

CONCORDIA UNIVERSITY RESEARCH COMMITTEE

Policies and Procedures Manual

I. Introduction

Concordia University places a high premium on the academic benefits of research whether conducted by faculty or students. It is critical that such research meet the highest ethical and scientific standards. Concordia University, Portland has established the Concordia University Research Committee (CURC) which reviews research proposals in order to assure that such rights are upheld. This document outlines the policies and procedures adopted by Concordia University, Portland to guide this process and to assure that we are in compliance with federal guidelines governing research, including research involving human participants. Concordia University's CURC serves the function of the federally mandated Institutional Review Board (IRB) in the case of human participants research.

Concordia University faculty, staff, or students planning a research project must obtain approval from the CURC. Researchers who are not members of the Concordia University community but who wish to conduct research involving members of the Concordia University community as human participants must also gain such approval. For additional information, contact Dr. Charles Kunert, Dean of the Concordia University College of Theology, Arts, & Sciences, at 503-493-6538 or by e-mail (ckunert@cu-portland.edu).

II. Definitions

A. *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to general knowledge.

B. *Human subject* means a living individual about whom a researcher (whether faculty member or student) conducting research obtains:

1. Data through intervention or interaction with the individual, or
2. Identifiable private information.

"Intervention" includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

"Interaction" includes communication or interpersonal contact between researcher and subject.

"Private Information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the researcher or associated with the information) in order for obtaining the information to constitute research involving human participants.

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C. *CURC approval* means the determination of the CURC that the research has been reviewed and may be conducted at the University within the constraints set forth by the CURC and by other institutional requirements.

D. *Minimal Risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

III. Committee Membership

The CURC shall consist of five (5) members ratified by the Concordia University Faculty. Three (3) of the Committee members shall be full-time or part-time Concordia University faculty who are knowledgeable about and have experience in working with human participants. One member should have professional expertise in the social/behavioral sciences and one in the biological/health sciences, but the third faculty member should be a person whose primary discipline is in a non-scientific area. The three faculty representatives serve for a three-year term and each begins his or her term of service on a staggered basis. The faculty members will be nominated annually during the regular time for filling faculty committees at the end of the academic year by the members of the Academic Policies Committee.

One member of the CURC shall be designated annually by the Provost and shall be a person who is not affiliated with Concordia University and who is not part of the immediate family or a person affiliated with Concordia University.

The final member of the CURC will be a non-voting student observer appointed by the Associated Students of Concordia University President.

Every effort will be made to assure that the CURC membership represents a broad diversity of individuals.

The CURC may, at its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the CURC. These individuals may not vote on any research proposal.

IV. Meetings and Records

The CURC shall elect a Chairperson at the first meeting each academic year.

No action may be taken by the CURC at a meeting unless a quorum is present. A quorum shall be three (3) members provided at least one of the members constituting the quorum is the member appointed by the Administration who is not affiliated with the University. The CURC may approve research requests by a majority vote of the members at a meeting at which a quorum is present.

The CURC shall prepare and/or maintain:

A. Copies of all research proposals and accompanying materials for a period of no less than 3 years from the date of submission.

B. Minutes of CURC meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the Committee; the vote on those actions; the basis for disapproving

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research or requiring changes; and a summary of controverted material issues and their resolutions.

C. Records of continuing review activities.

D. Copies of all correspondence involving the CURC.

V. Authority

The CURC shall have the authority to approve, modify or disapprove all research requests subject to review by the President of Concordia University. The President shall not approve any research that has been disapproved by the CURC, but may return the request to the CURC for reconsideration.

The CURC may require that informed consent be obtained and that such consent be in accordance with paragraph IX.

The CURC shall have the authority to suspend or terminate approval of research that is not being conducted in accordance with the Committee's requirements or that has been associated with unexpected harm to participants. The University President also has the authority to suspend or terminate approval of research in his/her discretion.

VI. Criteria for Approval

A faculty member or student of Concordia University who intends to conduct research must have the approval of CURC or a Certification of Exemption prior to commencing the research.

