Approved 3/19/2013

Principal Investigator's Responsibilities

The Principal Investigator is responsible for ensuring the protection of research participants and conducting sound ethical research that complies with federal regulations, University policy and procedures.

Summary of Investigator's Responsibilities

- Acknowledging and accepting the ethical and legal responsibilities for protecting the rights and welfare of research participants;
- Complying with all applicable policies, procedures, guidance, and determinations of the IRB;
- Providing oversight and appropriate training for all research team members;
- Ensuring all research team members comply with IRB decisions, and requirements;
- Conducting the research as presented in the IRB approved protocol or as determined exempt by IRB Administrators;
- Promptly reporting
    - unanticipated problems involving risks to subjects or others to the IRB, §46.103(b)(5), IRB SOP #8;
    - any serious or continuing noncompliance with IRB requirements or determinations of the IRB, or the regulations to the IRB promptly, §46.103(b)(5), IRB SOP #7;
    - any suspension or termination of IRB approval (e.g., from another institution involved in the research) to the IRB and sponsor, if applicable §46.103(b)(5); and
- Keeping records relating to the research, including statements of significant new findings provided to subjects, and consent documents for at least three years after completion of the research §46.115(b), IRB Policy.

Additional responsibilities for non-exempt human subject research

- Obtaining and documenting informed consent of subjects or subjects' legally authorized representatives prior to the subjects' participation in the research, unless these requirements have been waived by the IRB, §46.116; §46.117, IRB SOP #5 and IRB SOP #6;
- Obtaining prior IRB approval for any modifications of previously approved research, including modifications to the informed consent process and document, except those necessary to eliminate apparent immediate hazards to subjects. Changes to eliminate apparent immediate hazards to subjects must be reported promptly to the IRB, §46.103(b)(4), IRB SOP #4;
- Completing progress reports and requests for continuing review in accordance with the policies, procedures, and determinations of the IRB, §46.103(b)(4), §46.109(e), §46.115(a)(1), IRB SOP #3;
- If IRB approval of a specific study expires before continuing review and approval occur, investigators must stop all research activities involving human subjects related to that study, except where they judge that it is in the best interests of already enrolled subjects to continue to participate. When investigators make this judgment, they must promptly notify the IRB, §46.103(b)(5), IRB SOP #3; and
- Completing a Study Closure form when all human subject research activities have been completed, IRB SOP #8.

Resources: 45 CFR Part 46, and http://answers.hhs.gov/ohrp/categories/1567