RESEARCH ETHICS REVIEW APPLICATION
UNIVERSITY OF THE POTOMAC INSTITUTIONAL REVIEW BOARD
REQUESTING APPROVAL TO CONDUCT RESEARCH
Version – June 1, 2021

IMPORTANT NOTE FOR STUDENT RESEARCHERS

It is the researcher's responsibility to make sure that the IRB application and all supporting materials are submitted to IRB@potomac.edu. The IRB staff always confirms receipt of IRB materials. Data collection should not commence prior to receiving explicit IRB approval from IRB@potomac.edu.

WHAT IS IRB APPROVAL?

The Institutional Review Board (IRB) consists of faculty, terminally qualified and experienced in conducting research and/or leading academic research studies. The IRB is responsible for ensuring that all University of the Potomac research complies with the university's ethical standards and meets U.S. federal regulations and any applicable international guidelines. IRB approval indicates the institution's official assessment is that the potential risks of the study are outweighed by the potential benefits.

Outside of the explicit dates and terms of IRB approval, researchers are not entitled to any protections, recognition, funding, or other support provide by University of the Potomac.

WHO SHOULD USE THIS IRB APPLICATION FORM?

This application should be completed by all students and faculty who are conducting research projects of any scope involving collection or analysis of data from living persons (whether from surveys, interviews, observation, student work, or records of any type). The only categories of research that do not need to be submitted for IRB approval are literature reviews, hypothetical research designs, and faculty projects that are completely independent of University of the Potomac. Research projects conducted by fulltime employees of UOTP are also under the purview of the UOTP IRB. Instead of completing this form, staff researchers should send an email inquiry to IRB@potomac.edu to initiate the IRB approval process for staff research.

WHEN SHOULD I WORK ON AND SUBMIT MY IRB APPLICATION?
Questions about the IRB application and related materials may be submitted to IRB@potomac.edu at any time.

It is expected that doctoral students will review IRB requirements as they are writing the proposal and to that end, this IRB application can be used as a worksheet to help think through the ethical issues of data collection. However, the student would need to complete the IRB application after proposal approval in order to address the details of the final, approved research design.

HOW LONG DOES IRB REVIEW TAKE?
Researchers should allow a minimum of 4-6 weeks for IRB review (4 weeks for minimal risk studies and 6 weeks for studies involving vulnerable populations). This form takes 1-2 hours to complete, depending on the complexity of the study. Once the IRB staff confirms that the IRB application is complete, the IRB application will be scheduled for review at the next available IRB meeting (typically within 10 business days). Feedback from the board will be returned within 5 business days (amounting to a total of 15 business days for the initial review). Note that when a study is "approved with revisions," the researcher should allow an additional 10-15 business days for those revisions to be reviewed and approved. If the revisions do not adequately address the ethical concerns, then an additional round of revisions and review might be necessary. The IRB members make every effort to make the revision requirements as clear as possible.

CAN I CONTACT MY RESEARCH PARTICIPANTS BEFORE IRB APPROVAL?
Note that researchers may NOT begin recruiting participants (i.e., obtaining consent form signatures) prior to IRB approval.

WHAT IF I NEED TO CHANGE MY RESEARCH PROCEDURES AFTER IRB APPROVAL?
Researchers must reapply for IRB approval if changes are made to the research procedures after IRB approval.

WHAT ARE THE CRITERIA FOR IRB APPROVAL?
The purpose of this IRB application is to collect enough specific information to document that the study's benefits outweigh the costs and that the procedures are in compliance with federal regulations and university policies. To those ends, the board will evaluate the IRB application based on how well the following ethical principles are upheld:

Beneficence = maximize possible benefits and minimize possible harms
Justice = fairly distribute benefits and burdens of research
Respect for Persons = acknowledge participants' autonomy and protect those with diminished autonomy

<u>General Description of the Proposed Research</u>
- Demonstrate the ethical rationale for each component of data collection by describing how each will be analyzed to address the research question(s).

- Provide specific descriptions of the tasks the participants will be asked to complete.

Potential Risks and Benefits
- Describe anticipated risks and benefits of study participation.
- Make provisions to minimize risks to research participants and document those procedures.

