

# IRB New Proposal Form - 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: Primary Investigator Information

Please complete the following form for ALL NEW project submissions. If you are an AIC employee working on a project that has been approved by another institution's IRB, you are considered the Primary Investigator at AIC, regardless of your role on the project. 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](mailto:anne.stuart@aic.edu) with any questions. If you are an AIC Student, you MUST include your advisor as an additional investigator.

- **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

**Are you working on this study as part of a project that has been approved by an IRB at another institution? \***

*Radio Button:*

- No
- Yes

- **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

## Page 2: Additional Investigators (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 3: 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 4: Conflict of Interest

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 5: Section II: Proposal Submission Information

**Date of Form Submission \***

*Text Box*

**Research Project Title \* (Please limit to 12 words)**

*Text Box*

**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:*

- *Full Board Review*
- *Expedited Review*
- *Exempt Review*

## Page 6: Exempt/Expedited Confirmation (Conditional)

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*

Please describe the possible risks associated with participation in this study. \*

*Text Area*

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.*
- The research has been approved by another institution's IRB.*
- None of the above apply to this study.*

## Page 7: Full Description of Risks and Measures to Minimize Risks (Conditional)

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 8: 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 9: Consent Process

Describe how consent will be obtained and from whom and steps that will be taken to minimize coercion or undue influence to participate.

Checkboxes & Text:

- 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. AIC Consent Template: AIC- IRB\_ Consent\_Form\_2022.pdf \*

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 10: Recruitment Process

**How many total subjects will be recruited for the study? *Please remember that posting a recruitment statement on Social Media IS recruiting.* \***

*Text Box*

**Where will subjects be recruited from? Check ALL that apply!\***

*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. Please describe.*

**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 and exclusion 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*

**Are additional permissions required to recruit your sample? (This includes, but is not limited to, permissions to post a recruitment blurb on a website, social media page or to conduct secondary data analysis). \***

*Radio Button:*

- *Yes - Please indicate where/who from, including access to data sets*
  - *Textbox provided*
- *No*
- *N/A*

**Will participants be paid or otherwise compensated for research participation? \***

*Radio Button:*

- *No*
- *Yes*

## Page 11: Research Project Procedures

**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.

Provide a brief Brief Summary and non-technical description of the study using everyday vocabulary. (LIMIT 150 words) \*

*Text Area*

**Purpose and Rationale** Provide a brief summary of the background information, state the research question(s), and tell why the study is needed. (LIMIT 300 words) \*

*Text Area*

Describe 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.

Limit:300 words

**Hint:** Put this information in a numbered list for clarity! 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. Items may be attached at the end of this document. \*

*Text Area*

Describe the study sample. Include age range, gender, race, ethnicity.(Be specific, if you are doing secondary analysis or studying regular educational procedures, your sample consists of your de-identified data). \*

*Text Area*

**Data Monitoring and Analysis:** Describe how the qualitative and/or quantitative data will be analyzed. Describe the provisions for monitoring the data to ensure the safety of participants (eg Codes/pseudonyms/etc.). \*

*Text Area*

**Data Monitoring and Safety - Please be specific! \***

*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 12: 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. This form will not be accepted or

approved without signatures and dates. By placing a check next to my role and typing in my Full Name and Date, I am providing my electronic signature. \*

*Checkboxes:*

- Principal 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 13: 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 14: 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. Upload consent language if conducting an anonymous survey.**

*File Upload*

**Please upload your Assent Form here. Note: Assent forms are used for Minors under age 18.**

*File Upload*

**Please upload your Information Sheet here. Note: Information sheets are ONLY required in cases where consent is being waived.**

*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. (Possible items here include: Survey or data collection tools, additional IRB certificates. etc.)**

*File Upload*

Fields marked with an asterisk ( \* ) are required.