

Human Subjects Review Board

One Old Ferry Road

Bristol, RI 02809

**IRB Authorization Agreement**

Name of Institution or Organization Providing IRB Review (Institution A): Please Complete

IRB Registration #: Please Provide

Federal wide Assurance (FWA) #, if any:

**Name of Institution Relying on the Designated IRB** (Institution B): **Roger Williams University**

OHRP Federal wide Assurance (FWA) #: **FWA00018407**

The Officials signing below agree that Institution B may rely on the designated IRB for review and continuing oversight of its human subject research described below: (choose one)

(\_\_\_) This agreement applies to all human subject research covered by Institution B’s FWA.

(\_X\_\_) This agreement is limited to the following specific protocol(s):

Name of Research Project:

Name of Roger Williams University Principal Investigator:

RWU IRB Study Number:

External IRB Study Number (if any):

Sponsor or Funding Agency:

Award Number, if any:

(\_\_\_) Other (describe):

The Reviewing Institution’s IRB agrees to the following in regard to the above listed research protocol or activities:

1. Provide initial and continuing review in accordance with 45 CFR 46 and its FWA.
2. Arrange for prompt reporting to the Relying Institution’s IRB of any of the following, as defined and determined by the Reviewing Institution’s IRB:
   1. Any unanticipated events or problems involving risks to subjects or others.
   2. Any serious or continuing non-compliance.
   3. Any suspension or termination of IRB approval.
3. Comply will all applicable Federal, State and Local laws and regulations.
4. IRB meeting minutes will be made available to the Relying Institution’s IRB upon request.
5. Copy the Relying Institution on all correspondence to regulatory agencies if reporting of an event is required.

The Relying Institution remains responsible for the following:

1. Ensuring research activities at its site are in compliance with the IRB’s determinations and with the terms of its OHRP-approved Assurance.
2. Adhering to its institutional conflict of interest policies and procedures and providing the Reviewing Institution with any applicable COI management plan related to the study.
3. Ensuring principal investigators and other research personnel involved in the research are appropriately qualified and meet its institutional standards for eligibility to conduct research, including, but is not limited to, having the required professional staff appointments, credentialing, insurance coverage, and background checks for their assigned role in the research and training in the protection of human subjects.
4. Maintaining, implementing or have access to a human subjects’ research post approval monitoring (PAM) process, function, program or service not directly involved with the research that can conduct and report the results of for-cause and not-for-cause audits of the research study listed above to ensure compliance with human subject’s protections regulations and other relevant requirements. The PAM process, function, program or service must monitor the conduct of research under this Agreement and ensure any relevant findings are reported to the Reviewing Institution.

This document must be kept on file at both institutions and provided to OHRP upon request. This agreement will become effective upon the date of the last signature by the institutional officials below and will remain in effect until such time that either institution provides 30 days written notice of termination to the other institution.

Signature of Signatory Official (Institution A):

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_

Print Full Name:

Institutional Title:

Signature of Signatory Official (Institution B):

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_

Print Full Name: **Becky L. Spritz, Ph.D.**

Institutional Title: **Director, RWU Human Subjects Review Board**

Appendix A

Please provide the contact information for the individual at Institution A and Institution B who should be copied on all correspondence regarding the study.

Institution A:

Name:

Institutional Title:

Address:

Email:

Phone Number:

Institution B:

Name:

Institutional Title:

Address:

Email:

Phone Number: