIEW PROTOCOL

PART ONE - Coversheet

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | ORIGINAL SUBMISSION |  | PROTOCOL MODIFICATION |  | RENEWAL |

(If Renewal or Modification, See Protocol #\_\_\_\_\_\_). If there are changes, submit a complete copy, highlighting the changes.

1. PROJECT TITLE (Please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Principle Investigator (faculty) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Title \_\_\_\_\_\_\_ Dept. \_\_\_\_\_\_\_\_\_\_\_\_ Phone \_\_\_\_\_\_\_\_\_\_\_\_

Co-Investigator (student) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Title \_\_\_\_\_\_\_ Dept. \_\_\_\_\_\_\_\_\_\_\_\_ Phone \_\_\_\_\_\_\_\_\_\_\_\_

LSSU Proposal No. (If applicable) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Total Project Period: From \_\_\_\_\_\_\_\_ to \_\_\_\_\_\_\_\_ Application Deadline or Date of Transmittal \_\_\_\_\_\_\_\_\_\_\_

1. Is the project EXTRAMURALLY FUNDED? Circle: No Yes Funding Source \_\_\_\_\_\_\_\_\_\_
2. Should we notify your funding source when you have IRB approval? Circle: No Yes   
   (Provide address to IRB Office)
3. Is the project INTERNALLY FUNDED? Circle: No Yes Funding Source \_\_\_\_\_\_\_\_\_\_
4. Is the project THESIS Research? Circle: No Yes

Determination of Risk: EXEMPT: Review: See list of exemptions. These exemptions do not apply to research involving prisoners, fetuses, pregnant women, or in vitro fertilization. See instructions for additional information and an explanation of the review process. MINIMAL RISK, and RISK OF DECEPTION: See instructions for definitions, instructions, and an explanation of the review process. INVESTIGATORS WHO ARE REQUESTING APPROVAL OF MINIMAL RISK OR RISK OF DECEPTION MUST ATTACH the certificate of completion for the CITI Web-based training course in Human Subjects Research, either Biomedical Basic, or Social-Behavioral-Educational Basic,

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| EXEMPT |  | No(s).\_\_\_\_\_\_\_\_ | MINIMAL RISK |  | RISK OR DECEPTION |  |

1. The IRB must review all protocols that have extramural funding. The Board must also review any protocols marked minimal risk or risk or deception in II above. Check all of the following descriptors which apply to your research:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | |  | Minors |  | Fetuses |  | Pregnant Women |  | Prisoners | |  |  |  |  |  |  |  |  | |  | Test subjects for new drugs or clinical devices | | |  |  |  |  | |  |  |  |  |  |  |  |  | |  | Abortions |  | Illegal Behavior |  | Mentally Disabled or Handicapped | | | |

1. Principle Investigator Assurance:

I have read the statement of LSSU research ethics, including the responsibility to obtain Informed Consent from subject(s) and will comply.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | | Principle Investigator (Printed)(If student,) |  | Faculty Advisor (printed) Required for students | | Principal Investigator (Signature) (Date) |  | Faculty Advisor Signature Required for Students (Date) |   OVER |

Protection of Human Subjects

Questionnaire

Project Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principle Investigator(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Telephone: # \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Please answer all of the following questions related to your research proposal. Circle the appropriate answer from among those listed, either No, Yes, or N.A. for not applicable.

