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| UNAFFILIATED COLLABORATING INVESTIGATOR AGREEMENT |

This form is to be completed and signed by key personnel who are not volunteers approved through the School of Medicine; who are not students or employees of the University of Virginia (UVA); and who want to collaborate with a Principal Investigator (PI) conducting approved research overseen by the UVA Institutional Review Board for Health Sciences Research (IRB-HSR).

**Definitions of Collaborating Individual Investigators**

1. A collaborating **independent** investigator is:
	1. not otherwise an employee or agent of UVA;
	2. conducting collaborative research activities outside the facilities of UVA; and
	3. not acting as an employee of **any** institution with respect to their involvement in the research being conducted by the assured institution.
2. A collaborating **institutional** investigator is:
	1. not otherwise an employee or agent of UVA;
	2. conducting collaborative research activities outside the facilities of UVA;
	3. acting as an employee or agent of a **non-assured** institution with respect to their involvement in the research being conducted by UVA; and
	4. employed by, or acting as an agent of, a **non-assured** institution that does not routinely conduct human subjects research.

| IRB-HSR #/ UVA Study Tracking#:       | PI Name:        |
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| Protocol Title:        |
| Unaffiliated Collaborating Investigator’s Name:       |

1. The above-named Unaffiliated Collaborating Investigator:
* Has reviewed:

1) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (or other internationally recognized equivalent; see section B.1. of the Terms of the Federalwide Assurance (FWA) for International (Non-U.S.) Institutions);

2) The U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46 (or other procedural standards; see section B.3. of the Terms of the FWA for International (Non-U.S.) Institutions);

3) The FWA and applicable Terms of the FWA for UVA; and

4) The relevant institutional policies and procedures for the protection of human subjects.

* Has completed the CITI Online tutorial for investigators available on the University of Virginia HRPP Education and CITI Training IRB-HSR website available at [HRPP Education and CITI Training | Human Research Protection Program (HRPP)](https://hrpp.research.virginia.edu/teams/hrpp-education-and-citi-training) or equivalent training program from another institution.
* Has reviewed and will follow the research protocol (protocol title listed above)
1. The Investigator understands and hereby accepts the responsibility to comply with the standards and requirements stipulated in the above documents and to protect the rights and welfare of human subjects involved in research conducted under this Agreement.
2. The Investigator will comply with all other Federal, State, and local laws and regulations that may provide additional protection for human subjects.
3. The Investigator will abide by all determinations of the IRB-HSR and will accept the final authority and decisions of the IRB-HSR, including but not limited to directives to terminate participation in designated research activities.
4. The Investigator will complete any additional educational training required by the IRB-HSR prior to initiating or during the course of research covered under this Agreement.
5. The Investigator will report promptly to the IRB-HSR any proposed changes in the research conducted under this Agreement. The investigator will not initiate changes in the research without prior IRB-HSR review and approval, except where necessary to eliminate apparent immediate hazards to subjects.
6. The Investigator will report immediately to the IRB-HSR any unanticipated problems involving risks to subjects or others in research covered under this Agreement, in conformance with applicable DHHS and FDA regulations and IRB-HSR procedures for such reporting.
7. The Investigator, when responsible for enrolling subjects, will obtain, document, and maintain records of informed consent from each subject or the subject’s legally authorized representative as required under DHHS and FDA regulations (or other international or national equivalent) and stipulated by the IRB-HSR.
8. The Investigator acknowledges and agrees to cooperate with the IRB-HSR in fulfilling its responsibility for initial and continuing review, record keeping, reporting, and certification for the research referenced above. The Investigator will provide all information requested by the IRB-HSR in a timely fashion.
9. In conducting research involving FDA-regulated products, the Investigator will comply with all applicable FDA regulations and fulfill all investigator responsibilities (or investigator-sponsor responsibilities, where appropriate), including those described at 21 CFR 312 and 812.
10. The Investigator will not enroll subjects in research under this Agreement prior to its review and approval by the IRB-HSR.
11. Emergency medical care may be delivered without IRB-HSR review and approval to the extent permitted under applicable Federal regulations and State law.
12. This Agreement does not preclude the Investigator from taking part in research not covered by the Agreement.
13. The Investigator acknowledges that they are 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.

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| Unaffiliated Collaborating Investigator's Signature: | Date:       |
| Name (Last, First, MI):       | Degree(s):       |
| Email:       | Phone #:       |
| Address:       |
| City, State/Province, Zip, Country:       |
| Affiliated Institution or Organization (if applicable):       |