

Concordia University Texas
Institutional Review Board
Research Proposal Guidelines

Introduction

The purpose of this manual is to guide the successful creation and submission of an Institutional Review Board (IRB) proposal that clearly communicates the information needed by the IRB to effectively and efficiently protect the human participants of your research. If you are as student researcher and have further questions about developing your proposal, please consult your faculty supervisor. All other researchers should contact the CTX IRB at irb@concordia.edu.

FREQUENTLY ASKED QUESTIONS

Why use the IRB?

By university policy and federal government statues, the CTX IRB exists to ensure that the rights, safety, and value of human participants in research are adequately protected. The CTX IRB must thoroughly review and approval all research activities conducted by university employees, faculty, or students that involve human participants and by all external researchers involving CTX employees, faculty, or students as human participants.

What is an IRB proposal?

An IRB proposal is a document describing aspects of a planned research activity involving human participants that can be used by the IRB to assess potential risks to the safety of participants, the protection of their rights, and the reasonable expectation that research will generate generalizable knowledge. Generalizable knowledge is considered a benefit to others. Risk to research participants must be reasonable in relation to the knowledge that can be expected to result from the study. If a clear

and agreed-upon answer already exists, asking research participants to assume the risks of research that will provide the same information is not acceptable since no new knowledge would be gained from the study. The IRB proposal is the only documentation utilized by the IRB in its review process. Note that it is not uncommon for the IRB to request clarification or additional information after a proposal has been submitted in order for it to effectively conduct a review.

What information do I need to complete an IRB proposal?

IRB proposals are expected to provide general information (including title and purpose), a summary of the methodology being used, identification of the research's target population, the sampling and recruitment procedures that will be employed, and a description of how the safety, privacy, and rights of participants will be protected. Typically accompanying this is a copy of any Informed Consent, survey/interview questions, or other procedural documentation that the IRB needs to effectively and efficiently review your proposal.

When should I submit an IRB proposal?

Researchers must submit an IRB proposal before any human participant is recruited for your research. For student researchers, it is highly recommended that a faculty supervisor or committee review and recommend proposals as completed and adequate before submission to the IRB. The IRB does not provide "pre-review" of draft proposals.

What should I expect from the IRB review process?

Once the IRB has all the information needed to review proposal, you should expect the review process to take up to six weeks. Be aware that the IRB takes the responsibility of protecting human participant involved in research very seriously and therefore complete reviews thoroughly and with due diligence.

Once the review process is complete, the IRB either approves the proposed research, does not approve the proposed research, or defers approval of the proposed research pending additional clarification or information. Please ensure that all study documents are provided with your completed application and submitted to irb@concordia.edu.

The following provide details on what is expected when completing the IRB proposal template. Please do not hesitate to reach out to the IRB if you have any questions about this process.

Please use this guide/manual in conjunction with the research proposal template provided.

- 1. Title:** A title page contains the name of the proposed research, candidate, supervisor (if known) and the department or school to which it will be submitted. The proposed research title should be clear, precise and should summarize the details which are given in the proposed research.
- 2. Principal Investigator:** List the name, CTX Banner ID, Department. If the PI is currently a CTX student, a CTX faculty or staff must be identified as a supervision or sponsor of the research being proposed.
- 3. Purpose:** Provide a brief overview (1-3 paragraphs) of your study written for a general audience explaining the purpose of the research and theories and/or hypotheses to be tested. DO NOT copy/paste a lengthy literature review in this section. Do not overuse academic jargon. If the proposed research has IRB approval from another institution or external agency, please provide this documentation.]
- 4. Specific Aims:** Describe the specific aims, purpose, intent, and/or objectives of the Human Research. State the hypotheses to be tested, if applicable. Explain how the project meets the definition of research (a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge).
- 5. Background and Significance:** Describe the relevant prior experience, gaps in current knowledge, and any relevant preliminary data.

6. Research Sites and Study Team: Research location refers to the geographic location that the research will take place, not to the people or institutions that you may be collaborating with. Knowing the location helps the IRB determine the local context of the research as well as if there are additional laws, regulations, and/or policies researchers need to adhere to. All Research Locations should be listed.