While the CURC must review and approve research by both students and faculty, it is not intended as a substitute for courses in research design and ethics. Before a student submits a proposal to the CURC, the supervising faculty member of student conducting the research is required to communicate the principles of research design and ethics and for previewing the student's proposal for ethical acceptability. Faculty are particularly responsible for communicating to their students the safety standards particular to their fields of study, such as the use of specialized equipment and the protection of participants in risk categories (i.e., children, disabled persons, etc.). Students should consult with their faculty supervisor to make an initial determination of whether the proposed research is likely to be considered as Exempt, Expedited or Full Review Research. Any student planning to conduct research involving human participants that is independent of course work must also have the approval of a faculty sponsor in his or her field of study and the CURC.

In order to approve research covered by this policy, the CURC shall determine that all of the following requirements are satisfied:

1. Risks to participants are minimized by (i) using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk, and (ii) whenever appropriate, using procedures already being performed on the participants for diagnostic or treatment purposes.

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2. Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the CURC should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies participants would receive even if not participating in the research). The CURC should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
3. Selection of participants is equitable. In making this assessment the CURC should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by section IX.
5. Informed consent will be appropriately documented as designated in section X.
6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.
7. When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.
8. When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, the Committee shall ensure that additional safeguards have been included in the proposal to protect the rights and welfare of these participants.

VII. Procedure

Prior to commencing research, a student or faculty member must either (1) apply for review and approval of the research from the CURC (if the research qualifies as Expedited or Full Review research) or (2) submit a Certification of Exemption (Appendix III) to the CURC (if the research qualifies as exempt). In addition, all researchers who intend to use human participants in their research, must complete and submit the Investigator's Assurance Form (Appendix II) to the Chair of the CURC. The application for review or Certification for Exemption should be submitted as early as possible to allow the Committee sufficient opportunity to consider it. Faculty and students who are planning research must prepare a statement describing the proposed research and determine which of the three review processes is applicable (Exempt, Expedited, or Full Review as defined below). The relevant forms (found at the end of this document) and other required documents should then be submitted to the CURC.

TYPES OF HUMAN PARTICIPANTS REVIEW

There are three types of research review: Exempt, Expedited, and Full. The criteria for each review follows. Note that the titles of research review refer to the process involved in review, not the time required to perform the review.

EXEMPT REVIEW

If a researcher is able to check "no" to all items on the CURC Checklist (Appendix V) and meet at least one (1) of the five (5) criteria on the Certification of Exemption Form (Appendix I), the research is eligible for an exemption. The Checklist and the Certification of Exemption form signed by the appropriate faculty member for student research will be submitted to the Chairperson of CURC along with a brief description of the research. This signed document suffices to qualify the research as preliminarily exempt but should the Chairperson determine that there is a question about whether the research is Exempt, he/she will direct that the researcher seek Full or Expedited Review.

The following categories of research are exempt from research review:

1. Any form of research which does not utilize human participants such as historical and library research (also non-human chemistry and physics research).
2. Research involving the collection or study of existing data, documents, records, or pathological or diagnostic specimens, if these sources are publicly available.
3. Research involving the collection or study of existing data, documents, records, or pathological or diagnostic specimens, and the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants, such as in content or secondary data analyses.
4. Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement), survey or interview procedures, or observation of public behavior and the participants are elected or appointed public officials or candidates for public office, or the participants cannot be identified directly or through identifiers linked to the participants.
5. Taste and food quality evaluation and consumer acceptance studies where wholesome foods without additives are consumed, or in which 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.
6. Classroom projects and/or demonstrations that do not exceed the minimal risk threshold, collect only anonymous data, and use only participants who volunteer for the project and who are informed of the implications of participation.

EXPEDITED REVIEW

An application for Expedited Review may be approved when the research would only involve Minimal Risk. Minimal Risk applies to research which does not use deception, which does not study populations defined as "at risk" and which does not involve risks beyond those encountered in normal daily affairs. If any of the questions on the CURC Checklist (Appendix V) are answered affirmatively, the Expedited Review procedure may not be used. An original copy of the form for Expedited Review (Appendix IV), along with the CURC Checklist must be submitted to the Committee Chair, but the proposal may be reviewed and approved by a member of the CURC designated by the Chairperson without a meeting. The proposal is to be submitted in both hard copy and electronically to the Chairperson. Expedited Reviews will be conducted

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only by Committee members who have a professional background in the area of research covered by the proposal. The research may proceed with the project when approval of the Expedited Review is obtained. The designated reviewer shall not have authority to disapprove the research. If the reviewer cannot approve the application for Expedited Review, it shall be placed on the agenda for the next meeting of the full Committee. All Expedited Review approvals will be reviewed by the CURC at its meeting following the approval. If two (2) members of the Committee disagree with the approval of the Expedited Review, the research will be suspended and the research will be subject to Full Review procedures.

