ARCADIA UNIVERSITY
— COMMITTEE ON THE PROTECTION —
OF RESEARCH SUBJECTS

Institutional Review Board (IRB)
Application for Expedited/ Full Board Review

Please fill in all parts of this form that are required. Provide a non-scientific or lay summary of the project that must include the items listed below. The Protocol Summary will be reviewed only if all required sections are completed. **(The spaces provided will expand as you type and will become scroll boxes).** *NOTE: If the protocol is part of a grant, please upload the grant documents (proposal and budget) to the IRBNet package as an appendix.*

1. **Background and Objectives - Describe the purpose of the study. Describe any past studies that are related to this study (short literature review).**

2. **Data Use (Select all that apply):**
   ☐ Dissertation, Thesis, Undergraduate honors project
   ☐ Publication/journal article, conferences/presentations
   ☐ Results released to agency or organization
   ☐ Results released to participants/parents
   ☐ Results released to employer or school
   ☐ Other Click here to enter text.

3. **Study Population - Are the human subjects involved in the proposed activity included in the following categories? (check all that apply, at least one box must be checked)**
   ☐ Minors
   ☐ Prisoners
   ☐ Terminally ill subjects
   ☐ Economically and/or educationally disadvantaged persons
   ☐ None of the above
   ☐ Pregnant women, human fetuses, neonates
   ☐ AIDS/HIV-positive subjects
   ☐ Subjects with intellectual disabilities
   ☐ Minorities
   ☐ Other Click here to enter text.

4. **Supplemental Materials - Attach a copy of the following items as applicable to your study (Please check the ones that are attached):**
   ☐ Research Methods (Research design, Data Source, Sampling strategy, etc).
   ☐ Any Letters (cover letters or information letters), Recruitment Materials, Questionnaires, etc. which will be distributed to participants.
   ☐ If the research is conducted off-site, provide a permission letter.
   ☐ If the research is part of a proposal submitted for external funding, submit a copy of the proposal and budget submitted to the funder.

5. **Inclusion and Exclusion Criteria - Describe the criteria that define who will be included or excluded in your study sample. If you are conducting data analysis only describe what is included in the data set you propose to use.**

6. **Number of Participants - Indicate the total number of anticipated participants to be recruited and enrolled.**

7. **Recruitment Method - Describe who will be doing the recruitment of participants. Describe when, where, and how potential participants will be identified and recruited. Describe and attach materials that will be used to recruit participants (attach documents or recruitment script with the application).**

8. **Consent Process - Describe the process and procedures process you will use to obtain consent. Include a description of: who will be responsible for completing the consent process with participants, where the consent process will take place, how consent will be obtained; and 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.**

9. **Procedures Involved - Describe procedures including:**
   - **Who will facilitate the procedures and when they will be performed?**
   - **The duration of time participants will spend in each research activity.**
   - **Surveys or questionnaires that will be administered (Attach all surveys, interview questions, scripts, data collection forms, and instructions for participants).**
   - **Interventions and sessions (Attach supplemental materials).**
   - **Lab procedures and tests and related instructions to participants.**
   - **Video or audio recordings of participants.**
   - **Previously collected data sets that that will be analyzed and identify the data source.**
   - **How data will be analyzed.**

10. **Compensation or Credit - Describe the amount and timing of any compensation or credit to participants. Identify the source of the funds to compensate participants**

11. **Risk to Participants - List the reasonably foreseeable risks, discomforts, or inconveniences related to participation in the research. Consider physical, psychological, social, legal, and economic risks.**

12. **Potential Benefits to Participants - Realistically describe the potential benefits that individual participants may experience from taking part in the research. Indicate if there is no direct benefit. Do not include benefits to society or others.**

13. **Confidentiality - Describe the following measures to ensure the confidentiality of data: Who will have access to the data? Where and how data will be stored? How long the data will be stored? How and when will data be de-identified?**

---

14. **External IRB:**
    a) **Is this proposal currently under review or has it been reviewed and approved by another institution's IRB?** IF YES, include a copy of the proposal and if available, IRB approval from that institution. If the proposal has not yet been submitted to the other institution, please note an anticipated date of submission and a copy of the other institution's review guidelines.

    ☐ Yes ☐ No

    Anticipated date of Submission:

b) **Is this a collaboration with another institution (if yes, please move to section 3 c)?**

☐ Yes ☐ No

c) **Is each institution doing their own review or will one institution serve as the primary IRB through an Authorization Agreement?**
☐ Each institution will complete their own review.
☐ An Authorization Agreement will be signed.

---

15. **Project Funding:**
How is the research project funded? *
☐ Research is not funded by external sponsor. (Go to question 4)
☐ Funding decision is pending. (A copy of the grant proposal and budget that was submitted to the funder must be provided prior to IRB approval)
☐ Research is funded by external sponsor. (A copy of the grant proposal and budget that was submitted to the funder must be provided prior to IRB approval)

a) **What is the source of funding or potential funding? (Check all that apply)**
☐ Federal ☐ State ☐ Foundation
☐Other Click here to enter text.

b) **Please list the name(s) of the sponsor(s):**

---

16. **HIPAA:**
a) **Is any of the data coming from covered entities* under HIPAA?**

☐ Yes ☐ No

IF YES, please describe:

b) **Is a data use agreement** required?**

☐ Yes ☐ No

c) **Is a HIPAA Waiver of authorization*** requested?**

☐ Yes ☐ No

*** Covered Entity-** A health plan, a health care clearinghouse, or a health care provider who transmits health information in electronic form in connection with a transaction for which HHS has adopted a standard.

**** Data Use Agreement-** An agreement into which the covered entity enters with the intended recipient of a limited data set that establishes the ways in which the information in the limited data set may be used and how it will be protected.

*** **Waiver of Authorization-** The documentation that the covered entity obtains from a researcher or an IRB or a Privacy Board has waived or altered the Privacy Rule's requirement that an individual must authorize a covered entity to use or disclose the individual's PHI for research purposes.

17. **Conflicts of Interest**

a) **Do you or any member of your research group, spouses or any dependent children have any interest (i.e. any property of financial interest including stock in the sponsor company, patents, trademarks, copyrights or licensing, supplemental research grants or consulting arrangements) in the test drug/product, device, or research procedure that is the subject of this study that could affect any of the following: the study outcome, data analysis, enrollment of subjects, study design.**

☐ Yes ☐ No

IF NO, please move on to section 16.

IF YES, please disclose below and the ways in which the researchers will minimize harm to research subjects and/or the objectivity of research. Please discuss how these conflicts will be managed during the period of the trial. Include language disclosing such interest in the consent form for the use by research subjects.

In addition, for industry-sponsored trials, please attach the documentation submitted to the sponsor as required by 21CFR54.1, if applicable.

b) **If related to a grant, have all investigators filed a current annual Significant Financial Interest Form?**

☐ Yes ☐ No

c) **Among the research team, is there any financial interest that could affect any of the following: the study outcome, data analysis, enrollment of subjects, study design?**

☐ Yes ☐ No

IF YES, please describe and disclose in the consent form.

d) **Are there any plans for commercial development related to the findings of this study?**

☐ Yes ☐ No

IF YES, please describe

e) **Will participants financially benefit if the findings are commercialized?**

☐ Yes ☐ No

IF YES, please describe

18. **CITI Training- Have the Principal Investigator, Co-PI(s), and faculty advisor (if PI is a student) taken the on-line CITI Course in the Protection of Human Research Subjects? (IF YES, include certificates on IRBNet submission)**

☐ Yes ☐ No