

IRB Amendment WORD Template

Please do NOT submit this document as part of your ONLINE PROPOSAL. This version in WORD is provided for classroom and draft use.

Page 1 Cover Page

- **Please complete the following form for ALL AMMENDMENT REQUSTS for previously APPROVED projects. Please note this form should be used even if your ORIGINAL IRB APPROVAL was completed on paper. The form will guide you through the relevant sections depending on the nature of your project. If you have additional information to add and cannot locate a space, please indicate this in the "Additional Information" Box at the end. Please contact Anne Stuart, IRB Chair at anne.stuart@aic.edu with any questions.**

- **My original IRB Approval was completed: ***

Checkboxes:

- On paper
- Electronically through this system

- **Please indicate the IRB Approval Number for this project: ***

Text Box

- **Please indicate the Approval date for this project: ***

Text Box

- **Research Project Title ***

Text Box

Page 2 Investigator Information

- **Date of Form Submission ***

Text Box

- **Principle Investigator Name ***

Text Box

- **Principle Investigator Department/Program/Division ***

Text Box

- **PI Level: ***

Select:

- Faculty
- Student
- Staff
- Other

- **PI AIC Email Address: ***

Text Box

- **PI Phone: ***

Text Box

- **Where did you complete Human Subjects Research Protection Training? ***

Select:

- CITI
- TRi State -Canadian Program
- OHRP
- NIH
- Other _____
- I have not completed my training yet

- **PI Research Ethics Training Certificate Number: ***

Text Box

- **PI Research Ethics Training Expiration Date: :** (Note: If your certificate does not include an expiration date, indicate the date 3 years from your training date) *

Text Box

- **Are there additional co-investigators, research staff, or student assistants involved in the project? Please note students MUST list their Research Advisor/mentor as an Investigator ***

Select:

- No
- Yes

- **Please indicate which of the following criteria apply to your proposed research: ***

Checkboxes –

- The study will include children, prisoners, and/or pregnant women.,
- The study data will obtain information or bio-specimens from the individual or intervention, and uses, studies, or analyzes that information.,
- The study data will obtain, use, study, analyze or generate information that includes identifiable private information or identifiable bio-specimens.,
- The research is conducted in established or commonly accepted educational settings involving normal educational practices,
- The research involves educational tests, survey procedures, interview procedures, or observation of public behavior.,
- The research involves benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses or audiovisual recording if the subject prospectively agrees to the intervention and information being collected.,
- The study is secondary research for which consent is not required.,
- Participation in the research poses no more than minimal risk to the subjects.,
- This study has been approved by another institution's IRB. I am submitting to AIC because I am a faculty, student or staff of AIC involved in the research.

Submission Type and Rationale: (Please visit Human Subjects Regulations Decision Chart (<https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html#c2>) before checking box. *

Radio Button: Button-

- Full Board Review
- Expedited Review
- Exempt Review

Page 3: Amendment Request

- **Please indicate why you are requesting a Project Amendment at this time (Check more than one if needed): ***

Checkboxes :

- Adding Investigator(s)/staff to the project
- Removing Investigators/staff from the project
- Changing the Recruitment Process
- Changing the Inclusion criteria or number of participants
- Changing the Study Protocol
- Requesting extension of approval dates
- Adding/removing study sites
- Adding/changing consent form
- New information indicates that risks to subjects have changed
- A new Conflict of Interest is present

- **Does your amendment request involve another institution's IRB? ***

Checkboxes:

- No
- Yes (Please provide name of Institution)

Page 4: Change in Project Approval Period (Includes extensions) (Conditional)

- **Describe why you are requesting a change in approval dates: ***

Text Area

- **When do you expect the study to be completed? ***

Text Box

Page 5: Additional Investigators (Complete for every investigator) (Conditional)

- **Investigator Name ***

Text Box

- **Investigator Department/Program/Division ***

Text Box

- **Investigator Level ***

Radio Button:

- Faculty
- Student
- Staff
- Other

- **Investigator Email ***

Text Box

- **Investigator Phone Number ***

Text Box

- **Where did you complete your Human Subjects Protection Training? ***

Select:

- CITI
- TRi State -Canadian Program
- OHRP
- NIH
- Other
- I have not completed my training

- **Investigator Research Ethics Training Certificate Number: ***

Text Box

- **Investigator Research Ethics Training Expiration Date: ***

Text Box

- **Are there additional co-investigators, research staff, or student assistants involved in the project? ***

