Concordia University Texas

POLICIES & PROCEDURES MANUAL FOR RESEARCH INVOLVING HUMAN PARTICIPANTS

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CONCORDIA UNIVERSITY TEXAS
POLICIES FOR RESEARCH INVOLVING HUMAN PARTICIPANTS

Summary This document establishes the organizational structures and policies for a university-wide INSTITUTIONAL REVIEW BOARD (IRB) to oversee, review, approve, and monitor all research activities involving human subjects conducted by, or with, Concordia University Texas (CTX) students, faculty, or staff.

Purpose of Policy The purpose of this policy it to ensure that CTX follows ethical standard procedures for institutions of higher education in the independent review of research involving humans.

Administrative Structures The IRB will function under the administration of the Director of Institutional Research & Effectiveness, who will constitute the Office of Institutional Review and assume responsibility for the revision and implementation of these policies. This will include the establishment of an IRB Policy Committee to oversee the creation of the CTX Institutional Review Board.

Support & Resources Budget and administrative support for the creation and on-going implementation of the CTX IRB will be provided by the Office of the Provost.

Implementation

December 2016	Review of updated draft policies by Provost's Council
January 2017	Review and approval of Research Ethics policy by Executive Leadership. Formation of IRB Policy Committee
March 2017	Formation of Institutional Review Board. Presentation of basic of CTX IRB policies to faculty
June 2017	Training workshop for IRB members
August 2017	Office of Institutional Review begins receiving proposal submissions

CTX IRB POLICIES & PROCEDURES FOR RESEARCH INVOLVING HUMAN PARTICIPANTS originally developed by N. Chitchester and T. Buchanan with the assistance of the Office of Institutional Research, Concordia University Wisconsin, in 2010. Changes and updates to the policy made by T. Buchanan in 2016.

CONCORDIA UNIVERSITY TEXAS
POLICIES FOR RESEARCH INVOLVING HUMAN PARTICIPANTS

PART I: OVERVIEW

PART II: GUIDELINES FOR PROPOSAL REVIEW

PART I: OVERVIEW

Concordia University Texas recognizes the need for investigations in which human beings may serve as research participants. As an institution of higher learning established by the Lutheran Church-Missouri Synod (LCMS), Concordia University Texas (CTX) is especially cognizant of its moral obligation to those individuals who volunteer as participants in research studies. Consequently, CTX has established and empowered an Institutional Review Board (IRB) to review all research investigations conducted by its students, faculty, and staff involving human beings as research participants, regardless of their funding sources. Through its IRB, the University seeks to meet the highest ethical standards of research involving human participants as well as its sacred responsibility for insuring that the dignity, safety, welfare, and privacy of all are adequately protected. The policies of CTX with respect to research, development, and related activities involving human participants are based on the following principles:

> "So in everything, do to others what you would have them do to you, for this sums up the Law and the Prophets." (Matthew 7:12).

Participation in any research study must be voluntary and the information provided to recruit individuals and gain their consent must be adequate and appropriate. Prior to volunteering to participate individuals must be clearly informed that they are not obligated to participate, that there are no consequences for lack of participation, and that appropriate and reasonable alternatives to participation may be available.

Risk(s) to an individual or group must be deemed acceptable when measured against possible benefit(s) or by the importance of the knowledge to be gained as a result of participation. All such risks shall be communicated clearly in writing prior to participation.

Research and training activities involving human participants must be supervised by qualified persons.

Except for activities covered by the exemptions presented in Appendix C, all research programs which involve human participants must be reviewed by, and receive the approval of, the full IRB prior to the recruitment of participants and the initiation of the proposal. Continuing research programs are subject to annual review. Exemptions from full-board review are invoked by an Exemption Application (see Appendix A).

The principles contained herein strive to be consistent with the Nuremberg Code (1949), the World Medical Association's Declaration of Helsinki (1964) the Belmont Report (1979), and Title 45 of the United States Code of Federal Regulations (2005).

The interpretation and implementation of these policies is the responsibility of the CTX IRB and the Office of the Provost. The following Guidelines for Proposal Review establish procedures for reviewing and approving any and all research and training programs involving human participants related to the educational mission of Concordia University Texas.

PART II: GUIDELINES FOR PROPOSAL REVIEW

1. INTRODUCTION

1.1. The responsibility for providing independent review and continuing surveillance of research, development, and related activities involving use of human participants is delegated by CTX to the Institutional Review Board (IRB) established for this purpose. Fundamental concerns in this process reside in the determination of the risks and potential benefits of the investigation, appropriateness of methods used to obtain consent, and protection of the rights and welfare of the individuals involved.

1.2. The following guidelines have been established to provide a mechanism for implementing the policies of CTX. The guidelines outline the conditions under which a subject may be "at risk" when he/she participates in an experiment and specify the minimum review requirements to be used by the IRB.

2. DEFINITIONS

The following terms are defined as they relate to the review of activities involving human participants.

2.1. Research is defined as a systematic investigation, including development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

2.2. Human Participant - A human participant is a living individual about whom an investigator (whether professional or student) conducting research obtains: (1) data through direct or indirect intervention or interaction with the individual or (2) identifiable personal information. Intervention includes both physical procedures by which data are gathered and manipulations of the individual or the individual's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and individual.

2.3. Risk – Risk is exposure to the possibility of injury, including physical, psychological, or social injury to an individual or group as a consequence of participation in an activity which departs from, or increases, the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service. Such risk may involve patients, outpatients, donors or organs, tissues, body fluids, and services when they may be identified directly or through identifiers, informants, and normal

volunteers, including students who are placed at risk during training in medical, psychological, sociological, educational, and other types of activities.

