Institutional Review Board Manual

July 2012, revised July 2013, revised December 2014, revised July 2017, revised July 2019 (including 2018 revisions to The Common Rule), revised February 2022

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Introduction

This manual is designed to explain the process for obtaining Institutional Review Board (IRB) approval/certification for research involving human subjects at Concordia University Chicago (CUC). All research involving human subjects conducted by either Concordia students or personnel is reviewed by the IRB. The CUC IRB was established by the Board of Regents to comply with the standards for research of the U.S. Department of Health and Human Services' Office for Human Research Protections (OHRP) and is described in section 4.00.101 of the CUC's Administrative Policies and Procedures Manual.
All research involving human subjects that is conducted by Concordia students or personnel is submitted to the IRB for review. This includes research projects both funded and unfunded. Research conducted by an investigator affiliated with Concordia at an off-campus site(s) or in collaboration with an investigator at another institution is submitted to the Concordia IRB.

There are three different mechanisms used by the IRB to review research projects: full board review, expedited review, and exempt review. Investigators can find instructions on how to submit applications for IRB review in Section 2 of this manual.

The IRB also reviews applications from faculty/instructors for research that involves human subjects for the purpose of teaching and training students in research. These classroom projects are supervised by the instructor. Please see the *Faculty Assurance Form for Classroom Projects* in Section 3 of this manual. Many projects that involve interactions with people do not meet the CUC's definition of "research with human subjects." For example, many evaluations and classroom projects do not require IRB review. Please see the definitions in Section 2 of this manual for more information.

If after reviewing this manual you have any questions or are unsure whether your research requires review, please contact the IRB at: IRB@CUChicago.edu

To read about the federal guidelines governing IRBs please refer to:
https://www.hhs.gov/ohrp/sites/default/files/revised-common-rule-reg-text-unofficial-2018-requirements.pdf

Manual Organization

This manual has three main sections: The first describes the purpose of the CUC IRB. The second reviews the application process. And the third contains forms, or instructions for downloading forms, needed for investigators to complete the application process.

Section 1: Purpose

Concordia University Chicago recognizes its ethical, legal, and federally mandated responsibilities to safeguard the rights and welfare of human subjects in all research conducted by its students and personnel. Its ethical responsibilities are guided by the principles outlined in the *Belmont Report* of respect for persons, beneficence, and justice. Concordia's federally mandated responsibilities come from the Department of Health and Human Services (DHHS) and are outlined in Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46). These regulations mandate that all institutions engaged in research with human subjects provide the dual protections of Institutional Review Board review and informed consent from the participants.

The ethical and federally mandated responsibilities mentioned above serve as the foundation for an agreement between Concordia University Chicago and the DHHS's Office for Human Research Protections called a Federalwide Assurance (FWA). Concordia University Chicago has filed and received approval of its FWA from the OHRP. This assurance (FWA #00018965) covers research conducted by CUC-affiliated students and personnel.

The IRB for Concordia University Chicago is supported by the Office of the Provost and is headquartered on the River Forest campus. Members of the IRB represent the interests of the University and the broader community. Members consist of faculty possess varied backgrounds and expertise. The IRB also includes at least one member not affiliated with the University. The IRB meets once a month, and minutes of its meetings are filed in the IRB Office.

It is the responsibility of individual investigators to familiarize themselves with the policies and procedures set forth in the IRB Manual. The University regards any infringement of these policies and procedures as a serious breach of professional standards. The University's willingness to defend researchers in litigation depends on strict adherence to policies and procedures regarding IRB approval. Members of the Concordia community may bring issues of general policy regarding human subjects in research to the attention of the IRB. Questions should be sent in writing to the Chairperson of the IRB. Interpretation of applicability of IRB rules and regulations are solely the legal right and responsibility of the IRB.

Responsibilities of the IRB

The Concordia University Chicago Institutional Review Board ensures CUC remains compliant with the US Department of Health and Human Services Code of Federal Regulations (45CFR46) regarding the protection of human research participants in terms of welfare, rights, and privacy. The IRB ensures that all research conducted in conjunction with CUC is ethically compliant, that the benefit of all research activity outweighs the risk, and that all CUC researchers engage ethically with other institutional review boards with which our work intersects. The IRB certifies the investigator's compliance with guidelines for the ethical treatment of human research participants. Although the IRB does not approve the academic merit of research studies, the IRB does consider the design and data-gathering procedures of the study to the extent to which they impact the rights and well-being of human subjects, as well as consider the overall beneficence of CUC related research. The purview of the IRB does not include the epistemological foundations, social perspectives, or value judgements of the research of either faculty or students. Based on assessment of risk/benefit, the IRB can approve, disapprove, or require modifications to applications.