- a. Collaborating Sites refer to institutions or study staff that are also taking part in the research study. All Collaborating Sites should be listed.
- b. If conducting an online study, please indicate the location of the researcher who is conducting the study.)
- c. Additional considerations for International Research: Provide the IRB with a description of the local research context. This includes consideration of the following:
 - i. Local requirements such as customs affecting the research, local age of majority, local scientific and ethical review structure (i.e. national, regional, local state law, institution-based model).
 - ii. Socioeconomic factors that may impact study-related costs, compensation, and reimbursement, if any; consideration of provisions to minimize potential for undue influence resulting from economic benefit.
 - iii. Political factors such as the stability of local government; consideration of provisions to ensure physical safety for participants and/or local study staff).
 - iv. Cultural beliefs, norms, attitudes as they relate to the proposed research. For example, survey/interview questions may be innocuous in one culture, but offensive to another; secular vs. religious cultures; expectations regarding autonomy; home dynamics (e.g. impact of parent-child relationship of consent procedures), etc.

- d. If a site does not have a local reviewing body, e.g. IRB/research ethics committee, the IRB may require Community Advisory Board (CAB) review. A CAB should include a minimum of 3 members who are independent of study staff to avoid any perceived or potential conflict of interest(s). The members should include one lay, non-scientist member, but otherwise include members with appropriate experience/expertise based on personal or professional qualifications, e.g., citizen of the country where the research will be conducted, investigator well-versed in proposed methodologies, etc. At a minimum, the CAB should review the recruitment/consent process and materials, study procedures, and dissemination of study results, if applicable.
- 7. Study Team:** Describe the experience, resources, training, and qualifications for the principal investigator as well as any study team members who will conduct research activities on this study.
- 8. Study Design and Procedures:** Describe the time allocated to complete the study. Provide an anticipated date of study completion.
- a. Provide a timeline of all procedures being performed, including follow-up visits and procedures being performed to monitor participants for safety or minimize risks.
 - b. Describe procedures taken to lessen the probability or magnitude of risks.
 - c. Describe what data will be collected, including long-term follow-up data.
 - d. If study includes qualitative data collection, describe all procedures and information collected.
 - e. Identify documents that will be used to collect data (e.g., questionnaires, surveys, interview guides). Source documents, such as case report forms – prepared by a study sponsor for clinical trials, do not need to be submitted, but should be mentioned in the Research Protocol.

- f. Specify whether participants will be audio or video recorded, and outline plans for transcription and destruction, if applicable.
 - g. Differentiate routine clinical/standard care from research procedures, if applicable.
 - h. Differentiate procedures conducted by CTX staff from those conducted by non-CTX members of the research team.
 - i. Describe primary and secondary study endpoints (i.e. events or outcomes that can be measured to determine effect of research intervention), as well as any primary and secondary safety endpoints (for qualitative research, study endpoint may include completion of 6-month survey).
 - j. If proven beneficial, describe whether plans exist to make the intervention (e.g., investigational drug/biologic/device) available post-study (consider accessibility and cost to participants).
 - k. Specify whether or not the research involves deception (i.e., providing participants with false information) or incomplete disclosure (i.e., withholding information from participants), and, if so, provide justification.
- 9. Data and safety monitoring plan.** Describe the plans to periodically evaluate the data collected regarding both harms and benefits to determine whether participants remain safe.
- i. Describe; what data will be reviewed, including safety and efficacy data, how safety information will be collected (e.g., with case report forms, at study visits, by telephone), the frequency of data collection, including when safety data collection begins, the person or entity (e.g., a Data and Safety Monitoring Board) responsible for reviewing the data, the frequency or periodicity of cumulative data review, statistical measures for analyzing safety data to

determine whether harm is occurring, and any conditions that would trigger an immediate suspension of the research.

10. Recruitment Methods: If a multi-center study in which participants are recruited by methods not under the control of the local site, e.g., call center or national advertisements, describe those methods.

- a. The IRB must review and approve the content of all recruitment and advertisement materials, including oral communications, before implementation. For advertisements, submit the final copy of printed advertisements. When advertisements are recorded for broadcast, provide the final audio/video recording. To avoid re-taping due to inappropriate wording, submit the proposed (draft) wording of the advertisement to the IRB. Otherwise, provide the final English copy of these materials and include a version number and/or date within each document.
- b. When community based participatory research is involved, define the term “community” as it relates to this protocol and describe provisions to engage this community in design and study conduct. Identify any community partners.

