

**Protocol Packet: LSSU Institutional Review Board (IRB) for the Protection of Human Subjects**

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# PROTOCOL PACKET

# LSSU INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS

***What is Human Subjects Research?***

**Definitions:**

**Human Subject** means a living individual about whom an investigator (whether professional or student) conducting research:

* 1. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
	2. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

**Research** means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research:

* + 1. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
		2. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
		3. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
		4. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

If 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 attached pages include guidelines and instructions to assist you in preparing a protocol to be submitted to the IRB. The synopsis on pages 5 – 8 will help you determine which parts of the protocol to complete and will give an explanation of the review process. If you have any additional questions regarding completion of the protocol or the federal regulations, please contact the Chair of the LSSU IRB ([irb@lssu.edu](file:///G%3A%5CMy%20Drive%5CLSSU%20IRB%5Cirb%40lssu.edu)).

***IMPORTANT – Undergraduate Research***: Because undergraduate students do not possess the necessary experience to independently conduct human subjects research, they **CANNOT** serve as a Principal Investigator and need to be supervised by someone who does. Therefore, any undergraduate student intending to conduct human subjects research (e.g., senior research project) at LSSU **MUST** have an LSSU Faculty member serve as the Principal Investigator of the research project.

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 STILL NECESSARY TO SUBMIT THE PROJECT PROPOSAL TO THE IRB CHAIR FOR REVIEW.

The 1-page description of the project **must** include the reason for the exemption and be written lay persons terminology.

**EXEMPTIONS *DO NOT* APPLY TO RESEARCH THAT IS MORE THAN MINIMAL RISK, INVOLVES DECEPTION OR CONCEALMENT, OR IS EXCLUDED BY FEDERAL POLICY FOR THE PROTECTION OF HUMAN SUBJECTS (‘**[**COMMON RULE**](https://www.ecfr.gov/cgi-bin/text-idx?m=02&d=01&y=2021&cd=20210204&submit=GO&SID=3353def94479d2b37628b470db97d76b&node=pt45.1.46&pd=20200717)**’).**

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 (§46.104 Exempt research):

1. **Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices** that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. **Educational tests, surveys, interviews, observations of public behavior.** Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:
	1. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
	2. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
	3. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a Limited IRB review\*\*\* to make the determination required by §46.111(a)(7).

***Research with children does not qualify for this exemption if*:**

1. The research involves surveys, interviews, and/or observations of public behavior when the research team participates in the activities observed,

*OR*

1. if Limited IRB review\*\*\* is required
2. **Benign behavioral interventions**. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
	* 1. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
		2. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
		3. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a Limited IRB review\*\*\* to make the determination required by §46.111(a)(7).

***Research with children does not qualify for this exemption*.**

**Benign behavioral interventions**. For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

**Deception**. If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

1. **Secondary research uses of identifiable private information or identifiable biospecimens** for which consent is not required, if at least one of the following criteria is met:
	1. **Publicly available**. The identifiable private information or identifiable biospecimens are publicly available.
	2. **Not identifiable as recorded**. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
	3. **Use of PHI**. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or
	4. **Use of federally generated or collected information or biospecimens**. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*
2. **Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads** (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs.
3. **Taste and food quality evaluation and consumer acceptance studies**:
	1. If wholesome foods without additives are consumed,

*OR*

* 1. 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.
1. **Storage or maintenance for secondary research for which broad consent is required**: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a Limited IRB review\*\*\* and makes the determinations required by §46.111(a)(8).
2. **Secondary research for which broad consent is required**: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:
	1. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);
	2. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;
	3. An IRB conducts a Limited IRB review\*\*\* and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and
	4. The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

\*\*\*A "**Limited IRB review**" is required under the 2018 Revised [Common Rule](https://www.ecfr.gov/cgi-bin/text-idx?m=02&d=01&y=2021&cd=20210204&submit=GO&SID=3353def94479d2b37628b470db97d76b&node=pt45.1.46&pd=20200717) for certain Exempt human subjects research categories. Its purpose is to ensure privacy/confidentiality protections are in place with exempt research that involves the collection of sensitive, identifiable data (under §46.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7), and (8)).

The "Limited IRB reviewer" must determine that, per 45 CFR 46.111(a)(7), "When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data."

