# **REQUIREMENTS FOR CONDUCTING RESEARCH WITH HUMAN PARTICIPANTS**

* Read and fully understand the following resources prior to beginning the application. These are not exhaustive, and are not intended to replace, substitute, or override any information in required IRB training. Instead, these are common areas where IRB applications occasionally see issues:
  + **Responsibilities of Investigators**: <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/investigator-responsibilities/index.html>
  + **Informed Consent**: <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/informed-consent/index.html>
  + **Informed Consent Frequently Asked Questions**: <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html>
  + **Vulnerable Populations**: <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/vulnerable-populations/index.html>
  + **IRB Approval Process**: <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/protocol-review/index.html>
  + **Decision Tree (for whether research involving human subjects requires IRB review)**: <https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html>

# **SCOPE OF THE IRB**

* The IRB exists to ensure the protection of human participants involved in research studies, thus ensuring human participants’ rights and welfare.
* The IRB is not intended to serve to highlight, correct, or make suggestions on grammar, clarity, or design unless it affects or could affect the human subjects under investigation (for example, ambiguous language that may cause the protections to be questioned).

# **Instructions**

1. Complete each section of this form without changing its format. The IRB recommends having the document proofread for any errors, omissions, typos, or free of grammatical errors or unclear or vague wording prior to finalizing the document. The Principal Investigator (PI) is responsible for ensuring that the document is thoroughly review and aligned across the application and all supporting documentation.
2. Then, save it as a PDF, electronically sign the investigator agreement in the **INVESTIGATOR AGREEMENT**, and obtain electronic signatures indicating faculty approval under the **FACULTY SUPERVISOR APPROVAL** section (required if the PI is a student) and departmental approval under the **DEPARTMENTAL APPROVAL** section. Any track changes, edits, proofreading, and/or comments must be removed prior to moving to the next step.
3. The PI will email the signed application form, a Word version of the form, and all supporting documents to [irb@fxua.edu](mailto:irb@fxua.edu).

Please note: Applications that are incomplete, unclear, inconsistent, insufficiently proofread for language use and mechanics, and/or different from the provided template will be returned immediately for revisions, which will mean a delay in processing time.

# **A. Project Information**

## **A1. Project Overview**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Submission Date | Click or tap here to enter text. | | | |
| Application Type | New Project | Modification to IRB Project #: Click or tap here to enter text. | | |
| Project Title | Click or tap here to enter text. | | | |
| Project Type | Faculty Research | Student Research *(Specify type and faculty supervisor below)*  Class project *(Provide course #)*: Click or tap here to enter text.  Master’s thesis  Doctoral dissertation  Independent project  Faculty Supervisor: *(Required for any research with a student as the PI)*  Name: Click or tap here to enter text.  Email: Click or tap here to enter text. | | Other *(Describe)*: Click or tap here to enter text. |
| Proposed Timing | Start Date: Click or tap here to enter text. | | End Date: Click or tap here to enter text. | |

## **A2. Investigators** *(Investigators are those individuals who participate in conducting* [*research activities with human subjects*](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/investigator-responsibilities/index.html)*.)*

## **Principal Investigator** *(The Principal Investigator [PI] is the person with primary responsibility over the study and serves as the primary contact for the IRB. Students conducting research as part of course would be designated as the PI under faculty supervision.)*

|  |  |  |
| --- | --- | --- |
| Name | Click or tap here to enter text. | |
| Professional Title | Click or tap here to enter text. | |
| School/Department | Click or tap here to enter text. | |
| Telephone | Click or tap here to enter text. | |
| Email Address | Click or tap here to enter text. | |
| IRB Training | CITI Social-Behavioral-Educational Basic Course  *Record #*:Click or tap here to enter text.  *Expiration date*: Click or tap here to enter text. | NIH Good Clinical Practice eCourse  *SBM tracking ID #*: Click or tap here to enter text.  *Expiration date*: Click or tap here to enter text. |

