**Lewis Clark State College**

**Institutional Review Board**

### Guidelines

**Lewis-Clark State College**

**Lewiston, ID 83501**

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# INTRODUCTION

The charge of the LCSC Institutional Review Board (IRB) is to protect the rights and welfare of human participants involved in research by minimizing risk and ensuring that participants agree to participate voluntarily from an informed perspective. This is mandated by federal regulations governing research involving human participants. The IRB operates as a committee reporting to the Provost, to provide a climate for research and scholarly activity that is fertile and flexible insofar as possible while protecting the well-being of human participants.

The present system of human-participant research review is the outgrowth of concern about research on human participants that began decades ago. In 1974 the National Research Act created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Commission published the **Belmont Report,** which set forth the following basic ethical principles for the conduct of research involving human participants:

* Respect for Persons - Acknowledgment of the autonomy of the individual and the responsibility to provide special protection for individuals with reduced autonomy
* Beneficence - A twofold responsibility: 1) do no harm, and 2) maximize possible benefits and minimize possible harm.
* Justice - Fairness in distribution of benefits expected to be realized from research as well as its burdens

The applications of these principles resulted in the establishment of review boards at institutions conducting research using human participants. Those institutional review boards, including the LCSC IRB, ensure that in the conduct of such research:

* risks are minimized and reasonable in relation to anticipated benefits
* participants give *informed* consent
* rights and welfare of the participants are maintained

The regulations are stated in[**45 CFR 46**](http://www.access.gpo.gov/nara/cfr/waisidx_00/45cfr46_00.html); they were first published in 1974 and last updated in 1991. Sixteen federal agencies adopted the core of the regulations in a common federal policy in 1991.

The Office for Human Research Protections (OHRP), formerly the Office for Protection from Research Risks, an administrative unit within the Department of Health and Human Services (DHHS), oversees the regulations and provides guidance on ethical issues in biomedical or behavioral research.

**NOTE:** The LCSC IRB has attempted in this Guide to present a simplified explanation of the requirements for approval of research involving human participants, but the federal regulations take precedence. Most of the text comes from the US Department of Health & Human Services, Office of Human Research Protections and from the Federal regulations, 45 CFR 46.

**A.** **Statement of Policy**

To protect the rights, well-being and personal privacy of individuals, to assure a favorable climate for the conduct of scientific inquiry, and to protect the interests of Lewis-Clark State College, the policy and procedures described below have been established for the conduct of research involving human participants.

The following general principles apply equally to all research involving human beings, whether using college resources or external funding sources. Lewis-Clark State College assumes responsibility for communicating and explaining these principles to college personnel, and for providing guidelines to affect their observance.

1. Lewis-Clark State College and the individual members of its faculty, staff, and student body recognize their responsibility for protection of the rights and welfare of human participants.
2. Appropriate professional attention and facilities shall be provided to insure the safety and well-being of human participants. No subject in a research activity shall be exposed to unreasonable risk to health or well-being.
3. Research involving children (persons under 18 years of age), other legal incompetents, and persons unable to give informed consent may be approved if there is no risk or suffering for the individual participant. On the other hand, research involving a child, another legal incompetent, or a person unable to give informed consent should not be approved if there would be a significant risk or suffering without the possibility of benefit to the individual participant. Title 45, Code of Federal Regulations, Part 46, Subpart D, shall be followed for research involving children.
4. The confidentiality of information received from participants in experiments or respondents to questionnaires shall be fully protected, both during and after the conduct of a research activity, within the limits of the law.
5. Before an individual participates in research involving risk or substantial stress or discomfort, this shall be carefully explained; the investigator shall be satisfied that the explanation has been understood by the participant; and the consent of the participant shall be obtained. The elements of informed consent are established by the Federal government and by Lewis-Clark State College.
6. A request by any participant for withdrawal from a research activity shall be honored promptly without penalty or without loss of benefits to which the participant is otherwise entitled, within the limits of the research.

**B. Oversight**

All research involving human participants shall be subject to approval by the Lewis-Clark State College IRB in accordance with U.S. Department of Health and Human Services Policy for the Protection of Human Subjects and LCSC policies.

**C. Appeal Process**

If a subcommittee of the IRB makes a decision that the investigator believes to be unduly restrictive on the proposed research, the investigator may appeal, in writing, for review by entire membership of the IRB.

If the IRB makes a decision that the investigator believes to be unduly restrictive on the proposed research, the investigator should first discuss the matter with the Chair of the IRB, taking care to explain the reasons for believing that the proposed procedures are in compliance with LCSC policy and with Federal regulations. If the issue cannot be resolved satisfactorily by negotiation, the investigator may appeal the decision of the committee, in writing, to the Provost.

Upon receipt of an appeal the Provost shall convene an *ad hoc* committee constituted so as to fulfill the Federal requirements pertaining to Institutional Review Boards, and with a majority of the members being past but not current members of IRB at Lewis-Clark State College. The *ad hoc* committee shall consider the appeal and issue a recommendation within no more than sixty days from receipt of the appeal by the Provost. The *ad hoc* committee shall give the investigator an opportunity to present orally, or in writing, or both, the reasoning underlying the appeal. Upon completion of the review, the *ad hoc* committee shall communicate its decision in writing to the Provost, giving the reasoning for the decision. A copy of the decision of the *ad hoc* committee shall be given to the investigator. The decision of the *ad hoc* committee shall be treated as a decision of the LCSC IRB.

# ABOUT THE

# INSTITUTIONAL REVIEW BOARD

***Who administers the Institutional Review Board (IRB)?***

Protection of the rights and well-being of human participants involved in research is a concern of Lewis-Clark State College (LCSC) and is mandated by specific provisions in the Code of Federal Regulations (CFR). As required by the federal regulations, the IRB was established at LCSC to assure protection of human participants and to ensure compliance with the regulations. Not only is the welfare of human participants important to LCSC, but there is a fiscal component as well. Non-compliance with the federal regulations can have an adverse effect on research funding.

All agencies of the federal government that conduct or sponsor research relating to human participants are concerned with protection of the rights and well-being of the participants. However, the Office for Human Research Protections (OHRP) of the Department of Health and Human Services and the Food and Drug Administration are the lead agencies for oversight of research involving human participants. OHRP has general responsibility for the protection of human research participants and ensures compliance with 45 CFR 46. FDA regulates the use of experimental drugs and medical devices and ensures compliance with 21 CFR 50, 56.

The College’s IRB policies and procedures apply to any research activity which involves human participants, whether such research is undertaken on a large or small scale, whether it is preliminary or fully designed, whether it is student or faculty research, whether it is funded or non-funded, and whether it involves minimal risk or more than minimal risk.

***Who serves on the IRB?***

LCSC’s IRB is composed of at least five members. Members are primarily faculty, with at least one representative from the community. The makeup of the Board is intended to provide a diversity of viewpoints and to provide complete review of human-participant research activities. An expert is consulted when projects to be reviewed are outside the expertise of the members; this is allowed and encouraged by the federal regulations.

***What must be approved by the IRB?***

In accordance with its charge to protect human participants involved in research, the IRB must review and approve any research related to human participants, whether or not it is funded externally, if the research is:

* sponsored by units of LCSC
* performed by, or involves, LCSC faculty, staff, and/or students, regardless of where the study is performed
* conducted using College-owned facilities or equipment

EACH PROPOSED PROJECT MUST BE APPROVED **BEFORE** THE RESEARCH IS BEGUN.