The IRB is formed to encourage and assure research with human subjects 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, or students, whether on or off campus, and for any individual or group desiring to conduct any research or study on human subjects on campus or at other facilities under the responsibility of the University.

The IRB will conduct periodic reviews, at least annually, of ongoing research projects. This periodic review may be more frequent, if deemed necessary to the IRB.

Membership of the IRB

The IRB will consist of at least five qualified individuals with diverse backgrounds. This should include at minimum one faculty member from the Natural Sciences Department and at least one faculty member with a nonscientific background. Membership will also include a faculty member from the Psychology Department, a faculty member from an educator preparation (P–12 licensure) program, a faculty member who specializes in the field of Ethics, and two community members. Whenever possible, membership of the IRB will reflect the Colleges proportionally. Legal counsel must be available to the committee. Membership to this committee will be by appointment of the President upon recommendation by the Provost's Office. The Chair will be a faculty member.

Meetings of the IRB

The IRB meets once a month, and minutes of its meetings are filed in the Institutional Review Board Office.

Conflict of Interest

Conflict of Interest – A member of the IRB may not certify or approve of any application for which the IRB member has a direct interest, either as an investigator, committee member, or faculty sponsor of a student's project.

Research Conducted at the Place of Employment

Applications to conduct research at the investigator's place of employment are carefully reviewed because of the risk of a dual relationship that the investigator may have with the research participants.

IRB Certification (Training) and Compliance

Any investigator or supervisor seeking IRB approval must first complete IRB Certification as described in Section 2 of this manual. Evidence of this certification must be submitted to the IRB along with any application materials. Presently, the CUC IRB utilizes IRBnet; certification records must be linked to investigator and supervisor IRBnet profiles. This evidence is submitted with each application even if the investigator has previously submitted it.

Section 2: Process

Introduction to the Application Process

The investigator with their instructor/supervisor (if applicable) determines the level of risk to the proposed research study's participants and completes the appropriate request for IRB review (all forms are in Section 3 of this manual or are available in the CUC IRBNet Library). All questions on the application must be answered fully and all supporting documents included. Application review will only begin once all materials are received by the IRB.

For doctoral candidates, a full dissertation proposal and proposal defense ballot must be included with the IRB application package. Doctoral candidates may only apply for IRB review after the dissertation proposal has been successfully defended and all revisions approved by the committee. In cases when there is a change in dissertation committee composition between the defense of the proposal and the IRB application submission, a committee change form should be included with a current chair listed as a supervisor for the research.

Once submitted to the IRB, the IRB Chair or their designee will confirm the level of application (full board review, expedited review, or exempt review) and then forward the full IRB review applications to the IRB committee for review at the IRB monthly meeting. Applications for expedited or exempt review are forwarded to the IRB Chair or their designee for review. A summary of these expedited and exempt reviews is given to the IRB committee at the IRB monthly meeting.

The IRB will make every reasonable effort to review applications in the shortest time possible. Exempt and expedited reviews typically take 10-15 business days, and those needing full IRB review are only reviewed once monthly.

All applications to the IRB and communication from the IRB are done in writing.

Following completion of the research project, a Project Completion Report Form (see Section 3) should be completed and submitted to the IRB.

Step 1: Certification (Training)

Concordia University Chicago is a member of the Collaborative Institutional Training Initiative (CITI Program). This organization is dedicated to serving the needs of institutions like ours in terms of human research protections training. To conduct or supervise research at CUC, it is required that all researchers submit evidence of appropriate CITI Program training along with any application materials to the IRB. Each time an investigator submits an application to the IRB, a copy of this evidence is also submitted.

As CUC has an institutional membership with CITI, the training is provided at no cost to individuals affiliated with our institution. Credentials are issued at the completion of each required module. Investigators and supervisors should log in to www.citiprogram.org and affiliate with CUC. There will be a number of courses available to you.