The following categories of research involving human participants and no more than minimal risk qualify for Expedited Review:

1. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

2. Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

3. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory

acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

4. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human participants. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
5. Collection of data from voice, video, digital, or image recordings made for research purposes.
6. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
7. Continuing review of research previously approved by the convened CURC as follows:
 - (a) where (i) the research is permanently closed to the enrollment of new participants; (ii) all participants have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of participants; or (b) where no participants have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.

FULL REVIEW

Any type of research that does not meet the criteria for either exempt or expedited review must be processed through full review procedures. If any of the questions on the CURC Checklist (Appendix V) are answered affirmatively, a Full Review is required. Proposals requiring a Full Review will be submitted in an original hard copy, using the form for Full Review (Appendix IV), along with the CURC Checklist, to the Committee Chair. The researcher shall also submit an electronic copy of the proposal to the Chair. The Committee will meet at least once per semester to review these proposals and will announce its meeting date to enable researchers an opportunity to submit their proposals in time for the meeting. Approval of Full Review proposals requires an affirmative vote from a majority of members at a meeting at which a quorum is present. If proposals for Full Review are submitted after a scheduled meeting, each Committee member may review the proposal individually, and if all members unanimously approve, the research may begin. If any Committee member disapproves of the proposal or demands a meeting, a meeting must be held to review the proposal.

VIII. Disapproval

If the CURC decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the researcher the opportunity to respond in writing or in person.

IX. Informed Consent

Except as provided elsewhere in this policy, no researcher may involve a human being as a subject in research covered by this policy unless the researcher has obtained the informed consent of the subject or the subject's legally authorized representative. A researcher 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 researcher, the faculty member, the institution or its agents from liability for negligence.

A. Basic elements of informed consent.

Except as provided in paragraph C of this section in seeking informed consent the following information shall be provided to each subject:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the subject;
3. A description of any benefits to the subject or to others which may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
6. 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;
7. 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 to the subject; and
8. 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:

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When appropriate, one or more of the following elements of information shall also be provided to each subject:

1. 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;
2. Anticipated circumstances under which the subject's participation may be terminated by the researcher without regard to the subject's consent;
3. Any additional costs to the subject that may result from participation in the research;
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. A statement that significant new findings developed during the course of the research which may related to the subject's willingness to continue participation will be provided to the subject; and
6. The approximate number of participants involved in the study.

C. The CURC 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 CURC finds and documents that:

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

X. Documentation of Informed Consent

A. Except as provided in paragraph B of this section, informed consent must be documented by the use of the written consent form (Appendix III) signed by the subject or the subject's legally authorized representative. A copy must be given to the person signing the form.

B. The CURC may waive the requirement for the researcher to obtain a signed consent form for some or all participants if it finds either:

1. 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

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

In cases in which the documentation requirement is waived, the CURC may require the researcher to provide participants with a written statement regarding the research.

{See also Appendix VI: Notes on Informed Consent for a fuller explanation of the process of obtaining informed consent.}

XI. Research Participation Requirements

If participation in research as participants is required for students enrolled in a course, the instructor must:

1. include this requirement in the course outline
2. provide students with a reasonable number of research projects to choose from
3. provide students who do not want to participate as participants with an appropriate alternative requirement that is no more time consuming than research participation.

XII. Class Demonstrations and Laboratory Activities

Brief demonstrations of research techniques or laboratory activities with minimal risk in relevant courses do not require review by the CURC. Faculty should follow the standards of professional ethics in carrying out such demonstrations.

XIII. Ongoing Research

The committee shall continue to review ongoing research at intervals appropriate to the degree of risk, but not less than once per year. Investigators conducting ongoing research shall provide the committee with a status report at the designated interval. Any aspects of the research involving changes in the degree of anticipated risk, outcome, or similar effects on human participants, are to be reported.