|  |  |  |
| --- | --- | --- |
| 1. Check the category of review requested: | Exempt Status \_\_\_\_\_ |  |
|  | Minimal Risks, Expedited Review \_\_\_\_\_ |  |
|  | Risk or Deception Project, Full Review \_\_\_\_\_ |  |
| 2. Does this project involve human subjects participating in: | |  |
| A. Biomedical procedures | | NO YES N.A. |
| B. Procedures to elicit information (personality tests, questionnaires, inventories, surveys,  observations, etc.) | | NO YES N.A. |
| C. Procedures specifically designed to directly modify the knowledge, thinking, attitudes,  and feelings, or other aspects of the behavior of the subjects | | NO YES N.A. |
| 3. If biomedical procedures are involved: | |  |
| A. Are provisions for emergency medical care necessary? | | NO YES N.A. |
| B. Has a qualified M.D. or other health professional participated in planning the project  (if yes, attach a signed letter from that person which indicates his/her level of  involvement in the project.) | | NO YES N.A. |
| C. Will this study involve drugs, chemical agents, radiation, or high intensity sound? (If  the answer is yes provide documentation of the qualifications of the individual who will  prescribe/administer the treatment) | | NO YES N.A. |
| 4. Does this study involve giving false or misleading information to subjects or withholding  information from them such that their “informed” consent is in question?  (If the answer is yes provide justification and a plan for debriefing subjects) | | NO YES N.A. |
| 5. Are procedures to be used new or innovative? | | NO YES N.A. |
| 6. Will the procedures: | | |
| A. Cause any degree of discomfort, harassment, invasion of privacy, risk of physical  injury, or threat to the dignity of subjects, or be otherwise potentially harmful to the  subject? (if the answer is yes, give details) | | NO YES N.A. |
| B. If answer to 6a is yes, have specific provisions been made to correct/treat harmful or  adverse conditions that may arise? (if the answer is yes, give details) | | NO YES N.A. |
| 7. Do the potential benefits from the conduct of this study outweigh the risks to subjects? | | NO YES N.A. |
| 8. Will this project involve subjects who are: minors (less than 18 years of age), pregnant women,  mentally disabled, physically handicapped, institutionalized, students? | | NO YES N.A. |
| 9. Do procedures include obtaining parental/guardian consent and/or institutional authorization for  access to subjects if minor, mentally retarded/disabled, or institutionalized subjects are involved? | | NO YES N.A. |
| 10. Are procedures for maintaining confidentiality of all subjects’ data fully described? | | NO YES N.A. |
| 11. Will subjects receive any compensation for participating (money, course credit, etc.)  (if the answer is yes, give details) (For example, college students will receive extra credit in courses and if their parents give permission, the preschoolers will be given stickers) | | NO YES N.A. |
| 12. Average amount of time required for each subject’s participation (in hours) \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |  |
| 13. Number of volunteers (subjects) to be involved in this study: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |  |

\*NOTE: If you have answered yes to # 3, 4, 6, 8 or 9 your study does not meet the criteria for exempt status.

\*\*NOTE: Please be sure to attach the cover sheet, abstract, survey tools, consent forms, and other documentation as indicated in the Protocol packet.

HUMAN SUBJECTS REVIEW PROTOCOL

PART ONE-Abstract

ALL PROTOCOLS MUST INCLUDE A ONE-PAGE ABSTRACT. YOU MAY USE THIS PAGE OR INSERT YOUR OWN.

Request for Review for \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Principal Investigator) (Advisor)

HUMAN SUBJECTS REVIEW PROTOCOL

PART TWO – Instructions

**Part Two should be limited to four pages, with an additional one or two pages for your proposal and “Informed Consent” documentation.** The Principal investigator (Pl) must supply all appended materials (e.g., questionnaires, and other support materials), unless the questionnaires are already on file in the Human Subjects Committee Files. It is the Pl‘s responsibility to determine this.

Describe the subject population and summarize procedures to be used according to the following outline. IT is not requested that the entire protect design be included, but that procedures involving human subjects be fully described. More detail is required for any procedure that could potentially be harmful, such as the use of electric shook, hypnosis, unusual stress. drugs, or the imposition of demeaning and dehumanizing conditions.

NOTE: USE THIS OUTLINE FORMAT

I. SUBJECTS

1. Describe the pool (s) of human subjects you will be using:

1. Gender, race or ethnic group, age range, etc.

2. Affiliation of subjects, e.g., institutions, hospitals, general public;

3. Subjects' general state of health (mental and physical);

a. If a requirement of the research is that subjects be in good mental or physical health, indicate how good mental physical health will be determined and who will determine that mental physical health.

4. List proportionate number of subjects involved in the study.

1. If human subjects are minors, mentally incompetent, or legally restricted groups, give explanation as to the necessity for using these particular groups.
2. If the subjects are minors, and if parents are not allowed to see the results of their child’s participation, the parents should be notified of that fact ahead of time. In most situations parental consent is required for research with minors. The IRB may alter the consent process or waive the requirement for you to obtain a signed consent form for some or all subjects if you meet the requirements set forth ‘in the Federal Register, June 18, 1991, Vol. 56, No. 117. [See pages1280l6 and 28017 General requirements for informed consent and Document of informed consent.

