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 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 Lastly, anyone using unpublished data from human subjects that was collected at Roger Williams must submit their research protocol to the HSRB for approval.

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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

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.

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 liabilement methods.

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.*

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

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- ¶ 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 enoncomplian