XIV. Research Quality

Faculty who supervise student research are responsible for evaluating the quality of student's finished work. A faculty member's approval of a student's proposal to the CURC is not necessarily an endorsement of the scientific quality of the proposed work, but only its acceptability with regard to planned treatment of human participants. Similarly, faculty who conduct research ultimately answer to their peers when submitting research for publication. The CURC will only make judgments about the scientific merit of a proposal when research involving risk is proposed, in which case, the Committee must consider whether the potential benefits of the research to the participants and to society, outweigh the risks.

APPENDIX I
RESEARCH INVESTIGATION
Certification Of Exemption

Student Researcher (SR) and Faculty Sponsor (FS): (Print names)

(SR): _____ (FS): _____

Department: _____ Project Title: _____

CERTIFICATION OF EXEMPTION FROM APPROVAL BY CONCORDIA UNIVERSITY RESEARCH COMMITTEE (Check and initial all applicable conditions, sign below and provide brief substantiating description of research design on reverse side.)

I certify that the project identified above is exempt from review and approval because it meets the criteria(ion) specified below:*

- ____ SR & FS initials
- ____ (1) The research will be conducted in established or commonly established settings, involving normal education practices. For example:
- ____ (i) Research on regular and special educational instructional strategies;
 - ____ (ii) Research on effectiveness of instructional techniques, curricula or classroom management techniques.
- ____ (2) The research involves use of education tests (__cognitive, __diagnostic, __ aptitude, __ achievement), and the subject cannot be identified directly or through identifiers with the information.
- ____ (3) The research involves survey or interview procedures, in which:
- ____ (i) Participants cannot be identified directly or through identifiers with the information;
 - ____ (ii) Subject's responses, if known, will not place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability;
 - ____ (iii) The research does not deal with sensitive aspects of subject's own behavior (illegal conduct, drug use, sexual behavior or alcohol use);
 - ____ (iv) The research involves survey or interview procedures with elected or appointed public officials, or candidates for public office.
- ____ (4) The research involves the observation of public behavior, in which:
- ____ (i) The participants cannot be identified directly or through identifiers;
 - ____ (ii) The observations recorded about an individual could not put the subject at risk of criminal or civil liability or be damaging to the participants financial standing or employability;
 - ____ (iii) The research does not deal with sensitive aspects of the subject's behavior (illegal conduct, drug use, sexual behavior or use of alcohol).
- ____ (5) The research involves collection or study of existing data, documents, records, pathological specimens or diagnostic specimens, or which:
- ____ (i) The sources are publicly available; or
 - ____ (ii) The information is recorded such that the subject cannot be identified directly or indirectly through identifiers.

I further certify that the project will not be changed to increase the risk of exceed the exempt condition(s) without filing an additional certification or application for approval by the Concordia University Review Board.

Signature: Researcher Date

Signature: Faculty Sponsor (if researcher is a student) Date

Signature: Concordia University Research Committee Representative Date

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*The original Certification of Exemption is to be sent to the Chair of the CURC with a brief description of the proposed research. If the Researcher has any questions about the Exemption status of this project, he or she is encouraged to seek confirmation and optional approval of the CURC.

Brief Description of Proposed Research:

APPENDIX II
INVESTIGATION INVOLVING HUMAN PARTICIPANTS
Investigator's Assurance Form

Principal Investigator: _____ E-Mail: _____
Co-Principal Investigator: _____ E-Mail: _____
Department: _____ Date of Application: _____
Mailing Address: _____ Campus phone #: _____
Cell or Work #: _____
Title of Proposed Study: _____
Proposed Duration of Project (months/years): _____ Anticipated Start Date: _____

Please note that data collection cannot begin until approval is granted by the CURC of Concordia University!

INVESTIGATOR'S ASSURANCE

- A.** I will promptly report changes in the proposed study and any unanticipated problems involving risk to participants, including adverse reactions, to the Concordia University Research Committee.
- B.** I assure that documentary evidence of informed consent will be retained for at least three years after the proposed study has been completed or discontinued.
- C.** Since the CURC is obligated to review this activity at least on an annual basis, I will furnish it with a progress report no later than six weeks prior to the expiration of my project's approval.
- D.** I, the undersigned, will be responsible for the ethical standards of this project, and for protecting the rights and welfare of the participants.