Data Integrity and Confidentiality
- Describe procedures to maintain data confidentiality and integrity.
- If data includes personal identifiers, submit signed certificates of confidentiality for everyone who has access to the data (except faculty members).
- If applicable, complete extra sections relevant to protected health information.

Potential Conflicts of Interest
- Disclose and manage potential conflicts of interest.

Data Collection Tools
- Describe all tools (surveys, interview questions, etc.) and authorizations related to data collection including evidence of compliance with copyright holder's terms of usage, permission to reproduce the instrument in the dissertation, or confirmation that the tool is public domain (as applicable).

Description of the Research Participants
- Describe the study population, particularly inclusion and exclusion criteria, to demonstrate that those who shoulder the burden of the research will actually benefit from it.
- Describe how any vulnerable populations will be protected from safety/privacy risks and pressure to participate.

Informed Consent
- Make provisions to obtain and document informed consent from all study participants and the appropriate parents, guardians, or caregivers.
-Submit **unsigned** copies of any relevant consent documents.

Final Checklist and Electronic Signatures
-Students must obtain faculty approval before submitting this form to IRB@potomac.edu.

This form must be completed and submitted via email. If you have questions as you are completing the form, please contact IRB@potomac.edu.

IRB APPLICATION FORM
SUBMITTED TO THE INSTITUTIONAL REVIEW BOARD
UNIVERSITY OF THE POTOMAC

PROJECT INFORMATION

1. Enter Researcher's name in blue space below:	2. Student ID (If Applicable)

3. Every researcher must submit a copy of a Human Research Protections training completion certificate with this application. UOTP accepts Human Research Protections training certificates from either NIH, NCI, or CITI. A completion certificate is good for 3 years.
Enter an X in the appropriate blue box below to indicate which training module was completed:

	National Institutes of Health (NIH): http://phrp.nihtraining.com
	Collaborative Institutional Training Initiative (CITI): http://www.citiprogram.org
	National Cancer Institute (NCI)
	Other research ethics training:

4. Researcher's email address:

5. Names of research collaborators and roles (if researcher is a **student**, please provide the name of the faculty member supervising this research):

6. Email address(es) of the supervising faculty and any other co-researcher collaborators:

7. Provide the researcher's program affiliation at UOTP

8. Project Title:

9. Enter an X in the blue box next to the study type that best describes the IRB approval requested:

	Doctoral Study
	Master's study
	Research for a course (specify course number: _____ and course end date: _____)
	Faculty Research
	Other:

Please describe the overall goal of the project, research questions, and types of data to be collected.

II. Research Design

Please include a brief description of your overall research design, how the data will be collected and how you intend to analyze the data.

Please append your Informed Consent Document to the IRB Application.
Please append any Survey Instruments that you have designed for This Research Project.

III. COMMUNITY RESEARCH STAKEHOLDERS AND PARTNERS

Research participants are individuals who provide private data through any type of interaction, whether verbal, observed, typed, recorded, written, or otherwise assessed. Research participants' understanding of the study and willingness to engage in research must be documented with **CONSENT FORMS**, after IRB approval. For example, an educator comparing two instructional strategies by interviewing adult students in his classes would need to have each participant student sign a consent form.

Community partners include any schools, clinics, businesses, non-profits, government entities, residential facilities, or other organizations who are involved in your research project. Community partners' understanding of the study and willingness to engage in research must be documented with a **LETTER OF COOPERATION**. To continue with the same example, the educator comparing two instructional strategies would need a Letter of Cooperation from the school confirming (a) that the school approves the teacher's implementation of two different instructional strategies and (b) that the school approves the interview activities. If you have questions about whether an individual or an organization should provide permission for some aspect of the research, please email IRB@potomac.edu.

Stakeholders include the informal networks of individuals who would potentially be impacted by the research activities or results (such as parents, community leaders, etc.). UOTP students are required to disseminate their research results in a responsible, respectful manner and are encouraged to develop this dissemination plan in consultation with the relevant community partners. Sometimes it is appropriate to provide a debriefing session/handout to individual participants immediately after data collection in addition to a general stakeholders' debriefing after data analysis.

