

Guidelines for Preparing an RWU HSRB Initial Application

(revised 8/16/2022)

This document guides you through the questions of the RWU Human Subjects Research Board (HSRB) application. ***It is highly recommended that you prepare the questions outlined below PRIOR to initiating your application in this document – you can then copy and paste into Etrieve.***

Failure to address questions and upload documents may result in delay in the review of your application and/or may require resubmission.

The HSRB Initial Application will be submitted as an Etrieve package. The responses to this form will be written into the Etrieve form and supplemental material will be uploaded.

PLEASE DO NOT BEGIN THE APPLICATION UNTIL YOU HAVE REVIEWED THE QUESTIONS BELOW AND HAVE ALL RESPONSES AND DOCUMENTS FULLY PREPARED FOR SUBMISSION.

NOTE regarding attachments:

For some of the questions on the survey, you will need to submit attachments, preferably as Microsoft Word (.doc, .docx) or Adobe Acrobat (.pdf) files. Please be sure these documents are accessible and legible prior to your submission. The questions requiring documentation are highlighted in **text boxes** in the outline below.

HSRB APPLICATION OUTLINE

Welcome to the RWU Human Subjects Review Board (HSRB) application. This form should be completed for the following types of applications:

- **NEW:** You have never applied for HSRB approval for this research protocol. (Submitted via ETRIEVE)
- **REVISED/APPEAL:** You have already submitted this protocol for approval and the HSRB has requested edits/modified information. (Submitted via Qualtrics for Fall 2022)
- **RENEWAL:** This protocol was previously approved by the HSRB, but it has been more than one (1) year since the protocol ended/the protocol term limits have expired. (Submitted via Qualtrics for Fall 2022)

If you need to submit a Protocol update for a study that has already been approved, please use the link to the [Protocol Change Application](#) on the HSRB website. (Submitted via Qualtrics for Fall 2022)

1. **Project title** (*Recommended length of 12 words/24 characters or less*)

2. **Your name**

3. **Your email**

4. **Your preferred name and title as identified for HSRB correspondences**

Examples: Dr. Snow, Mr./Mrs./Ms. Snow, Charlotte/Ng/Carlos/Charles

5. **Your RWU affiliation**

- *Student, Staff, Faculty, I am not affiliated with Roger Williams University*

If you are a student, you will need to attach a letter or email from your faculty advisor confirming that they have read and approved your research plan.

Suggested language: 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.

If you are not affiliated with Roger Williams University, you must provide the name of your co-investigator(s) at RWU.

6. List all RWU and non-RWU co-investigators and research team member, their preferred names/titles, emails, and institutional affiliations (if non-RWU)

Examples: Charlotte Snow, Dr. Snow, csnow@rwu.edu; Charles Snow, Charles, Charles.snow@gmail.com, Research Consortium of RI

7. CITI Training certificate or equivalent (required for each researcher/co-investigator for all projects) (pdf only)

Instructions available on the [HSRB website](#).

Submit as a single file the certificates of all co-investigators and research assistants earned by completing the CITI Social and Behavioral Research Training course

Note: If one or more of the researchers' CITI certifications has expired, they will be required to renew their certificate prior to HSRB approval.

8. Type of application.

- New: *You have never applied for HSRB approval of this research protocol.* (Submitted via Etrieve)
- Revised application/appeal: *You have already submitted this protocol for approval, and the HSRB has requested more information.* (Submitted via Qualtrics for Fall 2022)
- Renewal: *This research protocol was previously approved by the HSRB, but it has been more than one (1) year since the protocol ended/the protocol term limits have expired. NOTE that additional information regarding the status of the original proposal may be requested.* (Submitted via Qualtrics for Fall 2022)

For Revised applications/appeals or Renewals, you will be prompted to enter the original HSRB protocol number.

9. Type of project (check all that apply).

- Basic or Applied Research (*not classroom related—faculty/staff/graduate student project, student thesis, Honors capstone*)
- Class project with research component (*includes projects at the individual, group, or class level*)
- Community-engagement (*surveys, interviews, & activities part of involvement with community partners*)
- Program evaluation (*pre and/or post surveys of program effectiveness*)

- Assessment of teaching and learning
- Other (*please explain*)

If a class project, you will be prompted to provide the course name and number and the course instructor's name and email.

10. Is the research being funded from an external source?

If yes, you will be prompted to enter: Type of funding (federal, state/local, foundation/private, institutional/university); Name of funding source; Grant/project title

You will also be prompted to upload a copy of the grant proposal and award letter (as a single file).
If yes, please identify the funding source and if affiliated with the U.S. Department of Health and Human Services. A list of the agencies affiliated with HHS can be found on their website here: [HHS Agencies](#) You must also attach a copy of your grant proposal and/or award letter.

11. Briefly summarize the topic of your research and describe the research goals and/or hypotheses for your study.

Briefly summarize, in non-technical language, the question(s) you are investigating. What is the purpose of the research? Responses should be 50 words or less.