An individual is considered to be "at risk" if he/she may be exposed to the possibility of physical, psychological, sociological, or other harm as a consequence of participation as a subject in research, development, or related activities. The determination of when an individual is at risk is a matter of the application of common sense and sound professional judgment to the circumstances of the activity in question. Responsibility for this determination resides at all levels of the CTX proposal review process including the investigator.

2.4. Proposal - The description of a research, development, training, or related empirical study which is presented to a review committee for evaluation. A research study may encompass several individual investigations using related techniques on a common theme. The proposed research study will be presented in sufficient detail to enable the IRB to (1) assess the role of the human subject in the activity, and (2) determine whether provisions have been made for adequate protection of the subject's rights and welfare. (See Appendix C. for a sample proposal template.)

2.5. Types of Review – The type of review each submitted proposal receives will be determined by the IRB Administrative Office to be one of the three following categories:

2.5.1. Exempt – Based upon the criteria listed in Appendix A, a submitted proposal may be deemed exempt and automatically approved by the IRB requiring no further action.

2.5.2. Expedited Review – If a proposal is deemed nonexempt and upon review by designated members of the IRB to neither involve risk nor involve special human populations (see below), is shall be forwarded to three constituent members of the IRB for expedited review.

2.5.3. Full Review - If a proposal is not deemed nonexempt and upon review by designated members of the IRB to either involve risk or involve special human populations (see below), is shall be forwarded to the entire membership of the IRB for full review.

2.6. University Administrative Units - The administrative office which assumes institutional responsibility for oversight of applications to sponsoring agencies external to the University shall be the Office of the Provost.

2.7. Notification - Official notification to the researcher, the advisor, and a sponsoring agency by the CTX IRB and/or the Office of the Provost that an activity involving human participants has been reviewed and approved by the IRB will be carried out in accordance with the guidelines contained herein.

3. IMPLEMENTATION GUIDELINES

3.1. Policy Development and Promulgation

3.1.1. Development and promulgation of policy related to research, development, and related activities in which human participants are involved shall be the responsibility of the Office of the Provost, including informing and educating CTX student, faculty, and staff of the requirements of institutional review.

3.1.2. IRB procedures shall be reviewed by the Academic Cabinet before recommended to the Provost and President for final approval. Continuing oversight of IRB policies and procedures will be the responsibility of the IRB Policy Committee (see below).

3.1.3. Administration of policies relating to research involving human participants shall be the responsibility of the Office of the Provost, including forming, training, and supporting the CTX Institutional Review Board.

3.2. IRB Policy Committee

3.2.1. Composition (6) -- The IRB Policy Committee shall be established by the Provost and include the Chair of the IRB (cf. 3.4.1.1), academic Deans, Dean of Students, the Director of Institutional Research & Effectiveness, and the Senior Director of Risk & Compliance.

3.2.2. Responsibilities and Functions

3.2.2.1. Policy Development and Promulgation (see Section. 3.1)

3.2.2.2. Appeals – The IRB Policy Committee will review any dispute between a researcher and the IRB regarding disposition of a proposal. However, it

cannot approve a proposal that the full IRB has denied; it can only recommend reconsideration.

3.2.2.3. Eligibility for IRB Membership – The Policy Committee will maintain a directorate of non-university employees (non-affiliated members) who may serve on the IRB. The presence of non-affiliated members from the community on IRBs offers greater public awareness, communication, cooperation and sensitivity on personal and social implications of research and human subject issues. Additionally, these members provide protection against development of insular or parochial board attitudes. Finally, the phrase "from the community" is intended to apply, in the broad sense, to the larger community served by the University and not to the small population of persons involved as participants in a particular activity or project.

3.3. IRB Administrative Office

3.3.1. Composition --The IRB Administrative Office will include the Director of Institutional Research & Effectiveness, and appropriate clerical support to ensure that records are maintained accurately and in a timely manner.

3.3.2. Responsibilities and Functions

3.3.2.1. The IRB Administrative Office will receive directly from investigators, or in the cases where research is being conducted by CTX students via their advisors or department/program chairs, all research proposals which involve human participants. It will review all proposals to ensure that they are 1) complete and 2) that the type of review recommended by the investigator is in accordance with CTX IRB guidelines. The IRB Administrative Office is authorized to change the recommended type of review to ensure conformance with the guidelines.

3.3.2.2. The IRB Administrative Office is responsible for developing the agenda of nonexempt, full-review proposals for meetings of the IRB and providing IRB members of the appropriate documents. For expedited proposals, the IRB Chair will assemble a three-member *ad hoc* committee selected from the IRB membership to review the proposals.

3.3.2.3. The IRB Administrative Office will make a preliminary determination of type of review required for each submitted proposal.

3.3.2.4. The IRB Administrative Office will forward certification of IRB approval of proposed research to the appropriate agency only after all modifications required by the IRB have been incorporated to the satisfaction of the IRB.

3.3.2.5. The IRB Administrative Office will designate procedures for the retention of signed consent documents for at least three years past completion of the research activity.

3.3.2.6. The IRB Administrative Office will maintain and arrange access for inspection of IRB records as provided for in the IRB guidelines.

3.3.2.7. The IRB Administrative Office will arrange for and document in its records that each individual who conducts or reviews human subject research has received appropriate training in protecting human research participants.

3.3.2.8. The IRB Administrative Office will serve as the University's interface between IRBs and external agencies for reporting of adverse reactions and serious violations of regulations.

3.3.2.9. The IRB Administrative Office will ensure that all affiliated performance sites that are not otherwise required to submit assurances of compliance with Federal regulations for the protection of research participants at least document mechanisms to implement the equivalent of ethical principles to which this institution is committed.