10. Please identify all community stakeholders who should hear about your research results and indicate your specific plan for disseminating your results in an appropriate format.	
11. Enter an X next to the description that best describes the community research partner's role in data collection. Mark all that apply.	
☐	I am relying solely on public records and/or means to recruit participants and collect data, and thus, I have no community research partner.
☐	My community research partner has already agreed to assist in participant recruitment and/or data collection and I am submitting their letter of cooperation with this IRB approval.
☐	I am required to provide a copy of UOTP's IRB approval to a funder or community partner before they can provide me with their formal approval. I seek UOTP's conditional IRB approval at this time (which can be finalized once the UOTP IRB receives the community partner's letter of cooperation).
☐	Other:
12a. Name the organization(s) at which you intend to recruit participants and/or collect data as well as any funders involved in the study:	
12b. Name the individual who is authorized to approve research within each of the community partner organizations:	
12c. Please briefly describe how you chose each of the partners listed above:	

IV. POTENTIAL RISKS AND BENEFITS

Describe, if any, anticipated risks for study participation. In addition, how will you seek to minimize potential risks to your study population, such as protecting your study participants' identity.

Describe, if any, anticipated benefits for study participation and how you intend to use this research to benefit society.

IV. DATA INTEGRITY AND CONFIDENTIALITY

Describe in what formats you will obtain data and how you plan on storing it. Describe what security provisions will be taken during data collection, data transfer

Describe the specific plans for handling adverse events involving research participants that might require immediate referral, stopping data collection, management of a new conflict of interest, re-assessment of risks and benefits, or responding to breached confidentiality. These plans must be tailored by the researcher for the specific research context and population.

ADDITIONAL ISSUES TO ADDRESS WHEN THE RESEARCH INVOLVES PROTECTED HEALTH INFORMATION

***Protected Health Information (PHI)** is defined under HIPAA (Health Insurance Portability and Accountability Act of 1996) as health information transmitted or maintained in any form or medium that:

A. identifies or could be used to identify an individual;

B. is created or received by a healthcare provider, health plan, employer or healthcare clearinghouse; and

C. relates to the past, present or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of healthcare to an individual.

13. As part of this study, the researcher(s) will:
☐ Collect protected health information* from participants
☐ Have access to protected health information* in the participants' records
☐ None of the above

V. POTENTIAL CONFLICTS OF INTEREST

14 This item asks you to disclose information relevant to separating your multiple roles as clearly as possible, with the goal of ensuring authentically voluntary participation in your study. Doctoral research directly benefits the student (allowing him or her to obtain a degree), and so the researcher should minimize the potential for either (a) conflict of interest or (b) perceived coercion to participate. Researchers who are in positions of authority must take extra precautions to ensure that potential participants are not pressured to take part in their study. Data collection should be as detached as possible from the researcher's authority.
Examples:
-a professor researcher may recruit students AFTER grades have been assigned
-a manager researcher may conduct ANONYMOUS data collection so that subordinates do not perceive their responses or [non]participation as being associated with their job standing

At the time of study recruitment, are the potential study participants aware of any of the researchers' other professional or public roles? (Such as teacher, business owner, community leader, supervisor, etc.?)

☐ No.

☐ Yes, at the time of recruitment some of the participants are aware of the researcher's Insert title here role, and the following measures will be taken to separate the researcher's dual roles and minimize perceived coercion to participate: Insert explanation here

15. This item asks you to disclose information related to possible financial conflicts of interest, with the goal of maintaining research integrity. Is it possible that the financial situations or professional positions (to include promotions, contracts, clients, and reviews) of the researchers or their families could be directly impacted by the design, conduct, or results of this research?

☐ No.

☐ Yes, and the conflict of interest is being managed by the following disclosures/measures: Insert explanation here

16. Will the researcher give participants or stakeholders any gifts, payments, compensation, reimbursement, free services, or extra credit? It is acceptable to compensate your participants as long as the compensation cannot be interpreted as coercive among the participant population. For example, a $5 gift card to a coffee house is fine as a thank you gift, but an Ipod would not be, especially if the participants are teenagers. It is often better to eliminate compensation all together or make sure that 100% of your sample gets the same compensation (as opposed to only compensating those in your experimental group).

