

Unaffiliated Investigator Agreement

Name of Institution: Barton College

Unaffiliated Investigator's Name: _____

Specify Research Covered by This Agreement:

1. Title of Project:
2. Principal Investigator: _____
3. Sponsor(s) or Funding Agency(ies):

The above-named Unaffiliated Investigator has reviewed the relevant institutional policies and procedures for the protection of human subjects.

- (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 National, State, or local laws or regulations that may provide additional protection for human subjects.
- (3) 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.
- (4) The Investigator will complete any educational training required by the Institution and/or the IRB prior to initiating research covered under this Agreement.
- (5) The Investigator will report promptly to the 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.
- (6) The Investigator will report immediately to the IRB any unanticipated problems involving risks to subjects or others in research covered under this Agreement.
- (7) The Investigator 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.
- (8) 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.
- (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).

