|  |  |
| --- | --- |
|  |  |
|  |  Page: 1 of 7 |
|  | **PREPARED BY**: IRB Staff | **APPROVED BY**: Heather Clark  |
| **DOCUMENT TITLE:**HRP 503 A Social Behavioral Protocol | **DEPARTMENT:** Office of Research Integrity and Assurance (ORIA) | **EFFECTIVE DATE**: 12.01.2023 |

|  |
| --- |
| **INSTRUCTIONS**Complete each section of the application. Based on the nature of the research being proposed some sections may not apply. Those sections can be marked as N/A. Remember that the IRB is concerned with risks and benefits to the research participant and your responses should clearly reflect these issues. You (the PI) need to retain the most recent protocol document for future revisions. Questions can be addressed to research.integrity@asu.edu. **PIs are strongly encouraged to complete this application with words and terms used to describe the protocol is geared towards someone not specialized in the PI’s area of expertise.** |
| **IRB: 1. Protocol Title**:  |
| IRB: 2. Background and Objectives 2.1 List the specific aims or research questions in 300 words or less. 2.2 Refer to findings relevant to the risks and benefits to participants in the proposed research. 2.3 Identify any past studies by ID number that are related to this study. If the work was done elsewhere, indicate the location.TIPS for streamlining the review time:* Two paragraphs or less is recommended.
* Do not submit sections of funded grants or similar. The IRB will request additional information, if needed.
 |
| Response:  |
| IRB: 3. Data Use - What are the intended uses of the data generated from this project?Examples include:Dissertation, thesis, undergraduate project**,** publication/journal article, conferences/presentations**,** results released to agency, organization**,** employer, or school**.** If other, then describe. |
| Response: |
| IRB: 4. Inclusion and Exclusion Criteria4.1 List criteria that define who will be included or excluded in your final sample. Indicate if each of the following special (vulnerable/protected) populations is included or excluded: * Minors (under 18)
* Adults who are unable to consent (impaired decision-making capacity)
* Prisoners
* Economically or educationally disadvantaged individuals

4.2 If not obvious, what is the rationale for the exclusion of special populations?4.3 What procedures will be used to determine inclusion/exclusion of special populations?TIPS for streamlining the review time.* Research involving only data analyses should only describe variables included in the dataset that will be used.
* Course evaluation data: if there is any intent to use the course evaluation data for research, submit to the IRB to get approval.
* For any research which includes or may likely include children/minors or adults unable to consent, review content [[here]](https://researchintegrity.asu.edu/human-subjects/special-considerations)
* For research targeting Native Americans or populations with a high Native American demographic, or on or near tribal lands, review content [[here]](https://public.azregents.edu/Policy%20Manual/1-118-Tribal%20Consultation.pdf)