☐ No.

☐ Yes. More information is provided below.
What compensation will be given? Insert type of compensation here
At what point during the research will the compensation be given?
Insert when compensation will be given here
Under what conditions will the compensation be given? (i.e., how will compensation for withdrawn participants be handled?) Insert description here

VI. DATA COLLECTION TOOLS

In order to approve your study, the IRB needs to review the full text of each data collection tool (e.g., surveys, interview questions, etc.). This application's final checklist will direct you to send

your data collection tools and evidence of compliance with the copyright holder's usage terms at the same time you submit this IRB form. If any further changes are made to the data collection tools after they have been IRB-approved, you must submit those changes for IRB approval.

READ THIS IF YOU ARE USING A PUBLISHED INSTRUMENT:

Many assessment instruments published in journals can be used in research as long as commercial gain is not sought and proper credit is given to the original source (United States Code, 17USC107). However, publication of an assessment tool's results in a journal does not necessarily indicate that the tool is in the public domain.

The copyright holder of each assessment determines whether permission and payment are necessary for use of that assessment tool. Note that the copyright holder could be either the publisher or the author or another entity (such as the Myers and Briggs Foundation, which holds the copyright to the popular Myers-Briggs personality assessment). The researcher is responsible for identifying and contacting the copyright holder to determine which of the following are required for legal usage of the instrument: purchasing legal copies, purchasing a manual, purchasing scoring tools, obtaining written permission, obtaining explicit permission to reproduce the instrument in my dissertation, or simply confirming that the tool is public domain.

Even for public domain instruments, University of the Potomac requires students to provide the professional courtesy of notifying the primary author of your plan to use that tool in your own research. Sometimes this is not possible, but at least three attempts should be made to contact the author at his or her most recently listed institution across a reasonable time period (such as 2 weeks). The author typically provides helpful updates or usage tips and asks to receive a copy of the results.

Many psychological assessments are restricted for use only by suitably qualified individuals. Researchers must check with the test's publisher to make sure that they are qualified to administer and interpret any particular assessments that they wish to use.

READ THIS IF YOU ARE CREATING YOUR OWN INSTRUMENT OR MODIFYING AN EXISTING INSTRUMENT:

It is not acceptable to modify assessment tools without explicitly citing the original work and detailing the precise nature of the revisions. Note that even slight modifications to items or instructions threaten the reliability and validity of the tool and make comparisons to other research findings difficult, if not impossible. Therefore, unless a purpose of the study is to compare the validity and reliability of a revised measure with that of one that has already been validated, changes should not be made to existing measures. If the study is being conducted for the purpose of assessing the validity/reliability of a modified version of an existing measure, the original measure must also be administered to participants.

17. Are any of your data collection tools published or based upon a published instrument?
☐ Yes → Complete #18 a-c.
☐ No → Skip to #19a if you are only using tools you created yourself.
18a. Name the copyright holder for each published instrument.

18b. Place an X next to each of the following legal usage terms that applies to the instrument. If you are using multiple published instruments, please enter the acronym for each measure (instead of an X) next to the usage terms that apply to that instrument.	
☐	I have obtained legal copies of the instrument.
☐	I have obtained a legal copy of the manual or scoring kit.
☐	I have obtained written permission to use the instrument in my research (submitted with this application).
☐	I have obtained explicit permission to reproduce the instrument in my dissertation (submitted with this application).
☐	I have confirmed that the tool is public domain: Insert citation here
☐	Other:
18c. If you are making any modifications to the existing tool, please describe the modifications and explain why they are necessary.	
19a. List the titles of all self-designed interview guides, coding protocols, surveys, document review protocols, etc. here:	
19b. Did an expert panel outside of the faculty committee review the self-designed tool(s)? Expert panel review is not required but increases validity of a student-designed tool and thus, factors into the ratio of benefits to risks.	
☐	No
☐	Yes
19c. Did you pilot any of these tools already in a previous IRB-approved study? Piloting is not required but factors into benefits/risks assessment.	
☐	No
☐	Yes. The UOTP IRB approval number was Insert IRB approval number here
19d. Do you plan to pilot any of these tools or procedures?	
☐	No.
☐	Yes. Briefly describe exactly what aspect of the study will be piloted and ensure the pilot steps included in item #1

