

9.0 INVESTIGATOR RESPONSIBILITIES

9.1 Principal Investigator Responsibilities

The principal investigator of the research study is ultimately responsible for assuring compliance with applicable University IRB policies and procedures, DHHS Federal Policy regulations, and FDA regulations; and for oversight of the conduct of the research study and the informed consent process.

9.2 General Responsibilities of Research Study Investigators

As a general condition for the approval of a research study, the IRB holds the principal investigator of the study mutually responsible for ensuring that:

- 1) the risks to involved research subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose the subjects to risk; and, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- 2) the risks to human research subjects are reasonable in relation to the anticipated benefits (if any) to the individual, and the importance of the knowledge that may be expected to result.
- 3) the selection of human subjects and patients for research participation is equitable.
- 4) individuals are adequately informed of the risks and benefits of research participation and the procedures that will be involved in the research; and that informed consent will be obtained from each prospective human research subject, or his/her legally authorized representative, in accordance with, and to the extent required, by University policies and federal regulations.
- 5) the informed consent of human research subjects will be obtained in advance of research participation and appropriately documented in accordance with, and to the extent required, by University policies and federal regulations.
- 6) where appropriate, there is routine monitoring of the data collected to ensure the safety of human research subjects.
- 7) the privacy of human research subjects is protected and the confidentiality of data is maintained.
- 8) appropriate additional safeguards are included in the study to protect the rights and welfare of human research subjects who are likely to be vulnerable to coercion or undue influence (e.g., children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons).

9.3 Specific Responsibilities of Study Investigators

The IRB holds the principal investigator and co-investigators of an approved research study responsible for:

- 1) promptly responding to all requests for information or materials solicited by the IRB Office, including the timely submission of the research study for IRB renewal.
- 2) ensuring that adequate resources and facilities are available to carry out the proposed research study.
- 3) abstaining from the enrollment of any individual in a research study (i) until such study is approved in writing, by the IRB; (ii) during any period wherein the IRB or sponsor/principal investigator has suspended study activities; or (iii) following IRB- or sponsor/principal investigator-directed termination of the study.
- 4) ensuring that all associates, colleagues, and other personnel assisting in the conduct of the research study are fully informed of (i) the study procedures; (ii) informed consent requirements; (iii) the potential adverse events associated with study participation and the steps to be taken to reduce potential risks; (iv) adverse event reporting requirements; and (v) data collection and record-keeping criteria.
- 5) conducting the study in strict accordance with the current IRB-approved research protocol except where a change may be necessary to eliminate an apparent immediate hazard to a given human research subject.
 - reporting promptly to the IRB Office any such deviations from the currently approved research protocol.
- 6) requesting IRB approval of any proposed modification to the research protocol or informed consent document(s) prior to implementing such modifications.
- 7) obtaining prospectively and documenting informed consent in accordance with the current IRB-approved informed consent document(s) (i.e., unless the IRB has granted a waiver of the informed consent process).
- 8) maintaining adequate, current, and accurate records of research data, outcomes, and adverse events to permit an ongoing assessment of the risk/benefit ratio of study participation.
- 9) reporting promptly to the IRB (and, if applicable, the sponsor and FDA) any internal or external adverse event that is considered to be 1) unexpected; 2) serious) and 3) possibly or definitely related to the study.
- 10) reporting promptly to the IRB any significant changes in the risk/benefit of study participation.
- 11) ensuring that, in the event of an adverse event, every reasonable effort is made to provide the involved research subject with adequate care to correct or alleviate the consequences of the adverse event to the extent possible.

- 12) ensuring that human research subjects are kept fully informed of any new information that may affect their willingness to continue to participate in the research study.
- 13) ensuring that all listed investigators have the appropriate credentials to conduct the portion of the study in which they are involved.
- 14) ensuring that conduct of the research study adheres to Good Clinical Practice guidelines, if applicable. If the study is regulated by the FDA, ensuring that all research investigators and coordinators have completed the Good Clinical Practices module available through the ISER system.