



Institutional Review Board
Guidelines for Submission of Ethical Review Protocols
Researchers Manual
Revised 2020

Introduction

The City University of Seattle ***Institutional Review Board Guidelines for Submission of Ethics Review Protocols*** is a resource to assist you in the completion of your Ethics Review Protocol. This researcher's manual will provide you with the description of the submission process, definition of ethical research concepts and a detailed description of the required components of each Ethics Review Protocol question.

The main role of the Institutional Review Board (IRB) is the review of all human participant research conducted at City University of Seattle to ensure that the research fulfills the requirements of the federal regulations. In the United States the regulations are under the Department of Health and Human Services, Office for Human Research Protection, Code of Federal Regulations Title 45 Part 46. In Canada the regulations are under Government of Canada, Panel on Research Ethics, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2; 2014).

City University of Seattle is committed to protecting the interests of research participants, as well as, ensuring the ethical conduct of human participant research.

As a researcher you are responsible for ensuring:

- That your research participants meet selection and eligibility requirements as defined by the research study.
- The research is approved by the IRB and conducted according your Ethical Review Protocol.
- That no recruitment of participants or collection of data begins prior to IRB approval.
- Participants' informed consent is appropriately obtained.
- The study is properly designed and scientifically valid.

Your Ethical Review Protocol declares that you understand and have adhered to the core principles for responsible research involving human research participants (Belmont Report):

- Respect for Persons: Informed Consent of participants
- Beneficence: Minimization of risks to participants
- Justice: Equitable selection of participants and distribution of benefits

Categories/Levels of Review

The IRB are faculty of City University of Seattle who are committed to providing you with expert, ongoing guidance for all ethical issues that are relevant to your research.

When you are uncertain about an ethical issue, don't hesitate to contact the IRB. If you require assistance in completion of the Ethics Review Protocol please contact the IRB (irb@cityu.edu) and request a consultation.

The IRB reviews research proposals according to the following criteria:

- Are the risks to participants minimized?
- Are the risks reasonable in relation to anticipated benefits?
- Is the selection of participants equitable?
- Is the study properly designed and scientifically valid?

Your study will undergo a preliminary review which consists of the following: (1) a review of the protocol to determine if there is missing information or information that requires further clarification, (2) a review of the consent and information forms to see if they contain the required elements set forth in 45 CFR 46.116 and 117, (3) a review of the recruitment procedures, (4) determination of the appropriate approval category.

Incomplete proposals will be returned to the researcher for resubmission.

There are three levels of IRB review:

Exempt

Only the IRB Chair or designated IRB member, may determine if a protocol is granted exempt status under the six categories described in 45 CFR 46.101(b). If the research fits into an exempt category and is low risk to participants, it will not need to go through expedited or full board review. The IRB Chair or designated IRB member, may determine that the research does not qualify as exempt in which case the research is forwarded for expedited or full-board review. Exempt research must be minimal risk and not expose participating participants to psychological, social or physical risks.

Exempt research does not mean that the research does not require IRB approval. It means that the research is exempt from continuing IRB review and approval. However, all modifications to a study that have been certified exempt must be submitted to the IRB for prospective review and certification of exemption prior to implementation.

Expedited

Expedited research must be no more than minimal risk. As defined in the federal regulations, "minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45 CFR 46.102(i)). Only the IRB Chair or an IRB member may determine if a protocol is granted expedited status under seven of the nine categories as published in the federal register as 45 CFR 46.110 and 21 CFR 56.110. Categories 8 and 9 do not pertain to initial review.

Only the Chair or an IRB member can make one of the following three determinations in regard to the protocol and consent forms:

- **APPROVED:** IRB approval indicates that the IRB reviewer(s) has concluded that the research and consent forms meet the federal criteria for approval.
- **MODIFICATIONS REQUIRED IN ORDER TO SECURE APPROVAL:** The IRB reviewer(s) withhold approval pending submission of revisions/additional information.
- **FULL REVIEW REQUIRED:** The IRB reviewer(s) may determine that the protocol requires full review by the IRB at a convened meeting.

Full Board Review

Proposed research that does not qualify for either exempt status or expedited review will be sent to the convened board for review.