## **Faculty Supervisor** *(If a student conducts research and is designated as the PI, complete this section. If more than one faculty member is advising the student, the primary faculty supervisor should be used. Investigators are those individuals who participate in conducting* [*research activities with human subjects*](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/investigator-responsibilities/index.html)*.)*

|  |  |  |
| --- | --- | --- |
| Faculty Name | Click or tap here to enter text. | |
| Professional Title | Click or tap here to enter text. | |
| School/Department | Click or tap here to enter text. | |
| Telephone | Click or tap here to enter text. | |
| Email Address | Click or tap here to enter text. | |
| IRB Training | CITI Social-Behavioral-Educational Basic Course  *Record #*:Click or tap here to enter text.  *Expiration date*: Click or tap here to enter text. | NIH Good Clinical Practice eCourse  *SBM tracking ID #*: Click or tap here to enter text.  *Expiration date*: Click or tap here to enter text. |

## **A3. Funding**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 1. Will this research be funded? | Yes  No  *If yes, continue to #2 and provide a detailed budget as an attachment with your application.* | | | | |
| 1. Type of Funding | Grant | Contract | Internal funding | | Other *(Specify)*: Click or tap here to enter text. |
| 1. Name(s) of Funder(s) | Click or tap here to enter text. | | | | |
| 1. Contract or Grant # | Click or tap here to enter text. | | | | |
| 1. Funding Period | Start date: Click or tap here to enter text. | | | End date: Click or tap here to enter text. | |
| 1. Potential Benefits | *Is there any possibility that the funder(s) might benefit financially or professionally from the outcomes of this study?*  Yes  No  *If yes, please explain:* Click or tap here to enter text. | | | | |

# **B. Personnel**

*Identify all personnel who will work on this project, listing the Principal Investigator (PI) first, followed by the Faculty Supervisor, as relevant. The PI must be affiliated with Fairfax University of America. Each student conducting thesis or dissertation research must submit an individual application and serve as the PI for his/her own research project. The Faculty Supervisor must have sufficient expertise with the content and research methods of the project to be qualified to oversee the conduct of the research.*

*Everyone involved in any aspect of the research (supervising students during the research process, including but not limited to recruiting and/or interacting with participants; transcribing, coding, and/or analyzing data; etc.) must submit proof that the required training in the protection of human research participants has been completed and will not expire before the project’s first annual review.*

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Investigators** | | | | | **Involvement in Research** | | | | **IRB Training** *(Include record # & expiration date)* |
| **#** | **Full Name** | **Title/Status**  *(e.g., Associate Professor, student)* | **Affiliation** *(university & school)* | **Email Address** | **Role** *(e.g., PI, faculty supervisor, additional investigator, research assistant, consultant)* | **Will this person…** | | |
| have contact with human participants? | be involved in the consent process? | have access to private identifiable data? |
| **1** | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Principal Investigator | Yes  No | Yes  No | Yes  No | CITI  NIH  Click or tap here to enter text. |
| **2** | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Yes  No | Yes  No | Yes  No | CITI  NIH  Click or tap here to enter text. |
| **3** | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Yes  No | Yes  No | Yes  No | CITI  NIH  Click or tap here to enter text. |
| **4** | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Yes  No | Yes  No | Yes  No | CITI  NIH  Click or tap here to enter text. |
| **5** | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Yes  No | Yes  No | Yes  No | CITI  NIH  Click or tap here to enter text. |
| **6** | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Yes  No | Yes  No | Yes  No | CITI  NIH  Click or tap here to enter text. |
| **7** | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Yes  No | Yes  No | Yes  No | CITI  NIH  Click or tap here to enter text. |

*Include additional rows as needed.*

# **C. Project Description**

*Changes to aspects of section C would require review and approval from the IRB; therefore, ensure that all sections are completed thoroughly and in anticipation of potential future needs or considerations.*

## **C1. Project Overview**

*In 500 words or fewer, please provide a concise, non-technical overview of your project in prose, including the motivation for the research, its goals, the major variables under study, the research design (methods and procedures), and how the data will enable you to answer the research questions. (You will elaborate on this with more specific details in the tables below.)*

Click or tap here to enter text.

## **C2. Research Questions**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Research Question**  *List each research question in its own row.* | **Variables**  *List the variables that will be explored/measured to answer this research question.* | **Sources of Data**  *Identify the persons, artifacts, or records from which data will be gathered.* | **Data Collection Tools**  *Identify the instruments (e.g., tests, interviews, focus groups, surveys, observations, writing samples) that will be used to collect data on each variable. Describe the source of the data collection tool (e.g., self-made questionnaires, existing tools used in other research identifying the author/s and source).* | **Data Analysis**  *Describe the types of data that will be produced by the instruments (e.g., qualitative, categorical, ordinal) and the procedures that will be used to analyze the data.* |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
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*Include additional rows as needed. All instruments must be included as attachments.*

## **C3. Procedures**

|  |  |  |  |
| --- | --- | --- | --- |
| **Step**  *Outline the steps that will be involved in your study, from recruitment and informed consent through data collection and debriefing.* | **Description**  *Describe each step in detail. What will the researchers do, and what will the participants do?* | **Timing**  *Note the intended start and end dates for each step and how long it will take for each participant.* | **Location**  *Describe where these procedures will take place.* |
| 1. Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| 2. Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| 3. Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| 4. Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| 5. Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| 6. Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| 7. Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| 8. Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |

*Include additional rows as needed.*

# **D. Participants**

## **D1. Number**

*Approximately how many people do you expect to participate in your study? What is the maximum number of participants you seek approval to enroll?*

Click or tap here to enter text.

## **D2. Inclusion and Exclusion Criteria**

*What is the intended population for your proposed study? What are the criteria for inclusion and exclusion (e.g., age, educational background, language proficiency, marital status, country of origin), and why?*

Click or tap here to enter text.

## **D3. Participant Identification**

*How will you find and identify eligible participants?*

Click or tap here to enter text.

## **D4. Recruitment Procedures**

*When, where, and how will potential participants be contacted and recruited? Be sure to include any potential intermediaries that would be involved in finding or recruiting subjects. These individuals may require serving as an* [*investigator*](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/investigator-responsibilities/index.html) *depending upon their role. In addition to describing the recruitment procedures here, provide all of the recruitment materials as attachments. These may include invitation emails, letters, flyers, advertisements, scripts of the wording that will be used to recruit participants in person, and so on.*

Timing: Click or tap here to enter text.

Location: Click or tap here to enter text.

Methods: Click or tap here to enter text.

Materials: Click or tap here to enter text.

## **D5. Voluntary Participation**

*How will potential participants indicate their desire to participate (or not) in the research? What measures will you take to ensure that participation is completely voluntary (i.e., with no perceived pressure or expectations to participate from any individuals, including non-members of the research team, such as teachers, employers, peers, or others)?*

Click or tap here to enter text.

## **D6. Participant Compensation**

*Will participants be given any incentives (e.g., extra credit for class) or compensation (e.g., money, gift cards) for participating in the research? If so, when and how will they be incentivized and/or compensated, and what will the incentives and/or compensation be?*

Click or tap here to enter text.

## **D7. Screening Procedures**

*How and when will you screen participants to determine inclusion/exclusion?*

Click or tap here to enter text.

## **D8. Participant Selection**

*What measures will you take to ensure equity in the participant selection process?*

Click or tap here to enter text.

## **D9. Assignment to Groups**

*If different data collection tools and/or procedures will be used with different subsets of participants, please describe how participants will be assigned to groups and how their experiences will differ.*

Click or tap here to enter text.

## **D10. Conflicts of Interest**

*Are there any potential conflicts of interest, whether real or perceived, between the researcher(s), faculty supervisor(s), and participants? Please describe the relationships among these parties, including any positions of authority or financial relationships.*

Click or tap here to enter text.

## **D11. Potential Involvement of Vulnerable Populations**

*Might your research involve participants from any of these special populations? Please complete the entire table below.*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **YES** | **POSSIBLY** | **NO** | **Justification**  *If* ***YES*** *or* ***POSSIBLY YES****, explain (1) why it is necessary or important to include participants from the relevant group, (2) how you will ensure that they do not feel any pressure to participate (real or perceived pressure), (3) what additional risks might be involved for them, and (4) what extra steps you will take to address those risks. If NO, describe how your recruitment and/or screening procedures will exclude this population.* |
| Children under 18 years of age |  |  |  | Click or tap here to enter text. |
| Prisoners or institutionalized individuals |  |  |  | Click or tap here to enter text. |
| Pregnant women |  |  |  | Click or tap here to enter text. |
| Elderly individuals |  |  |  | Click or tap here to enter text. |
| Individuals with physical disabilities |  |  |  | Click or tap here to enter text. |
| Individuals with intellectual disabilities |  |  |  | Click or tap here to enter text. |
| Participants incapable of giving consent |  |  |  | Click or tap here to enter text. |
| Economically disadvantaged individuals |  |  |  | Click or tap here to enter text. |
| Educationally disadvantaged individuals |  |  |  | Click or tap here to enter text. |
| Individuals with limited communication ability or impairments |  |  |  | Click or tap here to enter text. |
| Other potentially elevated risk populations *(Please specify)*: Click or tap here to enter text. |  |  |  | Click or tap here to enter text. |