II. PROCEDURES

1. Describe procedures used for contacting and enrolling subjects, eg, who contacts them and enrolls them in the study and how this is done. Use non technical language.
2. Describe information to be gathered, and the means for collection and recording it.
3. Describe personnel interacting with the subject.
4. At what location will the human subject involvement occur? Will research occur where hazardous or radioactive materials are stored?
5. State the duration of the project and amount of time required of each subject (if more than one instrument is being used, indicate the amount of time required for each instrument).
6. Payments - indicate the type of payment (e.g., cash, money order, cashiers check, etc.), amount of payment and when payment will be made. Three levels of confidentiality have been established for information requested by the University when issuing payment.

Level 1 indicates that confidentiality of the subjects is not a serious issue, eg, providing a social security number or other identifying information for payment would not pose a serious risk to subjects. Level 2 confidentiality indicates that confidentiality is an issue, but is not paramount to he study, eg. the subject is involved in a sensitive issue, but these issues are not illegal. For example, the study of individuals with contagious diseases would fall in this category. Level 3 indicates that confidentiality of subjects must be guaranteed. In this category identifying information such as a social security number would put a subject at increased risk. An example of this type of study would be any research involving illegal activity.

All research will be considered Level 1 research unless otherwise stated. If you believe your research is Level 2 or 3, you must justify this status. For further information, contact the IRB Chair.

III. RISK/DECECEPTION

1. Describe in detail any physical, psychological, social, legal, economic or other risks you can foresee, both immediate and long range:

1. Immediate risks;

2. Long range;

3. Rationale for the necessity of such risks;

4. Alternatives that were or will be considered;

5. Why alternatives may not be feasible.

1. B. “Non-Beneficial Research” is designed as research involving investigations of a person, his or her body, life, or surroundings, which is devoid of benefit to that person. If you plan to conduct this type of research and feel that there are no other methods available for obtaining the information needed, please justify and describe:

1. The extent of the risks (physical, psychological, social, legal, and other);

2. The importance of the knowledge to be gained;

3. Why you tool that the value of the information to be gained outweighs the risks.

1. If deception is to be utilized in gathering data, you must:
2. Justify and support the use of deception in the project;
3. Provide a detailed written description of the debriefing process, which includes a complete explanation of the study;
4. Certify that each individual has been debriefed.

If subjects are being recruited from LSSU classes, the faculty/staff members must be provided with the following:

1. Information on the form of deception being used;
2. A detailed explanation of the study;
3. A complete approved protocol.

**NOTE: FACULT/STAFF MAY REFUSE ACCESS T0 THEIR STUDENTS AS SUBJECTS DESPITE**

**IRB APPROVAL.**

IV. SAFEGUARDING SUBJECTS' IDENTITY

1. What uses will be made of the information obtained from the subjects? What elements of your project might be openly accessible to other agencies or appear in publications?
2. What precautions will be taken to safeguard identifiable records or individuals? These questions also apply to secondary sources of data.

1. Long-range use of data (by you and others);

2. Immediate use of data (by you and others);

3. Describe specific procedures to be used to provide confidentiality of data. (e.g., the data and master list will be kept in a locked cabinet).

4. State whether or not human subjects can be identified directly or through identifiers linked to the subjects.

V. INFORMED CONSENT

Obtaining the informed consent of a potential human subject for participation in an experiment or demonstration is as safeguard for protecting the well being of that person. It adheres to the basic ethical principle of voluntariness. Permitting the subject to make a fully informed decision to participate in an activity averts potentially inequitable or coercive conditions of human subject use and assures the voluntary nature of subject involvement. The IRB may alter the consent process or waive the requirement for you to obtained signed consent form for some or all subjects if you meet the requirements set forth in the Federal Register, June 18, ‘1999,Vol. 56, No. 117. [See pages 28016 and 28017 General requirements for informed consent and Document of informed consent.) When seeking informed consent be sure you give a sufficient amount of time for the subject to consider whether or not to participate. This will minimize the possibility of coercion or undue influence. Consent is given or revoked orally; this Informed Consent form only documents that you informed the subject of the risks and benefits and that the subject consented at that time to participate. The subject may at any time revoke that consent orally and therefore, you must continually monitor the subject’s consent.

For exempt protocol questionnaires, surveys, etc, informed consent may be obtained by including a cover page explaining all the elements of the study at the beginning, followed by a statement that completion of the questionnaire constitutes informed consent.

