

2020-2021 IRB Application Template v4

Please use this document template to create a CTX IRB application. **It is strongly recommended that the CTX IRB APPLICATION GUIDELINES are used to complete all fields contained in this template.** Copies of the guidelines and other resource materials can be found at www.concordia.edu/irb or requested from irb@concordia.edu.

1. Title

Provide a brief title (ten words or fewer) for the proposed research that identifies the focus of the proposed research.

Enter a brief title of proposed research here.

2. Principal Investigator (PI)

Provide the full name, institutional affiliation, and requested contact information below. Identify the capacity in which the PI will be conducting the proposed research; if the PI is a student, provide the name, affiliation, and requested contact information of a faculty supervisor or sponsor.

<i>Full Name</i>	<i>Institutional Affiliation</i>
<i>Email address</i>	<i>Telephone Number</i>

- PI is currently affiliated with Concordia University Texas.
- PI is **NOT** currently affiliated with Concordia University Texas.

In what capacity will the PI be conducting this research?

<i>Choose an item.</i>

If the PI is currently a student, please provide the name, title, and institutional affiliation of a faculty supervisor.

<i>Faculty Supervisor or Sponsor</i>	<i>Institutional Affiliation</i>
<i>Email address</i>	<i>Telephone Number</i>

Faculty Supervisor Certification

If the PI is currently enrolled as a student, a faculty supervisor or sponsor must certify that this completed application and all supporting documentation being submitted have been fully reviewed and certify all as complete and adequate for submission to the CTX IRB. *Note: Application certification date should be more than 30 days prior to application submission date.*

<input type="checkbox"/>	Check the box to the left to certify that you have fully read and reviewed this IRB application and all supporting documentation and determined that it is complete and adequate for submission to the CTX IRB for review.	
	Faculty Supervisor or Sponsor signature	Click or tap to enter a date.
	If signing electronically, please check this box: <input type="checkbox"/>	

3. Purpose

Provide a brief overview (1-3 paragraphs) of your study written for a general audience explaining the purpose of the research and theories and/or hypotheses to be tested. DO NOT copy/paste a lengthy literature review in this section. Do not overuse academic jargon. If the proposed prosed research has IRB approval from another institution or external agency, please provide this information and documentation. [See instructions at end of template for submitting additional documentation.]

Enter purpose of proposed research here.

4. Specific Aims of Proposed Research

Describe the specific aims, purpose, intent, and/or objectives of the proposed research. State the hypotheses to be tested, if applicable. Explain how the project meets the definition of research as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”

Enter aims of proposed research here.

5. Background and Significance of Proposed Research

If applicable, briefly describe the context for the proposed research, including relevant prior experience or results, gaps in current knowledge the proposed research will address, and any relevant preliminary data informing the proposed research.

Enter background of proposed research here.

6. Research Site(s)

Research site(s) refer to the geographic location where the research will take place, not to the people or institutions that you may be collaborating with. Knowing the location helps the IRB determine the local context of the research as well as if there are additional laws, regulations, and/or policies researchers need to adhere to. All research locations should be listed.

Enter research site(s) information here.

7. Conflict-of-Interest

Disclose in detail any current or prior relationship(s) or connection(s) the proposed research site(s) and/or participants for the IRB to evaluate any potential conflicts-of-interest or additional risks to participants that may exist associated with the proposed research.

Enter research site(s) information here.

8. Study Team

Describe the experience, resources, training, and qualifications for study team members who will conduct research activities on this study including the principal investigator, participant recruitment, data collection, or data analysis.

Enter study team information here.

9. Study Design and Procedures

Describe research design of the proposed study, the procedure(s) that will be conducted, including their general timeline. Briefly describe the type(s) of data to be collected, the time allocated to complete the study, and anticipated start and end dates for completion of the proposed research.

Enter study design and procedures here.

10. Participant Recruitment Method(s)

Describe the method(s) that will be used to recruit participants for the proposed research.

Enter participant recruitment methods here.

11. Consent Process for Participants

Describe the details of the participant consent process, including identification of who will be responsible for obtaining consent, and how consent will be obtained, e.g., written or oral consent.

Enter description of consent process here.

12. Participants and Target Population

Briefly describe the anticipated participants (e.g., gender, age, group membership, etc.) and target population (e.g., students, patients, employees, etc.) of the proposed research. Include your anticipated sample size (n) and justification that it will provide generalizable results (i.e., adequate statistical power or meaningful interpretation).

Enter description of participants here.

13. Inclusion and Exclusion Criteria

Describe the criteria that will be used to include or exclude potential participants from the study (e.g., age restrictions, health restrictions, group membership, etc.).

Enter all inclusion and exclusion criteria here.

14. Accessibility

If the proposed research specifically involves individuals whose participation may be limited by communication, language, or cognitive functioning describe the procedures that will be used to adequately obtain informed consent, permission or assent to participate.

