Institutional Review Board (IRB) Handbook

Guidelines to Human Participants Research

Irvine, CA
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I. INTRODUCTION

In compliance with federal regulations, the Institutional Review Board (IRB) of Concordia University Irvine oversees its obligations with respect to human participants. When people are involved as participants in research or related activities conducted under university auspices, both the institution and individual researchers are responsible for assuring the rights and welfare of participants are adequately protected. Such activities include any mode of human participant research conducted either on or off campus. These principles have been accepted and established by the university in accordance with federal regulations (Code of Federal Regulations, Title 45, Part 46) and professional ethics.

All research projects conducted by faculty, staff, and students involving human participants are considered Exempt, Expedited, or Full Board research, and all must be registered with and reviewed by the IRB *before initiation*. This handbook is designed to educate and guide CUI employees and students as they engage in systematic inquiry through research projects involving human participants.

Institutional Review Board irb@cui.edu

II. DOES YOUR PROJECT REQUIRE IRB REVIEW?

Activities involving interaction with and the collection of information about living individuals are integral components of the educational practices and administrative processes of the university. Not all of these activities meet the regulatory definitions of research and human participants. As such, not all of these activities require IRB review.

The initial determination as to whether a project is considered "human participants" and "research" is the responsibility of the researcher and CUI University Supervisor. This determination should be made in accordance with the guidance provided in this handbook.

Typically only projects meeting BOTH definitions of "research" and "human participants" as provided below come under the purview of the IRB (i.e. Exempt Review, Expedited Review or Full Board Review categories).

In making a determination about whether an activity constitutes research involving human participants, ask yourself the following questions:

Will the data collected be publicly presented or published?

AND

2. Do my research methods involve:

a. Direct and/or indirect interaction with participants via interviews, assessments, surveys, or observations;

OR

b. Access to identifiable private information about individuals (e.g., information that is not in the public domain)?

If the answer to both of these questions is “YES,” a project is considered research with human participants and is subject to federal regulations requiring IRB review.

There are three types of IRB review: Exempt, Expedited, and Full Board Review. The type of review required depends on the nature of the research project. See Step 1: Determine the Category of IRB Review for Your Research for more information.

Activities That May Not Require Review

The following activities do not typically require IRB review because they do not satisfy the definition of "research" – in other words, the researcher answers "no" to the first question above. Most often the following activities are thought of as learning experiences only, since the information gathered will not be used as actual "data" for publication or presentation. However, information obtained via any of these activities would be considered research if it were incorporated into a publication or presentation that would be used to contribute to generalizable knowledge.

1. ***Classroom Projects***

   In many academic programs, knowledge of research methods/methodology is vital to a well-rounded education. Instructors may encourage their students to design small projects simply to teach them how to properly conduct research. In most cases, the data will not be used to contribute to generalizable knowledge and may not require IRB review. See document: Guidelines for Classroom Projects Related to Human Participants for additional information).

2. ***Program Evaluations***

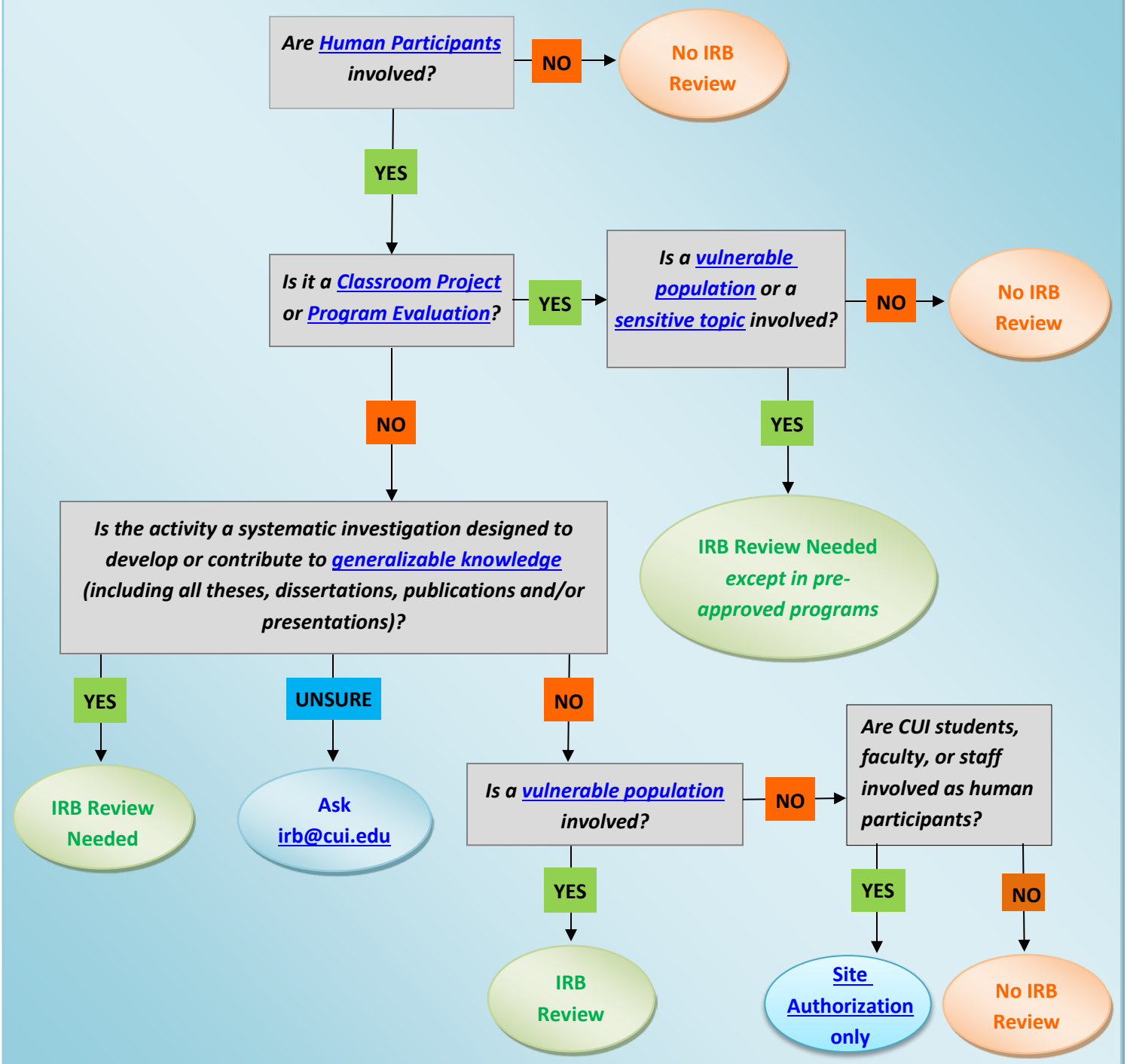
   Researchers may gather data from human participants through direct or indirect interaction for purposes of program evaluation. The information they collect will not be used to contribute to generalizable knowledge, rather the results will be used to improve or develop an internal program.

   Researchers are strongly cautioned to consider whether or not the information collected for a classroom project or program evaluation will be used to contribute to generalizable knowledge; the researcher must decide in advance, as it is not possible to retrospectively review and approve a project once data collection has begun. If a researcher is unsure about how the data will be used, it is better to err on the side of caution and submit an application for review.

   Please note that even when projects do not qualify as "research", as defined by federal regulations, they must be conducted with the utmost regard for university policies, ethical standards, and the welfare of human participants.

EXCEPTIONS: Any project or program evaluation gathering data from a vulnerable population and/or involving a sensitive topic requires IRB review even if it does not qualify as "research" unless a program has been pre-approved for this type of project.

Decision Tree: Does my project require IRB review?



III. IRB RESPONSIBILITIES

The IRB was formed to encourage and assure research with human participants will be done by recognized standards of scientific competence, ethical principles, and legal guidelines.

The IRB will review all research activities conducted by university faculty, staff, and students, whether on or off campus, and for any individual or group desiring to conduct any research or study on human participants on campus or at other facilities under the responsibility of the university.

IRB Staff may request consultation from the Chair when assigning reviewers. If it is determined that appropriate expertise is not available within the IRB, an internal or external consultant will be sought.

The IRB will conduct an annual review of ongoing research projects. If deemed necessary by the IRB, more frequent reviews will be conducted.

To enhance the visibility of the IRB, the university's Office of Institutional Research and Assessment (OIRA), in consultation with the IRB Chair, shall develop and maintain an IRB web page to publicize procedures, forms, IRB contact information, and human research protection training information.

The IRB should:

- Consist of at least five members with varying backgrounds to promote complete and adequate review of the research activities commonly conducted by the institution;
- Make every nondiscriminatory effort to ensure that the membership is not composed of entirely men or entirely women;
- Include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas;
- Include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution; and
- Not allow any member to participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

Please see the regulations at 45 CFR 46.107 for complete information on all of the required qualifications to properly compose an IRB.

For a copy of CUI's Institutional Review Board Policies contact irb@cui.edu.