***What are the rules if the research project is cooperative?***

If the principal investigator is affiliated with LCSC, the LCSC IRB must review the project and grant approval because:

* culturally dissimilar populations may constitute the sample
* the institutions involved may have different legal or regulatory constraints
* LCSC may have unique expertise not available at the other institution(s)

In cases where the cooperative institution has granted approval, the LCSC IRB still reserves the right to review the project. The LCSC investigator should submit the proposed project to the chair of the IRB for determination using the Projects with Outside IRB Approval form.

***What is required if the research is conducted off LCSC’s premises?***

If the principal investigator is conducting research off the premises of LCSC, e.g., a school or government agency, assurance of oversight by that entity must be provided to the IRB at the time of application. This must include the following–and any other germane information:

* letter of permission from the lead administrator (or his/her designee) to conduct the study
* evidence that the administrator or official oversight group has reviewed the protocol and accepted its use at that institution

If an IRB or equivalent exists at the external sites, the approval of the research protocol must be provided to the IRB prior to the start of the research, using the Projects with Outside IRB Approval form.

# HOW TO APPLY

Below is an outline of the steps to apply for approval of a research project that involves human subjects. If you have any questions along the way, contact the current IRB chair identified at www.lcsc.edu/irb.

1. Determine:

a. whether what you are proposing to do meets the definition of research on human participants

b. potential risks associated with the proposed research project

c. Whether **informed consent** is necessary

2. Complete the [**Application**](http://www.lcsc.edu/avptsp/OSP%20IRB%20Forms%20%26%20Information/hsrirb.htm) (available on the web page. <http://www.lcsc.edu/irb>). Each question must be answered, even if the response is "not applicable."

**NOTE**: Answer each question fully. The most frequent reason for delay in the approval process is lack of information. Usually, it is not the protocol that is questioned; rather, not enough information has been provided for the IRB to make a decision.

3. In most cases informed consent is necessary. Follow the suggested format for the consent form (Consent Form Guidelines available at www.lcsc.edu/irb). If you are not sure whether informed consent is necessary, contact your advisor.

4. Sign the first page of the Application and ask your adviser to sign there also.

5. Follow the checklist at the end of the Application to ensure you have complied with all necessary elements of the application process.

6. Submit the application by emailing it to the Institutional Review Board (irb@lcsc.edu) from your LC staff or student email account.

*THE IRB MUST APPROVE THE RESEARCH PROJECT* ***BEFORE*** *THE RESEARCHER(S) MAKE(S)* ***ANY*** *CONTACT WITH SUBJECTS.*

***Checklist for application submission:***

*Completed IRB application*

*Informed consent/assent forms*

*Outline or script to be provided prior to subjects’ agreement to participate*

*Instrument(s) [questionnaire, survey, testing]*

# DEFINITIONS AND EXPLANATIONS

***What constitutes research?***

According to the federal regulations, research is any “systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge” (46.102(d)). Any activity that meets this broad criterion and that is conducted by LCSC faculty, staff, or students using LCSC facilities, personnel, or students is considered research. This is so whether it is part of some other activity--such as a demonstration or service program--or whether the research is the entire project.

Following are questions that should help determine whether data gathering as part of training, demonstration, or service projects meets the definition of research as related to human subjects. A "yes" answer to any of these questions indicates a research component, and the project must be approved by the IRB before any work is begun.

* Will the researcher(s) seek out participants--or settings that contain participants--for the project, rather than the participants seeking the service or training?
* Will the findings of the investigation be analyzed, interpreted, or disseminated?
* If there is a likelihood that the knowledge gained from the encounter with the participants will be applied similarly so as to lead to a new procedure or process?

***What data gathering would not be considered research?***

Many forms of data gathering from human beings do not constitute research within the context of human-participant review requirements. Below are some examples:

* Data gathered for classroom training in research methods for which the only foreseeable purpose is to facilitate the student’s learning of research methodologies. Neither the instructor nor the student intends to disseminate the data gathered.
* Data gathered for administrative purposes only--to learn what is happening within a unit or institution and/or to improve services or operations
* Evaluation of data gathered for a contractor about a project or operation for which he or she is responsible, if neither the researcher nor the contractor intends to disseminate the data

***Are thesis and dissertation projects considered research?***

Projects involving a thesis or dissertation always are considered research because the University granting the graduate degree disseminates the research findings by placing the document in its library. Therefore, research involving human participants that culminates in a thesis or dissertation always must be submitted to the LCSC IRB for review.

***Would you provide further clarification as to whether student research projects require IRB review and approval?***

Yes. Student projects are an area that generates a good deal of questions as to whether they meet the definition of research and therefore require review.

Student research that involves human participants can be classified broadly into two categories:

1. ***Research practicum***, where students learn research skills. Students often are required to take courses requiring them to interview, observe, and otherwise work with human participants. The purpose of such project assignments is to train students in various research methods and to acquaint them with social, educational, and/or psychological processes. This does not require IRB review, since such projects typically do not lead to generalizable knowledge--that is not the intent of the assignment.
2. ***Directed or independent research projects***, e.g., honors or graduate theses, that require systematic data collection, with the intent to contribute to generalizable knowledge. Any such research project initiated or conducted by a student meets the definition of research. Therefore, it must be reviewed and approved by the IRB. This includes, but is not limited to, theses and dissertations.

***Do pilot studies require review?***

If a pilot project is designed simply to help the researcher refine data collection instruments and procedures or perfect the project design, it would not be considered research, since it would not contribute to generalizable knowledge. IRB review, therefore, would not be required.

However, if the investigator intends to publish the results or otherwise disseminate the findings of the pilot project or to use the results in subsequent research projects, then it would be considered research, and IRB review and approval would be required.

***Is oral history considered research?***

Because the intent of most oral history projects is ultimately dissemination of information (at some future date) about a particular historical period or event that has been gleaned from taped interviews with human subjects, it should be submitted to the IRB for review.

***Is there any research that does not require review?***

Federal regulations (45 CFR 46.101(b)) provide a list of activities that are EXEMPT from meeting the federal standards “unless otherwise required.” At LCSC we DO REQUIRE IRB review of research that falls into these EXEMPT categories, however, such research is EXEMPT from FULL BOARD REVIEW. This list can be found in this document.

There is only one category from the federal regulations (46.101) that in some instances does not require IRB review at LCSC:

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.”

Historical, literary, and journalistic research of public records may proceed without IRB review.

Situations arise in which records may be excerpted from a data source that does contain identified, sensitive information, but are provided to the investigator without identifiers. For instance, physicians might be asked to provide case summaries without identifiers. Such studies may be exempt from full review, providing that the person excerpting the records already has authorized access to them *for research purposes*, and the investigator has *no access to the original records*.

“Existing,” means that the data are “on the shelf” at the time the researcher develops a proposal for their use.

State and federal laws preclude the use of certain kinds of existing data (including health care information, records of drug and alcohol treatment, and records of psychiatric care) from use by researchers without human participants review, regardless of whether they are “existing” or recorded by the investigator in such a way that participants cannot be identified.

