**Virginia Department of Health**

**Institutional Review Board (IRB)**

**Principal Investigator’s Responsibilities**

The Principal Investigator (PI) has direct responsibility for the implementation of the research and for ensuring the protection of human participants in research. The PI must be knowledgeable of federal regulations and institutional policies and procedures related to the conduct of research. The following lists the major responsibilities of the PI.

The PI is responsible for ensuring that:

* all members of the research team comply with the findings, determinations, and requirements of the IRB.
* all members of the research team have completed the human subjects research training.
* all student members of the research team are provided appropriate supervision.
* the IRB protocol number and title of the research are cited in all correspondence to the IRB.
* continuing review and approval of the research has been accomplished within the timeframe stipulated by the IRB.
* any changes in research activity, including changes to the protocol, and/or consent form(s), completion or termination of the study, are promptly reported to the IRB by completing the Request for Modification form. No change in approved research may be initiated without the IRB’s approval except under conditions where it is necessary to eliminate apparent immediate hazards to human participants.
* no research is continued beyond the designated approval period.
* any unanticipated problems involving risk to subjects and others, and any adverse events are reported immediately to the IRB by submitting an Adverse Event Reporting Form.
* any significant new information that may affect the risk/benefit ratio is submitted promptly to the IRB.
* for every expedited/full review IRB protocol, all signed consent forms (if applicable) are maintained for at least three (3) years after completion of the study and are available for review as needed.
* only consent/assent/parental permission forms that have been reviewed and approved by the IRB may be presented to the research participants.
* all VDH IRB requests for information are responded to in a timely manner.

VDH IRB forms are available at <http://www.vdh.virginia.gov/OFHS/policy/irb.htm#forms>

The VDH IRB may be contacted by emailing VDHIRB@vdh.virginia.gov, or calling 804.864.7675

Dev Nair, PhD, MPH

VDH IRB Chair