Inquiries should be sent to irb@cui.edu to guarantee confidentiality and anonymity in reviewing the applications.

A. IRB Meetings

The IRB meets quarterly during the academic year or more often as needed; however, applications for IRB reviews will be evaluated throughout the 12-month year. The IRB will keep to the following time frames for review of IRB applications: for ***completed*** IRB applications, during the traditional academic school year excluding holidays, Exempt Reviews and Expedited Reviews up to 30 days; or up to 90 days for Full Board Review. For applications submitted in June and July, review time may be longer in certain programs.

B. Basic Research Principles

- Human participation in any research project or other regulated activity (e.g., experimental demonstration, training program, interview, or questionnaire) must be voluntary.
- Any risks to participants must be outweighed by the sum of the benefits to participants plus the knowledge gained by the study.
- Informed consent to participate in a project must be obtained from potential participants, preferably in writing, after presentation of information about the purposes, procedures, risks, and benefits of participation.
- The privacy of participants must be safeguarded by protecting confidentiality of information from or about participants and/or by maintaining their anonymity.

C. Responsibilities of Researchers

- Obtaining IRB review and approval of any research involving human participants covered under the regulations;
- Obtaining the legally effective informed consent of all participants to be included in the research study, unless any or all requirements for obtaining consent have been waived by the IRB during its review;
- Performance of the protocol as approved by the IRB; and
- Adherence to ethical principles in the conduct of the research.

IV. RESEARCHERS UNAFFILIATED WITH CUI

Unaffiliated researchers must obtain IRB approval from their own institution and submit proof of approval with their CUI IRB application. Additionally, unaffiliated researchers must obtain a CUI University Sponsor. It is the researcher's own responsibility to obtain a sponsor.

V. RULES FOR USE OF CUI STUDENTS, FACULTY, & STAFF AS HUMAN PARTICIPANTS

The Institutional Review Board oversees protection of human participants in research. It is periodically brought to the attention of the IRB that some students and/or staff/faculty who are approached by a researcher and asked to volunteer to be human participants in the researcher's project, feel some coercion to agree to participate, especially if the requesting researcher is their

supervisor, instructor, and/or someone who may eventually be in a position to influence their future.

The following was therefore adopted:

- Researchers are not permitted to actively recruit participants within their own departments
- Instructors cannot recruit or survey their own class
- Instructors cannot be present during the collection of data from their class

This does not preclude members of the researcher's department or students from freely volunteering to participate:

- Anyone is free to respond to recruitment advertisements (e.g., posters* or ads in publications)
- Surveys can be administered to students in a class by a 3rd party approved by the IRB in place of the instructor where survey participation is voluntary and responses are anonymous.

This guideline was adopted to protect CUI students and personnel against even the remote possibility of implicit coercion, while not impeding a researcher's ability to recruit adequate numbers of human participants, nor preventing those who wish to volunteer to do so.

If CUI students and/or staff/faculty are used as human participants, a Site Authorization Form must be submitted for approval along with the IRB application.

**All posters on CUI campus must be approved by ASCUI.comm@cui.edu, in addition to IRB approval.*

Rules for Use of CUI Student-Athletes as Human Participants:
In addition to the standard signatures required on the Site Authorization Form, the signatures of the Faculty Athletic Representative (FAR) and the coach(es) are required. Due to these additional authorizations, researchers should expect a longer IRB Review period. Coaches may not be present during recruitment or during collection of data for student-athletes.

IV. RULES FOR USE OF NON-CUI HUMAN PARTICIPANTS

Researchers must obtain permission from the outside institutions or agencies that either serve as a source of participants, a source of records and information, or on whose facilities the project will be conducted. Submit a completed Site Authorization Form for each location with the IRB Application. The title and type-written name of the individual with the authority to grant such permission, and the authority's signature, must be on the Site Authorization Form(s). Additionally, each location must be listed on the IRB Application Form.

VI. APPLICATION PROCESS

An Overview

Step 1:
Determine the Category of IRB Review for Your Research

Step 2:
Obtain a Training Certificate in Human Participants Research Protection

Step 3:
Select and Complete the Appropriate Application Form

Step 4:
Prepare Informed Consent Materials and Instruments

Step 5:
Check and Submit the Application and Supporting Materials

Step 6:
Receive Notification of IRB Decision

Step 7:
Appeal of IRB Decisions (If Needed)

Step 8:
Continuing Review, Modifications, Adverse Events, and Suspension

Step 9:
Completion of Study

A. Step 1: Determine the Category of IRB Review for Your Research

1. *EXEMPT REVIEW*

Certain categories of research involving human participants have been declared Exempt by federal regulations. The researcher should check the current list of "Possible Exempt Review Categories" below to determine if the project may be considered for Exempt Review by the IRB.

The researcher should submit the Exempt Review Application (and any additional program requirements if applicable), and indicate the basis for requesting Exempt Review.

Important Note:

Exempt does NOT mean Exempt from filing an application for review by the Institutional Review Board. Exempt means Exempt from documenting informed consent and from continuing review.

Possible Exempt Review Categories of Research on Human Participants

Unless otherwise required by department or agency heads, research activities in which the only involvement of human participants will be in ONE or MORE of the following categories are in the Exempt Review category.

a. 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.

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

c. Research involving survey or interview procedures, except where all of the following conditions exist: (i) Responses are recorded in such a manner that the human participants can be identified directly or through identifiers linked to the participants, (ii) the participant's responses, if they became known outside the research, could reasonably place the participants at risk of criminal or civil liability or be damaging to the participant's financial standing or employability, and (iii) the research deals with sensitive topics regarding the participant's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol. If the respondents are elected or

appointed public officials or candidates for public office, all research involving survey or interview procedures is Exempt Review without exception

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

e. Research and demonstration projects that are conducted by or subject to the approval of department or agency heads, and that 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.

f. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level 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.

56 FR 28012, 28022, June 18, 1991.

2. *EXPEDITED REVIEW*

Certain research activities involving no more than minimal risk and in which human participants are involved in special ways are approved by federal guidelines (46 FR 8392) for "Expedited Review."

The IRB will use an Expedited Review process for research that involves no more than minimal risk, and the researcher should check the current list of "Possible Areas for Expedited Review" below to determine if the project may be considered for Expedited Review by the IRB. The IRB Chair will determine whether a new research project is eligible for Expedited Review. The Chair will then seek one or more IRB members to conduct the review. If the reviewer(s) find that the research project cannot be Expedited, the research project must go to the Full Board for a vote. If approved, the research project is kept by the IRB office for future records, and requirements for annual review and informed consent apply.

The researcher must submit the Expedited Review Checklist and the Expedited/Full Board Application and Protocol Narrative (and any additional required documents), and indicate the basis for requesting Expedited Review.

Possible Areas for Expedited Review

Federal guidelines have suggested some areas where Expedited Review might be appropriate. Among these areas in medical and biological research are:

a. 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 FDA 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: (i) 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 participant or an invasion of the participant's privacy; (ii) weighing or testing sensory acuity; (iii) magnetic resonance imaging; (iv) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography; (v) moderate exercise, muscular strength testing, and flexibility testing where appropriate given the age, weight, and health of the individual.*

b. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research 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.*

c. Collection of data from voice, video, digital, or image recordings made for research purposes.

d. 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. *NOTE: Some research in this category may be Exempt from the HHS regulations for the protection of human* participants, *45 CFR46.101(b)(2) and (b)(3). This listing refers only to research that is not Exempt.*

e. Continuing review of research previously approved by the convened IRB as follows: 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 where no participants have been enrolled and no additional risks have been identified; or where the remaining research activities are limited to data analysis.

f. Continuing review of research, not conducted under an investigational new drug application or investigational device. Exemption where categories (b) through (e) do not apply but the IRB has determined and documented at a convened meeting that the

research involves no greater than minimal risk and no additional risks have been identified.

63 FR 60364-60367

3. *FULL BOARD REVIEW*

Full Board review is for proposed research that involves activities or procedures that put any human participant at physical, psychological, or social risk. Full Board review will require that a quorum of members be present at a regular meeting of the Institutional Review Board. A majority of those present and voting will determine the action on a specific study.

Categories for Full Board Review

Research studies involving more than minimal risk to human participants are required by federal regulations to be reviewed by the IRB Full Board in the following situations:

a. The research study involves vulnerable populations, sensitive topics, or a complex research design that would benefit from a review by the breadth of expertise represented at the Full Board.

b. The study has obtained an NIH Certificate of Confidentiality (CoC federal funded projects) that protects subject data from compelled disclosure. The CoC does not, however, protect sensitive data from accidental or malicious disclosure which may pose more than minimal risk to participants.

c. The study is referred to the Full Board by an expediting reviewer. *For example, a reviewer may seek guidance from the Full Board in determining whether a study meets the regulatory definition of minimal risk or when the scientific question posed by the researcher exceeds the expertise of the identified expediting reviewer pool.*

d. Studies which have been determined by IRB Chair to be MORE THAN MINIMAL RISK. Federal regulations define "minimal risk" as: the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

45 CFR 46. 102 (i)

Quorum Requirements

- Full Board review is conducted at convened meetings at which a quorum consisting of the majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. Approval of research is by a majority vote of the quorum.