By tradition and common practice, some journalistic, literary, and historical inquiries are not considered human participants research, and do not need to be reviewed at all. These are:

* 1. All accepted and established service relationships, such as client-professional and student-teacher relationships, where the sole purpose of the relationship is to provide a service to the client.
	2. Studies of material available to the public, such as published library materials or public documents and records.
	3. Studies of historical documents (e.g. letters, diaries, and personally identifiable government forms) that are at least 70 years old.
	4. Studies of archeological materials or other artifacts that are at least 70 years old. Note however, that this determination does not exempt the investigator from compliance with Federal Native American Graves Protection and Repatriation Act (NAGPRA) regulations.
	5. Studies based on records without personal identifiers.
	6. Studies based on surveys or interviews with public officials or candidates for public office.
	7. Studies of medical specimens without personal identifiers.

**If you have questions regarding whether a project would be considered research and would require review, talk with an IRB member or the IRB Chair.**

***What is the definition of "human subject" according to federal regulations?***

A human subject/participant is a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual, ***or*** identifiable private information.

***What is "intervention"?***

Intervention includes both physical procedures by which data are gathered and manipulation of the participant or the participant’s environment

***What is "interaction"?***

Interaction includes communication or interpersonal contact between investigator and participant. Following are some examples of the more common types of interaction:

* Mail questionnaires or surveys
* Personal interviews, structured or unstructured, with or without recognized instruments
* Telephone interviews and surveys
* Classroom instruments, evaluations, or exercises
* Examination of private records, e.g., medical, psychological, school, or legal records
* Observations of public behavior by identifiable individuals

***What constitutes "identifiable private information"?***

"Private information" includes information

* about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place
* provided for specific purposes by an individual
* not reasonably expected by the individual to be made public
* individually identifiable--the identity of the subject is associated with the information or can be ascertained readily by the investigator

***What is minimal risk?* (45 CFR 46.102(i))**

According to federal regulations, minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

***What is informed consent?* (45 CFR 46.116)**

Informed consent is the process by which prospective human participants, or their legal representatives, are informed

* of the nature and purpose of the proposed research, including risks, in a manner appropriate to their level of understanding and in non-technical language
* that they have the right to decline to participate or to withdraw from participation at any time without penalty
* given adequate time to decide if they want to participate

Informed consent is a critical part of the IRB approval process, and it is essential that investigators understand and comply with the regulations. Details are provided in the Informed Consent section of this Guide.

Additional requirements for informed consent exist for special populations such as children and prisoners. Investigators should take care to observe *all* requirements for consent.

***What is assurance?***

An "assurance" is a document negotiated between an institution and the Department of Health and Human Services (DHHS) assuring that the institution conducting research supported by DHHS will comply with its regulations [**45 CFR 46**](http://www.access.gpo.gov/nara/cfr/waisidx_00/45cfr46_00.html) for the protection of human subjects. An assurance is required for each project funded by DHHS.

Specific requirements for assurance can be found at **45 CFR 46.103**. For additional assistance, contact the IRB Chair.

**DEFINITION OF TERMS**

*Adverse Effect*: An "adverse effect" is any physical, psychological or social outcome of an investigation, which is detrimental to a subject. Also referred to as “adverse event,” or “side effect.”

*Anonymity*: "Anonymity" means that no member of the research group knows the identity of the subject, and that identification of subjects is not possible by the procedures employed or by the information obtained from subjects.

*Assent*: "Assent" is a child's agreement to participate in research after an adequate explanation has been provided. Assent shall not be assumed simply because a child does not object. See the section on CHILDREN for a discussion of when a child's assent must be obtained and the methods for obtaining assent. Assent would also be required for other vulnerable populates such as the mentally disabled, economically, or educationally disadvantaged populates.

*Certification*: "Certification" is a report by the college that the appropriate review body has approved the use of human participants in the proposed research. The DHHS and other funding agencies generally require such certification.

*Confidentiality*: "Confidentiality" is the restriction of information that identifies the participant, outside of the research group itself.

*Deception*: "Deception" occurs whenever information about a research activity is deliberately withheld from subjects.

*Emergency* *Applications*: "Emergency Applications" are those which relate to situations where research procedures must begin immediately or the opportunity will be lost.

*Incompetent*: In the context of the human participants review process, an individual who is unqualified to give or is incapable of giving informed consent (see definition below) is considered to be "incompetent." An incompetent individual may be a minor, an adult who has been declared legally incompetent, or an adult whose competency may be questioned because of an illness or an unusual circumstance.

*Informed Consent*: "Informed Consent" is the agreement of a participant to take part in research after the procedures, costs, and potential risks and benefits have been explained in a manner that the participant can understand.

*Institutional Review Board*: "Institutional Review Board" (IRB) is a committee which has been formally designated by an institution to review and approve research involving human participants. It is also known as the Institutional Review Board at Lewis-Clark State College.

*Intermediary*: An "intermediary" is an individual or organization that in another capacity has contact with prospective participants, and that cooperates with an investigator to contact them.

*Minimal risk*: (see "risk")

*Minor*: A person under eighteen years of age is legally a minor, unless that person has been declared an "emancipated minor." Investigators who propose to use "emancipated minors" should check with the IRB.

*Modifications*: "Modifications" are changes in the research after a human participant’s application has been approved.

*Personal and Sensitive Information*: This term includes any information about an individual which, if known to unauthorized persons or the general public, might reasonably be expected to cause embarrassment or discomfort, jeopardize that person's prospects of employment or education, or affect his/her financial or social status.

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

*Risk*: "Risk" is the potential for any physical, psychological or social outcome of an investigation that is detrimental to the participant (i.e. an adverse effect).

"Minimal risk" means that the risks of harm anticipated in the proposed research are 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 (from Title 45, Code of Federal Regulations, Part 46.102(i)).

Note: There are different types of adverse effects to which human participants may be at risk that are inherent in various research procedures. Risk is most obvious in medical and behavioral science research projects involving procedures, which may induce a potentially harmful altered physical state or condition. Some examples of such procedures are: the removal of organs or tissues for study, reference, transplantation, or banking; the administration of drugs or radiation; the use of indwelling catheters or electrodes; or the requirement of strenuous physical exercise.

There is a wide range of medical, social, and behavioral projects in which no risk of immediate adverse physical effects for the participant is involved (e.g. those involving the use of personality inventories, interviews, questionnaires, observations, photographs, tapes, records, and stored data). However, some of these procedures could involve a potential risk of discomfort, harassment, or a threat to the participant’s dignity. Also, the information, if not kept confidential, could present psychological, social, or legal risks.

There are also medical and biomedical projects concerned solely with organs, tissues, body fluids, and other materials obtained in the course of routine performance of medical services such as diagnosis, treatment, and care, or of an autopsy. The use of these materials obviously involves no element of physical risk to the subject. However, their use for research, training and service purposes, if known to unauthorized persons or the general public, could present psychological, social or legal risks. In these situations, review may be necessary to determine whether the circumstances under which the materials will be procured are appropriate, and whether appropriate consent should be, or can be, obtained for the use of these materials for project purposes, and that the confidentiality of individuals will be maintained.