OPTIONAL: If you prefer, you may upload a summary of your background literature, goals, and hypotheses as an attachment.

12. Estimated sample size/number of participants.

Please estimate the number of participants you intend to recruit as part of our research.

13. Describe the process of participant recruitment, including the target population (s). Be explicit regarding how the researchers will recruit participants and obtain informed consent.

14. Do any of the researchers have any existing or prior relationships or affiliations with the participants and/or with community agencies or organizations from which participants will be recruited?

- No
- Yes

If yes, please describe any affiliations the researchers have with either the participants and/or with the community agencies or organizations from which participants will be recruited. Explain what steps will be taken to ensure the recruitment is noncoercive and any potential conflicts of interest are addressed.

15. Research involving participants from outside RWU and that involves off-site data collection requires written permission from the cooperation institution.

Will you need permission from an agency, organization, or cooperating institution (other than RWU) to conduct this study?

- No
- Yes

If yes, please attach a copy of an original letter or email of permission or support from the organization(s) from which you will be recruiting participants and/or conducting your study.

16. **Provide a summary of the research protocol. This should include a description of the activities of BOTH participants and the researchers. Please also specify the location(s) for all research activities.**

OPTIONAL: If you prefer, you may upload a summary of your research methodology and procedures as an attachment.

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

- Survey: *You will distribute an electronic or paper survey to participants.*
- Archival: *You will use information previously collected for another purpose and/or which is currently stored in a secure, restricted database.*
- Ethnography/Observation/Participant Observation: *You will utilize methods that involve watching and/or interacting with your participants in a naturalistic environment.*
- Structure/semi-structured interviews: *You will use scripts or interviews to ask participants questions or solicit narrative accounts.*
- Experiment/Quasi-experiment: *You are investigating the effects of different treatment conditions or protocols.*
- Other: *Please explain*

For each method chosen, you will be asked to submit copies of your materials (surveys, interview questions, experimental stimuli, etc.).

For archival data, you will be required to explain the data set you will be using, the nature of your secondary analyses, and any institutional permissions required to access the data set.

18. **Please upload a copy of your informed consent. The informed consent must include the name and contact information for the Principal Investigator for the study. Templates of informed consent documents are posted on the HSRB website: [Informed Consent Templates](#)**

If multiple consent forms are required (due to language translations, different sets of procedures, etc.), you must upload a copy of each version.

19. **Will data be collected anonymously?**

Definition of anonymous: Collected in such a way that it can NEVER be associated with any individual including you as a researcher/PI. You will have no knowledge of which participant provided which data.

- No
- Yes

20. **Will data be collected confidentially?**

Definition of confidential: You will protect your participants' identifying information from access by anyone besides yourself and any co-investigators.

- No
- Yes

21. Will you make video and/or voice recordings or take photos as part of the research protocol?

- No
- Yes

22. Please explain how data will be coded, and what steps will be taken to remove participants' identifying information and store data in a manner to ensure that no one can trace information back to a particular participant. [not required for studies in which data is collected anonymously].

NOTE: If video or audio recordings will be used, provide details regarding what additional steps will be taken to secure the data and ensure confidentiality.

23. Briefly summarize the plan for data management and data analysis. Include a description of how data will be coded (if not specified above) and how long data will be stored. Please also summarize preliminary plans for data analysis.

NOTE: If the proposal will access archival data, please specify how the data analyses will expand upon previous research with this dataset to qualify as a "new" research project.

24. Please describe any potential benefits of participating in the research study.

25. Will incentives be offered to individuals for their participation in the research study?

- No
- Yes

If yes, describe any incentives and how they will be awarded to participants.

26. According to the Office of Human Research Protections (OHRP), risk of harm as a result in participating in a study includes "physical, psychological, economic, or social harm." Does your study pose any potential risks to participants?

- No
- Yes

If yes, describe any potential stressors to the participants, and the steps that will be taken to minimize the stressors and/or address potential risk of harm to participants.

27. Please indicate any potentially vulnerable participants included in your study, as defined by the Office of Human Research Protections (check all that apply).

As noted above, knowledge of the target populations guides the HSRB in the review process and application status (Exempt, Expedited, or Full), as defined by the Office of Human Research Protections (add cite here)

- Children (17 years or younger)
- Cognitively impaired persons
- Prisoners
- Pregnant women

- *Elected or appointed officials or candidates for public office*
- *Other*
- *None of the above*

If other, describe the other potentially vulnerable populations included in this study.

Please explain what special precautions will be employed to protect research participants. If children are to be recruited, please include an asset form.

***It is recommended that researchers consult and directly reference [OHRP Guidelines](#).*

28. Will your study require deception?

- No
- Yes

If yes, briefly explain why deception is necessary for this study. Explain what protocols will be utilized to debrief participants at the conclusion of the study and what measures will be taken to ensure any potential negative effects of the deception are addressed.

You will also be asked to upload a copy of the debriefing protocol to be used with your participants following the conclusion of the study.

29. OPTIONAL: Additional/supplemental materials

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.