- Should the quorum fail during a meeting (e.g., loss of a majority through recusal of

members with conflicting interests or early departures, or absence of a nonscientist member), discussion of protocols may continue, but the IRB may not take further actions or votes unless the quorum can be restored.

B. Step 2: Obtain a Training Certificate in Human Participants Research Protection

Researchers, co-researchers, and the faculty or staff person supervising or sponsoring a project related to any of the three IRB categories of human participant research, are required to submit evidence of training from the federal site detailed below.

NIH Online Certification Training

Protecting Human Research Participants (PHRP) at the National Institute of Health (NIH). Go to: http://phrp.nihtraining.com

IMAGE@PHRP

- This web-based training software consists of seven modules, four of which are followed by quizzes. The entire course will take approximately three hours to complete. After completing the course, obtain a Certificate of Completion and save as a PDF.
- Submit certificates for all researchers and supervisors with the IRB application. Certificates of completion are valid for three years but must be resubmitted with each new application.
- Equivalent CITI (Collaborative Institutional Training Initiative) human participant research training/certificate is also acceptable if date of completion is within three years.

C. Step 3: Select and Complete the Appropriate Application Form

Upon determining the appropriate category for your research, complete and submit the corresponding form(s):

For Exempt Review

- Exempt Review Checklist
- Exempt Review Application Form
- Other attachments (e.g., Site Authorization Form, Data Instruments/Surveys)

Whether or not written consent is used is left to the judgment of the researcher in Exempt research projects. However, oral consent must *always* be obtained from human participants in research (45CFR46).

Only the IRB can make the final determination that your application falls under the Exempt status category. Please ensure that your application is indeed Exempt by reviewing it with your university supervisor and going through the Exempt Review categories in this handbook.

Important Note:

In all research, informed consent is a federal requirement and informing research participants of the nature and purpose of your research is required.

Should your application in fact not fall under the Exempt category you will be notified through correspondence and your application will need to be re-submitted for Expedited or Full Board review.

For Expedited Review

- Expedited Review Checklist
- Expedited/Full Board Review Application and Protocol Narrative
- Other applicable attachments (e.g. Site Authorization Form, Data Instruments, Consent Forms, Translation of Consent Forms, etc.)

For Full Board Review

- Expedited/Full Board Review Application and Protocol Narrative
- Other applicable attachments (e.g., Site Authorization Form, Data Instruments, Consent Forms, Translation of Consent Forms, etc.)

Additional Information for Application

Online/Electronic Data Collection Tools

Any individual seeking IRB approval for a study involving the use of an electronic and/or online survey tool is asked to include information on the following on the application:

- How is informed consent information included in the body of the survey/instrument?
- If the respondent is under 18, how is parental permission going to be obtained?
- Does the survey tool allow for “no response” or “prefer not to respond” as an option?
- Does the respondent have the option to withdraw from the survey throughout the process? Even after responses have been entered (at the end of the survey)?

- What type of encryption is used during the transmission process? Typically, secure socket layer (SSL) suffices.
- How are IP addresses masked? (Does the tool allow you to turn off the collection of IP addresses and how is this done?)
- How is the data stored? Who "owns" the data?
- If stored on servers, how is the data removed from those servers and ultimately destroyed?
- Does the collection tool record a respondent timestamp?
- How often is data backed up on servers? Who owns those servers?
- What is the software company's privacy policy?
- What is the name of the software/package that you are using?

In addition, researchers are cautioned not to make any guarantees of confidentiality. The inclusion of the following in informed consent statements may be useful: *"Your confidentiality will be maintained to the degree permitted by the technology used. Specifically, no guarantees can be made regarding the interception of data sent via the Internet by third parties."*

Incentives/Rewards

Any individual seeking IRB approval for a study involving the use of incentives/rewards must include a description and explanation in the application, and is cautioned as follows:

- The CUI IRB does allow for the use of incentives/rewards so long as the incentives/rewards do not constitute undue inducement.
- A research participant's choice to participate in the research must be truly voluntary.
- No incentives/rewards that are thought to be "too good to refuse" will be approved.
- Consent documents must make clear how incentives/rewards are distributed, how this impacts the participants' anonymity and how these rewards are made to individuals if they discontinue participation in the study.

Recruitment Materials

Any individual seeking IRB approval for a study that uses recruitment materials should submit copies of these materials (email text, letters, flyers, posters, etc.) along with their IRB application. Recruitment materials may not be used until they are approved by the IRB.

Use of Electronic Signatures during the Consent Process

Any individual seeking IRB approval for a study involving the use of an electronic and/or online signatures as part of the informed consent process is asked to include information on the following in his/her application:

- Are electronic signatures legally valid within the research site jurisdiction?
- Are the consent documents provided to participants (and parents if the research

participants are minors) in a format they can retain (meaning save and/or print)?
- How is the electronic signature created?
- How do you know the signature is legitimate?
- Can the signed consent document be produced in hard copy for review by the participant (and parent if the participant is a minor) and researcher?

D. Step 4: Prepare Informed Consent Materials and Instruments

Expedited and Full Board Research Applications must attach an Informed Consent form unless a waiver has been approved by the IRB.

A researcher shall not involve a human participant in a research project without first having obtained informed consent of the participant or the participant's legally authorized representative, even though he or she has IRB approval for the study and an IRB approved consent form. **For Expedited and Full Board research projects this informed consent must be obtained and documented in writing** unless a waiver has been approved by the IRB. Both the participant and researcher should retain a copy of the signed consent form.

Legally effective informed consent includes at least the following:

- Identification of the researcher(s);
- An explanation of the nature and purpose of the research, the research method, the expected duration of the participant's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
- A description of any reasonably foreseeable risks or discomfort to the participant;
- A description of any benefits to the participant or to others which may reasonably be expected from the research;
- A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained;
- For research involving more than minimal risk, an explanation as to whether any compensation and/or an explanation as to whether any medical treatments is/are available if injury occurs and, if so, what they consist of or where further information may be obtained;
- The name of the person to contact for answers to pertinent questions about the project and the participant's rights, and who to contact in the event of a research-related injury;
- A statement that participation is voluntary, that refusal to participate or discontinuation of participation will involve no penalty or loss of benefits to which the participant is otherwise entitled.

A Sample Informed Consent Form, intended only as a guide, is provided. Researchers should present the required information for their particular study in the most appropriate format.

Minors and Parental Consent

Special protections are afforded minors (persons under age 18), including the need to obtain parental consent. See Sample Parental Consent Form. In the case of children over seven years

old, the child must also give consent. See Sample Child Assent Form. These documents must be attached with your application.

Consent forms should avoid the use of jargon, and need to be written in lay terms, plain language and be age appropriate.

If the research is not of a sensitive nature, and little or no risks are involved, waiver of parental consent may be requested by the researcher. However, waiver of parental consent can only be granted by the IRB. These same general protections also apply to the mentally incapacitated or other participants who have legal guardians.

Waiver of Written Consent

The IRB may waive the requirement for the researcher to obtain a signed consent form for some or all participants if either:

a. The only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. (Each participant will be asked whether he or she wants documentation linking the participant with the research and the participant's wishes will govern.); OR

b. 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.

Waiver of Informed Consent

Some research may be so indirect, innocuous, and innocent of imposition on the rights and welfare of human participants as to make informed consent a moot point. Therefore, any or all of the requirements for obtaining informed consent may be waived by the IRB during its review of the study. However, such action must be based upon clearly defensible grounds, and the principal researcher must include these justifications in the proposal submitted to the IRB. Specifically, waiver of informed consent may be granted if:

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

Additional Required Attachments may include:

- If a deception technique is to be used, be sure to also include a participant debriefing form.
- For non-English speaking human participants, translations of informed consent should be attached. Translations of consent forms in other languages must be certified via a Verification of Translation Accuracy Form.
- Site Authorization Form(s)

- Any other instruments, tools, protocols, recruitment materials and/or surveys used in the study need to be attached with the IRB application.

E. Step 5: Check and Submit the Application and Supporting Materials

1. ***Review your application. Your application will not be reviewed if it is not complete and thus, research will be delayed.***
   - Are all sections completed and have all of the questions been addressed in your own words?
   - Is the application signed by you, your university supervisor or sponsor, and any other researchers on the project?
   - Are all required materials for your particular project and your category of IRB reviews attached?
   - NOTE: Although the application forms indicate information needed, as each research situation is unique, you need to consider if there is information that YOU need to add to ensure that YOUR research best protects your human participants.

Important Note:

Missing information will delay IRB Review: make sure your application is complete, contains all necessary attachments, and has all required signatures.