Full Board reviews are conducted in accord with the criteria set forth in 45 CFR 46.111 and 21 CFR 56.111. The Board can make one of the following four determinations in regard to the protocol and consent forms:

- **APPROVED: IRB** approval indicates that the Board has concluded that the research and consent forms meet the federal criteria for approval.
- **MODIFICATIONS REQUIRED IN ORDER TO SECURE APPROVAL:** A vote for amendments required indicates the IRB has given the meeting Chair the authority to approve the minor revisions. The IRB withholds approval pending submission of minor revisions/additional information.
- **DEFERRED:** The IRB withholds approval pending submission of major revisions / additional information. For some studies, the IRB may appoint one or more members of the IRB to discuss the reasons with the investigator. Once the revisions have been made by the researcher the revised protocol is added to the next IRB meeting agenda for review.
- **DISAPPROVED:** Disapproval of a protocol usually occurs when the IRB determines that the risk of the procedures outweighs any benefit to be gained or if the proposed research does not meet the federal criteria for IRB approval.

To help evaluate the definition of the levels of IRB review, please refer to the OHRP decision charts:

<http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html>

Timelines for IRB Review

The length of time a study will take to be approved and a certificate of approval issued depends on the type or level of review required.

- Completeness of application
- Quality of application
- Timeliness of investigator response to requests for clarification and changes

Exempt Review (from date of application submission): 1 weeks

Expedited Review (from date of application submission): 2 weeks

Full Board Review (Ethical Review Protocols that require a full board review are reviewed at the monthly IRB meeting). Note: The outcome of the review will be sent to the researcher within a week of the IRB board meeting it was reviewed.

At any point in your research that you believe you are no longer compliant with the approved ethical requirements of your research, it is important to be proactive and contact the IRB. Your IRB is available to assist you from submission to termination of your research. The IRB's approach to addressing such issues is a nonjudgmental one, focusing instead on finding the most effective strategy to address the issue and minimize harm to research participants.

General Submission Guidelines

Prior to submission of the Ethics Protocol the researcher is responsible (Note: that for student research submissions the student's Faculty supervisor is responsible) to confirm to confirm that:

- Submissions must be on the **City University of Seattle IRB Ethical Review Protocol** form and are required to be electronic, addressed to: IRB@CityU.edu.
- Protocol submissions must be submitted to the IRB in a PDF named file in the following format: *Title the submitted document using only the last name of the researcher (e.g., "Smith.pdf"); if the submission is a resubmission, title the document as, for example "Smith Resubmission.pdf";* Any necessary additional documents submitted may be scanned as described below.
- Student submissions must be emailed to the IRB@CityU.edu by the Faculty supervisor with copy to the student;
- Faculty research submissions are emailed directly to IRB@CityU.edu by the faculty member;
- Include the date that the researcher has satisfactorily completed the ethics module on the top of the *Ethical Review Protocol*;
- To protect student and faculty confidentiality, all communication with IRB must be sent using only City University of Seattle email addresses. **Protocols received from or copied to email addresses other than City University of Seattle will be returned without review;**
- Submit only a final *Ethical Review Protocol* for review, not a version showing edits;
- When completing the protocol, answer fully each question; **incomplete answers or incomplete or missing attachments will result in the protocol being returned for resubmission.**

Your first step prior to submission of the Ethical Review Protocol is completion of the Research Ethics Training on blackboard.

Prior to submitting an *Ethical Review Protocol*, the student or faculty member must satisfactorily complete the City University of Seattle Ethics Module available on City University of Seattle Blackboard. Answering the module questions with a score of 70% or better constitutes “satisfactory completion”. Faculty researchers request enrollment via the IRB email (irb@cityu.edu). Faculty advisors request enrollment of their student(s) via the IRB email. Upon successful completion of the Ethics Training modules an email confirmation of completion of ethics training will be issued. Confirmation of completion of ethics training emails should be received approximately one week following completion of the ethics training modules.

Upon IRB approval of your Ethical Review Protocol you will be issued an IRB Certificate of Approval which you are required to keep for your records.

The following will assist you in completing your Ethics Review Protocol. You will find a detailed description of the required components of each section of the Ethical Review Protocol and each question within the Ethics Review Protocol document.