3.3.2.10. The IRB Administrative Office will be responsible for documenting, assessing, and reporting the activities of the IRB annually to the Provost for the purpose of detecting, correcting, and reporting (as required) administrative and/or material breaches in the protection of the rights and welfare of human participants as described in its policies.

3.3.2.11. The IRB Administrative Office will generate maintain a directorate of consultants (e.g., institutional researchers, legal counsel, medical specialists, etc.) who are available to provide counsel to the IRB.

3.3.2.12. The IRB Administrative Office will maintain all records in such a form that the status of any proposal can be readily accessed by members of the IRB,

the IRB Policy Committee, accreditation teams, or submitting investigators, and in the case of students, sponsoring faculty.

3.3.2.13. The IRB Administrative Office will provide information and educational programs concerning human subject research and CTX Institutional Review policies to the CTX community.

3.3.2.14. The IRB Administrative Office will provide support for training, education, and professional development opportunities to IRB members, including the creation and maintenance of electronic resources related to IRB activities (e.g., professional journal articles and book chapters) and a list of web-based resources. Members of the IRB and IRB Policy Review Committee may submit proposals to the IRB Administrative Office to assist in the funding of educational and professional development opportunities (i.e., conference travel attendance), consultant fees or honoraria, or to underwrite promotion of IRB-related activities on campus.

3.3.2.14. The IRB Administrative Office will engage in institutional effectiveness planning and reporting on an annual cycle.

3.4. Institutional Review Board – The full board will review all non-expedited, nonexempt human research proposals and its members will be called upon on an *ad hoc* basis by the IRB Administrative Officer or Chair of the IRB to review exempt proposals.

3.4.1. Composition

3.4.1.1. Chair: A member appointed by the President of CTX and should have a broad background in research, be a full-time member of the faculty, and not a member of a the IRB Administrative Office or IRB Policy Committee. The IRB Chair has full voice and voting privileges.

3.4.1.2. Constituent Members (minimum of 4, maximum of 8): One to two members representing each from the following academic areas: Business & Communication, Education, Humanities, and Natural Science). Constituent members will be appointed by the respective college Dean and approved by the IRB Policy Committee. At least two constituent members should have teaching or graduate-level training in ethics, including, but not limited to, theology, philosophy, bioethics, or medical ethics. Each constituent member has full voice and voting privileges.

3.4.1.3. Non-affiliated Members (2): Non-affiliated members are individuals not

otherwise affiliated with the institution and who are not part of the immediate family of a person who is affiliated with the institution. These individuals function as "community members" and are nominated by the IRB Policy Committee and appointed by the President. (See section 3.2.2.3). Each non-affiliated members has full voice and voting privileges.

3.4.1.4. *Ex Officio* Members (2): Both the Director of the School of Education and the university's Risk Manager will serve as *ex officio* members. Each *ex officio* member has voice, but not voting, privileges.

3.4.1.5. Student Member(s): With the approval of the IRB Policy Committee, upper-level undergraduate or graduate students may be appointed to the IRB with in an advisory role. Student members have voice, but not voting, privileges.

3.4.1.6. No member of the IRB, including *ex officio* and student members, may participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

3.4.2. Responsibilities and Functions

3.4.2.1. The IRB will review, and have the authority to approve, require modification in, or unapprove all human use research proposals in which a member(s) of the CTX faculty, staff, or student body is the principal investigator or in which participants are to be drawn from the CTX community. The IRB will also review proposed changes in previously approved human subject research. For approved research, the IRB will determine which activities require continuing review more frequently than every twelve months or need verification that no changes have occurred if there was a previous IRB review and approval. Continuing reviews require receipt by the IRB of appropriate progress reports from the investigator, including available study findings.

3.4.2.2. Documentation of IRB deliberations detailing its decisions and requirements for modifications will be promptly communicated to the IRB Administrative Office electronically. Decisions to conditionally approve, unapprove, or defer action will be supported by specific reasons and are communicated to the PI.

3.4.2.3. The IRB will convene formal meetings at least once each academic semester (Fall, Spring). A meeting is considered official by satisfying the requirements to meet quorum (see section 3.4.7). Attendance at

meetings of the IRB can be fulfilled either in person or remotely via telecommunication technologies (e.g., conference telephone call or a web-based interface).

3.4.2.4. The IRB has access to knowledge of subject populations, institutional constraints, differing legal requirements, and other factors which can affect the determination of risks and benefits to participants and participants' informed consent and can properly judge the adequacy of information to be presented to participants. The IRB Administrative Office The IRB will ensure that legally effective informed consent will be obtained and documented. The IRB will have the authority to observe or have a third party observe the consent process.

3.4.2.5. Where appropriate, the IRB will determine that adequate additional protections are ensured for fetuses, pregnant women, prisoners, and children. The IRB has the authority to obtain the necessary expertise to safeguard the informed consent process for these special populations.

3.4.2.6. The IRB has the authority to suspend or terminate previously approved research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to participants.

3.4.2.7. The IRB will forward to the IRB Administrative Office any significant or material finding or action, at least to include the following: 1) injuries or any other unanticipated problems involving risks to participants or others, 2) any serious or continuing noncompliance with the regulations or requirements of the IRB, and 3) any suspension or termination of IRB approval.

3.4.3. Appointment to the IRB

3.4.3.1. Qualification of Members – Members appointed to the IRB should possess competence to comprehend the nature of the proposals, committed to the thorough and adequate review of proposals, and be able to exercise judgment required to implement IRB policies. Members of the IRB shall not be involved in review of an activity in which they have a conflicting interest except to provide information requested by the IRB.

3.4.3.2. Term of Appointment - The chair and constituent members of the IRB are to be appointed (or re-appointed) before July 1, each for a maximum 3-year term. Term lengths may be modified by the IRB Policy Committee to provide continuity. Members may serve consecutive terms by reappointment. In order to fill vacancies, appointments to membership on the IRB may be made at any time by the IRB Policy Committee in compliance with policy 3.4.1 regarding the composition of the IRB.