11. Consent Process: Describe the setting of the consent process; identify who will be responsible for obtaining consent, and how consent will be obtained, e.g., written or oral consent.

- a. Avoid naming specific individuals, but rather study roles, e.g., research coordinators or nurses vs. John Doe.
- b. Describe the time that will be devoted to the initial consent discussion.
- c. Describe any waiting periods between (a) informing the prospective participant and obtaining consent and (b) obtaining consent and carrying out the study procedures. Describe any steps that will be taken to minimize the possibility of coercion or undue influence.

- d. Describe the process to ensure ongoing consent. Indicate that study staff will continue to ensure participants understand what the research is about and what their participation involves. Confirm that any new information which might influence a participant's decision to continue participation will be provided to participants, including re-consent where applicable.
- e. Indicate what language(s), if any, other than English are understood by prospective participants or their representatives. If non-English speaking participants will be enrolled, identify the languages consent will be conducted in and who will be responsible for translating. Describe the process to ensure that the information provided to those participants will be in that language understandable to the population. Provide an English copy of the consent document(s), as well as a copy of the local language translation when it becomes available. Include version number and/or version date within each document. Back-translations of foreign language consent forms are not required. For guidance on consent requirements, refer to "SOP: Informed Consent Process for Research" and "SOP: Written Documentation of Consent."
- f. **Participants and Target Population:** Briefly describe the study population (e.g., students, patients, etc.) and your anticipated sample size (n) of participants, and/or societal benefits.
- g. **Inclusion and Exclusion:** If applicable, list criteria that will be used to include or exclude participants from the study (e.g., age restrictions, health restrictions, etc.).
- h. **If the Human Research involves any special population, describe the process to obtain consent, permission or assent, including:**
 - i. Persons who have not attained the local legal age for consent to treatments or procedures involved in the research (children).

- ii. Describe whether parental permission will be obtained from:
 - 1. Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
 - 2. One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.
- iii. Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals' authority to consent to each child's general medical care.
- iv. Describe whether assent will be obtained from all, some, or none of the children, and if some children, which children population (e.g. age range) will be required to provide assent. Customarily, the IRB requires that investigators obtain assent from individuals ages 7 years or older; however, if this is not appropriate for the specific target population, please describe.
- v. When assent from children is obtained, describe whether and how it will be documented.
- vi. Describe the procedures in place to obtain consent when, if any, children reach the local age of majority during the course of the protocol.
- i. If the Human Research involves adults who may be unable to consent due to Cognitive Impairment Psychiatric (e.g., psychosis, neurosis, personality disorders) and Developmental (e.g., mental retardation) disorders, and organic impairments (e.g.,

stroke, dementia) may be associated with diminished mental or emotional function, including capacity to consent to participate in research.

- i. The investigation involves no more than minimal risk, or the research involves greater than minimal risk and the purpose of the research is therapeutic with respect to individual subjects and the risk is commensurate with the degree of expected benefit.
- ii. The Investigator should not assume that a prospective participant is unable to provide consent. Rather, should seek to objectively determine whether or not a prospective participant is capable of providing informed consent
- iii. Describe the process to determine whether an individual is capable of consent and address the following, if applicable:
 1. Assent by legally authorized representative will be obtained:
 - a. List the individuals from whom permission will be obtained in order of priority, e.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child.
 2. Determine which individuals are authorized under applicable law to consent on behalf of a prospective participant to their participation in the research procedure(s). If necessary, contact the IRB who will consult with the Office of the General Counsel to review the definition of “legally authorized representative” in 45 CFR 46.102(c) or 21 CFR 50(l) to make this determination.