*Scientific* *Merit*: "Scientific Merit" is the contribution to science and society that a research project may make. In research involving no more than minimal risks, the IRB is not charged with judging the scientific merit of a proposed study. However, in research that involves more than minimal risk, the IRB must balance risks against their judgment of the scientific merit of the proposed study.

In cases in which there would be moderate or high risk and in which there are problems in determining scientific merit, the IRB may use consultants in making this determination. The IRB will not approve research when the risk is significant and the project is judged to lack adequate scientific merit.

*Subject*: A "subject" or “participant” is a person whose physical, intellectual, emotional or behavioral characteristics are investigated for any purpose other than for the sole purpose of benefiting the subject as an individual. If a person, such as a family member, employer, or teacher, is asked to provide information about another individual, then both individuals are considered to be participants. Donors of organs, tissues, and body fluids for research purposes and individuals, whose records are used for research, are also considered to be participants.

Special regulations apply to prisoners, residents of institutions for the mentally ill and the mentally retarded, as well as pregnant women, the viable fetus, the newborn, children, and the dead. See Part D.5. and Federal Regulations for a description of these regulations.

Note: This definition of "subject" or “participant” excludes all accepted and established service relationships, such as the normal relationship of patients to physicians, students to professors, and other clients to professionals, in which the patient, student, or client is receiving aid or services intended only to meet his or her own personal needs. The professional-client relationship has the welfare of the client as the primary objective, whereas the investigator-participant relationship has the discovery of new knowledge as its primary objective.

The normal employee-employer relationship, in which legitimate services are exchanged for salary, wages, or remuneration in keeping with customary written or oral contracts, is also excluded from the definition of "subject." Payment of volunteers, however, does not alter their status as participants. If doubt exists as to whether the procedures are within the normal limits of the employees' work scope, the employees should be considered to be participating as human participants and their rights and welfare must be protected.

*Subject Advocate*: A "subject/participant advocate" is an individual who assists an adult participant who has not been declared legally incompetent, but whose ability to give informed consent is in question. The subject advocate should know the participant well enough to be able to attest to the participant’s probable agreement to participate.

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# TYPES OF IRB REVIEW

Federal regulations prescribe three types of review:

1. **Exempt**
2. **Expedited**
3. **Full board** (review by the entire IRB)

The chair of the LCSC Institutional Review Board reviews all submitted applications and classifies them according to the federal regulations. Board members reviewing the applications may disagree with the chair’s classification and ask for a more thorough review.

***What is exempted from review by the entire IRB?***

All proposed projects that involve human participants and that satisfy the definition of research (see ***Definitions and Explanations*** section earlier in this document) *must be reviewed* at *some level*. However, some research is exempted by federal regulation from review by the *entire* IRB. If a proposed research project meets the criteria for exemption from review by the entire IRB, it must be reviewed by one member of the Board and approved by the chair.

1. **Exempt Category of Research**

Following are the types of research which federal regulations permit a review by one IRB reviewer (i.e., **Exempt category**):

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 on the comparison among instructional techniques, curricula, or classroom management methods.”

The purpose of this category is to exempt from full review research on educational practices, in an educational institution. This category does not extend to research conducted in a school setting but not related to the instruction in that institution. For example, an evaluation of two methods of fourth grade classroom instruction in a local school district would qualify as exempt from full review research. A sociometric survey of children's preferences for playmates in the same school, involving the same children, would not qualify as exempt from full review research. As the example indicates, research on minor students *can* be exempt from full review if it is educational research in the sense intended here.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.”

"Educational tests" refers to standardized tests used for educational purposes, such as a scholastic achievement test. It does not refer to personality tests or clinical evaluations. Survey or interview studies qualify as exempt from full review unless the participants can be identified from the records, *and* there are risks to the participants due to the sensitive nature of their responses.

The Federal guideline refers only to risks associated with sensitive aspects of behavior. Lewis-Clark State College has determined that there are other types of information that might be considered sensitive and damaging if revealed, even though the information is not associated with behavior. For instance, knowledge that a person was at risk for a genetically determined disease might be a factor in denying that person employment. Therefore, LCSC will not treat as exempt from full review a survey or interview study where participants can be identified and *any* information is collected that could be detrimental to the participant, regardless of whether or not that information is based on the participant’s own behavior.

Studies of publicly observable behavior are exempt from Federal regulations unless there are potential risks of the type described and the data are recorded in a way that could be used to identify participants.

The College interprets "public behavior" to mean behavior that is apparent to an unconcealed observer, without the use of any special or surreptitious equipment, such as binoculars, special microphones, or recording devices.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior that is not exempt under paragraph (2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statue(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.”

*Research in this category may not need to be reviewed by the LCSC IRB. Details can be found in the Definitions and Explanations section earlier in this document.*

In the case of the researcher conducting research as part of an internship, “existing data” must be data that the agency collected in the normal course of their operation BEFORE the student began the internship. In such cases, the data belongs to the agency, and informed consent from the individual participants is generally not necessary.

However, the data is NOT considered exiting data, IRB approval MUST be received before any data collection begins, and informed consent MUST be secured from participants, if any of the following conditions apply:

* data is gathered after the student begins an internship with the agency or any participating agency;
* the student participates in any way with the development of the survey instrument or collection of the data, or
* the student intends to use the data for the senior research project prior to data collection.

5. Research and demonstration projects which are conducted by or subject to the approval of the 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 those programs, (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.”

The “department or agency heads” referred to are federal, not state, local, or college. This category of exempt from full review research refers to activities sponsored by federal agencies to evaluate their own benefit or service programs.

6. 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 of and for a use 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.”

The following five categories of research are **not exempt** from full review, and **always** require review: 1) research involving prisoners; 2) studies of pregnant women where the focus of the research is on pregnancy and/or the fetus; 3) research on fetuses in utero; 4) research on minor children unless the research qualifies as educational research in the sense of items 1. and 2. above, or where the research does not involve direct interaction with the child, and 5) research using non-public records.

**If you have questions regarding whether a project would be considered research and would require review, talk with an IRB member or the IRB Chair.**

1. ***What qualifies for expedited review?***

The expedited review procedure may be used for research projects that:

* Pose no more than minimal risk (not a given simply because they are included on the list)
* Involve one or more research activities listed in the federal regulations as qualifying for expedited review (see below)
* Propose modifications to previously approved research during the period (one year or less) for which approval has been granted

***How does expedited review work? How long does it take?***

Expedited reviews are conducted by at least two members of the IRB. After their initial evaluation, the reviewers may request review by the entire IRB (full board).

***What research activities are listed in the Federal Register (63 FR 60364-60367, November 9, 1998) as qualifying for expedited review?***

(1) Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

(2) blood samples by venipuncture, not exceeding 550 milliliters in an 8-week period, no more often than twice per week, from subjects 18 years of age or older who are in good health, not pregnant, and weigh at least 110 pounds. (See the Federal Register for specific guidelines for children.)

(3) Collection of biological specimens for research purposes by noninvasive means. (See Federal Register for a list of examples.)

(4) Collection of data through noninvasive procedures (no involving general anesthesia or sedation), excluding procedures involving x-rays or microwaves. Examples include:

* physical sensors applied either to the surface of the body or at a distance and do not involved input of significant amounts of energy into the subject or an invasion of the subject’s privacy;
* weighing or testing sensory acuity;
* MRI
* ECG, EEG, ultrasound, etc.
* Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(5) Study of existing data, documents, records, pathological specimens, or diagnostic specimens.