3.4.4. Guidelines For IRB Review

3.4.5. Overview - It is the policy of CTX that any research conducted by its faculty, staff or students involving human participants must come before the IRB for review and approval. Proposals already approved by an IRB of another institution may be recognized by the CTX IRB. These proposals should be submitted under expedited review. Involvement of individuals as participants in a research study is not permitted until the CTX IRB has reviewed and approved the proposal. Approval by the IRB is in effect for one year; projects lasting longer than one year must be re-submitted to the IRB for continued review. While investigators may contact organizations from which participants might be recruited, contacting participants for recruitment or obtaining consent is also prohibited until IRB approval is received.

3.4.6. Frequency of IRB Meetings – The IRB Policy Committee may establish guidelines for the frequency and scheduling of IRB meetings and proposal submission deadlines.

3.4.7. Quorum - A quorum of any IRB, duly convened, shall be no fewer than the voting majority of the total membership and must include one non-affiliated member. This may include those in attendance remotely via telecommunication technology.

3.4.8. Purpose of Review - In general, criteria for approval or disapproval of the proposal include the following.

(1) Any risks to participants are to be minimized (a) by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk, and (b) whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes;
(2) Any risks to the individual subject must be acceptable when measured against (a) the possible benefit to him/her and (b) the importance of the knowledge to be gained;
(3) Selection of participants is equitable;
(4) Methods to obtain consent and the substance of the information upon which the subject bases his/her consent to participate in a research study must be adequate to assure informed consent;
(5) Appropriate safeguards must be provided to protect the privacy of participants and to maintain the confidentiality of data gathered.

3.4.9. Scope of Review - The scope of the IRB is broad. Activities that fit the definition of research with human participants include (but are not limited by):

a) research with humans or human tissue;
b) surveys, interviews of human participants;
c) behavioral observation or recording of human participants;
d) review of human participants' records, living or deceased;
e) courses in research methods and class assignments that involve research with human participants ;
f) pilot studies and feasibility studies (including single subject studies);
g) research using data on human participants gathered in earlier projects (i.e., archival data);

Not all course-related assignments involving humans needs to be submitted to IRB for review and approval. For example, observing an infant’s movements during a child development course for the sake of learning about normal motor development would not need to be reviewed by the IRB because it is not research. That is, it is neither an activity that is intended for publication nor an activity that will advance previous work in another area. This does not absolve the instructor from the responsibility for ensuring the safety of the infants involved in the observation

3.4.10. Approval of Proposals - A proposal must be approved by a supermajority (75%) of the IRB members who are voting.

3.4.11. Types of Institutional Review

3.4.11.1. Initial Review – Proposals submitted to for review will be initially evaluated by the IRB Administrative Office to determine the type of review required. The initial review of exempt proposals should be completed and communicated to the principal investigator within seven (7) days of receiving a complete proposal. The initial review of non-exempt proposals should completed and communicated to the principal investigator no later than thirty (30) days following the proposal submission. Initial approval is valid for up to twelve months. If a study is proposed for longer than twelve months or the investigator cannot solicit sufficient participants during the twelve months for which the study was approved, the study will be subject to continuing review (see Section 3.3.8.3). Initial review of expedited proposals is conducted electronically or face-to-face by a three-member *ad hoc* committee assembled by the IRB Administrative Office. If the *ad hoc* committee is satisfied with the human use safeguards presented in the proposal, it is authorized to approve the proposal. However, any member of the *ad hoc* committee can recommend review by the full board.

3.4.11.2. Review of Proposal Changes -- The IRB shall require the investigator to report to the IRB for review any emergent problems or proposed procedural changes which may affect the status of the ongoing program with regard to the established review criteria. No changes, except those necessary to eliminate apparent immediate hazards, shall be made without prior approval by the IRB. In the event a project which has not used human participants finds it necessary to have humans involved, such use must be reviewed and approved in accordance with IRB policy prior to the use of human participants.

3.4.11.3. Monitoring Review – IRB may choose to require monitoring review of approved non-exempt projects based upon the its assessment of risk. Expectations for Monitoring review can be specified by the IRB on a case-by-case basis, including time between monitoring reviews and documentation necessary to verify compliance with an approved proposal. The IRB reserves the right to conduct, if it deems it necessary, a formal review of any significant changes in experimental procedure which affect the utilization of human participants.

3.4.11.4. Expedited Reviews – Non-exempt proposals involving members of the CTX community as investigator(s) or participants and already approved by a recognized IRB may be given an expedited review by the CTX IRB. The IRB Administrative Office will assemble a three-member *ad hoc* committee to review the proposal and the IRB approval documentation submitted by the investigator. If all documentation is in order and there are no human use concerns, the *ad hoc* committee is authorized to approve the proposal. However, any member of the *ad hoc* committee can recommend the proposal be submitted to the full board for review.

4. EVALUATION OF PARTICIPANT RISK

4.1. General Considerations

4.1.1. The CTX IRB chairperson may call any qualified consultants from the faculty or other sources as required. This is particularly appropriate where the participants are especially vulnerable, e.g., prisoners, children, and the mentally or physically disabled. The investigator and the IRB will meet jointly with the consultant for the latter's assessment of the risks and of the potential benefits of the research.