IRB Review Process

**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 and some may not apply to children. If it is exempt, your protocol packet should consist of:* A Coversheet, which is provided in the protocol packet, with Investigator Signature(s).
* Be sure to indicate the appropriate Exemption numbers.
* Completed Protection of Human Subjects Questionnaire.
* A 1-page project summary/abstract in lay person’s 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 form
 | You must submit your protocol to the Human Subjects Committee. Send all materials to the Human Subjects Chair, irb@lssu.edu or LBR 238 for review. When your project is approved for exemption, the Human Subjects Research Chair will send you a letter stating that determination. Otherwise, your project must be submitted for Expedited or Full Review.  |

**Submission of Minimal Risk/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 the 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, with Investigator Signature(s).
* Completed Protection of Human Subjects Questionnaire.
* Required Ethics Training: Complete CITI Human Subjects Research course, either Biomedical Basic, or Social & Behavioral Basic, Web course.
* A 1-page project summary/abstract in lay person’s 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 2 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 all materials to the Human Subjects Chair, irb@lssu.edu or LBR 238. Your materials will be reviewed by two (2) 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 (*see* Full Committee Review below). |
|  |  |
|  |  |
| **Submission of Full Committee Review Projects** |
| **Determination of Full Committee Review Status and Submission of Materials** | **Full Committee Review of Research** |
| **Any** project that does not meet the criteria for Exempt ***or*** Minimal Risk/Expedited Review **must** be submitted for Full Committee Review. Your submission should include the following:* A Coversheet, which is provided in the protocol packet, with Investigator Signature(s).
* Completed Protection of Human Subjects Questionnaire.
* Required Ethics Training: Complete CITI Human Subjects Research course, either Biomedical Basic, or Social & Behavioral Basic, Web course.
* A 1-page project summary/abstract in lay person’s terminology.
* A summary of your project using the outline format in Part 2 of the protocol packet including any required additional explanations, justifications, etc.
* Debriefing procedures for research involving deception.
* 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 all materials to the Human Subjects Chair, irb@lssu.edu or LBR 238. 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 1-year approval. Once you have met the conditions, you will receive a condition fulfillment indication and approval period. ***Note*: An approval letter will not be sent to funding agencies until all concerns are met and the protocol is approved.** If there are any modifications to the protocol during the approval period, these must be submitted to the Human Subjects Committee for further review. |

LAKE SUPERIOR STATE UNIVERSITY

HUMAN SUBJECTS REVIEW PROTOCOL

**PART 1 - Coversheet**

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

(If **Renewal** or **Modification**, see IRB Protocol #  **)**. If there are changes, submit a complete copy, highlighting the changes.

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

 Principal 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
5. DETERMINATION OF RISK: **EXEMPT** – See list of exemptions. These exemptions do not apply to research involving prisoners, fetuses, pregnant women, or in vitro fertilization, *OR* may not apply to children. 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 Research - Basic ***OR*** Social & Behavioral Research - 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 |  |  | Prisoners |
|  |  |  |  |  |  |  |  |  |
|  | Test subjects for new drugs or clinical devices |  |  | Economically or Educationally Disadvantaged |
|  |  |  |  |  |  |  |  |  |
|  | Abortions |  | Illegal Behavior |  |  | Individuals with Impaired Decision-Making Ability |

 |

1. Principal Investigator Assurance:

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

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|

|  |  |  |
| --- | --- | --- |
| Principal Investigator/Faculty Advisor (print)  |  | Co-Investigator/Student (print)  |
| Principal Investigator/Faculty Advisor (signature) (Date) |  | Co-Investigator/Student (signature) (Date) |

  |

**Protection of Human Subjects**

**Questionnaire**

Project Title:

Principal Investigator(s):  (Enter the name of the Principal Investigator ***OR*** Faculty Advisor, if this is an undergraduate student project)

Telephone: #

Please answer **ALL** the following questions related to your research proposal. Circle, underline, or **bold** the appropriate answer from among those listed (e.g., 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 [ ]  |  |
| * 1. Does this project involve human subjects participating in:
 |  |
| 1. Biomedical procedures
 | NO YES  |
| 1. Procedures to elicit information (personality tests, questionnaires, inventories, surveys, observations, etc.)
 | NO YES  |
| 1. Procedures specifically designed to directly modify the knowledge, thinking, attitudes, and feelings, or other aspects of the behavior of the subjects
 | NO YES  |
| * 1. If biomedical procedures are involved:
 |  |
| 1. Are provisions for emergency medical care necessary?
 | NO YES N.A. |
| 1. 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.  |
| 1. 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. |
| * 1. 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  |
| * 1. Are procedures to be used new or innovative?
 | NO YES  |
| * 1. Will the procedures:
 |
| 1. 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  |
| 1. 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. |
| * 1. Do the potential benefits from the conduct of this study outweigh the risks to subjects?
 | NO YES  |
| * 1. Will this project involve subjects who are: children (less than 18 years of age), pregnant women, mentally disabled, physically disabled, institutionalized?
 | NO YES  |
| * 1. Do procedures include obtaining parental/guardian consent and/or institutional authorization for access to subjects if a child, individuals with impaired decision-making ability, or institutionalized subjects are involved?
 | NO YES N.A.  |
| * 1. Are procedures for maintaining confidentiality of all subjects’ data fully described?
 | NO YES  |
| * 1. 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; if their parents give permission, the preschoolers will be given stickers)
 | NO YES N.A. |
| * 1. Average amount of time required for each subject’s participation (**in minutes *or* hours & minutes**):
 |  |
| * 1. 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 1-Abstract**