For research involving minors on campus, review content [[here]](https://cfo.asu.edu/minors-campus) * Research involving broader ASU student community where students are recruited outside IRB Principal Investigator’s unit requires Provost Committee Approval. Please reach out to shelly.potts@asu.edu for questions regarding this process.
 |
|  Response:  |
| IRB: 5. Number of ParticipantsIndicate the total number of individuals you expect to recruit and enroll. For secondary data analyses, the response should reflect the number of cases in the dataset. |
| Response:  |
| IRB: 6. Recruitment Methods6.1 Identify who will be doing the recruitment and consenting of participants.6.2 Identify when, where, and how potential participants will be identified, recruited, and consented.6.3 Name materials that will be used (e.g., recruitment materials such as emails, flyers, advertisements, etc.) Please upload each recruitment material as a separate document, Name the document: recruitment\_methods\_email/flyer/advertisement\_dd-mm-yyyy6.4 Describe the procedures relevant to using materials (e.g., consent form). |
| Response: |
| IRB: 7. Study Procedures7.1 List research procedure step by step (e.g., interventions, surveys, focus groups, observations, lab procedures, secondary data collection, accessing student or other records for research purposes, and follow-ups). Upload one attachment, dated, with all the materials relevant to this section. Name the document: supporting documents dd-mm-yyyy7.2 For each procedure listed, describe **who** will be conducting it, **where** it will be performed, **how long** is participation in each procedure, and **how/what data** will be collected in each procedure.7.3 Report the total period and span of time for the procedures (if applicable the timeline for follow ups). 7.4 For secondary data analyses, identify if it is a public dataset (please include a weblink where the data will be accessed from, if applicable). If not, describe the contents of the dataset, how it will be accessed, and attach data use agreement(s) if relevant.TIPS for streamlining the review time.* Ensure that research materials and procedures are explicitly connected to the articulated aims or research questions (from section 2 above).
* In some cases, a table enumerating the name of the measures, corresponding citation (if any), number of items, sources of data, time/wave if a repeated measures design can help the IRB streamline the review time.
 |
| Response:  |
| IRB: 8. Compensation 8.1 Report the amount and timing of any compensation or credit to participants. 8.2 Identify the source of the funds to compensate participants. 8.3 Justify that the compensation to participants to indicate it is reasonable and/or how the compensation amount was determined. 8.4 Describe the procedures for distributing the compensation or assigning the credit to participants.TIPS for streamlining the review time.* If partial compensation or credit will be given or if completion of all elements is required, explain the rationale or a plan to avoid coercion
* For extra or course credit guidance, see “Research on educational programs or in classrooms” on the following page: https://researchintegrity.asu.edu/human-subjects/special-considerations.
* For compensation over $100.00 and other institutional financial policies, review “Research Subject Compensation” at: https://researchintegrity.asu.edu/human-subjects/special-considerations for more information.
 |
| Response:  |
| IRB: 9. Risk to ParticipantsList the reasonably foreseeable risks, discomforts, or inconveniences related to participation in the research. TIPS for streamlining the review time.* Consider the broad definition of “minimal risk” as the probability and magnitude of harm or discomfort anticipated in the research that 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.
* Consider physical, psychological, social, legal, and economic risks.
* If there are risks, clearly describe the plan for mitigating the identified risks.
 |
| Response:  |
| IRB: 10. Potential Direct Benefits to Participants List the potential direct benefits to research participants. If there are risks noted in 9 (above), articulated benefits should outweigh such risks. These benefits are not to society or others not considered participants in the proposed research. Indicate if there is no direct benefit. A direct benefit comes as a direct result of the subject’s participation in the research. An indirect benefit may be incidental to the subject’s participation. Do not include compensation as a benefit. |
| Response:  |
| IRB: 11. Privacy and ConfidentialityIndicate the steps that will be taken to protect the participant’s privacy.11.1 Identify who will have **access to the data**.11.2 Identify where, how, and how long data will be **stored** (e.g. ASU secure server, ASU cloud storage, filing cabinets).11.3 Describe the procedures for **sharing, managing and destroying data**.11.4 Describe any special measures to **protect** any extremely sensitive data (e.g. password protection, encryption, certificates of confidentiality, separation of identifiers and data, secured storage, etc.).11.5 Describe how any **audio or video recordings** will be managed, secured, and/or de-identified.11.6 Describe how will any signed consent, assent, and/or parental permission forms be secured and how long they will be maintained. These forms should separate from the rest of the study data.11.7 Describe how any data will be **de-identified**, linked or tracked (e.g. master-list, contact list, reproducible participant ID, randomized ID, etc.). Outline the specific procedures and processes that will be followed. 11.8 Describe any and all identifying or contact information that will be collected for any reason during the course of the study and how it will be secured or protected. This includes contact information collected for follow-up, compensation, linking data, or recruitment. 11.9 For studies accessing existing data sets, clearly describe whether or not the data requires a Data Use Agreement or any other contracts/agreements to access it for research purposes. 11.10 For any data that may be covered under FERPA (student grades, etc.) additional information and requirements is available at <https://researchintegrity.asu.edu/human-subjects/special-considerations>.11.11 If your study is sponsored by HHS: NIH, you will need to comply with the revised 2023 NIH Data Management and Sharing policy. Additional information and requirements are available at https://libguides.asu.edu/NIH-2023. Please be aware, per 2023 NIH DMS policy, DMS plan is required at the time of proposal submission |
| Response:  |
| IRB: 12. Consent Describe the procedures that will be used to obtain consent or assent (and/or parental permission).12.1 Who will be responsible for consenting participants?12.2 Where will the consent process take place?12.3 How will the consent be obtained (e.g., verbal, digital signature)? 12.4 If your study is sponsored by HHS: NIH, you will need to comply with the revised 2023 NIH Data Management and Sharing policy. Additional information and requirements are available at https://libguides.asu.edu/NIH-2023. To comply with this policy, the informed consent should explain how data will be managed and shared. This sharing should be consistent with the DMS plan.TIPS for streamlining the review time.* If participants who do not speak English will be enrolled, describe the process to ensure that the oral and/or written information provided to those participants will be in their preferred language. Indicate the language that will be used by those obtaining consent. For translation requirements, see Translating documents and materials under <https://researchintegrity.asu.edu/human-subjects/protocol-submission>
* Translated consent forms should be submitted after the English is version of all relevant materials are approved. Alternatively, submit translation certification letter.
* If a waiver for the informed consent process is requested, justify the waiver in terms of each of the following: (a) The research involves no more than minimal risk to the subjects; (b) The waiver or alteration will not adversely affect the rights and welfare of the subjects; (c) The research could not practicably be carried out without the waiver or alteration; and (d) Whenever appropriate, the subjects will be provided with additional pertinent information after participation. Studies involving confidential, one time, or anonymous data need not justify a waiver. A verbal consent or implied consent after reading a cover letter is sufficient.
* ASU consent templates are [[here]](https://researchintegrity.asu.edu/human-subjects/forms).
* Consents and related materials need to be congruent with the content of the application.
 |
| Response:  |
| IRB: 13. Site(s) or locations where research will be conducted.List the sites or locations where interactions with participants will occur-* Identify where research procedures will be performed.
* For research conducted outside of the ASU describe:
	+ Site-specific regulations or customs affecting the research.
	+ Local scientific and ethical review structures in place.
* For research conducted outside of the United States/United States Territories describe:

