IRB Authorization Agreement

The purpose of this agreement is to document the relationship between:

***VIRGINIA COMMONWEALTH UNIVERSITY (Institution A)***

IRB Registration #: IRB00000410; IRB00000411; IRB00001127; IRB00002338

OHRP Federalwide Assurance (FWA) #: FWA00005287

FWA Expiration Date: Click here to enter a date.

*and*

***Click here to enter Institution B name. (Institution B)***

IRB Registration #: Click here to enter registration #.

OHRP Federalwide Assurance (FWA) #: Click here to enter FWA #.

FWA Expiration Date: Click here to enter a date.

*and*

***THE RESPONSIBLE INVESTIGATORS (named below).***

This agreement authorizes ***Institution B*** to rely upon the IRB review of ***Institution A*** for IRB review and continuing oversight of its human subject research described below:

**Institution A IRB Number (where review will occur):** Click here to enter VCU IRB #.

**PI Named on IRB Submission Form:** Click here to enter name.

**Human Subjects Protocol Title:** Click here to enter title.

**Institution B Investigator/Phone:** Click here to enter name. / Click here to enter phone number.

**Sponsor/Funding Source:** Click here to enter source name.

**Prime Awardee Institution:** Click here to enter text.

Title of Funding Proposal (if different than above): Click here to enter text.

**Person Responsible for Informing Institution B of IRB Status on an ongoing basis (including providing that institution with copies of requested IRB documents from Institution A):** Click here to enter name of VCU person responsible for conveying IRB information to Institution B.

**Expiration Date of this Agreement:** Closure/Termination of Study with the VCU IRB.

**Other:** Click here to enter Institution B name. has requested to defer IRB review to the VCU IRB.

The Institution A (Virginia Commonwealth University) has agreed for Institution B (Click here to enter Institution B name.) to rely upon its review of the above referenced protocol in fulfillment of the requirement of their OHRP-approved FWA.

The following terms are agreed upon by all parties and attested to by signature below:

***Institution A Responsibilities:***

1. The IRB will conduct its review in accordance with 1) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*; 2) the U.S. Department of Health and Human Services (DHHS) regulations for the protection of human subjects at 45 CFR 46; 3) the VCU Federalwide Assurance (FWA) document referenced above; and 4) relevant institutional policies and procedures for the protection of human subjects.
2. The IRB will make all relevant documents (including letters of approval, minutes of IRB meetings, and other reports) available to Institution Bupon request or provided through the principal investigator.
3. The IRB will exercise full authority over this research protocol, including authority to conduct site visits, supervise study activities, suspend, or terminate the research in order to ensure the protection of human subjects (without prior notice or cause).

***Institution A Investigator Responsibilities:***

1. The Investigator assures the IRB that the facilities and resources available are adequate to carry out the research planned.
2. The Investigator assures the IRB that the education and training of all staff associated with the study are adequate to carry out the responsibilities delegated to them.
3. The Investigator assures the IRB that continuing oversight will be exercised over the human subject research activities taking place under this protocol, and that any noncompliance will be reported directly to the Institution A IRB as well as the Institution B IRB.

***Institution B Responsibilities:***

1. Institution B is responsible for communicating any additional requirements of the institution to the Institution A Investigator.
2. Institution B is responsible for ensuring that resources are adequate to carry out the research planned to take place at Institution B (together with the Institution A Investigator).
3. Institution B is responsible for supporting the role, authority, and responsibilities of the Institution A IRB for this research.
4. Institution B is responsible for informing the Institution A IRB if Institution B plans to no longer rely upon Institution A for IRB review of the research referenced in this agreement.

***Institution B Investigator Responsibilities:***

1. The above-named Investigator has reviewed: 1) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*; 2) the U.S. Department of Health and Human Services (DHHS) regulations for the protection of human subjects at 45 CFR 46; 3) the Federalwide Assurance (FWA) documents referenced above; and 4) both relevant institutional policies and procedures for the protection of human subjects.
2. The Investigator will complete any educational training required by the Institution A IRB and/or the Institution B IRB prior to initiating research covered under this Agreement and will ensure that all key personnel involved with the human research activity have received appropriate training.
3. The Investigator will report immediately to the Institution A IRB any unanticipated problems involving risks to subjects or others in research covered under this Agreement (NOTE: this is required in keeping with OHRP guidance for awardee institutions).
4. The Investigator acknowledges that he/she is primarily responsible for safeguarding the rights and welfare of each research subject, and that the subject’s rights and welfare must take precedence over the goals and requirements of the research.
5. With respect to Significant Financial Interest disclosures, the Investigator will ensure that all personnel at Institution B engaged in the research will (choose applicable option):

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*The Officials and Investigators signing below agree that Click here to enter Institution B name. may rely on the Virginia Commonwealth University IRB, designated above, under the terms of this agreement. This document must be kept on file at both institutions and provided to the Department of Health and Human Services Office of Human Research Protections, upon request.*

***Virginia Commonwealth University***

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| --- | --- | --- | --- | --- | --- | --- | --- |
| FWA Institutional Official (or  designee) Signature: | |  | | | | Date: |  |
| Name: | Francis L. Macrina, Ph.D. | | Title: | Vice President for Research | | | |
| Address: | 800 East Leigh Street, Suite 115 | | Phone: | 804-827-2262 | | | |
|  | Richmond, VA 23298 | |  | |  | | |

***VCU Investigator***

*I agree and accept the responsibilities under this agreement as outlined above:*

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| VCU Investigator signature: | |  |  | | | | | Date: |  |
| Name: | Click here to enter text. | | | | Title: | Click here to enter text. | | | |
| Address: | Click here to enter text. | | | Phone: | | Click here to enter text. | | | |
|  | Richmond, VA 23298 | |  | | | |  | | |

***Click here to enter Institution B name. Investigator***

*I agree and accept the responsibilities under this agreement as outlined above:*

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Investigator Signature: | |  |  | | | | | | Date: |  |
| Name: | Click here to enter text. | | | | Title: | Click here to enter text. | | | | |
| Address: | Click here to enter text. | | | Phone: | | Click here to enter text. | | | | |
|  | Click here to enter text. | | | | | |  |  | | |

***Click here to enter Institution B name. Signatory Official***

*I agree and accept the responsibilities under this agreement as outlined above:*

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Institutional Official (or designee) Signature: | |  |  | | | | | | Date: |  |
| Name: | Click here to enter text. | | | | Title: | Click here to enter text. | | | | |
| Address: | Click here to enter text. | | | Phone: | | Click here to enter text. | | | | |
|  | Click here to enter text. | | | | | |  |  | | |