# **E. Risks and Benefits**

*There are always risks associated with research. The Office of Human Research Protections in the US Department of Health and Human Services describes minimal risk as follows: “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).*

## **E1. Identification of Risks**

*What risks may be involved in your research? Please check all anticipated risks and describe each of them in greater detail below.*

Psychological (e.g., presentation of materials that some participants may consider sensitive, offensive, or degrading; manipulation of psychological states, such as through stress, social isolation, or sensory deprivation; boredom)

Physical (e.g., discomfort, fatigue, risk of injury or bodily harm)

Educational (e.g., missing class time)

Legal (e.g., possible identification of child, spousal, or elder abuse or other illegal activity)

Social or economic (e.g., potential risks to participants’ reputations, employability -real or perceived)

Privacy-related (e.g., use of private records, such as educational, employment, or medical records; probing for personal or sensitive information; possible perceived invasion of the privacy of the participant’s family)

Use of deception (e.g., keeping any aspect of the study secret from participants)

Other: Click or tap here to enter text.

*Please elaborate on any risks identified above:*

Click or tap here to enter text.

## **E2. Assessment of Risks**

*According to* [*§46.102(j)*](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1102)*, “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.” Does your proposed research involve greater than minimal risk, as defined by OHRP?*   Yes  No

*Provide a rationale:* Click or tap here to enter text.

## **E3. Minimization of Risks**

*Describe the steps that will be taken to minimize any risks to participants.*

Click or tap here to enter text.

*Please also revisit the table in D11 to ensure that you have described the extra steps that will be taken to minimize the risks for any vulnerable populations that might be included in your study.*

## **E4. Benefits to Participants**

*Describe the potential benefits that participants might experience directly as a result of participating in your proposed study. If no direct benefits are expected, please state this fact.*

Click or tap here to enter text.

## **E5. Alternative Procedures**

*As relevant, describe any alternative procedures or treatments that might be advantageous to the participants.*

Click or tap here to enter text.

## **E6. Benefits to Society**

*Why is this research important and how would it be valuable? Describe the potential benefits of your research for society.*

Click or tap here to enter text.

## **E7. Assessment of Risk-Benefit Ratio**

*Explain why you believe this study is worth conducting despite the risks to participants that you have identified.*

Click or tap here to enter text.

# **F. Data Security and Management**

## **F1. Media Use**

*Describe any media that might be used to record information from or about the participants, with or without their knowledge. This could include, but is not limited to, the use of audio recording, video recording, photography, etc. Describe whether participants will be aware of this, and if any deception is planned, provide a strong justification for its use.*

Click or tap here to enter text.

## **F2. Personally Identifiable Information**

*Does this research involve collection of data that could identify individuals, either directly (e.g., name, student number, social security number, voice) or indirectly (e.g., through a combination of demographic information or self-reporting)?*

Click or tap here to enter text.

## **F3. Confidentiality**

*If personally identifiable information will be collected…*

1. *Who will have access to links between participants’ identities and other parts of their data (e.g., in spreadsheets, videos, survey forms, transcripts of interviews, etc.)?*

Click or tap here to enter text.

1. *How will the links between participants’ identities and the rest of their data be stored and protected?*

Click or tap here to enter text.

1. *In reports of the research (e.g., conference presentations, published articles, performance reports for funders), will all personally identifiable information in the data be redacted, modified, or otherwise masked to ensure participant confidentiality?*  Yes  No
2. *If yes, please describe in detail how this will be done. If no, explain why not and how the associated risks to participants will be minimized.*

Click or tap here to enter text.