Radio Button:

- Additional investigators are involved in the project
 - Students are involved in the project but are not investigators
 - No additional personnel are involved in the project
- **If there are additional investigators, please upload one file that includes the above information for all additional investigators here. Please note student assistant information will be entered on a separate page.**

File Upload

Page 6: Investigators/staff to be removed *(Conditional)*

- **Please list the name of each investigator/staff that will be removed from your protocol: ***

Text Area

Page 7: Student Involvement *(Conditional)*

- **Student Name ***

Text Box

- **Student Role ***

Checkboxes:

- Data Collection
- Data Analysis
- Literature Review
- Writing Report
- Administrative Activities
- Other

- **If there are additional students involved in the project, please upload one file that includes the above information for all additional students here. Please note investigator information is entered on a separate page.**

File Upload

Page 8: Conflict of Interest *(Conditional)*

- **Does a potential conflict of interest exist for the Principal Investigator or any of the research team members with this study? ***

Radio Button:

- No
- Yes (Please list each person and explain)

Page 9: Exempt/Expedited Confirmation *(Conditional)*

- **Indicate which of the following apply to your study (Please select all that apply): ***

Checkboxes:

- The information will be recorded in a way that subjects cannot be readily identified
 - Any disclosure of identifiable information outside of the research setting would not place the subjects at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability or reputation
 - The researcher records the information and the subjects can be readily identified. Please describe the information that will be identifiable
 - The research does not include children
 - None of the above apply to this study
- **Please describe the possible risks associated with participation in this study. ***

Text Area

- **The research has been approved by another institution's IRB. Please upload a copy of the IRB approval form which must include the Institution name, dates of approval and approval number.**

File Upload

Page 10: Full Description of Risks and Measures to Minimize Risks *(Conditional)*

- **Briefly describe the change in risk and then complete the rest of the questions: ***

Text Box

- **Identify which of the following risks might subjects encounter through this study: ***

Checkboxes:

- Risk of psychosocial harm (e.g., emotional distress, embarrassment, breach of confidentiality)
- Risk of economic harm (e.g., loss of employment, loss of professional standing within the community)
- Risk of legal jeopardy (e.g., disclosure of illegal activity or negligence)
- Risk of pain and/or physical injury.

- **Describe what will be done to minimize each risk. Identify and describe the procedures for follow-up, when necessary, such as medical or psychological referral. ***

Text Area

- **Is a Waiver of Documentation of Signed Informed Consent being requested? ***

Radio Button:

- No
- Yes

Page 11: Change in Consent Process *(Conditional)*

- **Which of the following are you changing about the consent process? ***

Checkboxes:

- Requesting waiver of consent
- Revising consent form or process to obtain consent

Page 12: Rationale for Waiver of Consent *(Conditional)*

- **The only record linking the subject to the research would be the consent document and the principal risk would be potential harm as a result of breaching confidentiality (e.g., study topic is sensitive so that public knowledge of participation could be damaging) ***

Radio Button:

- Yes
- No
- **Please provide any additional information related to why a waiver of consent is being requested. ***

Text Area

Page 13: Consent Process *(Conditional)*

- **Describe how consent will be obtained and from whom and steps that will be taken to minimize coercion or undue influence to participate. If using participants under the age of 18, describe how parental permission and assent of the child will be obtained. If decisionally-impaired adults are to participate, describe how surrogate consent will be obtained from a legally authorized representative. If non-English speaking individuals are to participate, describe how consent in the native language will be obtained. Attach copies of all consent forms, assent forms, information scripts, and scripts for oral consent with this application. ***

Text Box

- **Who will obtain consent? ***

Text Box

- **Indicate where and when subjects will be approached for consent: ***

Text Area

- **If any of the following apply, please explain how consent will be obtained. ***

Checkboxes:

- If using participants under the age of 18, describe how parental permission and assent of the child will be obtained
- If decisionally-impaired adults are to participate, describe how surrogate consent will be obtained from a legally authorized representative
- If non-English speaking individuals are to participate, describe how consent in the native language will be obtained, Subjects will be able to provide their own consent.

