**Roger Williams University HSRB application Preparation**

***Very Important:****Any text or item that appears in RED will need to be described in a separate attached document which will outline the details of your proposal. All documents will be uploaded in*appropriate sections *at the end of this application.*

**1. You are** *Your affiliation with Roger Williams University*

*If you are not affiliated with Roger Williams University, please supply the name of your contact at Roger Williams University.*

**2. Type of application**

New: *You have never applied for HSRB approval of this research protocol.*

Reapplication/appeal: *You have already submitted this protocol for approval, and the HSRB has requested more information.*

Renewal: *This research protocol has been approved previously, and it's time for its annual review. (You must attach a status report for the project; see question 45.)*

Change of Protocol: *This research protocol has been approved previously and since approval there have been changes made (e.g., informed consent, materials, etc.).*

**3. Type of project**

Administration, Class project, Faculty research, Graduate student, Staff, Undergraduate student

**4. Type of review requested** Exempt/Expedited/Full

**5. Your name, email address, title (Professor, Director, etc.)**

**6. If student, faculty advisor’s name and email**

**7. Department and School**

**8. Co-investigators (if any)**

**9. Project title**

**10. Grant funding supporting this research** *If yes, please identify the funding source. (You must also attach a copy of your grant proposal and/or award letter)*

**11. Research question** *Briefly summarize, in non-technical language, the question you are investigating. Do not simply copy and paste from your proposal. Provide just the information that the HSRB needs to understand your reasons for doing the research. PLEASE NOTE: "See attached" is not an acceptable response.*

**12. Target population** *Describe the target population from which you will recruit your subjects.*

**13. Estimated number of participants**

**14. Participant types you will include** *Check all that apply, in whole or in part, to your subject pool.*

*Children (17 years or younger)*

*Cognitively impaired persons*

*Prisoners*

*Pregnant women*

*Elected or appointed officials or candidates for public office*

*None of the groups listed above*

*If another targeted population, please describe.*

**15. Study location** *Where will the study be conducted?*

**16. Cooperating institution** *If you will perform your research at any place other than your home institution, you must attach an* ***exact duplicate******of the original******letter or email of permission or support from the institution where you will do the work*** *to the end of this application.*

**17. Methods of data collection**

*Select all methods of data collection you will use to perform your research.*

*Survey: you will distribute an electronic or paper survey to subjects.*

*Restricted database/secondary data: you will use only the data contained in a secure, restricted database.*

*Observation: you will watch your subjects but not interact with them.*

*None of these data types.*

***Very Important:****If you selected Survey you must describe how you will distribute and collect your surveys in a way that protects your participants' privacy and respects the voluntary aspect of their participation. Please describe as specifically as possible how participants will receive and submit their surveys in such a way that permits no one - including the researchers - to connect a survey with a participant. This includes any experimental studies in which participants will be assigned to a treatment condition and respond to questions relating to the study.   
  
If you selected Restricted database/secondary data you will need to describe what kind of data the particular database contains: Specifically, what population, how was it sampled and when was data gathering approved by an /IRBHSRB. If approval was needed please indicate the approval source. How is confidentiality and anonymity ensured? Who owns the data? Do they require that you have any kind of training or certification? How will you gain access to this database?   
  
If you selected Structured/semi-structured interviews you will use only the script or interview guide included in this application to interview participants.  
  
If you selected None you will need to describe the data collection method you will use in detail in an attached document at the end of this application.*

**18. Will data be collected anonymously?** *Anonymous: collected in such a way that it can NEVER be connected to an individual, and even you won't know which participant provided which data.*

**19. Will data be collected confidentially?** *Confidential: You will protect your subjects' identifying information from access by anyone besides yourself, your co-PIs, and/or your faculty advisor.*

**20. Will identifiers be removed?**

**21. Will you make video and/or voice recordings or take photos?** *If yes, please state the reason that you need these recordings.*

**22. Personal records** *Will you use personal (non-public) records as sources of data?*

**23. Deception** *Will your research require you to deceive your subjects to get the data you want?*

**24. Stress** *How would you describe the effects of your data collection on your subjects?*

*A potentially stressful experience*

*Not at all stressful*

**ATTACHMENTS**

**Research protocol** *(required for all projects)*

*Attach a detailed description of your project's goals, methods, and data analysis strategy. Be sure to include recruiting procedure and participation requirements, risk analysis, and benefits to participants. If your study includes vulnerable participants, please describe the special protections you will employ. Unless participants explicitly waive their right to privacy, all work with human subjects is presumed to be confidential. Please describe as specifically as possible what measures you will take to ensure that your data are not accessible to anyone besides you and any other co-PI on this study.*

*(pdf only)*

**Faculty advisor approval**

*Please attach a letter or email from your faculty advisor confirming that he or she has read and approved your research plan. Wording suggestion: I have reviewed this completed application and I am satisfied that the proposed research and its measures are adequate for the protection of human subjects. To the best of my knowledge, all the information in this application is truthful. (Word or pdf)*

**CITI Training certificate or equivalent** *(required for all projects) (pdf only)*

*Attach the certificate you earned by completing CITI's Social & Behavioral Research training course (*[*www.citiprogram.org*](http://www.citiprogram.org)*; instructions for setting up an account are available on the HSRB website. Training is valid for three years for faculty, staff and students.*

**Informed Consent (***required for all projects except those using restricted databases or secondary sources)*

Attach your Informed Consent - the document you will attach is on the [HSRB website](https://www.rwu.edu/who-we-are/administration-and-governance/committees-governance/hsrb/important-dates-and-forms). Informed Consent is required for ALL human subjects. The HSRB will also review oral consent if your participants are unable to give legal consent (less than 18 years of age or cognitively impaired). If this is the case you must obtain written consent from a guardian and oral assent from the participant. Attach a copy of the script you will use if obtaining oral consent/assent from the participant. *(Word or pdf)*

**Institutional permission** *(required if your research will be conducted in another institution other than Roger Williams University - Bristol or Providence Campus) (Word or pdf)*

*Attach a copy of the permission letter or email of permission of support from the institution where you will be conducting your study.*

**Grant proposal** *(required if your project will be funded by an external sponsor) (Word or pdf)*

*If you have applied for funding to support this proposal, attach your grant proposal here.*

**Status report** (required only for renewals and extensions)

Attach a status report of the project to date, including:

* a summary of any amendments or modifications since the last review
* a copy of the current informed consent document and any other newly developed materials relevant to your study - particularly if risks associated with the study have been modified
* the total number of participants involved in your study thus far

The forms you will attach are on the HSRB website *(Word or pdf)*

**Other documents** Attach final copies of the following documents that you will use in your study:

* Surveys - required for all survey research
* Interview - required for all projects using interview (for example focus groups, etc.)

*any other documents needed to assist the HSRB understand the scope of your study, how you intend to collect your data (Word or pdf)*

**Statement of Ethics and Submission Certification***(required final step in the application process)*  
  
*I have read the Roger Williams University Policy on Protection of Human Subjects and will comply with all of its ethical requirements. I certify that my research will include no other means for data collection beyond those that I have described in this application and have included in my materials. I certify that all the information in this application is truthful and that in the event any significant changes are made to this proposed study, I will inform the HSRB.*

*I have read this certification and, by submitting this application, agree to abide by its terms.*

*Type your name in the area below*