VII. DESCRIPTION OF THE RESEARCH PARTICIPANTS

20a. Provide the target number of participants**,** including numbers per group if your study involves multiple groups or a separate pilot sample:
20b. Provide a brief rationale for this sample size:
20c. Describe how potential participants will be found:
20d. Describe the sampling strategy and provide a brief rationale for why that strategy was selected (e.g., random sampling, maximum variation sampling, snowball sampling, criterion sampling, stratified purposeful sampling, convenience sampling, etc):

21. Please list all criteria for inclusion and exclusion of participants in this study (such as relevant experiences, age range, etc). Your inclusion criteria should define the sample's critical characteristics, based on the scope of the research question. Once you've defined inclusion criteria, if you have no further limitations on who can participate, just indicate "none" under exclusion criteria.

Inclusion criteria:

Describe how you will identify individuals who meet the inclusion criteria:

Exclusion criteria:

Describe how you will identify which individuals must be excluded:

22. Describe how potential participants' demographic variables will be relevant to obtaining an appropriate sample. (Quantitative researchers need to explain how a representative sample will be obtained in terms of gender, ethnicity, or any other relevant demographics. Qualitative researchers need to explain what demographic factors will be considered in selecting participants.)

23. The ethical challenge is to achieve the goal of equitable sampling that is appropriate to the research question while excluding vulnerable individuals whom the research procedures cannot adequately protect. At the same time, exclusion of any group reduces potential benefits to that group. So the IRB will separately weigh potential risks and benefits for each vulnerable group in this section.

The potentially vulnerable populations listed below may only be specifically recruited when (a) the vulnerability status is directly related to the research question and (b) adequate measures are taken to ensure safety and voluntary participation.

For each of the vulnerable groups below, indicate whether your procedures are designed to recruit any of the following as participants. **You need to place an X in one of the four blue boxes for each lettered category of vulnerable participants and add description of the protections to the right as indicated.**

A. Minors (17 and under)

☐	Yes: I will be specifically recruiting minors as participants. Protections are described to the right→	Describe protections from pressure to participate:	☐
		Describe protections from safety and privacy risks:	☐
☐	Possible: My participants might be minors but I may not know if they are. Protections are described to the right →	Describe protections from pressure to participate:	☐
		Describe protections from safety and privacy risks:	☐

☐	No: I will screen age so I can exclude minors. Exclusion procedures are described to the right →	Explain which screening procedure will enable exclusion of minors:	☐
☐	No: My recruitment methods automatically exclude minors.		
B. Residents of any facility (prison, treatment facility, nursing home, assisted living, group home for minors)			
☐	Yes: I will be specifically recruiting facility residents as participants. Protections are described to the right→	Describe protections from pressure to participate:	☐
		Describe protections from safety and privacy risks:	☐
☐	Possible: My participants might be facility residents but I may not know if they are. Protections are described to the right→	Describe protections from pressure to participate:	☐
		Describe protections from safety and privacy risks:	☐
☐	No: I will screen facility resident status so I can exclude them. Exclusion procedures are described to the right →	Explain which screening procedure will enable exclusion:	☐
☐	No: My recruitment methods automatically exclude facility residents.		
C. Mentally disabled individuals			
☐	Yes: I will be specifically recruiting mentally disabled persons as participants. Protections are described to the right→	Describe protections from pressure to participate:	☐
		Describe protections from safety and privacy risks:	☐
☐	Possible: My participants might be mentally disabled but I may not know if they are. Protections are described to the right→	Describe protections from pressure to participate:	☐
		Describe protections from safety and privacy risks:	☐
☐	No: I will screen mental disability status so I can exclude them. Exclusion procedures are described to the right →	Explain which screening procedure will enable exclusion:	☐
☐	No: My recruitment methods automatically exclude mentally disabled individuals.		
D. Emotionally disabled individuals			
☐	Yes: I will be specifically recruiting emotionally disabled persons as participants. Protections are described to the right→	Describe protections from pressure to participate:	☐
		Describe protections from safety and privacy risks:	☐
☐	Possible: My participants might be emotionally disabled but I may not know if they are. Protections are described to the right→	Describe protections from pressure to participate:	☐
		Describe protections from safety and privacy risks:	☐
☐	No: I will screen emotional disability status so I can exclude them. Exclusion procedures are described to the right →	Explain which screening procedure will enable exclusion:	☐

