Unaffiliated Investigator Agreement

Name of Investigator: _____

Name of Institution Providing Official IRB Approval (not Pepperdine):

_____

Research Study Covered Under This Agreement: _____

1. The above-named Unaffiliated Investigator has reviewed *the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (or other internationally recognized equivalent; see B1 of FWA Terms for institutions outside the United States); the U.S. Department of Health and Human Services (DHHS) regulations for the protection of human subjects at 45 CFR 46 (or other internationally recognized equivalent; see B3 of FWA Terms for institutions outside the United States), the Assurance referenced above, and the relevant institutional policies and procedures for the protection of human subjects.
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 National, State, or local laws or regulations that may provide additional protection for human subjects.
4. The Investigator will abide by all determinations of the IRB designated under the above Assurance and will accept the final authority and decisions of the IRB, including but not limited to directives to terminate participation in designated research activities.
5. The Investigator will complete any training required by the IRB prior to initiating research covered under this Agreement.
6. The Investigator will report promptly to the IRB proposed changes in the research conducted under this Agreement. The investigator will not initiate changes in the research without prior IRB/IEC review and approval, except where necessary to eliminate apparent immediate hazards to subjects.
7. The Investigator will report immediately to the IRB any unanticipated problems in research covered under this Agreement that involve risks to subjects or others.

8. The Investigator, when responsible for enrolling participants, will seek, document, and maintain records of informed consent from each subject or the subject's legally authorized representative as required under HHS regulations (or other international or national equivalent) and stipulated by the IRB.
9. The Investigator acknowledges and agrees to cooperate in the IRB's responsibility for initial and continuing review, record keeping, reporting, and certification. The Investigator will provide all information requested by the 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 IRB.
12. Emergency medical care may be delivered without IRB review and approval to the extent permitted under applicable Federal regulations and State law. However, such medical care may not be included as part of Federally-supported research.
13. This Agreement does not preclude the investigator from taking part in research not covered under the Agreement
14. The investigator acknowledges that her/his primary responsibility is to safeguard 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.

Investigator Signature: _____

Date: _____

Pepperdine IRB Institutional Official Signature: _____

Date: _____