(6) Voice, video, digital, or image recordings made for research purposes.

(7) Research on individual or group characteristics or behavior (such as studies of perception, cognition, game theory, or test development)~~.~~

***Do research projects using special classes of human*** participants ***(special populations) qualify for expedited review?***

Yes, under certain conditions. Federal regulations address “vulnerable populations” that require additional protection:

* Children
* Prisoners
* Pregnant women and fetuses
* Mentally disabled persons
* Economically or educationally disadvantaged persons

*Detailed information regarding these special classes of human subjects is available in the* **Special Populations** *section of this Guide.*

Applications for special-population expedited review will be examined by three IRB members, at least one of whom has expertise in the area of the proposed research, to determine if the proposed research poses minimal risk as defined by the federal regulations.

1. ***What research requires review by the entire IRB (full board)?***

All proposed research that does not meet the criteria for an exemption from review by the entire IRB or expedited review must be reviewed by all members of the IRB--this is referred to as “full board review.” That decision rests with the IRB chair or other Board members.

An application requiring review by the full IRB is first reviewed by the chair for completeness and a determination if additional information is needed. After the requested information is submitted or required changes have been made, the application is forwarded to the full IRB for review.

The investigator may be asked to be present when his or her application is reviewed by the full board, in order to clarify any uncertainties that may exist in the minds of the IRB members. If the investigator is a student and cannot be present, his or her adviser is welcome to appear in lieu of the investigator.

LCSC is subject to audit by federal agencies supporting research on human subjects, so the IRB reserves the right to audit approved projects after approval to ensure compliance with the regulations.

***Where can an investigator get further clarification on what types of studies require review and approval by the IRB?***

See the **Definitions and Explanations** section of this Guide.

****

# APPROVAL PROCESS

***What must the IRB take into consideration in reviewing an application?***

The IRB Guidebook (published by the Office of Protection from Research Risks, US Department of Health and Human Services) requires that IRBs:

* Consider the qualifications and professional development of the principal investigator and relate them to the degree of protocol complexity and risk to human participants
* Consider requiring that less experienced research investigators be sponsored by seasoned researchers
* Consider directing that proposals requiring skills beyond those held by the principal investigator be modified to meet the investigator’s skills, have additional qualified personnel added, or be disapproved
* Require investigators to prepare protocols, with complete descriptions of the proposed research. The research plan must include provisions for the adequate protection of the rights and welfare of prospective participants and ensure that pertinent laws and regulations are observed. Copies of informed consent must be included with protocols. Investigators are responsible for obtaining informed consent and ensuring that no human participant will be involved in the research before consent is obtained.
* Require that the research plan address quality assurance standards set by the institution as well as applicable external standards
* Require that appropriate reviews for scientific merit be conducted before the research is approved
* Require that mechanisms be in place for monitoring the progress of the research

***What are the criteria for approval?***

According to the federal regulations, the following criteria must be met for the IRB to approve a proposed research project:

1. Risk Minimization - Risks to participants should be minimized by using procedures that:

are consistent with sound research design

do not unnecessarily expose participants to risk

(whenever appropriate) are already being performed on the participant for diagnostic or treatment purposes

2. Risk vs. Benefit - The risk to the individual participant must be reasonable when measured against:

* The possible benefit to the prospective participant
* The importance of the knowledge to be gained

3. Participant Selection - Selection of participants should be equitable.

4. Informed Consent - Informed consent must be:

sought from each prospective participant or his/her legally authorized representative

appropriately documented

5. Safety - Adequate provisions must be made for monitoring the data collected to ensure the safety of participants, when appropriate.

6. Privacy - Appropriate safeguards must be provided to protect the privacy of participants and to maintain the confidentiality of data gathered.

7. Undue Influence - If some or all of the participants --such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons--are likely to be vulnerable to coercion or undue influence, additional safeguards must be included in the study to protect the rights and well-being of these participants.

***How long is IRB approval valid?***

The IRB is required to review research on an ongoing basis, and the interval of review is determined by the degree of risk. Approval is granted for a maximum of one year.

***Must an investigator reapply for IRB approval if the project continues?***

Yes. (See below.)

***What kind of review is required for application for continuation?***

The federal regulations require the same type of review for continuation as for the initial application. The IRB must review the protocol and any amendments as well as a status report on the progress of the research, including:

* Summary of enrollment of participants and their status, a description of any:
	+ Change in key personnel
	+ Adverse events or unanticipated problems involving risks to participants or others and how the principal investigator handled the event(s)
	+ Withdrawal of participants from the research and reason for withdrawal
	+ Complaints about the research
* A summary of any recent literature, findings, or other relevant information, especially information about risks associated with the research
* A copy of the current informed consent document

The **Continuation Form** can be found at the end of this document and the [LC IRB website](http://www.lcsc.edu/irb).

The investigator will be informed in writing of approval for continuation.

***What is required if there are modifications?***

If there are *any* modifications, e.g., change in the title, principal investigator, methodology, subjects’ status, etc., the principal investigator must submit a **Modification Form** (see the end of this document or the [LC IRB website](http://www.lcsc.edu/irb)) *The researcher should keep in mind that approval of a modification(s) does not change the original period of approval.* Approval can be granted for a maximum of one year from the date of the initial approval.

The request for any modification should refer to the project number assigned by the IRB, which appears on the approval letter. It should also provide a means for communication: phone number and/or e-mail address of investigator/applicant.

# PARTICIPANTS

***What must be included in the application to give the IRB a clear understanding of the proposed sample and its usage?***

The application must include at least the following:

* Description of the sampling procedure
* The population from which the sample is drawn
* The number of participants expected to participate
* The follow-up, if applicable
* How long the participants will be expected to participate
* Study sites
* Expected risks
* Expected benefits

***What can I do to ensure that prospective*** participants ***do not feel coerced?***

Investigators must be careful not to put undue pressure on prospective participants, either directly or implicitly by virtue of an imbalance of power inherent in roles, e.g., teacher-student or supervisor-employee.

In the case of students as prospective participants, a teacher/investigator must be very careful to assure students that their grade will not be affected by either participation or non-participation and that they can decline without any penalty whatsoever.

When employees are considered potential research participants, an investigator must be careful not to place colleagues, subordinates, or peers in an uncomfortable situation (fear of retribution) if they decline to participate.

***What steps should be taken to ensure the confidentiality of*** participants***?***

* Computer files should be password-secure
* Data should be:
	+ Reported in the aggregate
	+ Stored separately from identifiers
	+ Destroyed following completion of project unless there are extenuating circumstances, e.g., data will be used in a future research project
	+ Destroyed completely, i.e., if it is in physical form, it should be shredded, and if it is in electronic form, it should be deleted entirely

# INFORMED CONSENT

***What is informed consent?***

Informed consent is the process by which prospective human participants, or their legal representatives, are

* Informed of the nature and purpose of the proposed research, including risks, in a manner appropriate to their level of understanding and in non-technical language
* Informed that they have the right to decline to participate or to withdraw from participation at any time without penalty
* Given adequate time to decide if they want to participate

The investigator should meet with the prospective participant, determine if he or she is capable of giving consent, and then explain the study, covering the elements of informed consent (see below). To give valid informed consent, a potential participant should truly understand to what he or she is giving consent to. Therefore, it is vitally important that the researchers *communicate*, rather than just provide information. Asking questions to elicit questions or comments from the prospective participant is a good way to ascertain that he or she really understands what is being proposed.

