**REGENT UNIVERSITY**

**HUMAN SUBJECTS REVIEW APPLICATION**

Please submit *one electronic* copy of this form to your school’s HSR representative. Supporting materials should be appended to this document (see Attachments below).

Which type of HSR Application do you wish to submit?

 [ ]  Exempt

 [ ]  Expedited

**1.** **PRINCIPAL** **INVESTIGATOR (i.e., researcher):**

E-Mail: Click here to enter text.

Date: Click here to enter text.

**List of all project personnel (including faculty, staff, outside individuals or agencies):**

 If you are a **student**, please provide the following additional information:

 This research is for [ ] Dissertation [ ] Thesis [ ] Independent Study

 [ ] Other:

 Faculty Advisor’s Name: Click here to enter text.

**2. TRAINING**

 [ ]  I have completed CITI human subjects research training within the past three years.

**Please attach a copy of your training certificate(s)\***

Training Date: Click here to enter text.

\*Note: If you are proposing psychotherapy research, medical research, or other research that requires HIPAA training, you may be required to take the CITI supplemental module, “Research and HIPAA Privacy Protections” for clinical research. Check with your school’s HSR representative to verify.

**3.** **PROJECT TITLE:**

**4.** **IS THIS RESEARCH BEING SUBMITTED AS PART OF A FUNDED RESEARCH PROPOSAL?** [ ] Yes [ ] No

 If yes, please identify the funding source:

**5**. **ANTICIPATED LENGTH OF HUMAN SUBJECTS CONTACT**:

 Beginning Date: Click here to enter text.

 Ending Date: Click here to enter text.

**6.** **DESCRIPTION OF PARTICIPANTS**:

Number: Click here to enter text. Age Range: Click here to enter text.

 Briefly describe subject population:

**7.** **PROJECT DESCRIPTION**

Briefly describe (or attach) the methodology and objectives of your research (including hypotheses and/or research questions), the data collection procedures, and any features of the research design that involve procedures or special conditions for participants, including the frequency, duration, and location of their participation. The description should be no longer than 3 pages single space. Attach addendums for materials and detailed descriptions of the research if more space is needed. For example, if you are doing a group protocol, please include it as an addendum.*Please note that complete chapters of thesis/dissertation proposals will not be accepted.*

**HSR Project Description Checklist**

|  |  |  |
| --- | --- | --- |
| 1. **Is your data being recorded and stored anonymously?**
 | No[ ]  | Yes[ ]  |
| 1. **Is your data being reported/published anonymously?**
 |[ ] [ ]
| 1. **Will you be using existing data or records? If yes, describe in project description (#7 above)**
 | No[ ]  | Yes[ ]  |
| 1. **Will you be using surveys, questionnaires, interviews or focus groups with subjects? If yes, describe in #7 and include copies of all in application.**
 | No[ ]  | Yes[ ]  |
| 1. **Will you be using videotape, audiotape, film? If yes, describe in #7**
 | No[ ]  | Yes[ ]  |
| 1. **Do you plan to use any of the following populations? Regent students, Regent employees, Non-English speaking, cognitively impaired, patients/clients, prisoners, pregnant women? If yes, describe which ones in #7**
 | No[ ]  | Yes[ ]  |
| 1. **Do you plan to use minors (under 18)? If yes, describe in #7 and give age ranges**
 | No[ ]  | Yes[ ]  |
| 1. **Are official IRB or HSR sites, outside of Regent, engaged in the research? If yes, describe in #7 and give consent letter or their IRB/HSR information**
 | No[ ]  | Yes[ ]  |
| 1. **Are you collecting sensitive information such as sexual behavior, HIV status, recreational drug use, illegal behaviors, child/elder/physical abuse, immigrations status, etc? If yes, describe in #7.**
 | No[ ]  | Yes[ ]  |
| 1. **Are you using machines, software, internet devices? If so describe in #7**
 | No[ ]  | Yes[ ]  |
| 1. **Are you collecting any biological specimens? If yes, describe in #7**
 | No[ ]  | Yes[ ]  |
| 1. **Will any of the following identifying information be collected: names, telephone numbers, social security number, fax numbers, email addresses, medical records numbers, certificate/license numbers, Web universal resource locators (URLs), Internet protocol (IP) address numbers, fingerprint, voice recording, face photographic image, or any other unique identifying number, code or characteristic other than “dummy” identifiers? If yes, describe in #7**
 | No[ ]  | Yes[ ]  |
| 1. **Will there be data sharing with any entity outside your research team? If so, describe who in #7**
 | No[ ]  | Yes[ ]  |
| 1. **Does any member of the research team or their family members have a personal financial interest in the project (for commercialization of product, process or technology, or stand to gain personal financial income from the project)? If yes, describe in #7.**
 | No[ ]  | Yes[ ]  |
| 1. **As applicable, do you plan to provide a debriefing to your participants? If written, include in application as addendum**
 | No [ ]  | Yes[ ]  |
| 1. **Will there be any inducement to participate, either monetary or nonmonetary? If there is inducement please describe how the amount is not coercive in #7.**
 | No[ ]  | Yes[ ]  |
| 1. **Will there be any costs that subjects will bear (travel expenses, parking fees, professional fees, etc. If no costs other than their time to participate, please indicate)? If yes describe in #7**
 | No[ ]  | Yes[ ]  |
| 1. **Will subjects be studied on Regent University campus? If yes, please describe where the study will be done in #7**
 | No[ ]  | Yes[ ]  |
| 1. **Will subjects be obtained by internet only? If yes, please describe what internet forums or venues will be used to obtain participants in #7**
 | No[ ]  | Yes[ ]  |
| 1. **Are you using the Regent University consent form template? Whether using the template or requesting an alternate form, you must include a copy in your submission.**
 | No[ ]  | Yes[ ]  |

**8. PARTICIPANT RECRUITMENT**

Describe the sources of potential participants, how they will be selected and recruited, and how and where you will contact them. Describe all relevant characteristics of the participants with regard to age, ethnic background, sex, institutional status (e.g., patients or prisoners), and their general state of mental and physical health.

**9. INFORMED CONSENT**

 Describe how you will inform participants of the nature of the study. Attach a copy of your cover letter, script, informed consent form and other information provided to potential participants.

**10. WRITTEN CONSENT**

[ ]  I am requesting permission to **waive written consent**, based on one or more of the following categories (check all that apply):

[ ]  The only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality.

[ ]  The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

[ ]  I will be using a **written consent form**. Attach a copy of the written consent form with this application.

**11. CONFIDENTIALITY OF DATA**

What procedures will be used to safeguard identifiable records of individuals and protect the confidentiality of participants?

**12**. **ATTACHMENTS**: Attach copies of all relevant project materials and documents, including (check all that apply):

[ ]  A copy of your training certificate (required for principal investigator)

[ ]  Surveys, questionnaires, and/or interview instruments

[ ]  Informed consent forms or statements

**13. AFFIRMATION OF COMPLIANCE:**

By submitting this application, I attest that I am aware of the applicable principles, policies, regulations, and laws governing the protection of human subjects in research and that I will be guided by them in the conduct of this research. I agree to comply with procedures set forth on the University’s human subjects review webpage (<https://www.regent.edu/academics/academic_affairs/HSR/>) to ensure that the rights and welfare of human participants in my project are properly protected." I understand that the study will not commence until I have received approval of these procedures from the Human Subjects Review process.

[ ]  I submit the application with the understanding outlined above.