2. ***Submission Instructions***

   Submit application with all authorized signatures (typed names in signature lines are not accepted) and ALL additional required materials in ONE e-mail to irb@cui.edu.

   For fastest processing, the subject line should follow this format:
   [Program Category] IRB Application – [Level of Review] – [Last Name of Researcher(s)]

   Examples:
   - Traditional Undergrad – IRB Application – Exempt Review - Velazquez
   - MAED IRB Application – Expedited Review – Tran/Rodriguez/Smith
   - Faculty/Staff – IRB Application – Full Board Review - McCallister

   You are responsible for ensuring that the application was received by the IRB. If you do not immediately receive an automated electronic acknowledgement, please resend your application.

F. Step 6: Receive Notification of IRB Decision

During the traditional academic year, for ***completed*** IRB applications, Exempt Reviews and Expedited Reviews take up to 30 days for a decision or up to 90 days for Full Board Review (excluding holidays). For applications submitted in June and July, review time may be longer in certain programs.

Notifications of IRB decisions are delivered electronically. Researchers should retain copies of these emails as records of the IRB's approval or other decision.

The following decisions are possible:

- Approved
- Needs revision and resubmission
- Not approved

Criteria for IRB Approved Research:

When reviewing research activities involving human participants, the IRB seeks to determine that all of the following requirements are met:

1. Risks to participants are minimized and reasonable. Research procedures should be consistent with sound research design, and should not expose the participants to unnecessary risk.
2. Risks to participants are reasonable in relation to anticipated benefits, if any, to the participants. The IRB also considers the importance of the knowledge to be gained from the research when evaluating risks versus benefits.
3. Selection of participants is equitable. In making this assessment, the purposes of the research and the setting in which the research is conducted are considered. Indication of coercion or prejudice must be absent, and participation must be clearly voluntary.
4. Informed consent is sought and documented from each prospective participant, or from the participant's legally authorized representative.
5. Provision is made for collecting, utilizing, and storing data in a manner that protects the safety and privacy of the participants and the confidentiality or anonymity of the data.
6. Appropriate safeguards are included to protect the rights and welfare of the participants.

Expiration Date

If your application is approved, your research is only good for one year from the date of IRB approval. Once that date passes you may no longer recruit participants and must cease data collection. To continue research, please submit an Annual Review Form to the IRB 60 days prior to your expiration date.

G. Step 7: Appeal of IRB Decisions *(If Needed)*

If researcher wishes to contest an IRB decision, he or she may ask the IRB to reconsider. If further appeal is required for an Expedited or Exempt Review, the researchers may request a Full Board review by the IRB in writing. If following a Full Board review the researcher wishes to appeal a decision, this request must be made in writing and would be heard by a committee of the Vice Provost of Academic Affairs and the Academic Council. Appeals must be based on new information or conditions that were not heard by the IRB. In these instances, the length of IRB review time may be significantly extended.

H. Step 8: Continuing Review, Modifications, Adverse Events, and Suspension

Continuing Review

Researchers with projects that are approved for more than a 12-month period should submit an Annual Review Form each year.

Modifications/Changes to the IRB Application Following Approval

The researcher shall keep accurate and current records to assure the approved design is being followed. If there is any modification of the project, prior notification and consent of the IRB must be obtained. Use the Modification to Approved Protocol Form.

Adverse Events

Researchers should report promptly any adverse event related to the conduct of research, regardless of the severity. An adverse event should be reported to the researcher's supervisor (if applicable) immediately and a written report (using the Adverse Event Form) submitted to the IRB within 10 days of the event. Reports of adverse events will be reviewed at a specially convened IRB meeting in a timely manner.

Suspension of Research

The IRB has the authority to suspend a project at any time for justifiable reasons, such as failure to comply with applicable state or federal regulations, adverse reactions to a study intervention, or the inability to complete the study within the approved time period.

I. Step 9: Completion of Study

The researcher must report completion of the study to the IRB in writing at the indicated completion date. Use the Project Completion Form in the appendices. If the study continues longer than the approved time, a progress report should be submitted to the IRB, along with a request for continuation of the study approval and rationale for the continuation. Use the Modification to Approved Protocol Form.

VII. SENSITIVE TOPICS AND VULNERABLE POPULATIONS

All projects involving a sensitive topic and/or a vulnerable human participant population require IRB approval even if the intent is not to produce generalizable knowledge.

A. Sensitive Topics

Examples of sensitive topics are those that collect information:

- Relating to sexual attitudes, preferences or practices;
- Relating to use of alcohol, drugs or other addictive products;
- Pertaining to illegal conduct;
- That if released could reasonably damage an individual's financial standing,

employability, or reputation within the community;
- That would normally be recorded in a patient's medical record and the disclosure could reasonably lead to social stigmatization or discrimination;
- Pertaining to an individual's psychological well-being or mental health.

B. Vulnerable Human Participants

If the project involves a vulnerable population, then a Full Board Review is required (see Expedited and Full Board Review Application). Vulnerable human participant populations include:

- Minors (under eighteen years of age);
- Fetuses or products of labor and delivery;
- Pregnant women (in studies that may influence maternal health);
- Prisoners;
- Individuals with a diminished capacity to give informed consent;
- Individuals with special needs.

If at any point there is uncertainty as to whether or not a project involving human participants is of a sensitive nature or involves vulnerable populations it is the responsibility of the faculty and staff to consult the IRB.

VIII. DEFINITIONS

CUI University Sponsor: Non-CUI affiliated researchers are responsible for obtaining a CUI full-time faculty member to sponsor their work before submitting their IRB application for review. The CUI University Sponsor's name and signature must be on the application. Non-CUI affiliated researchers whose research proposals are approved by the CUI IRB are responsible for sharing their completed research (thesis, dissertation, publication, etc.) with the CUI University Sponsor and CUI IRB.

Generalizable Knowledge: Conclusions or insights which may be extended to populations outside the subset which is the focus of inquiry. Other characteristics of generalizable knowledge include, but are not limited to, the potential for replication and the potential to contribute to the knowledge base of the field of inquiry.

Human Participant/Human Subject: Federal regulations (CFR Title 45, Part 46, 2009) define a human participant as "a living individual from whom a researcher (whether a professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information."

Informed Consent: The knowing, legally effective consent of any individual or the individual's legally authorized representative; such consent can be obtained only under circumstances that provide the prospective participant or representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.

Measurement Instruments: in the context of this handbook: a device used by a researcher to obtain information from human participants such as a questionnaire, survey, or aptitude test.

Minimal Risk: means that the risks of harm or discomfort anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in the daily life of the participant or during performance of routine physical or psychological examinations or tests.

Program Evaluation: Researchers may gather data from human participants through direct or indirect interaction for purposes of program evaluation. The information they collect will not be used to contribute to generalizable knowledge, rather the results will be used to improve or develop an internal program.

Research: Federal regulations (CFR Title 45, Part 46, 2009) define research as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." This definition excludes instructional activities that are not designed to contribute in any way (e.g., through presentation or publication) to generalizable knowledge. Also excluded are activities related to routine course or program development/evaluation. Research includes all theses, dissertations, publications, and/or data-related external presentations. If results of a study are publicly disseminated in any way or will contribute to generalizable knowledge, then the study probably constitutes research and is within the IRB purview. If no dissemination is planned at the time the data is gathered but the possibility of future dissemination exists, the researcher is advised to submit the project for IRB review/approval before initiating the (research) project.

Risk: means that the possibility of physical, psychological, or sociological harm may occur as a consequence of participation in a research activity or if such participation would increase the risks beyond those encountered in ordinary, daily life.

Sensitive Topics: information from human participants relating to: sexual attitudes, preferences or practices; relating to use of alcohol, drugs or other addictive products; pertaining to illegal conduct; information that if released could reasonably damage an individual's financial standing, employability, or reputation within the community; that would normally be recorded in a patient's medical record and the disclosure could reasonably lead to social stigmatization or discrimination; and/or pertaining to an individual's psychological well-being or mental health.

Student Classroom Projects: Projects conducted during or outside of class with students enrolled in an official course (for credit or not for credit), as well as activities in fulfillment of class assignments involving interactions with individuals other than the members of the class. These assignments are typically initiated and completed within a Course. Faculty members may design assignments that engage students in interaction with individuals and involve collecting data from individuals to teach research methods or to help students understand concepts covered by the course. For the most part, these projects are not intended to create new knowledge or to lead to scholarly publication or presentation.

University Supervisor: for students, the University Supervisor is the faculty member is

responsible for oversight of the student's research project; for Staff/Faculty, the university Supervisor is usually their direct supervisor.

Vulnerable Populations: includes minors, the elderly, prisoners, pregnant women, handicapped or mentally disabled persons, among other populations.