3. Describe the scientific reason for involving this population in the research, with a description of the procedures that are designed to minimize risks to participants.
- j. Describe the process for assent of the participants. Indicate whether:
 - i. Assent will be required of all, some, or none of the participants. If some, indicated, which participants will be required to assent and which will not.
 - ii. If assent will not be obtained from some or all participants, include an explanation of why not.
 - k. Describe whether assent of the participants will be documented and the process to document assent.
 - l. Describe how consent of the participant will be documented in writing and indicate that participants will be provided with a copy of their signed consent form. If there are extenuating circumstances that make it impossible or inappropriate to meet this requirement, please describe. If the consent process will not be documented in writing, i.e., consent will be obtained, but the participant or representative will not sign a consent document please indicate how you have addressed the following criteria:
 - i. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
 - ii. That the research presents no greater than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context

- iii. If the Human Research involves a waiver or alteration of the consent process (consent will not be obtained, required information will not be disclosed, or the research involves deception) please indicate how the following criteria will be met:
 - a. The research involves no greater than minimal risk to the subjects;
 - b. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
 - c. The research could not practicably be carried out without the waiver or alteration; and
 - d. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
- m. If the research involves deception or incomplete disclosure, describe provisions in place to debrief participants after study procedures conclude.
- n. The debriefing process should include complete disclosure of all pertinent information relating to the protocol; an explanation of why deception and/or incomplete disclosure was necessary, and an opportunity for the participant to withdraw themselves (and all of their data) from the study.
- o. Describe who will be responsible for carrying out the debriefing process. This should be the principal investigator or a member of the study team who is knowledgeable about the research, the deception employed, and the debriefing process.

12. HIPAA Privacy Protections: If protected health information (PHI) is derived from a covered entity, e.g. a hospital or community health center, for purposes of this protocol, describe plans to obtain authorization to access protected health information or provide a rationale for

requesting a waiver of authorization. If requesting the latter, address why it is not practical to obtain an authorization and why the research cannot be conducted without obtaining PHI.

- a. **Note:** Standard Covered Entity Notice of Privacy Practices or Disclosure Statement documents are not considered authorization to access PHI for research purposes. A request for HIPAA authorization must be specific to the proposed research.

13. Family Educational Rights and Privacy (FERPA) Protection: FERPA is designed to protect the privacy of a student's education records at all public elementary and secondary schools and virtually all public and private postsecondary institutions (higher education).

- a. The parent or eligible student (adult 18 and over) shall provide a signed and dated written consent before an educational agency or institution discloses personally identifiable information from the student's education records, except as provided in §99.31.
- b. The written consent must:
 - i. Specify the records that may be disclosed;
 - ii. State the purpose of the disclosure; and
 - iii. Identify the party or class of parties to whom the disclosure may be made.
- c. When a disclosure is made under this section:
 - i. If a parent or eligible student so requests, the educational agency or institution shall provide him or her with a copy of the records disclosed; and
 - ii. If the parent of a student who is not an eligible student so requests, the agency or institution shall provide the student with a copy of the records disclosed.
- d. "Signed and dated written consent" under this part may include a record and signature in electronic form that:

- i. Identifies and authenticates a particular person as the source of the electronic consent; and
- ii. Indicates such person's approval of the information contained in the electronic consent.

14. Vulnerable Populations

- a. Include information regarding participant populations likely to be included in the study that may be vulnerable to undue influence, coercion, or increased risk because of their belonging to that group.
- b. **Vulnerable populations could include, but are not limited to,** children; pregnant women, human fetuses, neonates; prisoners; elderly; economically disadvantaged; employees or students of the investigator or sponsor; undocumented individuals; refugees; racial and/or ethnic minorities; illiterate or low-literacy; military personnel; terminally ill; cognitively impaired or mentally ill; persons with a stigmatizing disease or condition, e.g. AIDS/HIV, etc. Note that the IRB must make additional regulatory findings for the inclusion of pregnant women, neonates, fetuses, children, and prisoners.
 - i. Regulations do not specify what additional protections are necessary for these groups, the HHS regulations (45 CFR 46.111) do require that investigators include additional safeguards in the study to protect the rights and welfare of these individuals “when some or all of the subjects are likely to be vulnerable to coercion or undue influence” (see The Belmont Principle of Respect).
 - ii. Describe the specific safeguards/protections in place to prevent coercion and undue influence.
- c. **Adults Unable to Consent.** If the Human Research involves adults unable to consent, the investigator involves no more than minimal risk, or the research involves greater than

minimal risk and the purpose of the research is therapeutic with respect to individual subjects and the risk is commensurate with the degree of expected benefit. The Investigator should not assume that a prospective participant is unable to provide consent. Rather, should seek to objectively determine whether or not a prospective participant is capable of providing informed consent