**Institutional Review Board
Ethical Review Protocol**

City University of Seattle Ethics Training completed on this date: _____

Student researchers, faculty researchers and student faculty advisors are required to complete City University of Seattle ethics training prior to submission of their or their student's Ethics Review Protocol. Faculty researchers request enrollment via the IRB email. Faculty advisors request enrollment of their student(s) via the IRB email.

Upon successful completion of the Ethics Training modules an email confirmation to completion of ethics training will be issued.

1. Title of Project _____

Project title should be congruent with the stated research question. That is, the identified variables and concepts stated in the research question are clearly stated in the title of the project.

TIP: The title summarizes the main idea or ideas of your study. A good title contains the fewest possible words needed to adequately describe the contents and/or purpose of your research paper.

2. For Faculty Researcher(s)

Name:
Department/Division
Telephone
City U E-mail

City University of Seattle email is required.

3. For Student Researcher

Name
Faculty Supervisor
Department/Division
Degree sought
Telephone
City U E-mail student:
City U E-mail Faculty Advisor/Chair:

City University of Seattle advisor email is required.

4. Project Coordinator: _____

If your study has a research team this would be the identified principle investigator for the study.

5. Sponsor (if any):

If the study has research funding or is being conducted with another organization and that organization is providing resources or funding state name and contact information.

Fill in this protocol completely, including approved consent form(s) located on the IRB web page. Incomplete protocols will be returned for resubmission.

6. Abstract/Lay Summary

- Research question

This is a statement of your research problem. A research question is the main organizing principle guiding the analysis of the study. That is, the problem under investigation. The research question contains the language of inquiry of your stated research methodology. In quantitative designs the research questions is stated as hypotheses to be tested. In qualitative designs the research question is stated as “how’, or, “what” and uses qualitative words, e.g., explore, understand or discover.

A research question is a statement about an area of concern, a condition to be improved upon, a difficulty to be eliminated, or a troubling question that exists in scholarly literature, in theory, or in practice and that points to the need for meaningful understanding and deliberate investigation.

- Basis for the question including supporting quote (s) from research

Briefly summarize and synthesize your literature review to provide justification for the study. This places your study in the context of its contribution to understanding the research problem being studied. That is, you should include your primary references (in-text citations) and quotations from the literature that directly supports the purpose of your study. This includes references of current research you are building on and research on any specific concepts you are investigating in your research (maximum 300 wds).

Discuss the anticipated results and potential risks to the participants. Describe the significance of the research including potential benefit for individual participants or society at large.

- Purpose of the study

The purpose statement should provide a specific and accurate synopsis of the overall purpose of the study. Why is this an important area of study?

Try to incorporate a sentence that begins with “The purpose of this study is . . .”. Clearly identify the goal of the study in one precise sentence.

- Methodology

This is the foundation that demonstrates your study is scientifically and scholarly valid and that you have employed procedures that are consistent with sound research design.

The methods section describes the rationale for the application of specific procedures or techniques used to identify, select, and analyze information applied to understanding the research problem, thereby, allowing the reader to critically evaluate a study’s overall validity and reliability for quantitative studies and dependability, trustworthiness and transferability for qualitative studies. The methodology section of a research paper answers two main questions: How will the data be collected or generated? And, how will it be analyzed? The research design should be identified and should be appropriate to answer the research question(s) under study. Quantitative studies should identify the

statistical analysis being utilized. The researcher provides a clear definition of the research model, for example, qualitative, quantitative, action research or auto-ethnographic supported with the definition from the literature and reference to an author that is an expert in that methodology.

If you are conducting self-reflective research, such as an auto-ethnography or an autobiographical study identify and explain your research method. For self-reflective research, the main ethical concern is that individuals may be identified within the research work without their knowledge and/or consent. In self-reflective research, the IRB recommends you anticipate that in your research you may include information about a person that may identify him/her and to include a consent form to cover this situation should it arise. You should anticipate the possibility that you may directly or indirectly provide information about an identifiable person (e.g., a spouse, a parent, etc). To minimize harm to such individuals, you should obtain their consent in advance and allow them to view sections of the research report that include information about them, with permission to ask that sections they perceive as harmful to them be removed.

Minimal Risk per governmental regulation is defined as research that “poses no more risk to the human participants than that encountered in ordinary daily life”.

