**GUIDANCE 20**

**ROLES AND RESPONSIBILITIES OF INVESTIGATORS**

For every research protocol, the PI of record shall specifically identify in writing all other investigators who will actively participate in the research and in securing informed consent from subjects.

The responsibilities are:

1. Preparation of a research protocol and fulfillment of all subsequent obligations in connection with that protocol and strict compliance with all applicable regulations.
2. PI will not make any changes in the design or conduct of the research including addition of new subjects without the IRB approval. Exceeding the number of subjects to be enrolled beyond what has been initially approved by the IRB requires IRB approval.
3. PI may change the protocol without IRB approval when it is necessary to eliminate apparent immediate hazards to human subjects. When such protocol deviations are done for the safety of subjects, it must be immediately reported to the IRB.
4. PI will make every effort to minimize risk by using procedures which are consistent with sound research by reducing unnecessary risks using appropriate procedures.
5. PI must ensure that risks to subjects are reasonable in relation to anticipated benefit (if any).
6. Selection of subject population is equitable.
7. Obtain informed consent in advance of research participation.
8. Ensures that privacy and confidentiality is properly maintained.
9. 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).
10. PI is responsible for properly implementing an approved protocol using good clinical and/or human subject research practices.
11. PI is responsible for coordinating, supervising and monitoring the activities of all other persons participating in the research and for assuring that all personnel are properly trained to conduct human subject’s research.
12. PI is also responsible for timely submission of documents (21 days before the expiration date of an approved protocol) for the continuing review of the project, including reporting to the IRB all changes in the research activity, including amendments and all unanticipated problems (adverse events) involving risks to human subjects.
13. If a protocol has expired, NO subject enrollment should occur and all research activities must be stopped. Research activities include but are not limited to recruitment and enrollment of subjects, collection of specimens, surveys, review of medical records or other health information, and the performance of research tests/procedures, treatment or follow-up on previously enrolled subjects.
14. If treatment and/or follow-up of subjects are necessary for subject safety and welfare, the IRB must be informed in writing immediately. Either the Chair or IRB will consider these requests on a case-by-case basis so treatments are continued until the study is re-approved by IRB. Federal regulations require that the IRB consider only what is in the best interest of the subjects when determining whether continuation of previously enrolled subjects is appropriate while continuing review is in process.
15. PI’s are encouraged to attend the meeting to respond to questions raised by the committee's review of the proposal. The substitution of PI’s by their research coordinator or student is discouraged. The PI, research coordinator and/or student will be excused for the actual review and vote.
16. The PI is responsible for complying with all IRB decisions, conditions, and requirements and for ensuring that applicable laws and regulations are observed.
17. Unanticipated adverse events that are also unanticipated problems involving risks to subject or others (e.g., those that are related and or possibly related to the research) must be reported to the IRB and other appropriate agencies as they occur. Further guidance on reporting external un-anticipated adverse events and local unanticipated adverse is available at: <http://www.hhs.gov/ohrp/policy/advevntguid.html>.

<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126572.pdf>.

a. To report to adverse events to sponsors (Clinical trials), use forms supplied by the sponsor. In January 2009, FDA issued further guidance on reporting adverse events. The purpose was to distinguish between adverse events that are unanticipated problems that must be reported to IRBs from those that are not. For further information on adverse event reporting go to http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm079753.pdf.

**Additional Responsibilities of a Principal Investigator**

1. Protecting the rights and welfare of the participants.

2. Ensuring that the research receives IRB review and approval before any activity begins, including screening procedures.

3. Ensuring that all co-investigators and research staff comply with the conditions, findings, determinations and requirements of the IRB.

4. Ensuring that all pertinent regulations, laws, guidelines and procedures are observed by all co-investigators and research staff involved in the conduct of the study.

5. Identifying all collaborating sites in the protocol, indicating which aspects of the research will take place at each site, and ensuring that there is appropriate IRB review and approval at each site.

6. Assuring receipt of IRB approval from all collaborating institutions.

7. Ensuring that all co-investigators and study staff submit disclosures of financial and other personal interests in the study to the Research Dean and the IRB.

8. Ensuring that the protocol is followed in the conduct of the study, including inclusion/exclusion criteria, number of subjects recruited, obtaining consent, etc.

9. Ensuring that studies receive timely IRB continuing review and approval.

10. Obtaining prior IRB review and approval of all changes to the protocol and consent forms, except where necessary to eliminate immediate hazards to subjects or others.

11. Reporting to the IRB promptly any unanticipated problems involving risks to subjects or others, and any serious adverse events that are either unanticipated or anticipated.

12. Ensuring adherence to all HIPAA requirements.

13. Ensuring that the IRB is notified about any monitoring visits or FDA audits in advance of the visit, as well as the results of any such visits.

14. Discontinuing all study activities at the end of the IRB-designated approval period;

15. Submitting to the IRB all required study-closure documentation upon study completion or discontinuation.