IX. IRB RELATED FEDERAL ORGANIZATIONS AND REGULATIONS

- Office of Human Research Protections (OHRP): http://www.hhs.gov/ohrp/
- Federal Drug Administration: http://www.fda.gov/ForHealthProfessionals/default.htm
- Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research: http://www.hhs.gov/ohrp/policy/belmont.html
- Code of Federal Regulations (CFR) Title 45: Public Welfare, Part 46: Protection of Human Subjects: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

IMAGE@HHS.GOV

- Tips on informed consent: http://www.hhs.gov/ohrp/policy/ictips.html
- Informed consent checklist: http://www.hhs.gov/ohrp/policy/consentckls.html
- Informed consent guidance: obtaining and documenting informed consent of human participants who do not speak English: http://www.hhs.gov/ohrp/policy/ic-non-e.html
- Human subject decision charts: www.hhs.gov/ohrp/policy/checklists/decisioncharts.html

APPENDIX A: CHECKLIST FOR SUBMITTING YOUR IRB PROTOCOL

1. EXEMPT REVIEWS

- ☐ Take the IRB training http://phrp.nihtraining.com and download certificates of completion (for all researchers, university supervisor/sponsor, and if applicable external thesis/dissertation supervisor)
- ☐ Complete the Exempt Review Checklist
- ☐ Complete the Exempt Review Application and obtain signatures
- ☐ Complete Site Authorization Form(s) as applicable, and obtain signatures for non-CUI sites
- ☐ Attach any measurement instruments and other materials to be distributed to participants (e.g., surveys, tests, questionnaires, interview questions); and if applicable, translations AND have a Verification of Translation Accuracy Form signed by someone other than yourself who is adept in the language
- ☐ Attach recruitment materials, if using
- ☐ Submit all of the above together in one e-mail to irb@cui.edu with "(name of program) IRB Application - Exempt Review - (Last Name)" in the subject line

2. EXPEDITED AND FULL BOARD REVIEWS

- ☐ Take the IRB training http://phrp.nihtraining.com and download certificates of completion (for all researchers, university supervisor/sponsor, and if applicable external thesis/dissertation supervisor)
- ☐ Use the Expedited Review Checklist to determine if your project needs Expedited or Full Board review. If your project meets requirements for an Expedited Review, complete and attach the Expedited Review Checklist with your application
- ☐ Complete the Expedited & Full Board Application and Protocol Narrative and obtain signatures *Note: The Expedited and Full Board application is basically the same; however, the length of review time is longer for Full Board Applications.*
- ☐ Attach any measurement instruments and other materials to be distributed to participants (e.g., surveys, tests, questionnaires, interview questions)
- ☐ Attach appropriate consent form(s), letters, and scripts containing all of the elements of informed consent
- ☐ If applicable, provide translations of both the consent forms and all measurement instruments to be distributed to participants AND have a Verification of Translation Accuracy Form signed by someone other than yourself who is adept in the language
- ☐ If applicable, attach Site Authorization Form and other institutions' IRB approvals
- ☐ Attach recruitment materials, if using
- ☐ Submit all of the above together in one e-mail to irb@cui.edu with "(name of program) IRB Application - (type of review requested—expedited or full board) - (Last Name)" in the subject line

APPENDIX B: EXEMPT REVIEW CHECKLIST

Please check the reason you believe your study is Exempt Review and submit this checklist along with the Exempt Review Application electronically to: irb@cui.edu

☐ Research conducted in established or commonly accepted educational settings and involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

☐ Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), if information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

☐ Research involving survey or interview procedures, ***except where the following conditions exist:*** (a) responses are recorded in such a manner that the human participants can be identified directly or through identifiers linked to the subjects, ***AND*** (b) the subject's responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, ***AND/OR*** (c) the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol. (However, when the respondents are elected or appointed public officials or candidates for public office, all research involving survey or interview procedures is exempt without exception).

☐ Research involving the observation (including observation by participants) of public behavior, ***except where the following conditions exist:*** (a) observations are recorded in such a manner that the human participants can be identified, directly or through identifiers linked to the subjects, ***AND*** (b) observations recorded about the individual, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, ***AND/OR*** (c) the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.

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

If NO box can honestly be checked, your project is NOT eligible for Exempt Review, continue to the Expedited checklist.

APPENDIX C: EXEMPT REVIEW APPLICATION

This form is used when one or more descriptions from the Exempt Review Checklist match your research project. Send this application with the completed checklist electronically to: irb@cui.edu

Researcher's Name	
Researcher's Department and/or Course	
Researcher's CUI Email Address (or other if non-CUI affiliated)	
Researcher's Phone Number	
Researcher's CUI E# (if applicable)	
Title of the Project	

Researcher's Status: (check one)

☐ CUI Student ☐CUI Faculty ☐ CUI Adjunct Faculty
☐ CUI Staff ☐ Other (explain):_____

Other Researchers: (use cui.edu email, if applicable)

Name:_____ Role: _____
Email:_____ Phone: _____
Name:_____ Role: _____
Email:_____ Phone: _____
Name:_____ Role: _____
Email:_____ Phone: _____
Name:_____ Role: _____
Email:_____ Phone: _____

Researcher's University Supervisor/Sponsor information:

Name:_____ Role: _____
Email:_____ Phone: _____

This research is for (check one):

☐ Graduate Thesis or Project ☐ Independent Study
☐ Doctoral Dissertation ☐ Honors Project
☐ Classroom Project ☐ Presidential Show Case
☐ Other (please describe) _____

If you are conducting this research as part of an outside institution's program, list institution, degree, and program: _____

Beginning date: (must follow IRB approval) _____
End date: (must follow IRB approval) _____
Location(s) of the research: _____

Participants: check all below descriptions that describe your participants

☐ Female / ☐ Male
☐ Child Development Center
☐ Children (17 or younger)
☐ English as foreign language learners
☐ Adults competent to consent
☐ CUI students
☐ Inmates
☐ Children with special needs
☐ Patients in institutions
☐ Pregnant women
☐ Adults not competent to consent
☐ CUI Faculty/Staff
☐ Other, explain: _____

Total number of participants proposed: _____

Funding:

1. Are you seeking funding for this research? ☐ No ☐ Yes
2. Will participants be compensated for participating? ☐ No ☐ Yes
   If yes, describe in summary.
3. Does the funding agency require IRB approval? ☐ No ☐ Yes
   If yes, provide all relevant forms, instructions, etc. with this application.

Purpose(s)/Objective(s) of the study: (1-2 paragraphs)

Design/methodology of the study: (1-3 paragraphs, including who the subjects will be, how subjects are selected and the size of the sample, data collection procedures and plans for analysis. If using electronic data collection, please include information listed in Online/Electronic Data Collection Tools)

Potential risks for human participants: (1 paragraph)

How risks will be minimized: (1 paragraph)

Anticipated benefits of the study (1 paragraph)

Other Required Attachments:

- ☐ Copy of NIH Certificate(s) for all researchers/co-researchers and university supervisor(s)
- ☐ Copy of the completed Exempt Review Checklist
- ☐ Other materials as appropriate (e.g., Site Authorizations, measurement instruments, recruitment materials, translations, Verification of Translation Accuracy, etc.), please list:

RESEARCHERS AND SUPERVISORS ASSENT

I agree to follow the procedures outlined herein, and to ensure that the rights and welfare of human participants are properly protected. I will ensure the study does not commence until the study has been approved by the CUI IRB. I will promptly report additions, changes, or problems involving the rights or welfare of human participants to the IRB by sending the appropriate IRB form to the IRB at irb@cui.edu.

Printed Name of Researcher: _____ **Date:** _____

Signature of Researcher: _____

Printed Name of Co-Researcher: _____ **Date:** _____

Signature of Co-Researcher: _____

Printed Name of Co-Researcher: _____ **Date:** _____

Signature of Co-Researcher: _____

Printed Name of Co-Researcher: _____ **Date:** _____

Signature of Co- Researcher: _____

Printed Name of Co-Researcher: _____ **Date:** _____

Signature of Co-Researcher: _____

Printed Name of University Supervisor (or CUI Faculty Sponsor): _____

Signature of University Supervisor (or CUI Faculty Sponsor): _____

Title: _____ **Date:** _____

NOTE: *A member of the CUI faculty must be principal researcher, co-researcher, supervisor, or sponsor for projects utilizing human participants in research at Concordia University, Irvine. The faculty member is considered the responsible party for legal and ethical performance of the project.*

APPENDIX D: EXPEDITED REVIEW CHECKLIST

The following are research activities eligible for Expedited review. Note: the Expedited review procedure may not be used with human participant research involving prisoners (use Full Review Application). Place an X to the left of ***Expedited Category(s)*** *that apply to your research assignment.*

☐ Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for Expedited review. **OR**
b. Research on medical devices for which (i) an investigational device Exemption application (21 CFR Part 812) is not required; or (ii) the medical device is FDA cleared/approved and the medical device is being used in accordance with its cleared/approved labeling.

☐ Collection of blood samples by finger stick or ear stick from healthy, non-pregnant adults who weigh at least 110 pounds. Collection may not occur more frequently than 2 times per week.