ALL PROTOCOLS MUST INCLUDE A 1-PAGE ABSTRACT written in lay terms.

Title of Study: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Review requested by: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

 Principal Investigator ***OR*** Faculty Advisor, if this is an undergraduate student project

*<<< Type Abstract Below >>>*

**HUMAN SUBJECTS REVIEW PROTOCOL**

**PART 2 – Instructions**

**Part 2 should be limited to four (4) pages, with an additional one (1) or two (2) 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 project 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 shock, hypnosis, unusual stress, drugs, or the imposition of demeaning and dehumanizing conditions.

**<<< NOTE: USE THE OUTLINE FORMAT BELOW >>>**

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).

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

* 1. List approximate number of subjects involved in the study.
1. If human subjects are children, individuals with impaired decision-making ability, or legally restricted groups, give an explanation as to the necessity for using these particular groups.
2. If the subjects are children, 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 children.

II. PROCEDURES

1. Describe procedures used for contacting and enrolling subjects (e.g., 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 subjects.
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, cashier’s 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 (e.g., 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 the study (e.g. 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. Describe the risks and benefits of your research:

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

2. The importance of the knowledge to be gained including benefits to participants.

3. Why you feel 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: FACULTY/STAFF MAY REFUSE ACCESS TO 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. Immediate use of data (by you and others).
	2. Long-range 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

General requirements for informed consent (§46.116). Obtaining the informed consent of a potential human subject for participation in an experiment or demonstration is a 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. When seeking informed consent, be sure to 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. Subjects’ 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.

**Sample Format of an Informed Consent Form:**

A sample format of an informed consent form to be used in a research study is included at the end of the outline for Part 2. Modify this sample to fit your particular needs. An informed consent form should be written 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 (3) years after the completion of data collection.

***Please note***: If you choose to modify the sample, be sure to remove the descriptions/details included and replace the sample text with your own.

* Descriptions of what should be included are in parentheses.
* Details to include are indicated in italics.

VI. COOPERATING INSTITUTIONS

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. You must have an affiliation letter if you are doing your research off campus. Original signed affiliation letters must be included with this protocol application to the Human Subjects Committee.

**(SAMPLE) Informed Consent Form (SAMPLE)**

|  |  |
| --- | --- |
| (PROJECT TITLE)  | Patient – Professional Relationships |
| (Introductionshould include anexplanation ofpurpose of research.) | I 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 as it will assist us in making recommendations for improving the teaching of health professionals and the way they treat you.  |
| (Explanation ofProcedures) | *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 personnel, we feel that speaking with patients is the best 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 that* *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 indirectly*
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 subject’s participation may be terminated by the research investigator without requiring the subject’s 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 meantime, if you have any questions, please ask us or contact:Your Contact PersonDepartment or SchoolLake Superior State UniversitySault Ste. Marie, MI 49783Email of Contact PersonTelephone 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 participantin this study, please contact:Kristina J. Olson-Pupek, PhD, Chair, IRBProfessor of PsychologySchool of Kinesiology and PsychologyLake Superior State University650 W. Easterday Ave.Sault Sainte Marie, MI 49783irb@lssu.edu(906) 635-2422 |
| (Closing) | *\*\*\*The following two paragraphs and signature/date line* ***MUST*** *be inserted and printed on a separate piece of paper*: I have received an explanation of the study <<< *insert the Project Title here* >>> and agree to participate.I understand that my participation in this study is strictly voluntary.Name: Date: Signature: **This research project has been approved by the Lake Superior State Institutional Review Board for the Protection of Human Subjects for a 1-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.*** |
|  |  |

**Appendix/Appendices**

Please include any relevant policies (e.g., extra credit for student participation), copies of questionnaires/surveys to be administered to participants, hyperlinks or descriptions/pictures of materials that will be used in the data collection process (e.g., videos, equipment for taking physiological measurements, etc.), signed affiliation letters, debriefing statement (if required), and investigator(s) certificates of completion/completion reports demonstrating training in human subjects research (e.g., CITI course).