- i. Describe the process to determine whether an individual is capable of consent.
 - ii. Describe assent process of obtaining a legally authorized representative:
 - iii. List the individuals from whom permission will be obtained in order of priority, e.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child.
 - iv. Determine which individuals are authorized under applicable law to consent on behalf of a prospective participant to their participation in the research procedure(s). If necessary, contact the IRB who will consult with the Office of the General Counsel to review the definition of “legally authorized representative” in 45 CFR 46.102(c) or 21 CFR 50(l) to make this determination.
 - v. Describe the scientific reason for involving this population in the research, with a description of the procedures that are designed to minimize risks to participants.
- d. **Children.** If the Human Research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research (children), The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research recommends that the assent of children should be required when they are seven years of age or old (i.e. ages 7-17).

- i. Assent is defined as "a child's affirmative agreement to participate in research."
Also consider a child's passive resignation to submit to an intervention or procedure should not be considered assent.
 - ii. Children should be given the opportunity to express or discuss their willingness to participate in a given research project or not and recommends that the assent process should be developmentally appropriate to the age of the children.
 - iii. The investigator should consider the child's experience and level of understanding and compose a document that is at the same time respectful of the child and conveys the essential information the child needs to decide in a language the child can understand.
- e. **Neonates of uncertain viability** may be involved by meeting the following:
- i. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.
 - ii. The legally effective informed consent of both parents of the neonate is obtained or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained.
 - iii. Parents or legally authorized representative is fully informed regarding the reasonably foreseeable impact of the research on the neonate and the investigator engaged in the research will have no part in determining the viability of a neonate.

- f. **Non viable neonates.** Non-viable neonates may not be involved in research until it has been ascertained whether or not a neonate is viable, and the following additional conditions have been met:
 - i. The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective;
 - ii. The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research;
 - iii. The legally effective informed consent of either parent of the neonate or legally effective informed consent of either parent's legally authorized representative is obtained.
 - iv. A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by the Department of Human Services.

- g. **Pregnant Women:** Pregnant women or fetuses may be involved in research if all of the following conditions are met:
 - i. Provide data for assessing potential risks to pregnant women and fetuses;
 - ii. The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means; her consent is obtained in accord with the informed consent provisions

- iii. Any risk is the least possible for achieving the objectives of the research;
 - iv. If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions. Consent need not be obtained from the father if he is unavailable, incompetent, temporarily incapacitated, or the pregnancy resulted from incest or rape.
 - v. **For children who are pregnant**, assent and permission are obtained in accord within assent provisions.
 - vi. No inducements, monetary or otherwise, will be offered to terminate a pregnancy.
 - vii. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
 - viii. Individuals engaged in the research will have no part in determining the viability of a neonate.
- h. **Prisoners.** If the Human Research involves prisoners and the judgment of the Secretary of Health and Human Services, the proposed research involves solely the following:
- i. Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
 - ii. 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 the subjects;
 - iii. Research on condition particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in

prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research; or

- iv. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of the intent to approve such research.

15. Risks: Describe the reasonably foreseeable risks, discomforts, and/or inconveniences to participants and/or the group/community to which they may belong. Indicate the probability, magnitude, and duration of each risk.

- a. Identify whether any of the information collected, if disclosed outside of the research, could reasonably place the participant at risk of criminal or civil liability or be damaging to the participant's financial standing, employability, insurability, or reputation.
- b. Outline provisions in place to minimize each risk.
- c. Most risks encountered by participants in research fall into the following categories:
 - i. **Physical risks** may include pain, injury, and impairment of a sense such as touch or sight. These risks may be brief or extended, temporary or permanent, occur during participation in the research or arise after.

- ii. **Psychological risks** can include anxiety, sadness, regret and emotional distress, among others. Psychological risks exist in many different types of research in addition to behavioral studies.
- iii. **Social risks** exist whenever there is the possibility that participating in research or the revelation of data collected by investigators in the course of the research, if disclosed to individuals or entities outside of the research, could negatively impact others' perceptions of the participant. Social risks can range from jeopardizing the individual's reputation and social standing, to placing the individual at-risk of political or social reprisals.
- iv. **Legal risks** include the exposure of activities of a research subject "that could reasonably place the subjects at risk of criminal or civil liability."
- v. **Economic risks** may exist if knowledge of one's participation in research, for example, could make it difficult for a research participant to retain a job or to find a job, or if insurance premiums increase or loss of insurance is a result of the disclosure of research data.