***What EXACTLY is involved in informed consent?***

An investigator should cover the essentials of informed consent in his/her oral explanation to the prospective participant. Following are the basic “elements” as set forth in **45 CFR 46.116** and **21 CFR 50.20**:

* Statement that the study involves research and is being conducted through LCSC
* Explanation of the purposes of the research
* Expected duration of the participant’s participation
* Description of the procedures to be followed
* Identification of any procedures that are experimental
* Description of any reasonably foreseeable risks or discomfort to the participant
* Description of any benefits to the participant or to others that reasonably may be expected from the research
* Statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained or if data will be anonymous
* Statement regarding participation:
* That it is voluntary
* Refusal to participate will not involve a penalty or loss of benefits to which the participant is otherwise entitled
* Termination of participation at any time will not involve a penalty or loss of benefits to which the participant is otherwise entitled
* Explanation of whom to contact about:
* The research
* Research subjects’ rights
* Research-related injury to the subject

***Are there additional elements of informed consent?***

Yes. When appropriate, one or more of the following elements of informed consent should be provided:

* For research involving more than minimal risk, an explanation as to:
	+ Whether any compensation is available if injury occurs
	+ Whether any medical treatments are available if injury occurs
	+ If such treatments are available, what they consist of and where further information can be obtained
* A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant) that are unforeseeable at present
* Anticipated circumstances under which the participant’s participation may be terminated by the investigator without regard to the participant’s consent
* Any additional costs to the participant that may result from participation in the research
* Consequences of a participant’s decision to withdraw from the research, and procedures for orderly termination of participation by the participant
* Statement that significant new findings developed during the course of the research, which may relate to the participant’s willingness to continue participation, will be provided to the participant
* Approximate number of participants involved in the study

***Are any of the elements for written informed consent ever waived?***

The LCSC IRB may approve a consent procedure that omits or alters some or all of the elements of informed consent set forth above, or it may waive the requirement to obtain written (signed) informed consent. In order to do so*, the IRB must be able to document both of the following:*

The research or demonstration project

|  |
| --- |
| * Is designed to study aspects of public benefit or service programs and is subject to approval by state, local, or tribal government
 |
| * Would be impractical to carry out without the waiver of signed informed consent
 |

In such cases, *the IRB must be able to document the following for the proposed research*:

* It involves no more than **minimal ris****k** to the participants
* It would be impractical to carry out without the waiver of signed informed consent
* The waiver of written consent or alteration will not adversely affect the rights and welfare of the participants
* Acceptable alternatives to written consent are in place that satisfy federal regulations for informed consent. This could include, for example, public notice, oral consent following appropriate explanation of the project, and its benefits vs. Risks.
* Whenever appropriate, the participants will be provided additional information after participation

***What is involved in documentation of informed consent?***

Following an adequate explanation and allowance of sufficient time for the participant to decide whether or not to participate, the investigator should provide a consent form for documentation. Consent form guidelines and sample wordings are provided on the website, www.lcsc.edu/irb

The participant or his/her legal representative should sign the consent form. The person who signs the form should receive a copy of the document.

The investigator can choose from either of the two formats for documentation explained below:

1. A written consent form that contains the elements of informed consent noted above and required by **45 CFR 46.116**. This form may be read to the participant or his/her legally authorized representative. The participant or representative should be provided ample time to read the document before signing.

2. A short-form written consent document that states that the elements of informed consent explained above and required by **45 CFR 46.116** have been presented orally to the participant or his/her legally authorized representative.

When this method is used, the following requirements must be met:

* A witness must be present at the oral presentation.
* The IRB must approve a written summary of what is to be said to the participant or representative.
* The participant or representative signs the short form and receives a copy of it and the summary.
* The witness must sign both the short form and the copy of the summary.
* The person obtaining consent must sign the summary.

***Are there other requirements for documentation of consent?***

Yes. If the study is conducted off the LCSC premises, written permission from the administrator should accompany the application and supporting documents, or provided before final approval is granted. This permission must include a description of oversight procedures to be utilized at the study site.

***What are the requirements for consent if a participant*** ***can’t read?***

Federal regulations permit the reading of the elements of informed consent to illiterate persons who understand English, who then may “make their mark” on the summary. Both the witness and the person conducting the consent interview must sign the form. The short form is not required in this instance.

Investigators should be cautious when enrolling participants who may not truly understand what they are agreeing to do. The IRB considers illiterate persons as likely to be vulnerable to coercion and undue influence. Investigators should make sure additional safeguards are in place to protect the well being of this vulnerable population.

***Is the requirement to obtain a signed consent form ever waived?***

An IRB may waive the requirement for a signed consent form for **either** of the following reasons (45 CFR 46.117.C):

**1.** The only record linking the participant and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant is to be asked whether he or she wants documentation linking him/herself with the research; the participant’s wishes are to govern.

**2.** The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside the research context.

If the requirement for written documentation is waived, the IRB may require that the investigator provide participants with a written statement regarding the research.

The most important thing to remember is that it is the researcher’s responsibility to ensure that each participant has been made fully aware of the elements required in an informed consent, as specified in the federal guidelines. The IRB will, under certain circumstances, permit exceptions to a signed informed consent if these conditions are met.

**NOTE**:

Procedures for obtaining informed consent should *not* include a *guarantee* of confidentiality. Rather, the researcher should explain how he/she will make every reasonable effort to protect the confidentiality of the participant.

If responses are anonymous and no identifiers are ever obtained, a *written* consent form is not necessary, although informed consent is always necessary.

The LCSC IRB has attempted to present a simplified explanation of the requirements governing

informed consent, but the federal regulations take precedence. (See **45 CFR 46** and **21 CFR 50**

and **56**.)

***What is the IRB policy on deception of subjects?***

Although the IRB occasionally has approved projects involving deception of participants, it scrutinizes such projects to determine whether deception is necessary and if so, to what extent. In such cases, debriefing participants is required.

# SPECIAL POPULATIONS

***Are there special requirements for certain classes of participants?***

Yes. The following are considered “vulnerable populations” that require special protection:

* Children
* Prisoners
* Pregnant women and fetuses
* Mentally disabled persons
* Economically or educationally disadvantaged persons

****

# CHILDREN

***What are some of the basics in con******ducting research with children?***

Federal guidelines specifying protection for children as research subjects can be found in **45 CFR 46.401-409.**

Surveys or interviews or observations of public behavior when the investigator participates in the activities being observed with children require either expedited or full board review. They cannot be considered exempt.

* A child is anyone under the age of 18**.**
* Assent must be gained from the child as well as permission from at least one parent or guardian.
* “Assent” means a child’s affirmative agreement to participate in the research, but mere failure to object does not imply consent. See below for more detail on this.
* “Permission” means the agreement of the child’s parent(s) or guardian for the child to participate in the research.
* A “parent” is the child’s biological or adoptive parent.
* “Guardian” means an individual authorized by law to consent on behalf of a child to general medical care.