Check this box if faculty supervisor or faculty researcher believes this research constitutes minimal risk according to the above definition. The IRB will make final determination regarding the level of risk.

To satisfy the definition of minimal risk, the estimate of the anticipated harms and discomforts of the research for the proposed study population may not be greater than an estimate of "the harms and discomforts ordinarily encountered in daily life or during the performance of routine medical and psychological examinations or tests."

While the harms and discomforts ordinarily encountered differ widely among individuals and individual populations, an ethically meaningful notion of "harms and discomforts ordinarily encountered" should reflect "background risks" that are familiar and part of the routine experience of life for "the average person" in the "general population." It should not be based on those ordinarily encountered in the daily lives of the proposed participants of the research or any specific population.

In summary, minimal risk should be applied in manner that recognizes that risks are procedure-specific and population-dependent, but that the notion of "acceptably-low" risk is fixed. When the harms and discomforts of the proposed research as they are anticipated to impact the study participants are judged to fall below this acceptably-low risk threshold, the research is said to be "minimal risk."

7. Description of participants (include number, ages or age range, location, and special characteristics to include gender and ethnicity).

This is a general description of the population that you are recruiting your participants from. Include in your description the inclusion and exclusion criteria for participants.

8. If research is conducted through an agency or institution, complete the CityU Organizational Consent form to include the names, contact information, and contact persons for any institutions or agencies. If outside institution's consent form is used and attached, researcher is responsible to assure that all provisions are in concert with CityU approved Research Participant Informed Consent form. Submit completed organizational consent as " 'Student Name' Attachment A".

Some organizations may require IRB approval prior to giving organizational consent. If this is the case provide a statement indicating this. Once attained the Organization Consent form can be forwarded to the IRB as an appendix to the Ethics Review Protocol.

9. **Recruitment Phase** (Do not include your process of acquiring informed consent): Describe how participants will be identified or recruited. Include in your answer the exact wording of all recruitment notices, advertisement and/or scripts used to recruit participants. If the human participants include minors or vulnerable adults, include the script used to advise them of the study.

Describe how you will gain access to names, addresses, telephone numbers, or email addresses of potential participants. Provide a statement of the researcher's relationship, if any, to the participants (e.g., teacher, supervisor, etc.). Whenever the person doing the recruiting is in a position of authority over potential research participants, special care needs to be taken. For example, whenever the relationship between the researcher and research participant is such that coercion could be perceived to be a factor (e.g., when the researcher is also a caregiver or teacher), non-coercive means for inviting participation should be used. Examples of non-coercive methods include recruitment by a third person, posting notices to invite volunteers from the entire group concerned (e.g., the whole student body, rather than a specific class, or all employees of the institution), and procedures whereby the teacher/researcher is precluded from knowing which students have declined to participate in the research. Avoid the use of terminology that is considered coercive, i.e., with children avoid the use of "need your help", instead, use "asks you to participate".

Recruitment notices, advertisements and/or scripts need to include the component of informed consent as described in the City University of Seattle Participant Informed Consent, i.e., participation is voluntary, you have the right to withdraw at any point without negative consequences and your participation is confidential.

10. **Informed Consent Phase** (do include recruitment process or information): Describe your informed consent process. Include in your answer the exact wording to be used in your consent information letters, emails, telephone scripts to participants and parents/guardians, oral scripts and/or email scripts.

Include completed approved City U Informed Consent Form located on the IRB web page.

You need to state your role/position and the institution and program. Describe the study in enough detail that the participant will understand the purpose of the study. Include the component of informed consent as described in the City University of Seattle Participant Informed Consent form, ie, participation is voluntary, you have the right to withdraw at any point without negative consequences and your participation is confidential. Lastly, include how the participant can initiate contact with you if

they have questions about the research or are considering volunteering to participate.

For student-teacher research requiring parental consent for a minor to participate, include in your letter to parents an understandable description of the study including purpose and methodology. Indicate risks if any and who to contact if their child has any difficulties as a result of their participation, who to contact with complaints (Program Director). Include enough research description so parental consent is informed, i.e. they know exactly what they are consenting to. Include that study is being done in partial requirements of an advanced degree (name degree). This letter must meet the requirements of voluntary, informed consent. Ensure that it is clear that participation is voluntary, that they have the right to withdraw at any time without any negative consequences, that information about them will be kept confidential and how, and that they will be anonymous if the data collection ensures anonymity.

