Complete this form and submit it to the HRPP Office before submitting a protocol to an external IRB

1. Contact information

   Protocol Title: 
   Name of IRB: 
   Principal Investigator: 
   E-mail: 
   Phone: 
   Contact: 
   E-mail: 
   Phone:

2. Names of research personnel

   Name: 
   Description (role, institution, affiliation, etc):

3. Questions

   3.1 Yes No Have all personnel completed the required initial and continuing education and training for human research? See "HRP-800 INVESTIGATOR GUIDANCE: Investigator Obligations (HRP-800)" for education and training requirements.
   3.2 Yes No Have all personnel completed the required initial and continuing education and training for Conflicts of Interest?
   3.3 Yes No Is the research funded?
   3.4 Yes No Does the research involve any sites where the principal investigator is responsible for the research (i.e., personally conducts or oversees the research) and does not ordinarily have privileges to conduct the research?
   3.5 Yes No Is the research covered by an IND?
   3.6 Yes No Is the research covered by an IDE?
   3.10 Yes No Does the research involve adults unable to consent?
   3.11 Yes No Does the research involving obtaining consent for children from their parents or guardians?
   3.13 Yes No Will you follow the process of consent in "INVESTIGATOR GUIDANCE: Informed Consent (HRP-802)?"
   3.14 Yes No Will you follow the process of consent in "INVESTIGATOR GUIDANCE: Documentation of Informed Consent (HRP-803)?"
   3.15 Yes No Do any personnel involved in the design, conduct, or reporting of the research have a "Related Financial Interest"?

   "Immediate Family" means spouse, domestic partner, and dependent children.
   "Related Financial Interest" means any of the following interests in the sponsor, or product or service being tested held by the individual or the individual's immediate family:
   • Ownership interest of any value including, but not limited to stocks and options, exclusive of interests in publicly-traded, diversified mutual funds.
   • Compensation of any amount in the preceding 12 months including, but not limited to honoraria, consultant fees, royalties, or other income.
   • Proprietary interest of any value including, but not limited to patents, trademarks, copyrights, and licensing agreements.
   • Board or executive relationship, regardless of compensation.
   • Reimbursed or sponsored travel by an entity other than a federal, state, or local government agency, higher education institution or affiliated research institute, academic teaching hospital, or medical center.

Additional Submission Requirements

If after IRB approval, any information in this application changes, resubmit a copy of this application with revisions.

By submitting this form, the investigator attests to compliance with "INVESTIGATOR GUIDANCE: Investigator Obligations (HRP-800)"