☐ Prospective collection of biological specimens for research purposes by noninvasive means. *For example:*

a. Hair and nail clippings in a non-disfiguring manner;
b. Excreta and external secretions (including sweat);
c. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue;
d. Placenta removed at delivery;
e. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
f. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;

AND/OR

g. Sputum collected after saline mist nebulization, or inline suctioning.

☐ Collection of data through noninvasive procedures routinely employed in the research environment. *Examples include:*

a. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
b. 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;
c. Weighing or testing sensory acuity;
d. Magnetic resonance imaging;
e. Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
f. Excluding clinical procedures involving x-rays or microwaves. 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.

☐ Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research 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 subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not Exempt.

☐ Collection of data from voice, video, digital, or image recordings made for research purposes.

☐ Non-manipulative, non-stressful research on individual or group 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.

NOTE: Some research in this category may be Exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not Exempt.

☐ Written or oral presentation of Exempt Research.

If one or more categories are checked, the research assignment is eligible for Expedited Review. Attach checklist to your Expedited Application and Protocol material. If NO box is checked, your research will need FULL BOARD review.

CONCORDIA UNIVERSITY IRVINE

APPENDIX E: EXPEDITED & FULL BOARD APPLICATION & PROTOCOL NARRATIVE

Please complete the Expedited Review Checklist to determine if your study falls under Expedited or Full Board Review and mark the appropriate level of review. Note: The primary difference between Expedited and Full Board review is the length of time needed for the IRB to complete the review process. To be completed by the Principal Researcher. All items must be filled in. If "Not applicable," explain why.

LEVEL OF REVIEW: ☐ Expedited ☐ Full Board

Researcher's Name	
Researcher's Department and/or Course	
Researcher's CUI Email Address (or other if non-CUI affiliated)	
Researcher's Phone Number	
Researcher's CUI E# (if applicable)	
Title of the Project	

Researcher's Status: (check one)

☐ CUI Student ☐ CUI Faculty ☐ CUI Adjunct Faculty
☐ CUI Staff ☐ Other (explain):_____

Other Researchers: (use cui.edu email, if applicable)

Name:_____ Role: _____
Email:_____ Phone: _____
Name:_____ Role: _____
Email:_____ Phone: _____
Name:_____ Role: _____
Email:_____ Phone: _____
Name:_____ Role: _____
Email:_____ Phone: _____

Researcher's University Supervisor/Sponsor information:

Name:_____ Role: _____
Email:_____ Phone: _____

This research is for (check one):

☐ Graduate Thesis or Project ☐ Independent Study
☐ Doctoral Dissertation ☐ Honors Project
☐ Classroom Project ☐ Presidential Show Case
☐ Other (explain) _____

If you are conducting this research as part of an outside institution's program, list institution, degree, and program: _____

Beginning date: (must follow IRB approval) _____
End date: (must follow IRB approval) _____
Location(s) of the research: _____

Participants: check all below descriptions that describe your participants

☐ Female / ☐ Male
☐ Child Development Center
☐ Children (17 or younger)
☐ English as foreign language learners
☐ Adults competent to consent
☐ CUI students
☐ Inmates
☐ Children with special needs
☐ Patients in institutions
☐ Pregnant women
☐ Adults not competent to consent
☐ CUI Faculty/Staff
☐ Other, explain: _____

Total number of participants proposed: _____

Funding:

1. Are you seeking funding for this research? ☐ No ☐ Yes
2. Will participants be compensated for participating? ☐ No ☐ Yes
   If yes, describe in summary.
3. Does the funding agency require IRB approval? ☐ No ☐ Yes
   If yes, provide all relevant forms, instructions, etc. with this application.

PROTOCOL NARRATIVE

Please review Protocol Narrative Instructions at the end of this document for information on what is expected in each of the following sections. Provide enough information so that reviewers will have a clear and concise understanding of exactly what is planned for your proposed study. If you believe a section is not applicable to your study, indicate "N/A" and explain why. Incomplete information will delay the IRB Review process.

I. INVOLVEMENT OF OTHER INSTITUTIONS

II. HUMAN PARTICIPANTS INVOLVEMENT

Please complete all sections below. If a section is not applicable, indicate "N/A."

A. **Purpose of Study**

B. **Subject Population**

C. **Recruitment Plan**

D. **Methods, Materials and Devices**

E. **Confidentiality**

F. **Compensation**

G. **Potential Benefits**

H. **Potential Risks**

I. **Risk Reduction**

III. INFORMED CONSENT

Please complete all sections below. If a section is not applicable, indicate "N/A."

A. **Consent Process**

B. **Special Consent Provisions**

In addition to the completed Application & Protocol Narrative please attach following documents:

- ☐ Human Subjects Training Certificate(s) for all researchers and university supervisor(s)
- ☐ Expedited Checklist (if research does not require Full Board Review)
- ☐ Consent and/or Assent Forms you will be using
- ☐ If applicable, attach Site Authorization Form and/or other institutions' IRB approvals
- ☐ If applicable, attach data instruments (e.g., surveys/interview questions)
- ☐ If applicable, translations and verification of measurement instruments and consent forms
- ☐ If applicable, recruitment materials
- ☐ If applicable, **ATTACH** other materials required by your School or Program. **Please list additional materials: _____**

Upon approval, the researchers will receive an email from the chair of the IRB, or the chair-appointed School/Program reviewer, informing them that the researchers may proceed with the implementation of the study. If unapproved, the chair or IRB reviewer will provide feedback on what information and documentation is deficient, and in need of revision for approval.

Researchers are required to notify the IRB of substantive changes to protocol, unanticipated adverse, serious events experienced by participants, and project completion. Projects lasting longer than one year require annual research protocol renewal using the Annual Review Form.

RESEARCHERS AND SUPERVISORS ASSENT

I affirm that I have read and reviewed the accuracy of this application and accept responsibility for the ethical conduct of this research, protection of human participants, and maintenance of data and informed consent documentation as required by the IRB. I will commence the study only after receiving approval from the IRB and having complied with any required modifications. I will promptly report additions, changes, or problems involving the rights or welfare of human participants to the IRB by sending the appropriate IRB form to the IRB at irb@cui.edu. If the project continues for more than one year from the approval date, I will submit the Annual Review Form.

Printed Name of Researcher: _____ Date: _____

Signature of Researcher: _____

Printed Name of Co-Researcher: _____ Date: _____

Signature of Co-Researcher: _____

Printed Name of Co-Researcher: _____ Date: _____

Signature of Co-Researcher: _____

Printed Name of Co-Researcher: _____ Date: _____

Signature of Co-Researcher: _____

Printed Name of Co-Researcher: _____ Date: _____

Signature of Co-Researcher: _____

To be Read and Signed by the Researcher(s)' University Supervisor/CUI Faculty Sponsor and if applicable School Dean

I affirm that I have proofread and reviewed the accuracy of this application and accept responsibility for the ethical conduct of research, student supervision, and documentation maintenance.

I agree to follow the procedures outlined herein for my student(s) and to ensure that the rights and welfare of human participants are properly protected. I will ensure the research does not commence until the CUI IRB approval has been given. I will ensure that the researchers(s) promptly reports additions, changes, or problems involving the rights or welfare of human participants to the IRB.

Printed Name of University Supervisor (or CUI Faculty Sponsor): _____

Signature of University Supervisor (or CUI Faculty Sponsor): _____

Title: _____ Date: _____

If applicable:

Printed Name of School Dean: _____ Date: _____

Signature: _____

NOTE: *A member of the CUI faculty must be principal researcher, co-researcher, supervisor, or sponsor for projects utilizing human participants in research at Concordia University, Irvine. The faculty member is considered the responsible party for legal and ethical performance of the project.*

PROTOCOL NARRATIVE INSTRUCTIONS

Please review Protocol Narrative Instructions for information on what is expected in the Protocol Narrative. Provide enough information so that reviewers will have a clear and concise understanding of exactly what is planned for your proposed study. If you believe a section is not applicable to your study, indicate "N/A" and explain why. Incomplete information will delay the IRB Review process.

I. INVOLVEMENT OF OTHER INSTITUTIONS

A. *If research will be conducted through other institutions that either serve as a source of participants, a source of records and information, or on whose facilities your project will be conducted, list the name of each institution involved. Attach signed Site Authorizations from participating institutions, organizations, or agencies.*

B. *Disclose any affiliation that you have with the participating institution, including whether you are an employee, an intern, or have a personal financial interest within the institution.*

C. *Address any potential conflict of interest, real or perceived, that may arise as a result of your affiliation with a participating institution (e.g., whether you have a direct role in the treatment, assessment, or training of potential participants; whether you have a supervisory role over potential participants; whether you are providing services to potential participants unrelated to your research activities).*

[Please also keep in mind that access to certain kinds of records such as student records, employee records, and medical records are subject to privacy rules. In most cases, such records, when they contain individually identifying information, cannot be accessed for research purposes without the permission of the subject.]

II. HUMAN SUBJECTS INVOLVEMENT

A. Purpose of Study
In 1-2 paragraphs describe the purpose of the study: what is the research question/problem statement/hypothesis?