Signature of Principal Investigator Date

I have read and approved this proposal:

Department Head (PRINT) Signature Date

Note: If this is part of a thesis, the proposal must be approved PRIOR to CURC Review.

Thesis/Project Advisor (PRINT) Signature Date

Advisor's E-Mail Address: _____

Please complete and return this form, along with your CURC application, and 5 copies to the CURC:

Concordia University Research Committee
Luther Hall Room 119
Concordia University
2811 NE Holman
Portland, OR 97211
503-280-8680

APPENDIX III
INVESTIGATION INVOLVING HUMAN PARTICIPANTS
(Sample) Informed Consent

This template is provided for the researcher's guidance in developing an informed consent form. Modification can and should be made as needed in light of your specific project.

Title of Research Project:

Name of Research Project

Description of the Research Project:

This research project entails...(describe).... and its purpose is.....(describe).....
[use language a layperson can understand]

Description of Participant's Role:

What will the participant be asked to perform?
How much time will be required of the participant?
Are there any perceived or anticipated risks to the participant? If so, how will participants be assisted or referred for assistance?
Are there any benefits to the participant? Are there potential benefits to society?

Researcher(s)

This research project is being conducted by:
Name of researcher(s)
Address of researcher(s)
Telephone number(s)
e-mail address(es)
Name of Faculty research supervisor (if applicable)

Confidentiality:

With the use of a coding system, all information will be published in its aggregate form and there will be no publication of information that will link your participation with the data.
Anonymity and confidentiality of each participant will be maintained.
[If results are not kept confidential, who will have access to it?]

Consent to Participate:

I, (printed name of participant), do hereby, freely and without compensation, agree to participate in this study. Furthermore, I have been informed of the nature of the study and what is expected of me. In addition, I acknowledge that I am free of (contraindications for participation), and am over the age of 18 years old. The researcher, [name], has explained the research and answered all questions to my satisfaction. I understand that I can withdraw from this research project at anytime without penalty or prejudice. In the event of any unforeseen reactions, I will notify the researcher. Should I have any questions at a later time, I can contact the faculty research project supervisor, [name(s)], at telephone: . (Concordia University Phone number)

Date: _____

Signature: _____

APPENDIX IV

APPLICATION FORM

INVESTIGATION INVOLVING HUMAN PARTICIPANTS

THIS FORM IS FOR CLASSIFYING PROPOSALS FOR EXPEDITED REVIEW OR FULL REVIEW

Researcher(s) _____ Department _____

Faculty Sponsor (if researcher is a student) _____ Campus Phone # _____

Project Title _____

REQUEST FOR (circle one) EXPEDITED REVIEW FULL REVIEW

AND APPROVAL BY CONCORDIA UNIVERSITY RESEARCH COMMITTEE. For expedited review, initial all applicable conditions, sign below and provide a copy of a brief description of proposed research. For full review, attach a copy of a concise description of proposed research. If possible, limit descriptions to no more than two single spaced pages. If required by the nature of the research project, attach a copy of the informed consent document. The description and informed consent document must also be submitted electronically (as an email attachment) to the Chairperson of the Human Participants Research Review Committee.

Subject at Risk means any individual who may be exposed to the possibility of injury, as a consequence of participation as a subject in any research, development or related activity which departs from the application of those established and accepted methods necessary to meet his needs, or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of science.

Minimal Risk is defined when the risks of harm anticipated in the proposed research are not greater considering the probability and magnitude than those encountered in daily life or during performance of routine physical or psychological examinations or tests.

The project identified above, which involves the use of human participants, may be approved through an "Expedited Review" procedure because the research activities involve no more than minimal risk, as defined above, and the involvement of human participants will be one or more of the following:

_____	1.	Research on drugs and devices for which an investigational exemption is not required.
_____	2.	Moderate exercise by healthy volunteers.
_____	3.	Voice recordings made for research purposes such as investigation of speech defects.
_____	4.	Recording of data from participants 18 years or older, using noninvasive procedures routinely employed in clinical practice. Exemption does not include exposure to electromagnetic radiation outside the visible range
_____	5.	Study of existing data, documents, records, pathological specimens or diagnostic specimens.
_____	6.	Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subject's behavior and the research will not involve stress to participants.

