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Human Research Protections and
Institutional Review Board
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Unaffiliated Investigator Agreement

Study Title:		**Date:**
IRBNet #:	**Unaffiliated Investigator Name:**	

GUIDELINES FOR RESEARCH CONDUCTED BY UNAFFILIATED INVESTIGATORS

PHS is supportive of human subjects research conducted by investigators who are unaffiliated with PHS, while at the same time being mindful of risk/liability concerns and the impact on PHS resources. Individuals may, or course, collaborate with affiliated investigators to conduct investigations of mutual interest; this section is **not** meant to address or restrict such collaborations. However, there may be persons without direct or formal association to PHS who request authorization to use PHS facilities or patient populations in order to conduct a study involving human participants.

DEFINITION: UNAFFILIATED INVESTIGATOR

An Unaffiliated Investigator is any individual proposing to conduct research using any PHS property, facility, patient/employee population, or non-public information who is not:

- A physician or advanced-practice clinician with clinical privileges at a PHS facility;
- A private-practice physician on the PHS medical staff who does not have clinical privileges;
- A paid employee of PHS, including an employee currently enrolled as a student in an academic program related to the study;
- An employee of a PHS-contracted service (e.g., Tricore Labs, Radiology Associates of Albuquerque); or
- A resident who is participating in a program which has a clinical affiliation agreement with PHS.

Approval is required when a PI is not affiliated with PHS or is not covered under the IRB of another institution. Any human research activities being proposed by an unaffiliated PI may be covered under the PHS FWA only in accordance with a formal, written agreement stating a commitment to abide by PHS's policies/procedures and IRB oversight. The PHS **Unaffiliated Investigator Agreement** must be completed for this purpose, and submitted to the IRB Chair. PHS will maintain commitment agreements on file and provide copies to OHRP upon request. The IRB reserves the right to approve or deny requests for approval on a case-by-case basis.

CONDUCT OF RESEARCH

Responsibility for the actual conduct of the research remains solely with the unaffiliated investigator. It is understood that approval to conduct human subjects research at PHS in no way implies that either the PHS IRB or any PHS official assumes responsibility for the conduct of research by unaffiliated investigators. The unaffiliated investigator may independently enlist the aid of someone at PHS (a "facilitator") to assist with logistical matters, such as aiding in the distribution of recruiting materials. Researchers wishing to use PHS facilities, research spaces, or access to patient or employee data should consult the appropriate department authority for such information.

IRB APPROVAL

The PHS IRB retains oversight of human research conducted on campus by unaffiliated investigators and such investigators will be expected to comply with all PHS IRB policies and procedures. An unaffiliated investigator seeking to conduct research at PHS must have approval of the PHS IRB and show prior approval from their home institution's IRB, if any. The IRB may require that the researcher identify a collaborating investigator.

The unaffiliated investigator is responsible for ensuring that all matters of concern in PHS's review of the protocol are addressed in the protocol of the home institution, if any, as well. The PHS IRB reserves the right to ask for and obtain other evidence from the unaffiliated investigator to authenticate the proposed research to be conducted at PHS. This could include authorizations for the use of survey instruments and data collecting equipment and financial information for when participants are to be monetarily compensated.

Unaffiliated Investigator Assurance Statement

(1) The above-named Unaffiliated Investigator has:

- Reviewed ***The Belmont Report*: *Ethical Principles and Guidelines for the Protection of Human Subjects of Research*;**
- Reviewed the U.S. Department of Health and Human Services (DHHS) regulations for the protection of human subjects at 45 CFR 46;
- Reviewed the relevant PHS policies and procedures for the protection of human subjects in the *Human Research Protections Program Policies and Standard Operating Procedures* manual;
- Completed the CITI online human subjects research course for investigators available at https://www.citiprogram.org/ (documentation of training completion acceptable to the University must be attached; and
- Reviewed the research protocol (protocol title listed above).

(2) 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.

(3) The Investigator will comply with all other Federal, State, and local laws and regulations that may provide additional protection for human subjects.

(4) The Investigator will abide by all determinations of the PHS IRB and will accept the final authority and decisions of the PHS IRB, including but not limited to directives to terminate participation in designated research activities.

(5) The Investigator will complete any additional educational training required by the PHS IRB prior to initiating or during the course of research covered under this agreement.

(6) The Investigator will report promptly to the PHS IRB any proposed changes in the research conducted under this agreement. The investigator will not initiate changes in the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.

(7) The Investigator will report immediately to the PHS IRB any unanticipated problems involving risks to subjects or others in research covered under this agreement, in conformance with applicable DHHS

and FDA regulations and PHS IRB procedures for such reporting.

(8) 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 PHS IRB.

(9) The Investigator acknowledges and agrees to cooperate with the PHS IRB 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 PHS IRB in a timely fashion.

(10) 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.

(11) The Investigator will not enroll subjects in research under this agreement prior to its review and approval by the PHS IRB.

(12) Emergency medical care may be delivered without PHS IRB review and approval to the extent permitted under applicable Federal regulations and State law

(13) This agreement does not preclude the Investigator from taking part in research not covered by the agreement.

(14) 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.

Unaffiliated Investigator Signature	**Date**
PHS Institutional Official Signature	**Date**

Please sign, scan, and upload completed form to IRBNet