Investigator Responsibilities

1. Protect the rights and welfare of human research subjects;
2. Be knowledgeable about federal guidelines governing research and requirements for investigators delineated in CVMC's Policy and Procedures, RI-20;
3. Conduct the research according to the IRB-approved protocol;
4. Obtain a documented informed consent form (ICF) from each subject, or their legally authorized representative, and provide a copy of the signed and witnessed ICF to each subject (unless the IRB has waived some or all of this requirement);
5. Ensure each potential subject understands the nature of the research, what their participation entails, and the risks and potential benefits involved;
6. Promptly submit proposed amendments to the approved research study to the IRB, while not implementing any changes until written IRB approval is received (except where necessary to eliminate apparent immediate hazards to the subjects);
7. Submit study progress reports as often as prescribed by the IRB using the standard study progress report form;
8. Promptly report all adverse events (RI-20-V.E.) to the IRB;
9. Submit a Study Closure Form to the IRB upon completion of the research;
10. Retain study records as required by federal regulations (OHRP or FDA) following study completion.