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| UNAFFILIATED INVESTIGATOR AGREEMENT  *This form should be completed and signed by key personnel who are not volunteers approved through the School of Medicine, students or employees of UVA.* |

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

1. The above-named Unaffiliated Investigator:

* Has completed the CITI Online tutorial for investigators available on the IRB-HSR website at <https://research.virginia.edu/irb-hsr/citi-training> , or equivalent training program from another institution (documentation of training completion acceptable to the home institution must be attached);
* Will not have access to identifiable health information of UVA patients prior to those individuals signing a research consent form or HIPAA authorization form granting all study personnel access to the health information.
* 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 University of Virginia Institutional Review Board for Health Sciences Research (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 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.

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| Unaffiliated Investigator's Signature: | Date: |
| Name (Last, First MI): | Degree(s): |
| Address: | Phone #: |
| Email: |  |
| City, State/Province, Zip, Country: | |