☐	No: My recruitment methods automatically exclude emotionally disabled individuals.		
E. Pregnant women			
☐	Yes: I will be specifically recruiting pregnant women as participants. Protections are described to the right→	Describe protections from pressure to participate:	☐
		Describe protections from safety and privacy risks:	☐
☐	Possible: My participants might be pregnant but I may not know if they are. Protections are described to the right→	Describe protections from pressure to participate:	☐
		Describe protections from safety and privacy risks:	☐
☐	No: I will screen pregnancy status so I can exclude them from my sample. Exclusion procedures are described to the right →	Explain which screening procedure will enable exclusion:	☐
☐	No: My recruitment methods automatically exclude pregnant women.		
F. Subordinates of the researcher			
☐	Yes: I will be specifically recruiting my subordinates as participants. Protections are described to the right→	Describe protections from pressure to participate:	☐
		Describe protections from safety and privacy risks:	☐
☐	Possible: My participants might be my subordinates but I may not know if they are. Protections are described to the right→	Describe protections from pressure to participate:	☐
		Describe protections from safety and privacy risks:	☐
☐	No: I will screen subordinate status so I can exclude them. Exclusion procedures are described to the right →	Explain which screening procedure will enable exclusion of subordinates:	☐
☐	No: My recruitment methods automatically exclude my subordinates.		
G. Students of the researcher			
☐	Yes: I will be specifically recruiting my students as participants. Protections are described to the right→	Describe protections from pressure to participate:	☐
		Describe protections from safety and privacy risks:	☐
☐	Possible: My participants might be my students but I may not know if they are. Protections are described to the right→	Describe protections from pressure to participate:	☐
		Describe protections from safety and privacy risks:	☐
☐	No: I will screen student status so I can exclude my students. Exclusion procedures are described to the right →	Explain which screening procedure will enable exclusion of students:	☐
☐	No: My recruitment methods automatically exclude my students.		
H. Clients or potential clients of the researcher			

☐	Yes: I will be specifically recruiting my clients as participants. Protections are described to the right→	Describe protections from pressure to participate:	☐
		Describe protections from safety and privacy risks:	☐
☐	Possible: My participants might be my clients but I may not know if they are. Protections are described to the right→	Describe protections from pressure to participate:	☐
		Describe protections from safety and privacy risks:	☐
☐	No: I will screen client status so I can exclude them. Exclusion procedures are described to the right →	Explain which screening procedure will enable exclusion:	☐
☐	No: My recruitment methods automatically exclude my clients.		
I. Individuals who might be less than fluent in English			
☐	Yes: I will be specifically recruiting non-English speakers as participants. Protections are described to the right→	Describe protections from pressure to participate:	☐
		Describe protections from safety and privacy risks:	☐
☐	Possible: My participants might be less than fluent in English but I may not know if they are. Protections are described to the right→	Describe protections from pressure to participate:	☐
		Describe protections from safety and privacy risks:	☐
☐	No: I will screen non-English speakers so I can exclude them. Exclusion procedures are described to the right →	Explain which screening procedure will enable exclusion:	☐
☐	No: My recruitment methods automatically exclude non-English speakers.		
J. Individuals who are in crisis (such as natural disaster victims or persons with an acute illness)			
☐	Yes: I will be specifically recruiting individuals in crisis as participants. Protections are described to the right→	Describe protections from pressure to participate:	☐
		Describe protections from safety and privacy risks:	☐
☐	Possible: My participants might be in crisis but I may not know if they are. Protections are described to the right→	Describe protections from pressure to participate:	☐
		Describe protections from safety and privacy risks:	☐
☐	No: I will screen crisis status so I can exclude them. Exclusion procedures are described to the right →	Explain which screening procedure will enable exclusion:	☐
☐	No: My recruitment methods automatically exclude individuals in crisis.		
K. Economically disadvantaged individuals			
☐	Yes: I will be specifically recruiting economically disadvantaged individuals as	Describe protections from pressure to participate:	☐