APPENDIX V

CHECKLIST TO DETERMINE LEVEL OF REVIEW

The purpose of this checklist is to facilitate the review process and to identify the ethical issues with which the Committee is concerned. It is meant to be an aid for the researcher and for the Committee. If you check "Yes" to any of the following questions, these are areas which require some justification and attention on your part in writing up your

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proposal for CU Research Review. If you check "No" to each of these items, you may request an expedited review. If you check "Yes" to any item, a full review is required. Submit this form with a single copy of your research proposal directly to the CURC Chair. A copy of the research proposal must also be submitted electronically (as an e-mail attachment).

Please check YES or NO to each of the following questions:

- | | YES | NO | |
|-----|-------|-------|--|
| 1. | _____ | _____ | Will the populations studied be defined as consisting of any of the following: Minors (under 18), pregnant women, prisoners, mentally retarded, mentally disabled: (If YES, underline all that apply.) |
| 2. | _____ | _____ | Will it be possible to associate specific information in your records with specific participants on the basis of name, position, or other identifying information contained in your records, by individuals other than the researcher? |
| 3. | _____ | _____ | Will persons participating or queried in this investigation be subjected to physical discomfort, pain, aversive stimuli, or the threat of any of these? (If YES, underline all that apply.) |
| 4. | _____ | _____ | Will the investigation use procedures designed to induce participants to act contrary to their wishes? |
| 5. | _____ | _____ | Does the investigation use procedures designed to induce embarrassment, humiliation, lowered self-esteem, guilt, conflict, anger, discouragement, or other emotional reactions? (If YES, underline all that apply.) |
| 6. | _____ | _____ | Will participants be induced to disclose information of an intimate or otherwise sensitive nature? |
| 7. | _____ | _____ | Will participants engage in strenuous or unaccustomed physical activity? |
| 8. | _____ | _____ | Will participants be deceived (actively misled) in any manner? |
| 9. | _____ | _____ | Will information be withheld from participants that they might reasonably expect to receive? |
| 10. | _____ | _____ | Will participants be exposed to any physical or psychological risks not indicated above? (If YES, explain.) |

This is to certify that the project identified above will be carried out as approved by the CURC, and will neither be modified nor carried out beyond the period approved below without express review and approval by the CURC.

Signature: Principal Researcher

Date

Signature: Faculty Supervisor

Date

APPENDIX VI

Notes on Obtaining Informed Consent

The process of obtaining informed consent must comply with the requirements of 45 CFR 46.116. The documentation of informed consent must comply with 45 CFR 46.117. The following comments may help in the development of an approach and proposed language by investigators for obtaining consent and its approval by the CURC:

- Informed consent is a process, not just a form. Information must be presented to enable persons to voluntarily decide whether or not to participate as a research subject. It is a fundamental mechanism to ensure respect for persons through provision of thoughtful consent for a voluntary act. The procedures used in obtaining informed consent should be designed to educate the subject population in terms that they can understand. Therefore, informed consent language and its documentation (especially explanation of the study's purpose, duration, experimental procedures, alternatives, risks, and benefits) must be written in "lay language", (i.e. understandable to the people being asked to participate). The written presentation of information is used to document the basis for consent and for the participants' future reference. The consent document should be revised when deficiencies are noted or when additional information will improve the consent process.
- Use of the first person (e.g., "I understand that ...") can be interpreted as suggestive, may be relied upon as a substitute for sufficient factual information, and can constitute coercive influence over a subject. Use of scientific jargon and legalese is not appropriate. Think of the document primarily as a teaching tool not as a legal instrument.
- Describe the overall experience that will be encountered. Explain the research activity, how it is experimental (e.g., a new drug, extra tests, separate research records, or nonstandard means of management, such as flipping a coin for random assignment or other design issues). Inform the human participants of the reasonably foreseeable harms, discomforts, inconvenience and risks that are associated with the research activity. If additional risks are identified during the course of the research, the consent process and documentation will require revisions to inform participants as they are recontacted or newly contacted.
- Describe the benefits that participants may reasonably expect to encounter. There may be none other than a sense of helping the public at large. If payment is given to defray the incurred expense for participation, it must not be coercive in amount or method of distribution.
- Describe any alternatives to participating in the research project. For example, in drug studies the medication(s) may be available through their family doctor or clinic without the need to volunteer for the research activity.
- The regulations insist that the participants be told the extent to which their personally identifiable private information will be held in confidence. For example, some studies require disclosure of information to other parties. Some studies inherently are in need of a Certificate of Confidentiality which protects the investigator from involuntary release (e.g., subpoena) of the names or other identifying characteristics of research participants. The CURC will determine the level of adequate requirements for confidentiality in light of its mandate to ensure minimization of risk and determination that the residual risks warrant involvement of participants.
- If research-related injury (i.e. physical, psychological, social, financial, or otherwise) is possible in research that is more than minimal risk (see 45 CFR 46.102[g]), an explanation must be given of whatever voluntary compensation and treatment will be provided. Note that the regulations do not limit injury to "physical injury". This is a common misinterpretation.