4.1.2. The IRB must be alert to the possibility that investigators, program directors, or contractors may, quite unintentionally, introduce unnecessary or unacceptable hazards, or fail to provide adequate safeguards. This is particularly true of research that crosses disciplinary lines. The IRB should consider the proposal as a whole in order to determine that normally minor and acceptable risks are not aggravated by the way the proposal is designed. The IRB must assure itself that proper precautions will be taken to deal with emergencies that may develop even in the course of routine procedures. Also, relevant to the decision of the IRB is the protection of those rights of the subject that are defined by law. When an IRB feels that a legal opinion is needed concerning some aspect of a proposal, the IRB chairperson is authorized to obtain legal counsel.

4.1.3. Programs Involving Stress Stimuli and/or Emotional Stress - When, in view of the IRB, stress is present, it will be necessary for the IRB to be assured that the duration and intensity of such stress stimuli are within acceptable limits. Stress stimuli include, but are not limited to, electric shock, intense sound or light, vibration, loss of support, acceleration or deceleration greater than one *g*, etc. In those studies which involve emotional stress, the investigative plans must include adequate safeguards to control the severity of such stress reactions. Provisions must also be made for an adequate post-investigative explanation of

the experimental procedures (debriefing procedure) to be used immediately after the conclusion of each individual's participation. When appropriate, contact information for campus and or community-based resources for further education, support, or intervention shall be provided to participants.

4.2. Obtaining Consent

4.2.1. Informed Consent -- The informed consent of participants will be obtained by methods that are adequate and appropriate. "Informed consent" is the knowing consent from an individual, or his/her legally authorized representative, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud deceit, duress or other form of constraint or coercion.

4.2.1.1. The basic elements of informed consent are:

A fair explanation of the procedures to be followed, and their purposes, including an identification of those which are experimental, and the expected duration of the subject's participation.

A description of the attendant discomfort and risks reasonably to be expected.

A description of any benefits reasonably to be expected.

A disclosure of any appropriate alternative procedures that might be advantageous for the subject.

A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

An instruction that the person is free to withdraw his/her consent and to discontinue participation in the project or activity at any time without intimidation or prejudice to the subject.

With respect to biomedical or behavioral research which may result in injury, an explanation as to whether medical treatment and financial compensation are available if such injury occurs and, if so, of what it consists.

An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury.

4.2.1.2. When appropriate, any of the following additional elements of informed consent may be required by the IRB:

A statement that the treatment or procedure to be used may involve risks which are currently unforeseeable.

Anticipated circumstances under which the subject's participation may be terminated by the investigator without 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.

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 participants involved in the study.

In addition, the agreement, written or verbal, entered into by the subject, should include no exculpatory language through which the subject is made to waive, or to appear to waive, any of his/her legal rights, including any release of the University or its agents from liability for negligence.

4.2.2. Methods and Considerations

4.2.2.1. Consent must be obtained from the participants themselves with certain allowable exceptions: when the participants are not legally or physically capable of giving informed consent, because of age, mental incapacity, or inability to communicate, the IRB may consider the legality of consent by next of kin, legal guardians, or by other responsible third parties who is a representative of the subject's interests. It is in this kind of investigation that the responsible IRB and investigator will be required to exercise the

highest degree of discernment and judgment of the risk-benefit relationship. Careful consideration should be given not only to the prospective third parties' depth of interest and concern with the participants' rights and welfare, but also to whether the third parties are authorized to expose the participants to the risks involved. A parent, for example, may have no authority to expose his/her child to risk, except for the child's own benefit.

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The IRB should determine whether the consent, either secured as a written document or given verbally, or if implicit in voluntary participation in a well-advertised activity, is adequate in the light of the risks to the subject, and the circumstances of the research. The IRB should also determine whether the information to be given to the subject or to qualified third parties, orally or in writing, is a fair explanation of the procedure, its possible benefits, and its attendant hazards. In addition, the language used should be clear and unambiguous with every attempt to eliminate technical terms and jargon. Where debriefing procedures are considered as a necessary part of the research plan, the IRB should ascertain that these will be complete and prompt.

When a generalized form of consent is typically used, the IRB shall determine whether these routine procedures provide an adequate basis for the subject's informed consent to the particular procedures involved.

4.2.3. Mechanism

4.2.3.1. Sufficient information should be provided each subject and (1) the parent or guardian in the case of a minor child (for purposes of these guidelines, a minor child is defined as being younger than 18 years of age), or (2) a responsible third party in the case of incapacitated or infirm participants prior to the investigation to permit obtaining informed consent to participate. For adult participants it is highly recommended that an oral briefing is provided by the principal investigator or by a fully-informed assistant as to the general purpose of the research and as to the general procedures followed. An oral briefing, while highly recommended, is not required in all cases. However, in all research projects requiring informed consent, participants must sign the Concordia University Informed Consent Form. (Appendix B)

4.2.3.2. In the case of minor children or incapacitated or infirm participants, it is necessary that the parents, guardians, or other responsible parties, are given a briefing in written or oral form prior to the investigation in order to obtain their consent. As indicated on the Concordia University Informed Consent Form, the subject must be given an opportunity to decline to participate or to terminate participation without prejudice even if the parent, guardian, or other responsible party has signed a consent form.

4.2.3.3. When prisoners or persons from the vulnerable groups described above are participants of research, it is recommended that a signature is obtained from at least one person, not associated with the research, who has witnessed the signing of the consent form.

4.2.3.4. Research that is Exempt does not require informed consent unless requested by the IRB.

4.2.3.5. A copy of the form used as documentary evidence of informed consent must be provided to the subject and a copy must be retained by the principal investigator for at least three (3) years beyond the termination of the subject's participation in the proposed activity. Should the principal investigator and/or the academic advisor leave the University, signed consent forms are to be transferred to the appropriate academic department for the remainder of the 3 year period.