RESEARCHERS in HEALTH SCIENCES: For example, students and research supervisors in exercise science, health and human performance, etc. programs must take these courses:

Biomedical (Biomed) Comprehensive (ID: 243167)
Biomedical Responsible Conduct of Research (ID: 243160)

RESEARCHERS in SOCIAL and BEHAVIORAL SCIENCES: For example, students and research supervisors in educational, social science, behavioral science, psychology, etc. programs must take these courses:

Social-Behavioral-Educational (SBE) Comprehensive (ID: 243168)
Social and Behavioral Responsible Conduct of Research (ID: 243163)

ALL RESEARCHERS: You will see available optional modules that may be beneficial to you, depending on your research.

All CITI credentials should be uploaded to your IRBnet profile and linked to project application packages. If you possess a current HSR certificate from another institution, you may ask the IRB to review the credential.

Step 2: Selecting the category for review

The investigator should carefully review the descriptions below to determine which level of review applies to the study. Final determination of the review category is made by the IRB.

FULL BOARD REVIEW

Full review will be given to all those studies proposed that involve activities or procedures that put any human subject at physical, psychological, or social risk. Full review will require that a quorum of members be present at a regular meeting of the Institutional Review Board (IRB). A majority of those present and voting will determine the action on a specific study. The following actions are possible:

- Approval as submitted
- Approval with revisions
- Referral for resubmission
- Disapproval

EXPEDITED REVIEW

Expedited review procedures can be instituted for those studies that involve no more than minimal risk to human subjects, or that request approval of minor changes in approved research. The investigator 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 investigator must submit a Request for Expedited Review, along with the IRB application, and indicate the basis for requesting expedited review. The IRB Chair (or their designee) will review the request. The reviewer may recommend the following actions:

- Approval as submitted
- Approval with revisions
- Referral for resubmission
- Disapproval
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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:

1. 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.)
    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

cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
    a. From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or
    b. From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

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

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
    a. Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

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

7. 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 subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

8. Continuing review of research previously approved by the convened IRB as follows:
    a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
    b. where no subjects have been enrolled and no additional risks have been identified; or
    c. where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) 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.

Source: 63 FR 60364-60367, November 9, 1998.

EXEMPT REVIEW

Certain categories of research involving human subjects have been declared exempt from review in the federal regulations. The investigator should check the current list of "Possible Exempt Categories" below to determine if the project may be considered for exempt review by the IRB. The investigator should submit a Request for Exempt Review, along with the IRB application, and indicate the basis for requesting exempt review. The investigator will be notified if the IRB approves the request.

POSSIBLE EXEMPT CATEGORIES OF RESEARCH ON HUMAN SUBJECTS

Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

1. Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

a. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
b. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
c. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination as required by §46.111(a)(7).

3. (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
    a. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
    b. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
    c. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers liked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

    (ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

    (iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:
    a. The identifiable private information or identifiable biospecimens are publicly available;
    b. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

c. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of ''health care operations'' or ''research'' as those terms are defined at 45 CFR 164.501 or for ''public health activities and purposes'' as described under 45 CFR 164.512(b); or
d. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq*.

5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.
    a. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.
    b. [Reserved]

6. Taste and food quality evaluation and consumer acceptance studies:
    a. If wholesome foods without additives are consumed, or
    b. 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.

7. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by § 46.111(a)(8).

8. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:
    a. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with § 46.116(a)(1) through (4), (a)(6), and (d);
    b. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with § 46.117;
    c. An IRB conducts a limited IRB review and makes the determination required by § 46.111(a)(7) that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

Source: 45 CFR 46, July 19, 2018 edition of the Code of Federal Regulations

Step 3: Completing the application

See forms and references to forms in Section 3.

Research involving online/electronic data collection tools

Any individual seeking CUC IRB approval for a study involving the use of an electronic and/or online survey tool is asked to include information on the following in their 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 time stamp?
- How often is data backed up on servers? Who owns those servers?
- What is the software company's privacy policy?

In addition, investigators 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."

Research involving the use of incentives

Any individual seeking CUC IRB approval for a study using incentives/rewards is cautioned as follows:

- The CUC IRB does allow for the use of incentives/rewards so long as the incentives/rewards do not constitute undue inducement.
- A research subject's choice to participate in your 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 subjects' anonymity and how these rewards are made to individuals if they discontinue participation in the study.