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- The regulations prohibit waiving or appearing to waive any legal rights of participants. Therefore, for example, consent language must be carefully selected that deals with what the institution is voluntarily willing to do under circumstances, such as providing for compensation beyond the provision of immediate or therapeutic intervention in response to a research-related injury. In short, participants should not be given the impression that they have agreed to and are without recourse to seek satisfaction beyond the institution's voluntarily chosen limits.
- The regulations provide for the identification of contact persons who would be knowledgeable to answer questions of participants about the research, rights as a research subject, and research-related injuries. These three areas must be explicitly stated and addressed in the consent process and documentation. Furthermore, a single person is not likely to be appropriate to answer questions in all areas. This is because of potential conflicts of interest or the appearance of such. Questions about the research are frequently best answered by the investigator(s). However, questions about the rights of research participants or research-related injuries (where applicable) may best be referred to those not on the research team. These questions could be addressed to the CURC, an ombudsman, an ethics committee, or other informed administrative body. Therefore, each consent document can be expected to have at least two names with local telephone numbers for contacts to answer questions in these specified areas.
- The statement regarding voluntary participation and the right to withdraw at any time can be taken almost verbatim from the regulations ([45 CFR 46.116\[a\]\[8\]](#)). It is important not to overlook the need to point out that no penalty or loss of benefits will occur as a result of both not participating or withdrawing at any time. It is equally important to alert potential participants to any foreseeable consequences to them should they unilaterally withdraw while dependent on some intervention to maintain normal function.
- Don't forget to ensure provision for appropriate **additional requirements** which concern consent. Some of these requirements can be found in sections [46.116\(b\)](#), [46.205\(a\)\(2\)](#), [46.207\(b\)](#), [46.208\(b\)](#), [46.209\(d\)](#), [46.305\(a\)\(5-6\)](#), [46.408\(c\)](#), and [46.409\(b\)](#). The CURC may impose additional requirements that are not specifically listed in the regulations to ensure that adequate information is presented in accordance with institutional policy and local law.

[§46.116](#) - Informed Consent Checklist - Basic and Additional Elements

	A statement that the study involves research
	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

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	so, what they consist of, or where further information may be obtained
() Research Qs	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 to the subject
() Rights Qs	
() Injury Qs	
	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
Additional elements, as appropriate	
	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 participants involved in the study

§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 CURC, and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.	
WRITTEN	The consent form may be either of the following: 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.
DONE ORALLY	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 CURC 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 req't for signed	c. The CURC may waive the requirement for the investigator to obtain a signed consent form for some or all participants, if it finds either: 1. 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

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form	<p>will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or</p> <p>2. That the research presents no more than minimal risk of harm to participants, and involves no procedures, for which written consent is normally required outside of the research context.</p> <p>In cases in which the documentation requirement is waived, the CURC may require the investigator to provide participants with a written statement regarding the research.</p>
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CURC Latitude to Approve a Consent Procedure that Alters or Waives some or all of the Elements of Consent

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

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

Assent/ Waiver	The CURC shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the CURC the children are capable of providing assent. If the CURC 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 CURC determines that the participants are capable of assenting, the CURC may still waive the assent requirement under circumstances, in which consent may be waived in accord with §46.116 of Subpart A.
Parents	The CURC 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 CURC 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 participants (for

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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 participants in the research is substituted, and provided further that the waiver is not inconsistent with Federal, state or local law.

Note: The above CURC Policy and Procedure Manual was adopted by the CTAS Faculty on August 16, 2006 and approved by the CU Faculty as a part of the SCM governing Senior Thesis in CTAS on November 6, 2006.