The following is a sample format of an informed consent form to be used in a research study. Modify this sample to fit your particular needs. An informed consent forms should be in language understandable to the potential subjects. A copy of the Informed Consent must be given to each subject (or legal representative) and you must keep a copy of the signed Informed Consent form for a period of three years after the completion of gathering the data.

(SAMPLE) Informed Consent Form

|  |  |
| --- | --- |
| (PROJECT TITLE) | Patient – Professional Relationships |
| (Introduction  should include  explanation of  purpose of research.) | l am professor Mary Smith, of the Department of Sociology at Lake Superior State University. My student, William Jones, and I are conducting a study of how medical professionals relate to patients. We would appreciate your participation in this study, will assist us in making recommendations for improving the teaching of health professionals and the way they treat you. |
| (Explanation of  Procedures) | A full explanation of procedures which should include the following:   1. Number of questionnaires, interviews, etc. 2. Amount of time required for each questionnaire, interviews, etc. 3. Duration of project 4. Total amount of participation time for subjects 5. Identification of any experimental procedures 6. Approximate number of subjects involved in study |
| (Alternative Procedures) | Although we could study this question by just interviewing your doctor and the office,  we feet that speaking with patients is the beet way to find out if they are receiving good medical treatment. |
| (Risks and Benefits) | A full explanation of the risks and benefits of the study should include the following:   1. Any foreseeable risks or discomforts such as inconvenience of time   requirements, anxiety regarding sensitive questions, additional costs the  result from participation by the .subject   1. Any benefits to the subject or others, such as compensation - if compensation   will he given, indicate amount, when compensation will be given, and what  happens to compensation tithe subject withdraws from the study   1. Where medical treatments are available if injury occurs (if applicable) |
| (Safeguards) | This section should include information addressing the following areas:   1. Whether or not human subjects can be identified directly or through indirectly linked to the subjects 2. Agencies or groups to whom the data will be released 3. Published data will be in aggregate form (if applicable) |
| (Freedom to Withdraw) | This section should indicate the following   1. Participation is completely voluntary 2. Decision not to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled; if a subject withdraws, indicate what will happen to information gathered from that subject {e.g., quality of care and services they are otherwise entitled to will not diminish) 3. An explanation about the circumstances under which the subjects participation may be terminated by the research investigator without requiring the subjects consent, (if appropriate) |
| (Offer to Answer inquiries) | This section should state the following:  Once the study is completed. We will be glad to give the results to you. In the mean you have any questions, please ask us or contact:  Your Contact Person  Department or Schools  Lake Superior State University  Sault Ste. Marie, MI 49783  Telephone Number of Contact Person |

|  |  |
| --- | --- |
| (Third Party  Referral) | The information below must be included in every Consent Form:  If you have any complaints about your treatment as a participant  in this study, please call or write:  Ron Hutchins Ph.D., Chair, IRB  Academic Dean:  Schools of Nursing and Health Services, Recreation Studies and Exercise Science  Lake Superior State University  650 W. Easterday Avenue  Sault Sainte Marie, MI 49783  rhutchins@lssu.edu  (906) 635-4426 |
| (Closing) | The following two paragraphs and signature/date line must be inserted:\*  I have received an explanation on of the study and agree to participate.  I understand that my participation in this study' is strictly voluntary.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name Date  **This research project has been approved by Lake Superior State Institutional Review Board for the Protection of Human Subjects for a one year period.**  If the subjects are minors, the informed consent should be obtained from the parents of the subjects and a second signature line should be added **for the minor subject.** |
|  |  |

VI. COOPERATING INSTITUTIONS (Use the Sample “Affiliation Letter”)

Protocols for projects involving cooperating institutions must be accompanied by evidence of an affiliation letter with each cooperating institution, which (1) specifies the assignment of responsibility for the activities to be performed and (2) identifies the supervisory personnel in the agency. Original signed affiliation letters must be submitted to the Human Subjects Committee before data collection subject recruitment may begin. You need an affiliation letter if you are doing your research off campus. and are not an employee of the institution where you will be performing your research.

The sample “Affiliation Letter” may be rephrased so that it pertains to specific situations. It is the researcher’s responsibility to obtain the signature of his/her Department Chair and the signature of the individual with authority from the cooperating institution. The LSSU Board of Regents signature will be contained by the IRB Committee Chair. The original “Affiliation Letter" will be returned to the researcher and a copy will be retained in the IRB files.