Canadian studies using USA online survey companies or using Canadian online survey companies with their servers in the USA need to inform participants of US freedom Act. That is, the researcher needs to add the following to the Informed Consent form:

Please be advised that information about you that is gathered for this research study uses an online program located in the U.S. or a program that can be accessed from the US (FluidSurveys). As such, there is a possibility that information about you may be accessed without your knowledge or consent by the US government in compliance with the US Freedom Act.

Consent is a process not a form.

For consent to be informed, prospective participants shall be given adequate time and opportunity to assimilate the information provided, pose any questions they may have, and discuss and consider whether they will participate.

The consent process may include multiple steps:

Initial meeting: You will meet with the participant, provide a copy of the consent form to them, and go over the items on the form. In addition, take more time to explain the “What you will do” section in the study so that the participant knows exactly what is involved.

Time to digest: Give the participant some time to think about their participation in a non-pressured environment. This may be as simple as leaving the room for a moment so that they can go over the document in private. For studies that involve greater risk to the subject, it may be appropriate for a participant to take the consent document home to think about it and perhaps talk it over with family and friends before agreeing to participate.

Question/ answer period: Before a participant signs the consent form, give them a chance to ask questions about the study and ask for clarification. Sometimes participants may be intimidated to ask questions so take time to assess their understanding and make sure that they know what they are consenting to. For studies that involve greater risk, it may be appropriate to provide them with a questionnaire about the study or ask them to explain the study back to you to assess their readiness to participate.

Ongoing consent: The participant has the right to refuse participation at any time, regardless of whether he or she has already signed the consent form. The researcher should continually ensure that the participant is freely and voluntarily consenting to all study tasks. This may require observation for signs of hesitation or distress and asking permission to continue before beginning study tasks that may be challenging or aversive. At these times, the participant should be told, “Remember, you have the right to stop the study at any time or to skip portions of the study if you would prefer not to do them.”

- Be sure there is no data collected about third persons without their informed consent. Third person participants are individuals who can be identified in the research content by nature of their relationship with the researcher or other participants. Even if they have not been formally identified as research participants by the researcher they are entitled to privacy and confidentiality. The researcher would need to seek and secure informed consent for disclosures about third persons. Qualitative researcher that includes the lived experience of participants and/or the lived experience of the researcher, needs to ensure that any reference to others is anonymous and that informed consent has been obtained.
- Fill out the City University of Seattle informed consent form as it will be presented to potential participants, including all identifying information at the top and bottom, brief description and purpose of the study, and the type(s) of research participation activities
- Use only the City University of Seattle-approved Research Participant Informed Consent form for those 18 and over;
- Use only the approved Research Informed Consent for Parent/Legal Guardian of Participant for minors and adults with legal guardians who participate in research;
- Use only the City University of Seattle approved Research Participant Informed Consent for Internet Survey and Internet Data Collection. These forms are at the end of the *Ethical Review Protocol*.

11. What data collection tools will be used and how will they be administered? Include, as an attachment, an exact replica of data collection tools, e.g.: written questionnaires, interview questions, observation schedules and confirm the source and/or copyright permission for any collection tools from outside sources. Summarize the attachments here.

Attach the exact replica of the data collection tool as an appendix document to your Ethical Review Protocol submission. This includes structured or semi-structured questions developed by the researcher to collect data.

Data collection instruments that are not in the public domain require copy right permission from the author. Researchers need to include a copy of the copy right permission to use the data collection instrument in their research

All on-line survey research must make use of a secure on-line site. Provide a link to the survey organizations statement and/or policy of data protection, i.e., confidentiality.

- Clearly identify and describe the online data collection tool and provide a hyperlink to the survey tool or include the final survey as it will be posted on the internet.

- Clearly delineate the participant population (as in other forms of research data collection);
- Use only the City University of Seattle Research Participant Informed Consent for Internet Survey and Internet Data Collection Form as approved (i.e. not modified by the researcher or the online data collection tool) as the introduction informed consent to your survey.
- For all online surveys/questionnaires, include an option to not answer each question and an option to withdraw at the end of each survey page.
- If recruitment was by email, maintain email addresses of all online research participants and all online data collection according to City University of Seattle's storage and destruction guidelines for all human research data.

