

**INSTITUTIONAL REVIEW BOARD FOR HEALTH SCIENCES RESEARCH OF THE UNIVERSITY OF VIRGINIA
INVESTIGATOR AGREEMENT**

Title of Study:

BY SIGNING THIS DOCUMENT, THE INVESTIGATOR AGREES:

1. That no subjects will be recruited or entered under the protocol until the Investigator has received the signed IRB-HSR Approval form stating the protocol is open to enrollment
2. That any materials used to recruit subjects will be approved by the IRB-HSR prior to use.
3. That any modifications of the protocol or consent form will not be initiated without prior written approval from the IRB-HSR, except when necessary to eliminate immediate hazards to the subjects.
4. That any serious deviation from the protocol will be reported promptly to the Board in writing.
5. That adverse events that are serious and unexpected will be reported promptly to the Board.
6. That the continuation status report for this protocol will be completed and returned within the time limit stated on the form.
7. That if this study involves any funding or resources from an outside source, or if you will be sharing data outside of UVA prior to publication that you will contact the Dean's office regarding the need for a contract and letter of indemnification. If it is determined that either a contract or letter of indemnification is needed, subjects cannot be enrolled until these documents are complete.
8. That all subjects will sign a copy of the most current consent form that has a non-expired IRB-HSR approval stamp.
9. That the IRB-HSR office will be notified within 30 days of a change in the Principal Investigator or of the closure of this study.
10. That a new PI will be assigned if the current PI will not be at UVA for an extended period of time.
11. That no personnel will be allowed to work on this protocol until they have completed the IRB-HSR On-line training and the IRB-HSR has been notified.
12. That all personnel working on this protocol will follow all IRB-HSR Policies and Procedures as stated on the IRB-HSR Website www.virginia.edu.vprgs.ird and on the School of Medicine Clinical Trials Office Website: http://knowledgeink.healthsystem.virginia.edu/intranet/hes/cto/sops/sop_index.cfm

Principal Investigator
(Name Printed)

Principal Investigator
(Signature)

Date

BY SIGNING THIS DOCUMENT, THE CHAIR AGREES:

1. To work with the investigator and with the board as needed, to maintain compliance with this agreement.
2. That the Principal Investigator is qualified to perform this study.
3. That the protocol is scientifically relevant and sound.

Department Chair or Designee*
(Name Printed)

Department Chair or Designee
(Signature)

Date

*(Cannot be Principal Investigator or Sub-investigator)

The Board reserves the right to terminate this study at any time if, in its opinion, (1) the risks of further experimentation are prohibitive, or (2) the above agreement is breached.

For Use by IRB-HSR Office

IRB-HSR # _____

Revised 8-1-06