## **F4. Data Storage**

Refer to the [Frequently Asked Questions for investigators](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/investigator-responsibilities/index.html) for information on how long data/records must be maintained and requirements for protections of human subject.

|  |  |  |
| --- | --- | --- |
|  | **Electronic Data** | **Physical Data** |
| *How will the data be stored to ensure data security?* | Click or tap here to enter text. | Click or tap here to enter text. |
| *Where will the data be stored?* | Click or tap here to enter text. | Click or tap here to enter text. |
| *Who will have access to the data?* | Click or tap here to enter text. | Click or tap here to enter text. |
| *For how long will the data be retained?* | Click or tap here to enter text. | Click or tap here to enter text. |
| *What will happen to the data after the research is complete?* | Click or tap here to enter text. | Click or tap here to enter text. |
| *Who will be responsible for the records?* | Click or tap here to enter text. | Click or tap here to enter text. |
| *Who will have access to the records?* | Click or tap here to enter text. | Click or tap here to enter text. |

## **F5. Data Sharing**

*Will data be shared during or after the project? If so, what are the procedures for sharing data? (Note: This must be included in the informed consent process.)*

Click or tap here to enter text.

# **G. Informed Consent**

*Please refer to the* [*Frequently Asked Questions on Informed consent*](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html)*. Attach copies of all consent and assent documents as applicable.*

## **G1. Ability to Give Consent**

*Does your study require parental permission?*  Yes  No

*If competency to give informed consent may be an issue with some potential participants (e.g., due to intellectual capacity, language proficiency, or other communication ability), please describe how this will be determined and addressed.*

Click or tap here to enter text.

## **G2. Consent Process**

*Will the informed consent process include all of the following required elements? Please check the boxes below to indicate that you have checked your consent document/script to ensure that it includes this information. (For more detail, please see 45 CFR §46.116(b), available at* [*https://www.hhs.gov/ohrp/regulations-and-policy/regulations/index.html*](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/index.html)*. Direct link to the relevant section:* [*shorturl.at/qyHMX*](file:///C:\Users\kevin\AppData\Local\Microsoft\Windows\INetCache\Content.Outlook\B88DYY7Y\shorturl.at\qyHMX)*)*

Purposes of the research

Expected duration of participation

Procedures (including identification of any procedures that are experimental and alternative procedures that may be advantageous, if any)

Risks

Benefits

Confidentiality

Voluntary nature of participation

Procedures for withdrawal

For research involving more than minimal risk, information on compensation, medical treatments, and sources of additional information

For research involving collection of identifiable private information or biospecimens, a statement about removal and distribution of identifiers

Contact information (whom to contact with concerns or questions)

*What additional elements, if any, will be included in the informed consent process due to the nature of the proposed research? (Please see 45 CFR §46.116(c).)*

Click or tap here to enter text.

## **G3. Documentation of Consent**

*Prior to engaging in any research-related activities, will electronic or written consent be obtained from potential participants and/or their parents or guardians? In the table below, as relevant, please describe procedures for obtaining (if yes) or otherwise documenting (if no) both parental permission and the assent of any minors who may be involved.*

|  |  |  |
| --- | --- | --- |
| **Yes, Electronic Consent** | **Yes, Written Consent** (i.e., signing a form) | **No** |
| *From whom will electronic consent be obtained?*  Click or tap here to enter text. | *From whom will written consent be obtained?*  Click or tap here to enter text. | *Provide a rationale for not obtaining written consent.*  Click or tap here to enter text. |
| *How will electronic consent be obtained?*  Click or tap here to enter text. | *How will written consent be obtained?*  Click or tap here to enter text. | *How will potential participants (and their parents or guardians, if minors are involved) be informed of the research procedures, risks, benefits, and confidentiality?*  Click or tap here to enter text. |
| *What is the procedure for choosing not to participate? What will happen if a potential participant does not give electronic consent?*  Click or tap here to enter text. | *What is the procedure for choosing not to participate? What will happen if a potential participant does not give written consent?*  Click or tap here to enter text. | *How will informed consent/assent be documented?*  Click or tap here to enter text. |

## **G4. Voluntary Withdrawal**

*Describe the procedures for participants to withdraw from the study if they wish to do so for any reason. Please be sure to consider the various points in the study at which someone would still be able to withdraw, as well as the points at which withdrawal would no longer be possible, and specify what will be done with the data of participants who have decided to withdraw, whether the data are complete or incomplete.*

Click or tap here to enter text.