The federal regulations specify four categories of risk to children as subjects:

* Minimal risk
* Greater than minimal risk, but direct benefit to individual participants
* Greater than minimal to child, with no direct benefit to individual participant, but likely to yield generalizable knowledge about participant’s disorder or condition
* Otherwise not approvable, but presents opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children

***If there is only minimal risk, what are the requirements for research dealing with children?***

If only minimal risk is posed, the IRB requires both assent of children and permission of their parents or guardians.

**Minimal risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. (**45 CFR 46.303(d)**)

***If the proposed research involves greater than minimal risk to children but presents the prospect of direct benefit to the individual subject, what is required for approval?* (45 CFR 46.405)**

* The risk is justified by the anticipated benefit to the participants;
* The relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches and
* Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.

***If the proposed research involves greater than minimal risk to children and presents no prospect of direct benefit to the individual subject but is likely to yield generalizable knowledge about the subject’s disorder or condition, what is required for approval?* (45 CFR 46.406)**

* The risk represents a minor increase over minimal risk;
* The intervention or procedure presents experiences to participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
* The intervention or procedure is likely to yield generalizable knowledge about the participants’ disorder or condition that is of vital importance for the understanding or amelioration of their disorder or condition; and
* Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians.

***If the proposed research is not otherwise approvable but it presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children, can it be approved?* (45 CFR 46.407)**

It is extremely rare that the IRB can approve proposed research dealing with children if it does not meet the requirements of the first three categories. However, if an investigator has a project that falls into this fourth category, he or she should contact the IRB Chair for guidance.

***Is any research involving children exempt from full board review?***

According to the federal regulations, some types of research involving children are not required to be reviewed by the entire IRB. LCSC’s policy is to require at least an expedited review for any research involving children.

***What are the requirements for assent by children and permission by parents or guardians?* (45 CFR 46.408)**

The requirements for informed consent are the same for both adults and children, but parental permission is required as well. That is:

***Assent*** of the child must be obtained if, in the judgment of the IRB, he or she is capable of giving assent.

Elementary school-age children may provide oral or written assent to participate after the elements are explained at their level of understanding.

Middle school-age children and older can provide written assent.

***Written permission*** must be obtained from parents if a child is to participate in a research project. The degree of risk to the participant determines the number of signatures required.

* For studies not involving greater than minimal risk or those involving greater than minimal risk but presenting the prospect of direct benefit to the individual participants (see above), the signature of only one parent is sufficient.
* For any other category of research that involves children, the signature of both parents is required unless:

one parent is deceased, unknown, incompetent, or not reasonably available

only one parent has legal responsibility for the care and custody of the child.

The elements of informed consent must be included in the investigator’s explanation of the project to the child and his or her representative.

It is important that the investigator explain the study at a level the child is capable of understanding, as valid assent can be given only if the child understands what he or she is agreeing to do. Asking questions in order to elicit questions or comments from the child is a good way to ascertain that he or she really understands what is being proposed.

***What is required for documentation of assent/permission for research involving children?***

****See the explanation of documentation in the Informed Consent section of this Guide.

# WARDS

***Can children who are wards of the state or other entity be included in research projects?***

Yes, but certain stipulations are made for research that poses greater than minimal risk and that does not present the prospect of direct benefit to the participant:

The research must be related to their status as wards **or** it must be conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

If the proposed research meets the stipulations above, then the IRB must require appointment of an advocate for each child who is a ward; this is in addition to any other individual who acts on behalf of the child as guardian or *in loco parentis*. One individual may serve as advocate for more than one child. The advocate should be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child’s participation in the research and who is not associated in any way--other than the role of advocate or member of the IRB--with the research, the investigator(s), or the guardian organization.

****

# PRISONERS

Federal guidelines specifying protection for children as research subjects can be found in **45 CFR 46.301-306.**

***How is “prisoner” defined?* (45 CFR 46.303(d))**

***Prisoner*** means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures that provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

***What are the criteria to receive IRB approval to conduct research using prisoners?* (45 CFR 46.305)**

* Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in the prison are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited-choice environment of the prison is impaired.
* Risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers.
* Procedures for the selection of participants within the prison are fair to all prisoners and are immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the IRB justification in writing for following some other procedures, control participants must be selected randomly from the group of available prisoners, who meet the characteristics needed for that particular research project.
* Information is presented in language understandable to the participant population.
* Adequate assurance exists that parole boards will not take into account a prisoner’s participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole.
* If a follow-up examination is required or care of participants is necessary after the end of their participation, adequate provision has been made for such examination or care (considering the varying lengths of individual prisoners’ sentences) and for so informing participants.

The proposed research is limited to any of the following: **(45 CFR 46.306)**

* Study of the possible causes, effects, and processes of incarceration and of criminal behavior, provided that the study presents no more than minimal risk (see below), and no more than inconvenience to participants
* Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk, and no more than inconvenience to participants
* Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis [more prevalent in prisons than elsewhere], and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults)
* Research on practices, both innovative and accepted, that have the intent and reasonable probability of improving the health or well-being of the participant.

**Note:** All research involving prisoners requires the inclusion of a prisoner advocate as a member of the IRB. This person must either be a prisoner themselves or must qualify under OHRP guidelines as a prisoner advocate.

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# PREGNANT WOMEN

Federal guidelines specifying protection for children as research participants can be found in **45 CFR 46.201-207.**

The federal regulations specify that:

* The guidelines for research exempt from full board review (i.e., minimal risk research) (**45 CFR 46.101(b)(1)-(6)**) apply to pregnant women.

Detailed requirements pertaining to this special population can be found at **45 CFR 46.201-2**07.

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# ECONOMICALLY OR EDUCATIONALLY DISADVANTAGED PERSONS

# (45 CFR 46.111)

Federal regulations permit the reading of the elements of informed consent to illiterate persons who understand English, who then may “make their mark.” Both the witness and the person conducting the consent interview must sign the form.

Investigators should be cautious when enrolling subjects who may not truly understand what they are agreeing to do. The IRB considers illiterate persons as likely to be vulnerable to coercion and undue influence. Investigators should make sure additional safeguards are in place to protect the well-being of this vulnerable population.

# ADVERSE EFFECTS

Adverse effects that are unanticipated problems are events or circumstances that were unanticipated, possibly related to participation in the research, and suggest that the participants are at a greater risk of harm (physical, psychological, economic, or social) than was previously recognized. In order to comply with the regulations, these events **must** be reported immediately to the IRB chair and to the federal agency funding the research, if applicable. A**form for reporting adverse effects** is provided on the IRB website, [www.lcsc.edu/irb](http://www.lcsc.edu/irb)

Pursuant to 45 CFR 46

# CONTINUATION FORM

# Submit with signatures to the

# Lewis-Clark State College Institutional Review Board

**E-mail application as an attachment to the** **IRB Chair**

|  |
| --- |
| Title of Project |

**Please submit this form at least** **three weeks before the expiration date**. Please note: You may not recruit new human participants or continue your activity with previously enrolled participants beyond the expiration date unless you have received approval for the continuation of the project.