B. Subject Population
Describe the subject population in terms of age, gender, race, ethnicity, etc., including the estimated number of participants. State any inclusion/exclusion criteria used to select subjects. Explain the rationale for employing the type of subjects selected for the study.

C. Recruitment Plan
Describe the procedures for selecting subjects. Explain how subjects will be recruited. Stipulate who and where the potential subjects are, how they will be contacted, and what will be said to recruit them and by whom. Attach any recruitment materials, such as sign-up sheets, flyers, or text for media postings.

D. Methods, Materials and Devices

- *Briefly discuss the methodology used for your study and procedures (i.e., qualitative action research, intervention protocol). List the kinds of data instruments that will be used and attach copies to the protocol (e.g., surveys, questionnaires, interview questions, data intake sheets). If translation into another language is necessary, submit both the English version and the translated version of the data instruments.*

- *If using electronic data collection, please include information listed in Online/Electronic Data Collection Tools*
- *Describe any cognitive or psychological tests that will be employed and provide representative examples of any computer stimulus or other test materials.*
- *Describe how the researcher will record information and any devices that will be employed, including information on whether audio/video recording devices will be used. If participants will be recorded or photographed, describe how these materials will be used, including whether or not they will be presented in publication or dissemination.*

E. Confidentiality

- *Indicate whether or not any identifying information will be collected and/or reported. Describe reporting methods. If identifying information will be collected but not reported, describe mechanisms for maintaining confidentiality (e.g., pseudonyms, coding system). If subjects are to be identified with the data, indicate the extent to which the subject's name or other identifiers will be used.*
- *Specify how data/materials collected will be kept safe and who will have access to the data/materials.*

F. Compensation

State any compensation that will be awarded to subjects for participation in the study (e.g., cash payment, gift card, course credit, free treatment). If students will receive extra credit or course credit, state the alternative method(s) that will be available for earning the credit for those who do not wish to participate.

G. Potential Benefits

List any potential direct benefits such as health-related or psychosocial benefits to an individual research subject. List any indirect benefits such as how the research may contribute to the acquisition of generalizable knowledge.

H. Potential Risks

Describe any potential risks - whether physical, psychological, social, legal, or other - and assess their likelihood and seriousness. Examples of risks include: physical injury, allergies to the materials used in the study, loss of privacy, the release of potentially damaging personal information, psychological trauma, and emotional discomfort (e.g., anxiety, stress, depression).

I. Risk Reduction

- *Describe the procedures for protecting against or minimizing each potential risk listed above. For example, risk of loss of privacy may be reduced by storing all research material in a locked cabinet, by using codes rather than participant names on surveys, or by conducting an anonymous study. Describe special safety procedures, as needed, to avoid harm to subjects.*
- *List any psychological and/or medical help available in the event of harm. For example, if the risk of emotional discomfort is high, the researcher should provide the subjects with a list of referrals for counseling and attach this information to the informed consent document.*

III. INFORMED CONSENT

A. Consent Process

Describe procedures for obtaining informed consent from subjects, including procedures for obtaining assent from minors. Indicate who will obtain consent/assent, what language will be used, where and when consent/assent will be obtained, and what steps will be taken to minimize the possibility of coercion or undue influence.

B. Special Consent Provisions

If some or all subjects will be cognitively impaired, visually impaired, physically impaired, or have language/hearing difficulties describe how capacity for consent will be determined. If you anticipate the need to obtain informed consent from legally authorized representatives, please describe how you will identify an appropriate representative and ensure that their consent is obtained.

[If there are issues the board should consider which do not fall into any category above, please describe them here.]

APPENDIX F: INSTRUCTIONS AND SAMPLE: INFORMED CONSENT

The following is an example of an informed consent form and instructions regarding what information must be included. Written informed consent is required for Expedited and Full Board Review projects unless waived by IRB. Exempt Review research requires consent but does not usually require signed consent. Each research project is unique and the informed consent form should be customized to your study.

PROJECT TITLE

The study in which you are being asked to participate is designed to investigate (place your information in the context of what you are investigating). This study is being conducted by (your full name here) under the supervision of (your supervisor's full name, title, and school/department.). This study has been approved by the Institutional Review Board, Concordia University Irvine, in Irvine, CA.

PURPOSE: (Place an explanation of the purposes of the research).

DESCRIPTION: (A description of the procedures to be followed).

PARTICIPATION: (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).

CONFIDENTIALITY OR ANONYMITY: (How you will maintain the confidentiality of the research? Please note that the research is confidential or anonymous, not both; chose one or the other). Also, a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained if the information is collected confidentially; meaning you maintain the confidentiality of the participants' information. An example: Stored in locked filing cabinet, stored or password protected computer, etc…).

DURATION: (The expected duration of the subjects' participation).

RISKS: (A description of any reasonably foreseeable risks or discomforts to the subject, if there are no foreseeable risks to their participation in the research please state so).

BENEFITS: (A description of any benefits to the subject/s or to others which may reasonably be expected from the research, if there are no benefits to their participation in the research, please state so. Please do not claim benefits which you cannot possibly attribute to the research).

VIDEO/AUDIO/PHOTOGRAPH: (If applicable, include a statement that the research will include one or all of the noted categories. Example: I understand this research will be Video Recorded Initials____ and/or I understand this research will be audio recorded Initials___ and/or I understand this research will be photographed Initials___. You can also use a Yes □ or No □ with a box to checkmark, as noted. Please note that a separate video/audio/photograph permission form is available under the IRB Forms.).

CONTACT: (An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject - this is your advisor's(s') name, title, phone, and email address).

RESULTS: (Include an explanation as to where the results can be obtained after you have completed your study and disseminate the results for publishing. This should not include your name or phone number, but a place and exact location where the results can be obtained).

CONFIRMATION STATEMENT:

I have read the information above and agree to participate in your study. **Or**

I have read and understand the consent document and agree to participate in your study. **Or**

I understand that I must be 18 years of age or older to participate in your study, have read and understand the consent document and agree to participate in your study.

SIGNATURE: (Include a signature line as necessary. Note that Exempt Review research, if truly anonymous research, should not include a signature line. Please note that Parental/Conservator informed consents do require a signature line).

Signature: _____ Date: _____

Printed Name: _____

The extra copy of this consent form is for your record.

APPENDIX G: SAMPLE PHOTOGRAPHY/VIDEO/AUDIO USE - INFORMED CONSENT

If you plan to take photographs, videotape or audio record human participants, a form such as the one below should be used in addition to the general informed consent (Form F) for Expedited and Full Board Review studies. If your project is Exempt Review, then only a form such as this is needed. Each research project is unique and the informed consent form should be customized to your study.

PHOTOGRAPHY/VIDEO/AUDIO USE

As part of this research project, we will be making a photograph/videotape/audiotape recording of you during your participation in the experiment. Please indicate what uses of this photograph/videotape /audiotape you are willing to consent to by initialing below. You are free to initial any number of spaces from zero to all of the spaces, and your recording will no way affect your credit for participation. We will only use the photograph/videotape/audiotape in way that you agree to. In any use of this photograph/videotape/audiotape, your name would not be identified. If you do not initial any of the spaces below, the photograph/videotape/audiotape will be destroyed.

Please indicate the type of informed consent.
(ONLY LIST ITEMS APPLICABLE TO YOUR STUDY)

The photograph/videotape/audiotape can be studied by the research team for use in the research project.	Please initial _____
The photograph/videotape/audiotape can be shown/played to subjects in other experiments.	Please initial _____
The photograph/videotape/audiotape can be used for scientific publications.	Please initial _____
The photograph/videotape/audiotape can be shown/played at meeting of scientists.	Please initial _____
The photograph/videotape/audiotape can be shown/played in classrooms to students.	Please initial _____
The photograph/videotape/audiotape can be shown/played in public presentations to non-scientific groups.	Please initial _____
The photograph/videotape/audiotape can be used on television and radio.	Please initial _____

I have read the above description and give my consent for the use of the photograph/videotape/audiotape as indicated above.

Signature: _____ Date: _____

Printed Name: _____

The extra copy of this consent form is for your record.

APPENDIX H: SAMPLE PARENTAL INFORMED CONSENT

Parental informed consent is required for participation of minors in research (sample below) unless waived by the IRB. Each research project is unique and the informed consent form should be customized to your study.

Date XXX

Dear Parent(s),

I will be conducting a study in our classroom to determine [briefly discuss purpose here]. The study will last XXXXXXXXXXXXXXXXXXXXX. This is a part of my final research project for my master's degree at Concordia University Irvine, CA.

I am writing to ask permission to use the data I collect from your child during this process. Participation in this study involves XXXXXXXXXXXXXXXXXXXXXXXX.

XXXXXXXXXXXXX (type in the name of the institution's administrator) has approved this study for implementation at XXXXXXXXXXXXXXXX (type name of institution).

The significance of the study is XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX.

The benefits to your child for participating in this study include XXXXXXXXXXXX.