## **G5. Participant Debriefing**

*Will participants be debriefed after participating? If so, please describe the content, timing, and format of the debriefing.*

Click or tap here to enter text.

## **G6. Dissemination of Results to Participants**

*Will the results of the research be shared with participants after data analysis is complete? If so, please describe the timing and format.*

Click or tap here to enter text.

# **H. Research Conducted Outside of the United States**

*For any research conducted on participants, or with participants who are outside of the United States, describe how all applicable laws and requirements of research conducted on human subjects in those countries, in addition to the United States, would be assured.*

Does not apply to this research.

Click or tap here to enter text.

# **I. Research Conducted with Materials in a Foreign Languages**

*For any research that would be conducted in a foreign language or with documentation that is written in a foreign language, translations must be provided and be done by a qualified individual. This would include any scripts, informed consent materials, etc.*

Does not apply to this research.

If documents were translated, please describe who translated them and what qualifications they have to adequately translate materials for your study. Click or tap here to enter text.

# **J. Attachments**

*Please check and attach all supporting documents that apply to your proposal.*

Certificates of completion of training in the protection of human research participants (required of all investigators)

All recruitment materials (e.g., invitation emails, flyers, advertisements, scripts)

Informed consent and/or assent documents

Data collection instruments (e.g., tests, surveys, interview protocols)

Signed investigator agreement with faculty and departmental approval

Funding award letter and budget, if applicable

Letters of approval from cooperating entities, if applicable

# **K. Exemption Categories**

*Federal law 45 CFR §46.104(d) (*[*https://www.hhs.gov/ohrp/regulations-and-policy/regulations/index.html*](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/index.html)*) identifies 8 types of research that can be deemed exempt from further review (direct link:* [*shorturl.at/tOVY0*](file:///C:\Users\kevin\AppData\Local\Microsoft\Windows\INetCache\Content.Outlook\B88DYY7Y\shorturl.at\tOVY0)*). If you believe that your study falls within one of these categories, please identify the number of the category and provide an explanation.*

*Exemption category number:* Click or tap here to enter text.

*Explanation:* Click or tap here to enter text.

# **L.** **Investigator Agreement**

*In submitting this application, I certify the following:*

I (and all members of the research team) have successfully completed the required IRB training.

I have read and understand OHRP’s guidance on obtaining informed consent from all participants (45 CFR §46.116) and will follow it.

I will comply with federal, state, and local laws regarding the protection of human participants in research.

I will submit any future changes to the research project to the IRB for review and official approval prior to implementation, as these may alter the approved status of the project.

I will promptly report to the IRB, in writing, any new findings that develop during this study that may affect the risks and benefits to participants.

I will promptly report to the IRB, in writing, any unexpected or otherwise significant adverse events that occur in the course of this study.

I will maintain records of the data for at least three years following completion of this research.

I will not begin recruiting participants or conducting research unless and until the IRB grants official approval for this project.

Principal Investigator: Click or tap here to enter text. Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: Click or tap here to enter text.

# **M. Faculty Supervisor Approval** (Required if PI is a student)

*I confirm the accuracy of this application. I accept responsibility for the conduct of this research, the supervision of human participants, and the maintenance of informed consent documentation as required by the IRB. (NOTE: Signatures from the faculty supervisor do not guarantee that the research would be approved by the IRB).*

Faculty Supervisor: Click or tap here to enter text. Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: Click or tap here to enter text.

# **N. Departmental Approval** (Required if PI is a student)

*I have read this application and approve of the procedures that involve human participants. (NOTE: Signatures from the faculty supervisor do not guarantee that the research would be approved by the IRB).*

Chair or Other Administrator: Click or tap here to enter text. Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: Click or tap here to enter text.

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# **O. For IRB Use Only**

*This application has been reviewed by the IRB, resulting in the following determination:*

Approved; *Category*: Click or tap here to enter text.

Approved; *Subject to Restrictions*: Click or tap here to enter text.

Tabled; *Required Revisions*: Click or tap here to enter text.

Disapproved following Full Review; *Reasons*: Click or tap here to enter text.

Reviewer: Click or tap here to enter text. Authorized Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: Click or tap here to enter text.

IRB Chair: Click or tap here to enter text. Authorized Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: Click or tap here to enter text.