☐	participants. Protections are described to the right→	Describe protections from safety and privacy risks:	☐
☐	Possible: My participants might be economically disadvantaged but I may not know if they are. Protections are described to the right→	Describe protections from pressure to participate:	☐
		Describe protections from safety and privacy risks:	☐
☐	No: I will screen economic status. Exclusion procedures are described to the right →	Explain which screening procedure will enable exclusion:	☐
☐	No: My recruitment methods automatically exclude economically disadvantaged individuals.		
L. Elderly individuals (65+)			
☐	Yes: I will be specifically recruiting elderly individuals as participants. Protections are described to the right→	Describe protections from pressure to participate:	☐
		Describe protections from safety and privacy risks:	☐
☐	Possible: My participants might be elderly but I may not know if they are. Protections are described to the right→	Describe protections from pressure to participate:	☐
		Describe protections from safety and privacy risks:	☐
☐	No: I will screen age so I can exclude elderly individuals. Exclusion procedures are described to the right →	Explain which screening procedure will enable exclusion:	☐
☐	No: My recruitment methods automatically exclude elderly individuals.		

24. Please briefly justify the inclusion of each vulnerable group for whom you answered "Yes" or "Possible." Ensure that this response provides a rationale for why it is impossible or unethical to conduct the research without including the protected population.
25. If competency to provide consent could possibly be an issue for any participants, describe how competency will be determined and your plan for obtaining consent. If not applicable, please indicate NA.
instructional text goes here....

ADDITIONAL ISSUES TO ADDRESS WHEN PARTICIPANTS INCLUDE CHILDREN (AS PER FEDERAL REGULATIONS)

26. Will your sample include individuals less than 18 years of age?	
☐	Yes → Please complete questions 27-28.
☐	No → Please skip ahead to question 29.
27. If this study proposes to include minors, this inclusion must meet one of the following criteria for risk/benefit assessment, according to the federal regulations. Place an X in the appropriate blue box to indicate the level of risk.	
☐	Minimal risk
☐	Greater than minimal risk, but holds prospect of direct benefit to participants.
☐	Greater than minimal risk, no prospect of direct benefit to participants, but likely to yield generalizable knowledge about the participant's disorder or condition.
28. Please explain how the criterion in question 27 is met for this study.	

ADDITIONAL ISSUES TO ADDRESS WHEN PARTICIPANTS INCLUDE PRISONERS (AS PER FEDERAL REGULATIONS)

29. Is it possible that your sample will include prisoners? Place an X in the appropriate blue box below.	
☐	Yes → Please complete question 30 a-e.
☐	No → Please skip ahead to question 31.
30. Enrollment of prisoners requires that the IRB is able to document that the seven conditions under federal regulations 45 CFR 46 Subpart C are met. If you plan to recruit individuals who are at high risk of becoming incarcerated in a penal institution during the research (e.g., participants with substance abuse history, repeat offenders, etc.), it is best that the IRB can address the Subpart C requirements at the time of initial review. Otherwise, if a participant becomes incarcerated during the course of the research and the IRB has not previously reviewed and approved your research for enrollment of prisoners, all research activity must immediately cease for that individual until review and application of Subpart C regulations occurs by the IRB.	
a. Will this study examine the possible causes, effects, or processes of incarceration?	
☐	Yes
☐	No

b. Will this study examine the facility as an institutional structure?	
☐	Yes
☐	No
c. Will this study specifically examine the experience of being incarcerated?	
☐	Yes
☐	No
d. Will this study examine a condition(s) particularly affecting these prisoners?	
☐	Yes
☐	No
e. Will this study examine a procedure, innovation, or accepted practice that will have the intent or reasonable probability of improving the health or well being of the participants?	
☐	Yes, and residents will be assigned to groups by (provide explanation as to how groups will be formed here).
☐	No

Statement that subject may keep a copy of the informed consent form	☐
All potential conflicts of interest are disclosed	☐
Consent process and documentation are in language understandable to the participant	☐
There is no language that asks the subject to waive his/her legal rights	☐
If appropriate, indicates that a procedure is experimental (i.e., not a standard Rx)	☐
If appropriate, disclosure of alternative procedures/treatment	☐
If appropriate, additional costs to subject resulting from research participation	☐

FINAL IRB CHECKLIST

31. Please indicate below, by placing an X in the corresponding blue boxes, which method you are using to send each of your supporting documents. We ask that you send these supporting documents to the IRB at the same time you submit this application.