- **Attach copies of all consent forms, assent forms, information scripts, and scripts for oral consent with this application.**

- AIC Consent Template: AIC-_IRB_Consent_Form_2022.pdf

- **Will voice or video recordings be made? ***

Radio Button:

- Yes
- No

Page 14: Recruitment Process (Conditional)

- **Describe the change in recruitment process and complete the applicable questions below: ***

Text Area

- **How many total subjects will be recruited for the study? ***

Text Box

- **Where will subjects be recruited from? ***

Checkboxes:

- Public announcements or advertisement
- Social Media (Where?)
- AIC campus announcements
- Educational settings
- Institutional settings
- Subjects will not be recruited as the data is part of regular educational activities or is a secondary data set. These are still subjects and the sample must be described.

- **Describe what subjects will be told during recruitment. You must also attach copies of all consent forms, assent forms, information scripts, and scripts for oral consent with this application. ***

Text Area

- **Describe your inclusion criteria for the study and how subjects will be selected. Include rationale for any excluded groups of participants (age, gender, race, ethnicity, abilities). ***

Text Area

- **Is there a change regarding additional permissions required to recruit your sample? ***

Radio Button:

- Yes - Please indicate where/who from, including access to data sets
 - No, N/A
- **Is there a change in whether participants be paid or otherwise compensated for research participation? ***

Radio Button:

- No
- Yes

Page 15: Research Project Procedures *(Conditional)*

- **Answer all of the following questions. For all questions, if the study involves only secondary data analysis, focus on your proposed design, methods and procedures, and not those of the original study that produced the data you plan to use. For example, if you are using data that has or will be collected for educational purposes, please complete the Participant section based on what will be available in the data. Complete answers must be provided. While you may reference other documents with supporting information, do not respond solely by stating “see attached”. When attaching other documents please identify them clearly.**

Instructions

- **Provide a Brief Summary and non-technical description of the changes you are making to the study using everyday vocabulary. (Limit 200 words) Please note that NO changes are permitted until you have received IRB Approval. ***

Text Area

- **Purpose and Rationale Describe any changes in the purpose or rationale for the study that are informing your changes. (Limit 200 words) ***

Text Area

- **Describe changes the research study methods and procedures. Be sure to provide sequential description of what subjects will be asked to do, how data are to be collected (e.g., questionnaire, interview, focus group, etc.), and who will collect data. Indicate the number and duration of contacts with each subject and follow-up procedures. Copies of all materials (e.g., questionnaires, surveys, measures, tests, interview questions) to be used with participants must be included with the project submission. If a specific item cannot be included with the submission, it must be thoroughly described. ***

Text Area

- **Describe the study sample. Include age range, gender, race, ethnicity. ***

Text Area

- **Indicate Changes in Data Monitoring and Safety ***

Checkboxes:

- Where will data be stored?
- How will data be protected (Passwords/encryption/locked cabinets)?
- How will audio or video data be protected?
- How and when will data be destroyed?

Page 16: Investigator's Assurances

- **I certify that the information provided in this application is correct to the best of my knowledge, and that all persons directly involved in this project agree to follow the applicable policies and procedures regarding the protection of human subjects. I agree to inform the Human Subjects Review Committee of any substantive changes made after this project is approved. By placing a check next**

to my role and typing in my Full Name and Date, I am providing my electronic signature. *

Checkboxes:

- Principle Investigator
- Additional Investigator
- Student Assistant
- Faculty Advisor

- **Please upload an additional page to include any additional assurances. Every person involved must sign an assurance.**

File Upload

Page 17: Full IRB Review *(Conditional)*

- **Please note that if your project requires Full Board Review this means that every member of the IRB must review your proposal prior to voting on approval. You should expect additional time for this process to occur. Proposals requiring full review most often include written consent, child assent or additional protections and permissions. Please contact the IRB Chair if you have any questions about this prior to submitting your proposal.**

PAGE 18: Attachments

- **This page includes space to upload any additional attachments that accompany your proposal. Please read through the list carefully to make sure you have included all attachments required for your project. Incomplete proposals will not be reviewed.**
- **Please upload all Human Subjects Protection Training Certificates here:**

File Upload

- **Please upload your Consent form here.**

File Upload

- **Please upload your Assent Form here for child participants**

File Upload

- **Please upload your Information Sheet here for studies where waiver of consent has been requested**

File Upload

- **Please upload your Recruitment materials or script here:**

File Upload

- **Please upload any Permission Letters here**

File Upload

- **If you need permission from another IRB, please upload that documentation here**

File Upload

- **Please upload any additional documents here:**

File Upload

Fields marked with an asterisk (*) are required.