12. Will participants receive inducements or rewards? Give details.

Incentives are anything offered to participants, monetary or otherwise, for participation in research. If you plan to offer incentives to research participants, the IRB requires a description of the incentives, including its monetary value, or estimated monetary value, and your rationale for its use. It is important to consider if the amount of the incentive is such that the participants could consider it a form of inducement and therefore inhibiting voluntary participation. If an incentive is being offered participants must be made aware that if they begin the research but then withdraw, they will still receive the incentive.

13. How will the confidentiality of each participant be protected?

Consider the following definitions in your description of the confidentiality process for your study.

Anonymity: No one, including the principal investigator, is able to associate responses or other data with the individual participants. Note that this means that the researcher is not aware of the identity of the participants (e.g., submission of an anonymous survey).

Confidentiality: refers to a condition in which the researcher knows the identity of the research subject, but takes, steps to protect the identity from being discovered by others.

Participants have the right to a full disclosure of how their data will be kept secure and protected. This includes where and under what conditions it will be stored, who will have access to the data and whether those with access to the data have signed a confidentiality agreement with the researcher or not (e.g., transcribers). When confidentiality is to be protected, research data must be stored in a secure manner. This may include removing specific identifiers (e.g., contact information, combination of social factors which would make it easy to identify the participants) and using codes or pseudonyms. You should also take care to prevent data being released in a form that would permit identification of participants.

The following are examples of practices that may be implemented to increase the level of confidentiality:

- Use study codes on data documents (e.g., completed questionnaire) instead of recording identifying information and keep a separate document that links the study code to participants' identifying information locked in a separate location and restrict access to this document (e.g., only allowing primary investigators access);
- Encrypt identifiable data;

- Remove face sheets containing identifiers (e.g., names and addresses) from survey instruments containing data after receiving from study participants;
- Properly dispose, destroy, or delete study data / documents;
- Limit access to identifiable information;
- Securely store data documents within locked locations; and/or
- Assign security codes/encryption to computerized records.

If there will be research assistants of any kind, indicate who they are and their qualifications as assistants. Indicate that they will sign the IRB-approved Statement of Confidentiality.

14. How and where will data be stored and for how long?

- Electronic data storage

External drives (laptops, usb drives and portable drives) are required to be both password protected and files encrypted. Do not use N/A provide a declarative statement of how and where data will be stored.

- Cloud based data storage

As a general rule, research data should not be stored on third-party cloud service providers given the legal (who owns the data), breach of confidentiality (cloud data is stored anywhere in the world) consequences should the information being stored or processed be lost, stolen, or seen by unauthorized persons or organizations.

Research data that contains sensitive personal, non-public information (e.g. addresses, financial information, health information, or confidential educational records) must be stored on systems that are designed with security in mind and which typically use access control and encryption to prevent unauthorized access.

At this time City u does not have a contractual agreement with any cloud service therefore storing contains sensitive personal, non-public information (e.g. addresses, financial information, health information, or confidential educational records) data on cloud services is not approved by the IRB.

A dataset may be stored online (e.g. on a cloud storage system) only if it does not contain identifiable information (anonymized) and has first been encrypted so that, should there be a security breach, the data cannot be linked back to Individual participants. In order to be approved the researcher needs to provide the IRB with: (1) data storage location; (2) backup policy; (3) deletion policy; (4) rights that the cloud provider claims for the data; (5) isolation guarantees that the provider offers.

- Paper data storage Other data storage, e.g. audiotapes, videotapes

Do not use N/A provide a declarative statement of how and where data will be stored.

15. City University of Seattle requires data to be securely for a period of 5 years then permanently destroyed:

- Describe the permanent destruction methods for each data item:

16. Describe any possible risk or distress and safeguards in place to address risk or distress including access to counseling, with attention to vulnerable populations who may be participating in this research.

Participants have the right to be fully informed of any risks that may be associated with their involvement in the study. Risks are rarely, if ever, absolute; they are based on probabilities.