Students must obtain their supervising faculty member's approval before submitting any materials to the IRB.

	Emailed to IRB@potomac.edu	**Not applicable to my study**
Human Research Protections training completion certificate	☐	☐
Data collection tools (e.g., surveys, interviews, assessments, etc.)	☐	☐
All of the following that apply to any assessments' copyright holders: written/emailed permission to use the instrument, permission to reproduce the instrument in the dissertation, confirmation that the tool is public domain, proof of the researcher's qualifications to administer the instrument	☐	☐

Letters of Cooperation from community partner organizations (e.g., school) or individuals (e.g. cooperating teacher) who are assisting with participant recruitment or data collection	☐	☐	
Invitation to participate in research (e.g., letter, flier, phone script, ad, etc.)	☐	☐	☐
Signed Confidentiality Agreements for transcribers, statisticians, research assistant, etc.	☐	☐	☐
Consent/assent forms	☐	☐	☐

Please maintain a copy of this completed application for your records. Once the IRB application and all supporting documents have been received, the IRB staff will email the researcher and any relevant faculty supervisors to confirm that the IRB application is complete. At this time, the IRB staff will also notify the researcher of the expected IRB review date for the proposal.

The review date will be scheduled no later than 15 business days after your completion of this application. In the case of doctoral students, the review date will be scheduled no later than 15 business days after both A) the application is complete and B) the proposal is fully approved.

Notice of outcome of the IRB review will be emailed to the researcher and any supervising faculty members within 5 business days of the review. Please be aware that the IRB committee might require revisions or additions to your application before approval can be granted.

Neither pilot nor research data may be collected before notification of IRB approval. Students collecting data without approval risk expulsion and invalidation of data. The IRB will make every effort to help researchers move forward in a timely manner. Please contact IRB@potomac.edu if you have any questions.

FEEDBACK ON THIS IRB APPLICATION

32. The board is committed to making this IRB application as clear and specific as possible so that even novice researchers can provide all the information necessary for the board to evaluate the ethics of the proposed data collection. If you would like, please give us feedback on any questions or steps that you found unclear:

You will also have an opportunity to provide anonymous feedback at the end of the IRB review process.

RESEARCHER ELECTRONIC SIGNATURE

33. By placing an X next to each of these boxes and providing my email address below as an authentication, I am providing an electronic signature certifying that each of the statements below is true.	
☐	The information provided in this application form is correct, and was completed after reading all relevant instructions.
☐	I agree to conduct this and all future IRB correspondence via email.
☐	Neither recruitment nor data collection will be initiated until final IRB approval is received from IRB@potomac.edu.
☐	I understand that this research, once approved, is subject to continuing review and approval by the IRB.
☐	I, the researcher, will maintain complete and accurate records of all research activities (including consent forms and collected data) and be prepared to submit them upon request to the IRB.
☐	I understand that if any of the conditions above are not met, this research could be suspended and/or not recognized by University of the Potomac.
Enter researcher email address (provides authentication for electronic signature and thus must match email address on file with University of the Potomac):	

SUPERVISING FACULTY MEMBER ELECTRONIC SIGNATURE

34. As the faculty member supervising this research, I assume responsibility for ensuring that the student complies with University and federal regulations regarding the use of human participants in research. By placing an X in each of these boxes and providing my email address below as an authentication, I am providing an electronic signature certifying that each of the statements below is true.	
☐	I affirm that the researcher has met all academic program requirements for review and approval of this research.
☐	I will report any noncompliance on the part of the researcher by emailing notification to IRB@potomac.edu.
Faculty member should enter their email address (provides authentication for electronic signature and thus must match email address on file with University of the Potomac):	

Dissertation Chair Person's Signature: Date:

Dissertation Chair Person's Email: