Roger Williams University Policy on the Protection of Human Subjects

I. Human Subjects Research Policy

The Roger Williams University Human Subjects Review Board (HSRB) ensures the health, safety, privacy and dignity of all persons participating in original research conducted at Roger Williams University by any faculty member, staff, or student. It is intended to ensure that subjects of research are aware of their rights and protections.

These policies are influenced by the guidelines of federal regulatory agencies; however, the Roger Williams University Human Subjects Review Board is ultimately the agency responsible for creating and overseeing these policies. Roger Williams applies a single, comprehensive standard to original research involving human subjects. This policy applies to all original human subject research as defined in this document.

II. Who Completes an Application for Human Subjects Review

Any individual formally affiliated with Roger Williams (faculty, staff, students) engaging in scholarly research involving human subjects must apply for HSRB approval. This includes all studies taking place either on- or off-campus. Individuals who wish to conduct research with human subjects on campus but are not affiliated with Roger Williams University must also submit their research for review by the HSRB. The only time in which this does not occur is if the research has been approved by another federally registered HSRB/IRB. In this case, an Authorization Agreement must be signed in order to avoid duplication of review. If no one affiliated with Roger Williams is involved in the research and the PI has obtained HSRB approval, an administrative review may be conducted at the discretion of the Faculty Director/Chair[1] of HSRB. This is done to ensure that all required documentation is on file. Lastly, anyone using unpublished data from human subjects that was collected at Roger Williams must submit their research protocol to the HSRB for approval.

- Students engaging in independent research projects involving human subjects at Roger Williams University must submit an HSRB application as these projects are subject to HSRB approval.

- Students conducting research as part of a regular course assignment do not need to submit an HSRB application, unless the instructor chooses to invite committee review. Regardless, faculty members engaging in instructional research activities are expected to maintain a professional standard of research and ensure that standards are met to protect any human subject in accordance with his/her discipline.

- "Human subject research" involves systematic collection of personal or private data from living human beings. Please refer to the glossary of terms for additional indicators of research that falls under the purview of this committee. Any scholarly discipline may involve human subject research. For example, studies in sociology, anthropology, and psychology often involve human subjects. Additionally, studies in biology may sometimes involve human subjects and studies in the humanities have seen an increase in the use of human subjects. With this in mind, faculty and students are urged to evaluate their research agendas through the lens of this policy in order to determine whether or not their research qualifies as "human subjects research." This is true even if human subjects or any concerns regarding human subjects are traditionally not common in their disciplines.

[1] Faculty Director/Chair of HSRB are used synonymously throughout this document in this context

III. Terms

anonymous data: data that by virtue of the method of collection can never reasonably be connected with the person providing them. Anonymous data can be obtained by using questionnaires that are returned by mail (in envelopes with no return address or other identifying markers), questionnaires that are collected by one of a group of subjects and returned to the researcher, or internet surveys (with software that renders it virtually impossible to connect answers with respondents). Questionnaires that collect data anonymously do not require separate written consent; consent to use the data is implied when the respondent completes the questionnaire (a statement that explains this principle should be printed at the beginning of any such survey).

class projects: student project/presentation conducted solely in fulfillment of educational requirement for a specific class. There is no dissemination beyond the class. In this instance, class projects are not 'generalizable' – HSRB review is not required.

confidential data: non-anonymous data that a human subject gives an investigator with the understanding or assumption that the human subject's privacy will be honored. Divulging the source of non-anonymous data to an outside party, or failing to ensure that no outside parties will be able to connect data with their source, normally constitutes a violation of confidentiality. The HSRB presumes that all data collected from human subjects are properly considered confidential, unless subjects have explicitly waived their presumption of confidentiality in writing. Projects can collect data in a confidential manner but analyze on an anonymous basis. The consent information provided to participants should make these procedures clearly understood.

deception: intentionally misleading or providing untruthful information; concealing or withholding of information from a participant.

generalizable: designed to draw conclusions from the data; results are analyzed for predictive value; results can be applied to a larger population (i.e., applicability is not limited to the participants) or inform policy.

HSRB: the Human Subjects Review Board at Roger Williams is responsible for the ethical oversight of all research involving human subjects conducted by Roger Williams faculty, students, or staff, as well as such research conducted on the Roger Williams University campuses (Bristol and Providence) by outside investigators.

human subject: a living individual about whom an investigator (whether professional or student) conducting research: 1) obtains information through intervention or interaction with the individual, and uses, studies, or analyzes the information; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. Intervention includes both physical procedures by which information is gathered and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g. medical record). Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

non-anonymous data: data that, by virtue of how it is collected or the nature of the information, can be connected at some point, no matter how brief, to the person providing them. This category includes questionnaires that the researcher collects personally from a group of subjects (unless a ballot box or envelopes are used). It also may include cases in which the researcher can recognize the handwriting of one or more of his or her subjects and could therefore potentially match the data with a specific respondent.

oral history: a method of gathering and preserving historical information through interviews with participants about past events and ways of life. Oral history is not subject to HSRB review if the researcher does not seek to generalize to a larger population beyond the oral history case study. Researchers using oral history methods should follow the ethical guidelines of the Oral History Association, available at http://www.oralhistory.org/do-oral-history/principles-and-practices/

principal investigator (PI): the primary person conducting the research. The principal investigator is the faculty advisor, professor, mentor or chair (in case of thesis project) in all research projects involving student investigators.

program evaluation: program evaluation activities are those for which the primary purpose of the evaluation is to assess the program not to develop or contribute to generalizable knowledge. The evaluation is a management tool for monitoring and/or improving the program. In this instance, program evaluation projects are not 'generalizable – HSRB review would typically not be required.

research: a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge (i.e. designed to draw general conclusions, inform policy, or generalizable findings beyond the people, programs, or organizations being studied). Research using human subjects, even if it is conducted simply to verify existing hypotheses, theses, theories, or ideas, is considered original research.

For the purposes of this policy, the following are not considered "research" and thus do not fall under the purview of the HSRB:

- Scholarly and journalistic activities (e.g. oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus only on the specific individuals about whom the information is collected;
- works that deal entirely with secondary sources (public data sets are considered such secondary sources);
- activities in which human subjects perform exclusively for instructional purposes (though the intent or effort to publish data from such activities—at any time—converts these activities to original research involving human subjects);
- data gathering for the purposes of fundraising by office of advancement studies; market research for the purposes of admissions recruiting; recruiting efforts for faculty or staff; and statistical data collected for the management of institutional affairs.

risk: potential for physical, psychological, social, or financial harm. Anonymous surveys often constitute no-risk research. By contrast, minimal risk means that some potential for harm exists, but that the probability and magnitude of harm 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.

unreasonable harm: any physical, psychological, social, or financial damage or injury that can be avoided without sacrificing the goals of the research. Unreasonable harm also includes any damage or injury so extensive that it cannot be justified by any contribution the research might make to human understanding.

vulnerable: "individuals with impaired decision-making ability" replaces the term "mentally disabled persons." The definition of "vulnerable" has been updated to no longer include pregnant women, handicapped, or physically disabled individuals as examples of populations that are potentially vulnerable to coercion or undue influence.

IV. Guidelines for Research

All individuals conducting original research are responsible for protecting their subjects from the risk of unreasonable harm. The principal investigator has initial responsibility for determining whether such a risk exists. A faculty member is responsible for supervising research undertaken by students in the context of his/her courses or

departmental/program curriculum. If there is any doubt about risks, the principal investigator should contact the HSRB Faculty Director or a member of the HSRB.

All faculty, staff and students preparing to submit a protocol to the HSRB must first complete the online training course at www.citiprogram.org .The Collaborative Institutional Training Initiative (CITI) is the main ethical research certification program in the US. RWU subscribes to the service. CITI's courses are designed to teach, test, and certify persons conducting research on human and animal subjects. The online program is also a good complement to teaching ethics to students. Directions for completing the Training are on the University's HSRB website: https://www.rwu.edu/who-we-are/administration-and-governance/committees-governance/hsrb/required-training-citi.

The HSRB recognizes that training requirements vary by research. With that said, the CITI online training contains Responsible Conduct of Research courses that are customized to various disciplines. Faculty investigators and advisors are responsible for advising students of the training requirement associated with a particular area of expertise. If you are unclear as to the type of course requirement for your discipline, please contact the HSRB Chair. Investigators facing deadlines are reminded to complete or renew the required trainings before submitting an HSRB application. No research project regardless of discipline will take place without first completing the appropriate ethical training modules. Please refer to section addressing Non-Compliance for description of penalty associated with a finding of non-compliance.

At a minimum, research activities at Roger Williams should conform to the following standards:

1. Informed consent: The principal investigator must explain to subjects, before they participate, the objectives of the research, the procedures to be followed, the associated risks, and the potential benefits. Investigators must not use individuals as subjects unless they are satisfied that the subjects, or others legally responsible for the subjects' well-being, freely consent to participating and fully understand the consequences. In general, subjects should signal their agreement to participate by signing a written consent form, though a researcher may make the case for using oral consent instead. The requirement for written consent may be waived under one of the following conditions:

- the research involves no or only minimal risk
- the consent form will be the only evidence linking the subject and the research, and the primary risk of harm is to the subject's privacy

Broad consent may be obtained in lieu of informed consent for the storage, maintenance, and secondary research uses of identifiable private information. Research involving deception compromises a subject's ability to give truly informed consent. The Human Subjects Review Board will consider requests to waive some of the requirements for informed consent for research that intentionally involves deception, but only if all of the following criteria are met:

- the research cannot be conducted without the deception;
- the potential value of the research outweighs any potential risks to the subject;
- the subjects are informed of the true nature of the research as soon as possible;
- the research involves no more than minimal risk (federal requirement).

2. Confidentiality: Investigators must respect the privacy of their subjects. Investigators must protect confidential information given to them and must advise subjects in advance of any limits on their ability to ensure that the information will remain confidential.

3. Coercion: Subjects, including students who are participating in classroom experiments or faculty scholarship, must not be induced to participate by means or in circumstances that might affect their ability to decide freely. When course credit is offered for participating in research, some other mechanism to earn that credit must also be made available to those students who choose not to participate as human subjects. Rewards for participating should be in

line with the burden imposed by participating, to avoid presenting an undue influence on a person's ability to freely choose to participate (or not).

Researchers must inform subjects that they are free to withdraw from active participation in the research at any time. Subjects who indicate a desire to withdraw will be allowed to do so promptly and without penalty or loss of benefits to which any subject is otherwise entitled. At the minimum, this condition must be clearly stated as part of the informed consent statement.

4. Disclosure: An investigator must disclose to a subject, upon request, the source of support for the research.

V. The Human Subjects Review Board

According to federal guidelines (45 CFR, part 46), HSRB membership must include at least five members with various backgrounds to promote complete and adequate review of research. At a minimum, one member must be an individual whose primary research is scientific, one member must be an individual whose research is non-scientific, and at least one member must have no affiliation with Roger Williams. Additional members should represent more than a single area or profession. As such, the Roger Williams University Human Subjects Review Board (HSRB) is currently composed of nine individuals (including Faculty Director) from the RWU faculty and one member from outside of the University. Membership beyond the minimum requirement at RWU is a function of our diverse research community and is necessary to accommodate the amount of work associated with reviewing a considerable number of applications. The Faculty Director is appointed by the Provost. Records of the committee are stored electronically.

Institutional members of the Review Board are appointed by the Faculty Director and serve three-year terms from July 1 through June 30 with the understanding that, although the committee does not typically meet during June, July, and August, members may be contacted during the summer months if the need arises. The community member representative of the HSRB is invited by the Faculty Director after consultation with Board members, to serve on a yearly basis. The community member may serve as many consecutive terms as he or she is invited and willing. All members of the committee must have certification of training regarding research with human participants within the past three years from the start of their term with the board and must have passed the HSRB Member Course. Each committee member shall serve a three-year term, which is renewable commencing and ending on June 30 of each year. Committee member appointments are staggered so that only two new members will join the board at any given time.

VI. Procedures for Review: Exempt, Expedited, and Full Board Review

All research activities must be reviewed by the Human Subjects Review Board even when categorized as "exempt" status. In addition, please note that "expedited" does not mean "faster" review. It only refers to the federal categories of research that do not require full board review.

Final determination of exempt, expedited and full board review status is made by the Human Subjects Review Board. **This means that all research proposals involving human subjects must be submitted for HSRB review and approval.**

Effective September 1, 2018, the HSRB at Roger Williams University no longer acknowledges any studies previously deemed 'exempt from further review'. If you have any questions as to whether your study meets the above criteria or was formerly categorized as 'exempt from further review', please contact the HSRB Chair.

Exempt Category of Review

Review process to determine if the research protocol qualifies for exemption from further institutional review by meeting one or more of the following exempt categories:

1. Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless the information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection unless the information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
    a. For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.
    b. If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.
4. Research involving the collection or study of existing data, documents, or records if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
5. Research and demonstration projects which are conducted by or subject to the approval of a Federal department or agency heads, and which are designed to study, evaluate, or otherwise examine public benefit or service programs; procedures for obtaining benefits or services under those programs; possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies (with specific criteria found in guideline)s.

Expedited Category of Review

To be eligible for expedited review research must meet two criteria:

1. Pose no more than minimal risk to subjects. No more than minimal risk means that "the probability and magnitude of harm or discomfort anticipated in the research 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."

2. Consist of one or more research activities specified in the regulations 2017FederalPolicyHumanSubjects Eligible activities are similar to those for exempt research (some surveys, interviews, and data analysis) with the addition of some minor and non-invasive medical procedures, such as blood pressure readings, occasionally used by social and behavioral sciences. If the primary risk to subjects is a breach of confidentiality and that risk can be managed to no more than minimal, the research may be reviewed with through expedited process. Subject population and institutional policy may require review by the full Board even for a study with no more than minimal risk, such as a study of cognitively-impaired individuals. If research involves more than minimal risk and/or does not fall into one of the categories of activity eligible for expedited review, it must be reviewed by the full HSRB. This review involves consideration by a larger, more diverse group, thus bringing more perspectives and more experience to the review.

Full Board Review

Review process for research protocols that do not fall under the "exempt" or "expedited" categories, include vulnerable populations, and/or are determined by the Roger Williams University HSRB to involve greater than minimal risk to subjects (45 CFR 46 111). For those protocols that are reviewed by the full Human Subjects Review Board, it may be necessary to require the Principal Investigator and/or co-Investigator to be present at the meeting to discuss their protocol and answer questions posed by the Board. *Refer to the website for Full Board meeting schedule for the academic year.*

Continuing Review

The Human Subjects Review Board assigns the approval period at intervals appropriate to the degree of risk. In most cases, minimal risk research will not be subject to annual review by the HSRB, this is consistent with revisions to the Common Rule. However, at its discretion, the HSRB may require continuing review of studies that meet certain criteria, including, but not limited to the following: inclusion of vulnerable populations, criminal behavior, substance abuse and/or mental health data, involvement of external sites (e.g. secondary schools). The approval period will be indicated in the approval letter. If continuing review is required, the principal investigator must submit, before the date indicated in the approval letter, a status report of the project to date, including:

- the number of participants accrued
- a summary of adverse events and any unanticipated problems involving risks to subjects or others and withdrawal of subjects from the research or complaints about the research since the last review
- a summary of any relevant amendments or modifications to the research since the last review
- any other relevant information, especially information about risks associated with the research
- a copy of the current informed consent document and any newly proposed consent document

Appeals

If an application is denied because the Human Subjects Review Board determines the risks outweigh the benefits of the research, and the investigator disagrees with the committee's disapproval decision, the PI may appeal the decision by resubmitting the same application form and 1) a letter of appeal presenting the researcher's arguments for approval, 2) any other pertinent information in support of the appeal. The letter should be directed to the HSRB Chair and emailed to hsrb@rwu.edu. Appeals are considered by the full board at the next scheduled meeting date. The final decision of the HSRB is delivered in writing to the investigator. If the proposal is not approved, the research cannot be conducted.