Describe consent, permission, or assent procedures for special populations here.

15. Informed Consent Documentation

Include or attach sample copies of all documents or scripts that will be used to obtain informed consent or assent from research participants to this template. [See instructions at end of template for submitting additional documentation.]

16. HIPAA Privacy Protections

If protected health information (PHI) will be obtained or derived from a HIPAA-covered entity (e.g. a hospital or community health center), describe plans to obtain authorization to access protected

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

Will this proposed research obtain HIPAA protected information? Yes No

If **Yes**, describe plans for obtaining HIPAA authorization.

17. Family Educational Rights and Privacy (FERPA) Protection

FERPA is designed to protect the privacy of a student's education records at all public elementary and secondary schools and virtually all public and private postsecondary institutions (higher education). If FERPA-protected information will be obtained or derived from a FERPA-covered entity (e.g. school, college, or university), describe plans to obtain authorization to access protected educational information or provide a rationale for requesting a waiver of authorization. If requesting the latter, address why it is not practical to obtain an authorization and why the research cannot be conducted without obtaining protected educational information.

Will this proposed research obtain FERPA protected information? Yes No

If **Yes**, describe plans for obtaining FERPA authorization.

18. Vulnerable Populations

Include information regarding participant populations likely to be included in the proposed research that may be vulnerable to undue influence, coercion, or increased risk because of their belonging to that group.

Vulnerable populations could include, but are not limited to, children; pregnant women, human fetuses, neonates; prisoners; the elderly; the economically or educationally disadvantaged; employees or students of the investigator or sponsor; undocumented individuals; refugees; racial and/or ethnic minorities; illiterate or low-literacy individuals; military personnel; the terminally ill; cognitively impaired or mentally ill individuals; persons with a stigmatizing disease or condition (e.g. AIDS/HIV, mental illness, COVID-19). Note that the IRB must make additional regulatory findings for the inclusion of pregnant women, neonates, fetuses, children, and prisoners.

Will this proposed research specifically involve vulnerable populations? Yes No

If **Yes**, describe the characteristics of the population that may make it vulnerable to undue influence, coercion, or increased risk.

19. Risks

Describe any reasonably foreseeable risks, discomforts, or inconveniences to participants and the populations to which they may belong. Indicate the probability, magnitude, and duration of each risk.

Enter any foreseeable risks associated with participation in this proposed research.

20. COVID-19 Safeguards

Describe steps that will be taken to safeguard the research team and participants and reduce COVID-19 transmission risks if direct, in-person contact is required as part of the study procedure (e.g., required masking, social distancing, symptom evaluation, group size limits, etc.).

Enter relevant COVID-19-related safeguards for protecting research team and participants.

21. Benefits

Describe the potential benefits to individual participants, as well as to society, if any (Note: compensation is not a benefit and should not be addressed in this section.)

Enter the potential benefits of the proposed research here.

22. Participant Privacy

Describe the provisions implemented in the proposed research to protect participants' privacy.

Enter privacy provisions to be implemented here.

23. Data Confidentiality

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

Describe how the confidentiality of data obtained from participants will be maintained here.

24. Data or Statistical Analysis Plan

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

Provide a description of data analysis plan here.

25. Compensation for Research Participation

Some types of research involve a significant commitment from research participants in terms of time or effort, and investigators may wish to provide compensation. Describe any compensation that will be provided to study participants.

Enter description of compensation here.

26. Sharing Study Results

Describe the plan to share or disseminate results of the proposed study with individual participants and/or the participant group/community, if applicable. This includes both electronic or physical reports, theses, dissertations, papers, published articles, books, posters, and conference presentations.

Enter how the proposed results will be shared, disseminated, or published here.

27. External IRB Approval

If you have obtained IRB approval or exemption for the research described in this application from another institutional IRB, indicate this below and submit a copy of the letter or notification of approval or exemption along with this application. The CTX IRB requires submission of applications already approved or exempted by external IRBs, but may wish to consider external approval or exemption as part of its review process.

<input type="checkbox"/>	<i>I have obtained approval or exemption for the research described in this application from another IRB and have attached documentation of approval or exemption.</i>
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28. Unanticipated Events

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

- Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the research-related documents, such as the IRB approved research plan or Informed Consent document; and (b) the characteristics of the subject population being studied;
- Related or possibly related to participation in the research (in this guidance document, "possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research);
- Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social) than was previously known or recognized.