Safeguards to ensure participants are protected.* For information on international research, review the content [[here]](https://www.hhs.gov/ohrp/sites/default/files/2020-international-compilation-of-human-research-standards.pdf).

For research conducted with secondary data (archived data):* List what data will be collected and from where.
* Describe whether or not the data requires a Data Use Agreement or any other contracts/agreements to access it for research purposes.
* For any data that may be covered under FERPA (student grades, etc.) additional information and requirements is available [[here]](https://researchintegrity.asu.edu/human-subjects/special-considerations).
* For any data that may be covered under FERPA (student grades, homework assignments, student ID numbers etc.), additional information and requirements is available [[here]](https://researchintegrity.asu.edu/human-subjects/special-considerations).

Response:IRB: 14. Human Subjects Certification from Training.Provide the names of the members of the research team. ASU affiliated individuals do not need attach Certificates. Non-ASU investigators and research team members anticipated to manage data and/or interactwith participants, need to provide the most recent CITI training for human participants available at www.citiprogram.org. Certificates are valid for 4 years. TIPS for streamlining the review time.* If any of the study team members have not completed training through ASU’s CITI training (i.e. they completed training at another university), copies of their completion reports will need to be uploaded when you submit.
* For any team members who are affiliated with another institution, please see “Collaborating with other institutions” [[here]](https://researchintegrity.asu.edu/human-subjects/special-considerations)
* The IRB will verify that team members have completed IRB training. Details on how to complete IRB CITI training through ASU are [[here]](https://researchintegrity.asu.edu/human-subjects/training)
 |
| **Response:** |
| 15. Conflicts of Interest15.1? Do any of the team members have a financial interest in any entity involved in the project(s) under this IRB study? **Financial interest**: The receipt or expectation of anything of pecuniary (money) or proprietary (ownership) value from a non-ASU entity (domestic or foreign, private or public). Examples of possible interests (not limited to):• Compensation of any amount including (not limited to) consultant fees, payments for services, honoraria, royalties, or other income.• Ownership interest of any value including (not limited to) stocks and stock options, private equity, or other ownership interests.• Venture capital financing.• Intellectual property interests of any value including (not limited to) patents, trademarks, copyrights, and licensing agreements.• Board or executive relationship, regardless of compensation.• Reimbursed or sponsored travel by an entity other than a federal, state, or local government agency, higher-education institution or affiliated research institute, academic teaching hospital, or medical center.**15.2 Who holds the interest**? The individual involved in the research, or relative of this individual. Disclose financial interests in ERA MyDisclosures module.  For questions related to financial interests, email COI@asu.edu. |
| **Response:** |
| PROCEDURES FOR THE REVIEW OF HUMAN SUBJECTS RESEARCH |
|  |
| **General Tips:*** Have all members of the research team complete IRB training before submitting.
* Ensure that all your instruments, recruitment materials, study instruments, and consent forms are submitted via ERA when you submit your protocol document. Templates are [[here]](https://researchintegrity.asu.edu/human-subjects/forms)
* Submit a complete protocol. Don’t ask questions in the protocol – submit with your best option and, if not appropriate, revisions will be requested.
* If your study has undeveloped phases, clearly indicate in the protocol document that the details and materials for those phases will be submitted via a modification when ready.
* Review all materials for consistency. Ensure that the procedures, lengths of participation, dates, etc., are consistent across all the materials you submit for review.
* Only ASU faculty, full time staff may serve as the PI. Students may prepare the submission by listing the faculty member as the PI. The submit button will only be visible to the PI.
* Information on how and what to submit with your study in ERA is [[here]](https://researchintegrity.asu.edu/human-subjects/protocol-submission). Note that if you are a student, you will need to have your Principal Investigator submit.
* For details on how to submit this document as part of a study for review and approval by the ASU IRB, visit <https://researchintegrity.asu.edu/human-subjects/protocol-submission>.
 |
|  |
|  |