4.2.4. Waiver of Informed Consent

4.2.4.1. The IRB may choose to waive the requirement for informed consent in some cases; however, such action must be based upon clearly defensible grounds, and the principal investigator must include these justifications in the proposal. The IRB also may waive the requirement for a post-experiment explanatory debriefing. Again, however, this action must be based on clearly defensible grounds. In the event that participation is intended as a learning experience connected with some course or program of study, the post experiment explanatory debriefing cannot be waived.

4.3. Informing Participants About The Research

4.3.1. Extent of Information Given to Participants -- It is recognized that in some research it is not possible to fully inform the subject of the experimental procedures without destroying the validity of the research. For example, in a study of incidental learning, one cannot inform the subject that he/she will be tested for the retention of incidental rather than of task relevant information without biasing the subject's behavior in the original learning sessions. Thus, while it is recognized that informed consent need not be based on full pre-participation information, it is the responsibility of the IRB to set limits to the incompleteness of such information. Further, in those studies in which it is proposed to mislead the participants during data collection, the IRB has the responsibility of assessing whether this violates the rights or welfare of participants, and if such violation exists the IRB must set limits for such studies. Finally, in the event the participants are misled or deceived during data collection when they are participating as part of a learning experience connected with a course or program of study, it is particularly important to insure that the debriefing includes both a detailed description of the deception and a description of its need and the role it played within the experiment.

4.3.2. Timing of Information Given to Participants -- It is necessary for the principal investigator or a fully-informed assistant to give each subject an explanation to questions ensuing from the experiment following participation. It is strongly recommended that this occurs immediately following such participation for each subject, but if in the judgment of the IRB such information could adversely affect subsequent data collection in the same study, the full explanation may be delayed for a reasonable period of time. There is an exception to this delay: If

delay of debriefing could be expected to result in emotional stress to the subject, it is mandatory that the participant receive a full debriefing immediately following participation. In the cases of minor children, or incapacitated or infirm participants, an explanation should be provided to the parent, guardian or other responsible third party in addition to an explanation to the subject. Such "third party" explanation may be provided at a later date.

4.4. Children As Participants In Research – Special Considerations

4.4.1. The range of activities exempt from review by a CTX IRB is reduced when children are involved as participants in research. Specifically, research involving survey or interview procedures and research involving the observation of public behavior are not exempt from IRB review when these research activities involve persons under the age of 18 (hereinafter, "child" or "children").

4.4.2. Additional written assent is required of each child who is of ages 14, 15, 16, and 17 participating in non-exempt research. The requirement of written assent may be waived by the IRB for good cause shown. It should be noted that whereas written permission by parents must represent fully informed consent, written assent is merely the child's affirmative agreement to participate in the research.

4.4.3. Written permission is required of both parents or the child's guardian for each child under the age of 18 who will be the subject of research in a non-exempt category. The permission of one parent is sufficient if: (a) the other parent is not reasonably available or is incompetent; or (b) only one parent has legal responsibility for the care and custody of the child; or (c) the research is such that it either does not involve more than minimal risk to the child or involves more than minimal risk but also presents the prospect of direct benefit to that child. The requirement for written permission may be waived by the IRB where it is not a reasonable requirement to protect the participants (for example, neglected or abused children).

4.4.4. Children who are wards of the state or of any other entity may be included in research involving greater than minimal risk and no prospect of direct benefit to the individual children only if the research is related to their status as wards or is conducted in schools, camps, hospitals, or other similar settings in which the majority of children involved as participants are not wards. An individual must be appointed as advocate for the wards; the advocate may not be associated with the research, the investigators or the guardian organization. The advocate must have the background and experience to act in the best interests of the children

for the duration of their participation in the research. It is suggested that the principal investigator identify a suitable advocate and secure his or her consent to serve prior to review by the appropriate IRB. Advocates for child wards are not required for research involving no more than minimal risk or for research presenting the prospect of direct benefit to the individual children.

5. PROCEDURES FOR REVIEW

5.1. Initial Review of Research Proposals

5.1.1. The prospective principal investigator (PI) will submit the following to the IRB Administrative Office:

For Exempt Research – Submit full electronic copy of the Proposal Submission Document and all other required materials.

For Full Review – Submit full electronic copy of the Proposal Submission Document and all other required materials.

For Expedited Review – Submit required documents. (See Section 5.3)

5.1.2. The IRB will typically review proposals on an *ad hoc* basis as proposals are submitted. The IRB may establish a proposal submission deadline for specific educational programs or academic courses in order to facilitate the timely review of proposals.

5.1.3. The IRB Administrator will provide access to all submitted proposals and accompanying materials to all members of the IRB. *Exempt* proposals not needing IRB review will be archived. Review of *nonexempt, expedited* proposals will be assigned an three-member *ad hoc* team from the IRB membership by the IRB Chair or IRB Administrator. (See section 5.3). Review of nonexempt, nonexpedited (i.e., "full review") proposals will be assigned to the IRB by IRB Chair.

5.1.4. Even though federal, state, or local laws might require meetings of the IRB to be open to the public, investigators have the right to request that to the extent permitted by law, their materials be discussed and reviewed in executive session to insure confidentiality. It is essential that outside of any review meeting members and alternates treat any materials distributed to them as strictly

confidential. Only the IRB Administrator or the IRB Chair may officially notify the PI of the IRB's decision. The PI shall be available to the IRB to discuss the proposal or consent forms, if necessary. It will not be sufficient for the IRB to discuss the proposal with a research associate, a research assistant, or other representative of the primary investigator.

5.1.5 The IRB may take one of three actions in regard to the proposed proposal and consent forms. They may be APPROVED, APPROVED CONDITIONALLY, or UNAPPROVED.

5.1.6 If the proposal is not complete or lacks information, the IRB Administrator or the IRB may DEFER ACTION until more information is provided. In the event the proposal is deferred, the PI must be notified immediately regarding both that action and the reason for the action such that he/she has sufficient time to supply the members of the IRB with any needed additional information prior to the next scheduled meeting of the IRB

5.2 Disposition And Distribution Of Reviewed Materials

5.1.1 The Procedure for Approved Proposals is as follows:

When a proposal has been Approved, the IRB Administrator distributes an Approval Letter electronically to

the academic advisor (if appropriate),
the principal investigator (PI), and
the IRB file. This documentation of action taken must be retained for a period of three (3) years.

5.2.2 The Procedure for Conditionally Approved Proposals is as follows:

When a proposal has been Conditionally Approved, the IRB Administrator distributes a Conditional Approval Letter describing the imposed conditions to

the academic advisor (if appropriate),
the principal investigator (PI), and
the IRB file. This documentation of action taken must be retained for a period of three (3) years.

If the imposed conditions are acceptable, the PI will conduct the proposed research study incorporating the conditions as indicated by the IRB. The revised proposal is then processed through the IRB Administrative Office.

Should the academic advisor and/or PI be unwilling to accept the conditions, the proposal will be processed as though it had been Unapproved (Section 5.2.3).

5.2.3 The Procedure for Unapproved Proposals is as follows:

When a proposal has been Unapproved, the IRB Administrator distributes a Unapproval Letter to

the academic advisor (if appropriate),
the principal investigator (PI), and
the IRB file. This documentation of action taken must be retained for a period of three (3) years.

The academic advisor and/or PI will be informed in the letter of the reasons for disapproval. Every effort shall be made by the IRB and the PI to resolve those elements of the proposal which make it unacceptable. The PI may then submit a new proposal which is then processed through the IRB Administrative Office.

The PI may appeal the decision of the IRB when a proposal has been Unapproved or Approved Conditionally and mutual agreement cannot be reached as to an acceptable alternative. Upon written notification of appeal from the PI, the IRB Policy Committee will review the proposal a second time.

5.3 Expedited Review Procedures

5.3.1 Review of Proposed Changes in Current Research Programs

The academic advisor and/or PI shall immediately bring to the attention of the IRB Administrator or Chairperson any changes which the academic advisor and/or PI proposes to make in the research program which may affect the status of the research or training as it relates to use of human participants.

The IRB Administrator or Chairperson will decide whether the extent or type of changes proposed warrant a more extensive IRB review. If such a review is

deemed necessary, the chairperson shall schedule the review for the earliest feasible time. The academic advisor/PI shall not incorporate the proposed changes until the IRB has given its approval.

The IRB Administrator or Chairperson is also authorized to administer approval of amended proposal. A summary of any action taken by the IRB Administrator or Chairperson is reported to the IRB at its next meeting.

5.3.2 Continuing Review of Research Programs

The IRB Administrator shall forward a Continuing Review Form 2-3 months prior to the one year deadline to the appropriate academic advisors/PIs served by the IRB. In no instance shall an interval between consecutive reviews exceed twelve (12) months.

In considering the academic advisor/PI response to the Continuing Review Form and other information available to it, the IRB administrator will decide whether the research program requires more extensive review by the IRB. Should such review be required because of changes in personnel, experimental procedures, or consent forms the IRB administrator shall schedule the review at the earliest feasible time. The results of this review will determine whether the program can be permitted to operate under the existing proposal. Certification of continuing review will be transmitted to the academic advisor/PI by the IRB Administrator.

5.3.3 Initial Review of Project Approved by Another Institution's IRB

Investigators submitting projects for CTX IRB approval that have been approved at another institution must submit one copy of the letter of approval from the chair of the IRB from the outside institutions along with a copy of the proposal. Review of projects approved by another institution's IRB will be processed through the CTX IRB Administrative Office.

5.3.4 Institutional Data Collected for Non-Research Purposes

Investigators conducting projects for quality assurance purposes should submit a copy of all research materials (i.e. surveys, questionnaires, interview scripts, etc.) to the IRB administrative office for archival purposes.

6.0 COOPERATIVE ACTIVITIES

Cooperative activities are those which involve CTX as a participant with other grantees or contractors. The cooperative activity may be such that CTX acts as the prime grantee or contractor, or CTX may act as a subgrantee or subcontractor where another agency (i.e. industry, another university, etc.) serves as prime grantee or contractor.

In either instance, CTX may obtain access to all or some of the human participants involved through the cooperating institution(s). Thus, the policies and guidelines described above shall apply.

6.1 Procedures for Review

Initial and continuing institutional review may be carried out by one or a combination of procedures. Review may be conducted (1) at CTX, (2) at each cooperating institution, or (3) through cooperation of appropriate individuals or review boards representing the cooperating institutions. It is the responsibility of the PI to coordinate reviews of proposals which involve inter-institutional activities when necessary. The following relationships will be considered by the CTX IRB:

6.1.1 When the cooperating institution has an accepted assurance on file with the potential sponsor, the CTX IRB may request the cooperator to conduct its own independent review and to report to the CTX IRB. The cooperator's report shall include those aspects of the activity that concern individuals for whom the cooperating institution has responsibility in accordance with its own assurance. The CTX IRB may, at its discretion, concur with or further restrict the recommendations of the cooperating institution when CTX serves as prime grantee or contractor. It is the responsibility of the PI to maintain communication with IRBs at the cooperating institution(s). A cooperating institution should promptly notify the chairperson of the CTX IRB if it finds the conduct of the project or activity within its purview unsatisfactory.

6.1.2 When a cooperating institution does not have an accepted assurance on file with the potential sponsor, it may be necessary for that institution to negotiate an assurance before the total review process can be completed.