Only XXXXXXXXX , —my University Supervisor—and I will have access to your child's identity and to information that can be associated to your child's identity. The data and documentation will be destroyed by XXXXXXXXXXXX (type in date).

Use of data from your child is voluntary. You may contact me at any time regarding your child's participation. My phone number is XXXXXXXXXXXXXXX and my e-mail is XXXXXXXXXXXXXXXX.

Sincerely,
XXXXXXXXXXXXXXX

Please check the appropriate box below and sign the form:

- ☐ I give permission for my child's data to be used in this study. I understand that I will receive a signed copy of this consent form. I have read this form and understand it.
- ☐ I do not give permission for my child's data to be included in this project.

Student's Name: _____

Signature of Parents/Guardian: _____

Printed Name of Parents/Guardian _____

Date _____

APPENDIX I: SAMPLE CHILD ASSENT FORM

In addition to parental informed consent for minors, the assent of the child should be obtained unless waived by the IRB. Child assent forms must use simple and age appropriate language (sample below). Each research project is unique and the informed consent form should be customized to your study.

We are doing a study to learn about people who tell the truth and people who lie. We are asking you to help because we don't know very much about whether kids your age expect people to lie or tell the truth.

If you agree to be in our study, we are going to ask you some questions about types of people. We want to know if you think they usually tell the truth or if they usually lie. For example, we will ask you if a teacher, parent, or other people usually lie or usually tell the truth.

You can ask questions about this study at any time. If you decide at any time you do not want to finish, you can ask us to stop.

The questions we will ask are only about what you think. There are no right or wrong answers because this is not a test.

If you sign this paper, it means that you have read this and that you want to be in the study. If you don't want to be in the study, don't sign this paper. Being in the study is up to you, and no one will be upset if you don't sign this paper or if you change your mind later.

Signature of person obtaining assent: _____ Date: _____

Printed Name of person obtaining assent: _____

Your Signature: _____ Date: _____

Your Printed Name: _____

APPENDIX J: SITE AUTHORIZATION

Title of the Study	
Researcher/s	
Researcher/s' Affiliation with Site	
Researcher/s' Phone Numbers	
Researcher/s' CUI Email Address (or other if non-CUI affiliated)	
Researcher/s' University Supervisor	
University Supervisor's Phone & E-mail	
Location/s where Study will Occur	

Purpose of the Study (1-2 paragraphs):

Procedures to be Followed:

Time and Duration of the Study:

Benefits of the Study:

Persons who will have access to the records, data, tapes, or other documentation (see Application Process Step C.3 of handbook)**:**

Date when the records, data, tapes, or other documentation will be destroyed:_____

_____ _____

Researcher's Signature Date

Appendix K

----------Authorization----------

I understand that participation in this study is confidential. Only the researcher, collaborators, and supervising professor will have access to participants' identities and to information that can be associated with their identities. Please check the appropriate box below and sign the form:

_____ I **give permission** for my organization to participate in this project. I understand that I will receive a signed copy of this consent form. I have read this form and understand it.

_____ I **do not give permission** for my organization to participate in this project.

_____ _____

Authorized Signature Date

_____

Printed Name and Title

APPENDIX K: VERIFICATION OF TRANSLATION ACCURACY

Please either attach this form to your IRB application if the protocol includes translated documents or include this form when translated documents are submitted to the IRB. Researchers(s) may translate documents, but may not verify the accuracy of the translation. The IRB does not require that a certified translator perform the document translation. The verification may, for example, be provided by a member of the Department of Foreign Languages or an individual who has a bachelor's degree in that language. The form must be completely filled out and signed by the individual providing the verification. Duplicate fields are included if documents are submitted in multiple languages that require verification from different individuals.

Researcher's Name	
Co-Researcher/s' Names/s	
Title of Proposed Project	
Researcher/s' CUI Email Address (or other if non-CUI affiliated)	
Name of Verifying Individual	
IRB Tracking # (if already assigned by IRB)	

I, the undersigned, verify that all translated materials related to the above named study reflect the intent and spirit of the English text.

Name of Verifying Individual: _____

Signature: _____Date: _____

Language: _____

E-mail: _____

CONCORDIA UNIVERSITY IRVINE

APPENDIX L: ANNUAL REVIEW

DATE: ____/____/____

REVIEW CATEGORY: If your application was originally submitted and approved under the *Exempt Review category*, you DO NOT have to file for renewal. Please check off the appropriate category below if your application was originally approved under Expedited or Full Board review.

☐ Expedited ☐ Full Board

Researcher's Name	
Co-Researcher/s' Name/s	
Researcher/s' CUI Email Address (or other if non-CUI affiliated)	
Researcher's Phone Number	
Department	
Title of the Project & IRB #	
Date of original IRB approval	

The above human participants protocol is due for renewal. Please answer the following questions listed and email this form to irb@cui.edu.

Do you want to renew the above named protocol?

YES ☐ NO ☐

If you want to renew your protocol, please address the following questions listed below. If the answers to any one of the below questions is "YES" please elaborate the specific details on the back of this form or on a separate piece of paper and attach to this form.

Are there any changes in the original approved protocol/methodology that relate to the research conducted and/or human subjects utilized in your research?

YES ☐ NO ☐

Have there been any adverse events or unanticipated problem (s) that relate to the research conducted and/or human subjects utilized in your research?

YES ☐ NO ☐

Researcher(s) Assurance:

The information and answers to the questions above is true and accurate to the best of my knowledge and I understand that prior IRB approval is required before initiating any changes that may affect the human subject participant(s) in the originally approved research protocol. I also understand that in accordance with federal regulations I am to report to the IRB or administrative designee any adverse events that may arise during the course of this research.

Printed Name of Researcher: _____ **Date:** _____

Signature of Researcher: _____

Printed Name of Co-researcher: _____ **Date:** _____

Signature of Co-researcher: _____

Printed Name of Co-researcher: _____ **Date:** _____

Signature of Co-researcher: _____

Printed Name of Co-researcher: _____ **Date:** _____

Signature of Co-researcher: _____

Printed Name of Co-researcher: _____ **Date:** _____

Signature of Co-researcher: _____

Printed Name of University Supervisor (or CUI Faculty Sponsor): _____

Signature of University Supervisor (or CUI Faculty Sponsor): _____

Title: _____ **Date:** _____

To be completed by the IRB Reviewer

Approval of renewed protocol/methodology is granted from ____/____/____ to ____/____/____

Signature of IRB Reviewer: _____ Date: _____

Printed Name of IRB Reviewer: _____

CONCORDIA UNIVERSITY IRVINE

APPENDIX M: MODIFICATION TO APPROVED PROTOCOL

All items must be completed. If "Not applicable," explain why. This form and all related documents are submitted electronically to: irb@cui.edu

Researcher's Name	
Co-Researcher/s' Name/s	
Researcher/s' CUI Emails (unless not from CUI)	
Researcher/s' Phone Number	
Department	
Title of the Project & IRB #	
Date of Original IRB Approval	

Description of changes to the research project:

How do the requested changes impact the level of risk involved for participants?

Have there been any adverse events regarding human participants in your investigation? (Y/N)
If yes, please also complete an Adverse Events Form

To be completed by the IRB Reviewer

Date Change Form submitted: _____
Does the modification proposed change the review level? ☐ Yes ☐ No
Is the modification approved? ☐ Yes ☐ No
Notes:

Signature of IRB Reviewer: _____ Date: _____

Printed Name of IRB Reviewer _____

APPENDIX N: ADVERSE EVENT REPORT

All items must be filled in. If "Not applicable," explain why. This form and all related documents are submitted electronically to: irb@cui.edu

Researcher's Name	
Co-Researcher/s' Name/s	
Researcher/s' CUI Emails (unless not from CUI)	
Researcher's Phone Numbers	
Department	
Title of the Project & IRB #	
Date of Original IRB Approval	

Description of adverse event: *describe all circumstances related to this event. All hospitalizations and/or medical treatment must be reported. Include all notifications, correspondence, and other related materials related to the adverse event from the study sponsor or study sites. Include a statement regarding this adverse event and its relation to the study at Concordia University Irvine.*

To be completed by the IRB Reviewer

Date submitted:_____

Notes:

Signature of IRB Reviewer: _____ Date: _____

Printed Name of IRB Reviewer _____

APPENDIX O: PROJECT COMPLETION FORM

To be completed by the Principal Investigator. All items must be filled in. If "Not applicable," explain why. This form and all related documents are submitted electronically to: irb@cui.edu

Researcher's Name	
Co-Researcher/s' Name/s	
Researcher/s' CUI Emails (unless not from CUI)	
Researcher/s' Phone Numbers	
Department	
Title of the Project & IRB #	
Date of original IRB approval	
Date of study completion	

Brief Summary of Outcome:

To be completed by the IRB Reviewer

Date submitted:_____

Notes:

Signature of IRB Reviewer: _____ Date: _____

Printed Name of IRB Reviewer: _____