Examples of Risks: Psychological/emotional: increased sadness, anxiety, fear, depression, loss of privacy and re-traumatization, embarrassment, feeling demeaned Social: loss of status, respect, alienation, changes in relationship, social stigma attached to being involved in research on issues such as substance misuse, anorexia, etc. Physical: falls, pain, scarring, infection, physical violence Economic: costs of being involved in a study (child care, travel time, days off work), threats of job loss if participation becomes known.

Faculty Advisors/ Chairs need to confirm the following and sign (digitally) the Ethical Review Protocol.

The research Supervisor/advisor or Chair has confirmed the scientific and scholarly validity of the proposed research study in the following areas:

1. The research procedures are the least risky procedures that can be performed consistent with sound research design.
2. The research is likely to achieve its aims.
3. The proposed research is of sufficient importance to justify the risks entailed.
4. There are adequate resources to complete this study.

How to Successfully Prepare your Ethical Review Protocol for Submission: Step-by-Step Guide

Step 1: Register in the IRB Ethics Training course.

IRB Ethics Training registration is requested for student researchers by faculty advisors or course instructors who will send an email request that includes the student's CityU.edu email address to the IRB at IRB@cityu.edu. Faculty researchers send an email request to be registered in the IRB Ethics Training directly.

Step 2: Complete the Ethics Training with a minimum 70% passing grade.

Upon achieving the minimal passing grade of 70% an email Confirmation of Completion of Ethics Training will be sent. Students are responsible for forwarding the confirmation email to their respective faculty advisor or course instructor. A failing grade of less than 70 % requires the student to notify their course instructor or faculty advisor to get permission for a retest. The faculty advisor will email the IRB to have the Ethics Training modules reset.

Step 3. Review the IRB Policies and Procedure Handbook on the IRB web page.

Step 4. Download the Ethical Review Protocol Form from the IRB web page.

In order to enter content accurately into the form, first download the form to your personal computer, then save the form to your personal computer, open the saved form from your personal computer, and then

enter your content. You will know the Ethical Review Protocol PDF form is properly downloaded as you will see pop-up directions for each question.

Step 5. Before submitting your Ethical Review Protocol for IRB review, validate the following items are complete

- Check spelling and grammar.
- Review each question's pop-up directions to ensure you have included all the required information for each question.
- Attach only the approved City University of Seattle Informed Consent Forms directly from the IRB web page.
- If you are storing research data on an external drive (laptop/usb/flashdrive) you are required to have the data both password protected and encrypted. State this specifically in question #14.
- If you are storing your research data on a personal desktop PC then the research data is required to be password protected. State this specifically in question #14.
- Faculty advisors are required to sign the Ethical Review Protocols submitted by their students.

- Indicate possible risks of research participation even if they seem unlikely and how they will be addressed (e.g., stopping the participant's participation, taking a break and/or referrals to local sliding-fee scale mental health agencies or school counselors).
- List referrals that will be given to participants or parents/legal guardians.
- As part of seeking informed consent, all possible risks must be clearly made known to all research participants as well as parents and legal guardians where their consent is required.

Submission of this form electronically signifies that the researcher takes responsibility for the accuracy of the contents of this submission and that student researcher's Supervisor approves of the submission, in an equivalent manner to an original signature.

Student's research supervisor/advisor is responsible to ensure, confirm and accepts responsibility that the information in the submitted Ethics Review Protocol adheres to ethics of research with human participants as detailed in the respective legislation. (DHHP in the US/Tri council 2 in Canada). In addition, for student research, the faculty advisor named on the IRB Ethics Review Proposal is responsible for ensuring the scientific and scholarly validity of the proposed research. That is:

- Will the investigator use procedures that are consistent with sound research design?
- Will the investigator use procedures that do not unnecessarily expose participants to risk?
- Will the research design permit the investigator to answer the research question?
- What is the importance of the knowledge expected to result from the research?

The research Supervisor/advisor is responsible for reviewing the scientific and scholarly validity of the proposed research study. As research supervisor/advisor I confirm the following:

1. The research procedures are the least risky procedures that can be performed consistent with sound research design. Yes _____ No _____
2. The research is likely to achieve its aims. Yes _____ No _____
3. The proposed research is of sufficient importance to justify the risks entailed. Yes ___ No _____
4. There are adequate resources to complete this study. Yes _____ No _____

Name of Researcher

/Student Researcher Research Supervisor/Advisor Date