Investigators have the obligation to keep the HSRB informed of unexpected findings involving risks to subjects and

to report any occurrence of serious harm to subjects. The HSRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the HSRB requirements.

To submit an application for review, applicants will access the application through a link in the HSRB website http://rwu.co1.qualtrics.com/jfe/form/SV_1GiQSEUJHhUTQRD.

No application can be submitted without the following attachments:

- a research protocol
- a CITI training certificate or certificates that is no greater than 3 years old for faculty/staff/students at the time of the submission to show that all researchers on the project have completed the online Collaborative Institutional Training Initiative (CITI) Social/Behavioral Researchers module.
- copies of all stimulus materials and instruments (e.g., questionnaires, interview scripts, manipulation protocols, debriefing forms, etc.), translated if these items are not in English
- a completed consent form or script for verbal assent
- for students, an email from the researcher's faculty advisor certifying that the advisor has read and approved the research protocol

An application may also include these attachments as appropriate:

- evidence of permission from cooperating institutions (if any)
- any relevant grant application(s)
- non-disclosure or other agreements with owners of restricted data sets
- for renewals and extensions, a status report

Hard copy applications are not accepted.

Applications are acknowledged by email to the PI within twenty-four hours of submission. Review for proposals considered minimal or no risk (Expedited and Exempt) will be completed within ten working days. Applications that require full-board review will be reviewed at the scheduled semester full Board meeting. A majority of the committee members must be present to constitute a quorum. They may act in the case of a full board review only on applications submitted at least one week before the scheduled meeting or by the unanimous consent of the entire committee. The committee generally acts by consensus; if consensus cannot be reached, the committee decides in favor of the major opinion. Researchers whose applications are not approved by the HSRB will be provided a list of the concerns cited by the committee. Normally such researchers will be invited to respond, revise, and resubmit their application for a new review.

The researcher is responsible for keeping all data and documentation gathered during the research, including all signed informed consent forms and any publications resulting from the research. In the case of student research, the student's advisor will arrange for this documentation to be stored. These records are also kept for three years after the conclusion of the research. The HSRB reviews the list of all projects completed at Roger Williams University in mid-May of each year and provides a summary to the Provost of all reviewed projects for the academic year.

VII. Non-Compliance

All researchers conducting human subjects research are expected to comply with the provisions of the HSRB-approved study as well as all related federal regulations, RWU policies, and state and local laws. Examples of noncompliance include, but are not limited to:

- Failure to obtain HSRB approval prior to conducting human subjects research
- Continuation of research activities (i.e. enrolling new subjects, collecting data) after a study has expired

- Failure to obtain informed consent of research subjects
- Failure to follow research procedures as outlined in the protocol that was reviewed/approved by the HSRB
- Implementation of changes in research procedures prior to HSRB approval

If a researcher becomes aware of any noncompliance with respect to a specific study, a report must be made to the HSRB via the HSRB email address or anonymously via campus mail (sent to CAS Room 103). All allegations of noncompliance will be investigated by the HSRB, which will determine if the noncompliance is serious or continuing. During the investigation, a fact finding will be conducted, and if appropriate, a subcommittee will be appointed to further evaluate the noncompliance. The HSRB Chair, or if deemed necessary, the fully convened HSRB will review the investigation findings and determine whether the noncompliance is serious or continuing and any necessary corrective actions. If serious or continuing noncompliance is found and the study is federally funded, a letter will be sent to the Office for Human Research Protections.

VIII. Oversight and Authority

The Roger Williams University HSRB, as informed by the guidelines and regulations of various government agencies, is the author of these policies and shall change these policies only by consensus at official meetings of that body.