- I acknowledge that any unanticipated events that meet the above criteria will be reported promptly to the CTX IRB (check box required)*

CTX IRB PROPSAL TEMPLATE	<i>Enter full name of PI.</i>
COMPLETED BY:	<i>Click or tap to enter a date.</i>

Submitting Completed IRB Applications for Review

Step 1. Once your IRB Application is complete, save it to your local computer, network drive, or cloud storage space using the following format:

Year-XX-LastName_Initial_Application_MonthDay.docx

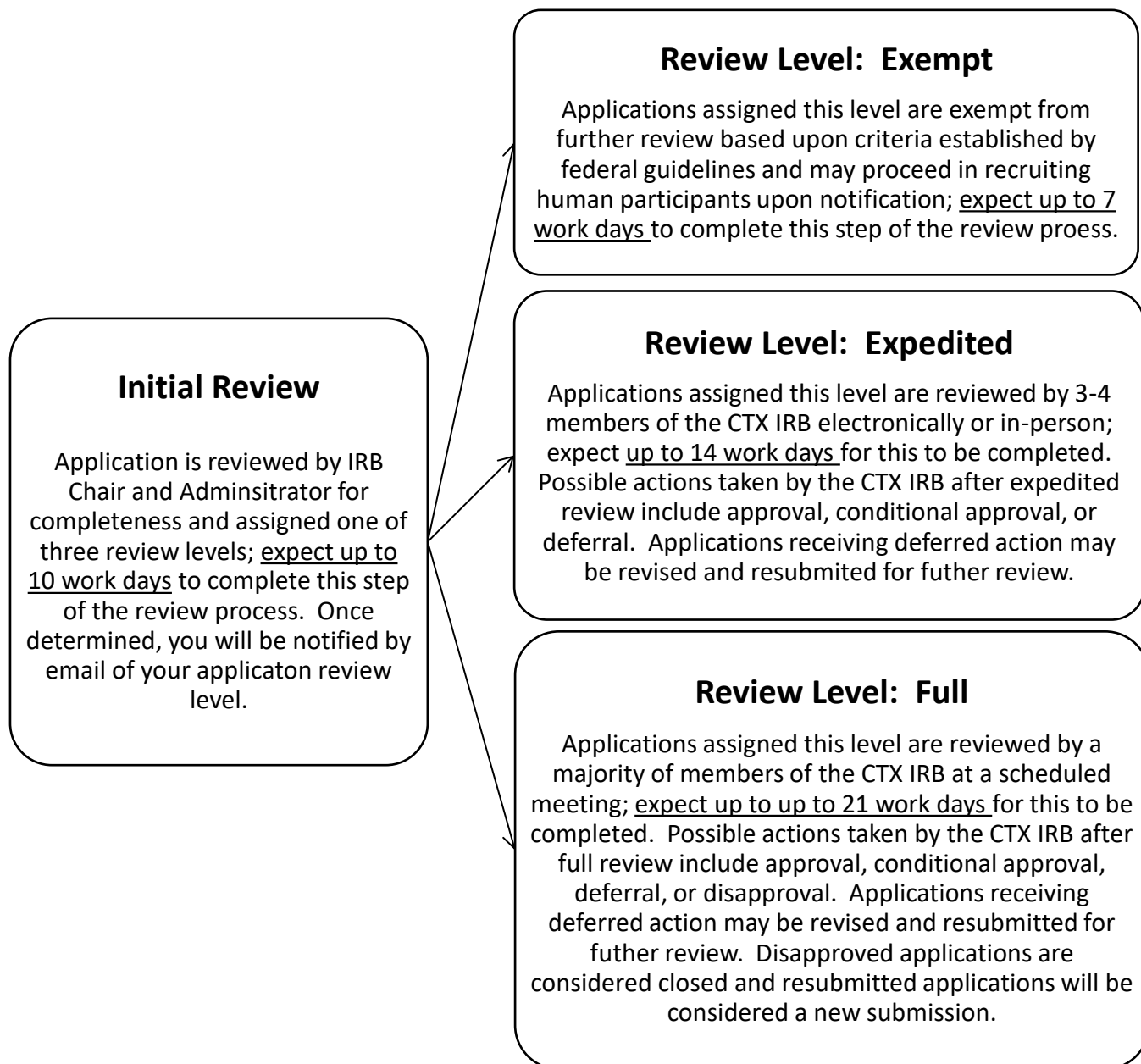
Example: **2019-XX-Smith_Initial_Application_July1.docx**

Step 2. Combine you completed IRB application and all supporting documentation (e.g., sample of Informed Consent, copies of survey items or interview questions, etc.) into a single electronic file (PDF is preferred).

Step 3. Attach and email the **completed IRB Application with supporting materials**

- to irb@concordia.edu
- please include subject line “**CTX IRB Application Submission**”

Overview of CTX IRB Applications Review Process



*Note that the time lengths provided above are targets the CTX IRB works to meet; however, times required to complete review may vary substantially due to the number of applications actively under review as well as revisions or edits made to the initial application. Changes made by the PI to an application under review, or those requested by the CTX IRB, will likely lengthen the review process. The CTX IRB recommends the submission of completed applications **no fewer than 60 days** before the recruitments of participants is planned to begin.*