6.1.3 Inter-institutional joint reviews. The University may wish to develop an agreement with cooperating institutions to provide for an IRB composed of representatives from the cooperating institutions. The composition of the IRB will be reported to the Office for Human Research Protections of the Department of Health and Human Services. For some inter-institutional reviews, it may be necessary to seek an amendment to CTX's assurance or to develop a special assurance to conform to requirements established by the sponsor. In any event, grant or contract funds are not to be released by CTX, in its role as prime grantee or contractor, until the appropriate review process has been completed.

PART III: APPENDICES

APPENDIX A. CATEGORIES OF EXEMPT RESEARCH

Categories of Research Activities that are Exempt from Full Board Review:

Note*: Individuals under the age of 18 constitute a protected class. Consequently, all projects involving minors will require full board review and are not exempt under Concordia University IRB policy.*

1. **Exemption For Education:** Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods is exempted.

2. **Exemption For Research Involving Educational Tests:** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) is exempted, unless (i) information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and (ii) any disclosure of the participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

3. **Exemption For Survey or Interview Procedures:** Research involving survey or interview procedures is exempted unless (i) information obtained is recorded in such a manner that human participants can be identified, directly or through identifier's linked to the participants; and (ii) any disclosure of the participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

4. **Exemption For Research Involving Observation of Public Behavior:** Research involving observation is exempted unless (i) information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and (ii) any disclosure of the participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

5. **Exemption For Research Involving Elected or Appointed Public Officials or Candidates for Public Office:** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempted under exemption #2, #3, and #4 above is exempted if: (i) the human participants are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

6. **Exemption For Collection or Study of Existing Data:** Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens is exempted if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified directly or through identifiers linked to the participants.

7. **Exemption for Research and Demonstration Projects Conducted by or Subject to Approval of Federal Departments or Agencies:** Research and demonstration projects which are conducted by or subject to the approval of department or agency heads are exempted if they 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.

8. **Exemption for Taste and Food Quality Evaluation and Consumer Acceptance Studies**: Taste and food quality evaluation and consumer acceptance studies are exempted if, (i) wholesome foods without additives are consumed; or (ii) a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

APPENDIX B: INSTRUCTIONS FOR SUBMITTING PROPOSALS FOR REVIEW

Instructions and materials needed to submit research proposals to the CTX IRB are available online via the university intranet, Tornado Times, at the page IRB Submission & Approval Process.

Resources maintained here include:

- Step-by-step guide for submitting proposals
- Detailed description of the review process
- Downloadable templated for proposal and informed consent forms
- Access to the IRB Policy and Procedures Manual and University Policy on Research Ethics

APPENDIX C. SAMPLE IRB PROPOSAL TEMPLATE

1. Title
   [Insert study title]

2. Principal Investigator (PI)
   [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 prosed research has IRB approval from another institution or external agency, please provide this documentation.]

4. Procedures
   [Briefly describe your research methodology and study design. Outline step-by-step what will happen to participants in this study. You must include information that allows the IRB to conduct an analysis of the risks and the potential benefits]

   a. Location
      [Describe where data collection and all other study activities will occur. Indicate the names of all sites or agencies (e.g., school districts, day care centers, etc.) involved in the research.

   b. Resources
      [Describe whether internal/external funds, personal funds, other resources will be used to support this research.]

   c. Study Timeline
      [Describe how long the project will take from data collection to dissemination of results.]

5. Measures
   [Describe all study measures. For surveys, focus groups, or interviews – clarify whether question items and measures are standardized, published, or designed specifically for this project. Attach interview guides, survey documents, etc.]

6. Participants
   a. Target Population
      [Briefly describe the study population (e.g., students, patients, etc.) and your anticipated sample size (N) of participants, and/or societal benefits.]
   b. Inclusion/Exclusion
      [If applicable, list criteria that will be used to include or exclude participants from the study (e.g., age restrictions, health restrictions, etc.).]
   c. Benefits

[List any potential benefits that participants may expect from the study, such as, health information, and/or other intrinsic value stemming from study participation.]

d. Risks
[Discuss any possible risks that participants may incur by participating in the study. Explain what will be done to minimize those risks (if applicable). Describe procedures regarding notification of the IRB and treatment of participant in the event that a participant is harmed during the study.]

e. Recruitment
[Discuss how potential participants will be recruited to participate. Provide a description or attach copies of all recruitment materials (e.g., flyers, scripts, letters, e-mails, etc.) that will be used.]

f. Obtaining Informed Consent
[Explain all informed consent procedures. If consent forms will be used, attach a copy. If applying for a waiver of signed consent, specifically state this and explain why. If the study includes non-English speaking participants, describe the qualifications of who translated the document(s) and provide certifying statement that the translation is accurate (see section 6.4.1 of the Policies and Procedures Manual). If the study involves deception, describe the procedures for debriefing the participants.]

7. Privacy and Confidentiality
[Describe how you will protect the identity of study participants (privacy).

Confidentiality of the Data or Samples

a. Describe how data or samples (i.e., blood, salvia, tissue, etc.) will be collected.
b. Describe how the data or samples will be securely stored and how you will achieve this.
c. Provide the length of time the data or samples will be kept.
d. Describe whether data or samples will be kept confidential (i.e., data can potentially be linked to participants) or anonymous (i.e., impossible to link data and participants). You must include if the data or samples will be shared by other researchers for research purposes not detailed in this study.
e. If the data or samples will be destroyed, describe when and how the destruction will occur.]

8. Compensation/Incentive
[Clarify if participants will be compensated for participation specify how participants will receive compensation (e.g., required course credit, extra course credit, cash, a gift card, etc.). Compensation should not unduly influence potential participants and upload corresponding debriefing documents. This includes any incentive (e.g., lottery or prize drawing) designed to encourage participation.]