16. Benefits: Describe the potential benefits to individual participants, as well as to society, if any.

Note: compensation is not a benefit and should not be addressed in this section.

17. Participant Privacy: Describe the provisions implemented to protect participants' privacy.

- a. Privacy is defined as a person having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.
- b. Privacy also refers to the right of individuals to limit access to/about themselves from/by others, especially information shared with researchers. This includes identifiable information, HIPAA-defined protected health information, research data, photos, video recording, even information contained in biological specimens.

- c. It involves consideration of whether the participants will be comfortable with the research procedures. For example, conducting interviews in a private room or visiting a participants' home in an unidentifiable manner, such as in an unmarked car, wearing plain street clothing.
- d. Describe steps that will be taken to reduce any sense of intrusiveness that may be caused by study questions or procedures.

18. Data Confidentiality: Confidentiality pertains to the treatment of information that a participant has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission.

- a. Describe the provisions implemented to limit dissemination of identifiable data.
- b. The recommended location for all research data, including electronic and digital files, is a secure file server. Physical copies of research data (e.g. paper files, audio tapes, video tapes, etc.) should be stored in a locked file cabinet in a locked office. It is expected that for digital media, data will be securely erased by overwriting the information.
- c. Email should not be used to transmit any research data.
- d. USB/flash drives, CDs, or external hard drives should only be used if those devices are encrypted and preferably remote wipeable.
- e. **For online survey research, please note that online surveys tools typically default to collect IP address, which is considered an identifier.** The Research Protocol should describe whether or not IP address is collected and, if not, confirmation that this field will be deactivated in the survey tool.

19. Data/Statistical Analysis Plan

- a. Describe plans for analysis (including the statistical method, if applicable) and sample size/power calculation, if applicable

20. Compensation for Research Participation

- a. Some types of research involve a significant commitment from research participants in terms of time or effort, and investigators may wish to provide compensation.
- b. During the informed consent process, investigators should explain to potential research participants:
 - i. If there will be compensation for their participation in the research
 - ii. Appropriate expectations for receiving full, partial, or no compensation if research participants complete the study or withdraw prior to its completion
 - iii. That compensation is meant to reimburse research participants for their time, research-related inconveniences and/or research-related discomforts
 - iv. Compensation is not a benefit of the research.

21. Sharing Study Results

- a. Describe the plan to share study results with individual participants and/or the participant group/community, if applicable. This includes reports, policy papers, published journal articles, editorials etc. (with the use of information garnered from this research)

22. Unanticipated Events: In general, include any incident, experience, or outcome that meets all of the following criteria and must be reported to the IRB promptly:

- a. Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the research-related documents, such as the IRB-approved research plan and informed consent document; and (b) the characteristics of the subject population being studied
- b. Related or possibly related to participation in the research (in this guidance document, "possibly related" means there is a reasonable possibility that the incident,

experience, or outcome may have been caused by the procedures involved in the research)

c. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social) than was previously known or recognized.

d. The reporting of an unanticipated problem by the researcher to the IRB begins the process of assessing the unanticipated increased risk(s) to subjects or others, and determining what course of action should be taken to protect the subjects.

Please complete the IRB proposal using this guide with your proposal template. Please ensure that you have submitted a complete application to the CTX IRB via email irb@concordia.edu or the IRB website <https://www.concordia.edu/resources/institutional-review-board.html>. A complete application will include:

- A complete IRB proposal application
- A copy of the Informed Consent to be provided to the potential human participants
- A copy of the Assent Form to be used if applicable
- A copy of any questionnaire or survey instrument to be used
- A copy of any additional material mentioned in the proposal that will be provided to the human participants in the research including and not limited to reading material, intervention material, curriculum/curricula; advertisements etc.
- A copy of any disclosure or request of information material to be used
- Evidence of all protections to be put in place for vulnerable and special populations
- Ensure that your contact information is up-to-date and included in the application: in particular, your email, phone number and mailing address.