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

Current IRB Approval Number Expiration Date

**Principal Investigator(s):***I acknowledge that this represents an accurate and complete description of my research.*

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

Name of Primary PI Signature of PI Date

|  |
| --- |
|  |

Additional Researchers’ Names

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

Mailing Address Division

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Telephone Number |  | E-mail address (Student's lcmail account) |

**Adviser (complete if PI is a student):** I agree to provide the proper surveillance of this project to ensure that the rights and welfare of the human participants are properly protected.

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

Name of Adviser (typed) Signature of Adviser Date

|  |  |  |  |  |
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Adviser’s Address Adviser’s e-mail address Telephone

***I. Research Activity Status*** (please check as applicable):

\_\_\_ New participant enrollment still in progress.

\_\_\_ Enrollment closed, but participants are still undergoing study procedures.

\_\_\_ Enrollment closed, participants have completed study procedures, but are still in follow-up.

\_\_\_ Participant involvement completed, need approval for continued use of identifiers for data analysis only.

1. ***Participant Status:***

|  |  |
| --- | --- |
| Number of participants approved in original IRB application |  |
| Number of participants actively enrolled in the study |  |
| Number of additional participants needed to complete the study |  |

***III. Research Progress Report:***

1. Provide a summary of the **purpose** of this research activity, the study population, sample procedure, and methodology.

2. Provide a summary of your progress to date, to include any changes you have made to the methodology during the last period of approval which were approved with a modification.

3. Describe any changes in the risks or benefits to participants over the last period of approval.

4. If you propose changes in this activity for the next period of approval, summarize the changes. Also attach copies of the revised consent or assent forms and any other revised study materials, if applicable.

5. Have there been any changes in key personnel? \_\_\_Yes \_\_\_No If yes, explain why the changes were made.

***IV. Adverse Events:***

1. Did any adverse effects occur? \_\_\_Yes \_\_\_No

2. If yes, provide the number of adverse events: \_\_\_\_\_ Explain how you handled each adverse event.

3. Were any of these adverse events unexpected or more serious than expected? \_\_\_Yes \_\_\_No

4. If yes, did you send us an Adverse Event report? \_\_\_Yes \_\_\_No

5. If no, please complete the Human Participants Adverse Effect Report and send it to the IRB Chair immediately with this continuation form.

6. Number of complaints: \_\_\_\_\_\_\_\_ Explain how you handled each one.

7. Number of participant withdrawals: \_\_\_\_\_\_\_\_ For each, explain why the participant chose to withdraw or why you withdrew the participant from the study.

8. Number of protocol violations: \_\_\_\_\_\_\_\_ Explain how you handled each one.

1. ***Grant Status***

Funding: Please review and update the grant and contract information listed below, if applicable.

Is there new funding proposed for this activity? \_\_\_Yes \_\_\_No If yes, send us one complete copy of the proposal and explain if there are any differences between this new proposal and what is approved in this application.

Please include all funding, current and pending, for this Continuation/Renewal application.

**Funding Type:**

\_\_\_Research Grant \_\_\_Fellowship \_\_\_Training Grant \_\_\_Contract \_\_\_Other, specify:

Funding Agency: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator (on proposal): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Agency Number (if known): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Proposal Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Status: \_\_\_New \_\_\_Competing \_\_\_Non-Competing

Start Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ End Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Funded? \_\_\_Yes \_\_\_No

Pursuant to 45 CFR 46

# MODIFICATION FORM

**Submit with signatures to the**

**Lewis-Clark State College Institutional Review Board**

**E-mail application as an attachment to the** **IRB Chair**

Please be sure to attach any revised materials.

Modifications may not be implemented until they have received approval.

***The approval of any modification does not change the original period of approval of your IRB application.***

|  |
| --- |
| Title of Project |

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Current IRB Approval Number Expiration Date

**Principal Investigator(s):***I acknowledge that this represents an accurate and complete description of my research.*

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Name of Primary PI Signature of PI Date

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Mailing Address Division

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|  |  |  |
| Telephone Number |  | E-mail address (If a student, use lcmail account) |

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| Additional Researchers’ Names: |

**Adviser (complete if PI is a student):** I agree to provide the proper surveillance of this project to ensure that the rights and welfare of the human participants are properly protected.

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Name of Adviser (typed) Signature of Adviser Date

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Adviser’s Address Adviser’s E-mail address Telephone

1. Describe in detail the proposed changes, to include any change in title, methodology, sample size, sample population, assent or consent form, recruitment of participants, investigator(s), research sites, etc.

2. Explain the reason for the request if it involves the methodology/study design.

3. Do these requested changes pose additional risks to participants?

\_\_\_\_No

\_\_\_\_Yes 🡪 If yes, please describe.

4. Submit all materials that are being revised and highlight changes.

Pursuant to 45 CFR 46

# HUMAN SUBJECTS ADVERSE EFFECT REPORT

**Lewis-Clark State College Institutional Review Board**

Send two (2) copies of this form, and one (1) copy of the consent form signed by the participant, to the Lewis-Clark State College IRB. Keep one copy of this form for your files. MUST BE TYPED.

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| Title of Project |

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Current IRB Approval Number Expiration Date

**Principal Investigator(s):** *I affirm that this represents an accurate and complete description of the adverse effect(s) related to this research.*

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Name of Primary PI Signature of PI Date

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Mailing Address Division

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Telephone Number |  | E-mail address (If student, use lcmail account) |
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Additional Researchers’ Names

**Adviser (complete if PI is a student):**

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Name of Adviser/Chair (typed) Signature of Adviser/Chair Date

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

Adviser’s Address Adviser’s e-mail address Telephone

1. Did this event occur to a participant enrolled in your study? \_\_\_Yes \_\_\_No
2. Was the event attributable to a study procedure? \*Cannot be ruled out \_\_\_Yes \_\_\_No
3. Was the event unexpected or more serious than expected? \_\_\_Yes \_\_\_No
4. Is this kind of adverse event described in the currently approved consent form? \_\_\_Yes \_\_\_No
5. Will the event require changes in the consent form or in the research procedures? \_\_\_Yes \_\_\_No
6. If yes, attach a copy of the revised consent form with the changes highlighted.
7. Have you reported this event to the study sponsor? \_\_Not applicable \_\_\_Yes \_\_\_No
8. Have you reported this event to the FDA? \_\_\_Not applicable \_\_\_Yes \_\_\_No
9. Have you reported this event to the NIH Office \_\_\_Not applicable \_\_\_Yes \_\_\_No
10. Has this kind of event happened before in connection with this study? \_\_\_Yes \_\_\_No

**If yes, explain below**.

1. Who is financially responsible for the treatment of this adverse event?

\_\_\_Not applicable

\_\_\_Sponsor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_Participant/participant’s insurer: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_Other - - please explain \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Estimate of cost for treatment: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_Not applicable

Where was care provided: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_Not applicable

Participant’s name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_Not applicable

Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_Not applicable

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date(s) of occurrence: \_\_\_\_\_\_\_\_\_ Location of event: \_\_\_\_\_\_\_\_\_\_\_\_ Time (am, pm): \_\_\_\_\_

Description of adverse effect and action take (use additional pages, if necessary):

\*If any relationship between the event and the study can be ruled out, do not submit this form.

**Signature of Investigator \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of IRB Chair \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**