Research involving the use of recruitment materials

Any individual seeking CUC 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.
Required Elements:

- Study title and IRB study number.
- The word "research." Make it clear that this is a research study.
- "Concordia University Chicago"
- The PI's name.
- A contact name with either a phone number or e-mail address.
- Eligibility criteria, if applicable, should be noted briefly. Especially if payment depends on meeting these criteria. For example, "English speaking only," "Women only," etc.
- State whether participants will be paid for their time and effort. The amount of payment may be included but should not be the most prominent element on the page. Compensation should not be excessive considering the nature of the project. Payment should be stated as a range of amounts or stated as "at least" or "up to" for payments dependent on the amount of participation.

Research involving the use of electronic signatures during the consent process

Any individual seeking CUC 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 their application:

- Are electronic signatures legally valid within the research site jurisdiction?
- Are the consent documents provided to participants (and parents if the research subjects 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 subject (and parent if the subject is a minor) and researcher (PI)?

Step 4: Written approvals

The investigator should seek prior written approval(s) of the appropriate administrator(s), at Concordia and/or any off-campus sites involved in the study. Evidence of these approvals should be submitted as attachments to the IRB application.

Step 5: Attaching informed consent materials and instruments

See a checklist of required informed consent elements in Section 3. Also note that all instruments, tools, protocols, recruitment materials and/or surveys need to be attached if they will be used in the study. If a deception technique is to be used, be sure to also include a participant debriefing form.

Step 6: Submitting the application and supporting documents

All documents are submitted electronically via IRBNet at IRBnet.org.

The PDF forms available in the CUC IRBNet library are writable and savable. Please download these forms, complete these PDF forms electronically, save them, and submit them via IRBNet. These PDF forms must be submitted as PDFs and should not be converted to another format.

Step 7: Notification of IRB decisions

Notifications are made electronically. Investigators should retain copies of these communications as records of their approvals.

Step 8: Appeal of IRB decisions

If an investigator wishes to contest an IRB decision, they may ask the IRB to reconsider. If further appeal is required for an expedited or exempt review, the investigator may request a full board review by the IRB in writing. If following a full board review the investigator wishes to appeal a decision, this request must be made in writing and would be heard by a committee of the Senior Vice President of Academics and the college Deans. Appeals must be based on new information or conditions that were not heard by the IRB (this procedure is described in the CUC Administrative Policies and Procedures Manual, 4.00.101).

Step 9: Continuing review, modification, or adverse events

Continuing review

Investigators with projects that are approved for more than a 12-month period should submit an Annual Review Form each year. See Section 3.

Modifications/changes to the IRB application following approval

The investigator 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/Changes Form in Section 3.

Adverse events

Investigators should report promptly any adverse event related to the conduct of research, regardless of the severity. An adverse event should be reported to the investigator's supervisor (if applicable) immediately and a written report (using the Adverse Events Form in Section 3) submitted to the IRB within 10 days of the event. Reports of adverse events are reviewed at the IRB monthly meeting or at a specially convened meeting as needed.

Step 10: Completion

The investigator must report completion of the study to the IRB in writing at the indicated completion date. Use the Project Completion Form in Section 3.

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 concurrent rationale for the continuation. Use the Modification/Changes Form in Section 3.

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.

Definitions

Concordia University Chicago uses the following definitions of terms as adapted from the *Code of Federal Regulations* (CFR Title 45, Part 46, 2018) and the *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research* (1978).

Human Subject – Federal regulations define a human subject as "a living individual about whom an investigator (whether a professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information."

Minimal Risk – 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.

Research – Federal regulations 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.

Section 3: Forms

Faculty Assurance Form for Classroom Projects

This form is available for download in the CUC IRBNet online Library.

Request for Expedited Review

This form is available for download in the CUC IRBNet online Library.

Request for Exemption from Review

This form is available for download in the CUC IRBNet online Library.

IRB Application

This form is available for download in the CUC IRBNet online Library.

Informed Consent Checklist

Ethical practice and law requires that a participant's consent be intelligent, knowing, and voluntary. Investigators are responsible for composing consent forms, obtaining consent, and keeping documentation of this process. Use the informed consent checklist (ITEM 18 on the IRB application) to be sure that you have included all required elements. Consent materials shall not be distributed to research participants until IRB approval has been secured.

Annual Review Form

This form is available for download in the CUC IRBNet online Library.

Modifications/Changes Form

This form is available for download in the CUC IRBNet online Library.

Adverse Events Form

This form is available for download in the CUC IRBNet online Library.

Project Completion Form

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