SAMPLE: FERPA CONSENT TO RELEASE STUDENT INFORMATION

TO: _____ (Name of University Official and Department that will be releasing the educational records)

Please provide information from the educational records of _____
[Name of Student requesting the release of educational records] to: _____
[Name(s) of person to whom the educational records will be released, and if appropriate the relationship to the student such as “parents” or “prospective employer” or “attorney”]

(Note: this Consent does not cover medical records held solely by Student Health Services or the Counseling Center – contact those offices for consent forms.)

The only type of information that is to be released under this consent is:

- ____ transcript
- ____ disciplinary records
- ____ recommendations for employment or admission to other schools
- ____ all records
- ____ other (specify) _____

The information is to be released for the following purpose:

- ____ family communications about university experience
- ____ employment
- ____ admission to an educational institution
- ____ other (specify) _____

I understand the information may be released orally or in the form of copies of written records, as preferred by the requester. I have a right to inspect any written records released pursuant to this Consent (except for parents’ financial records and certain letters of recommendation for which the student waived inspection rights). I understand I may revoke this Consent upon providing written notice to [Name of Person listed above as the University Official permitted to release the educational records]. I further understand that until this revocation is made, this consent shall remain in effect and my educational records will continue to be provided to [Name of Person listed above to whom the educational records will be released] for the specific purpose described above.

Name (print) _____

Signature _____

**The United States Department of Health & Human Services
National Institute of Health Consent Guidelines**

General requirements for informed consent

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.

An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.

The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. **No informed consent, whether oral or written, may include any exculpatory language** through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Informed Consent Checklist

(a) Basic

- A statement that the study involves research
- The information that is given to the subject or the representative shall be in language understandable to the subject or the representative
- An explanation of the purposes of the research
- The expected duration of the subject's participation
- A description of the procedures to be followed
- Identification of any procedures which are experimental
- A description of any reasonably foreseeable risks or discomforts to the subject
- A description of any benefits to the subject or to others which may reasonably be expected from the research
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
- For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained
- Research, Rights or Injury:** An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
- Any additional costs to the subject that may result from participation in the research
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
- A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject
- The approximate number of subjects involved in the study

(c) IRB Latitude to Approve a Consent Procedure that Alters or Waives some or all of the Elements of Consent:

An IRB may approve a consent procedure, which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent, provided the IRB finds and documents that:

- (c) 1. The research or demonstration project is to be conducted by, or subject to the approval of, state or local government officials, and is 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; and
- (c) 2. The research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve consent procedure, which does not include, or which alters some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

- (d) 1. The research involves no more than minimal risk to the subjects;
- (d) 2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- (d) 3. The research could not practicably be carried out without the waiver or alteration; and
- (d) 4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

**Special Requirements - 45 CFR 46 Subpart D - Additional DHHS Protections for Children Involved as Subjects in Research
Assent/Waiver**

The IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted, or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances, in which consent may be waived in accord with §46.116 of Subpart A.

Parents

- The IRB may find that the permission of one parent is sufficient for research to be conducted under §46.404 or §46.405.
- Where research is covered by §46.406 and §46.407, and permission is to be obtained from parents, both parents must give their permission, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
- If the IRB determines that a research protocol is designed for conditions or for a subject population, for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in Subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, state or local law.

§46.117 Documentation of Informed Consent Checklist

- (a) Except as provided in paragraph "c" of this section, informed consent shall be documented by the use of a written consent form approved by the IRB, and signed by person signing the form.

The Consent form may be either of the following:

Written

- (a) 1. A **written consent** document that embodies the elements of informed consent required by §46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator should give either the subject or the representative adequate opportunity to read it before it is signed.

Oral

- (a) 2. A **short form written consent** document, stating that the elements of informed consent required by §46.116 have been presented **orally** to the subject or the subject's legally authorized representative. When this method is used, there shall be a **witness** to the oral presentation. Also, the IRB shall approve a **written summary** of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

Waiver of Requirement for Signed Form

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

- An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects, if it finds either:
- That the only record linking the subject and the research would be the consent document, and the **principal risk** would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
- That the research presents **no more than minimal risk** of harm to subjects, and involves no procedures, for which written consent is normally required outside of the research context.

§46.118 Applications and proposals lacking definite plans for involvement of human subjects.

Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made.

However, except for research exempted or waived under §46.101(b) or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the department or agency.

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