**GUIDANCE 37**

**PRINCIPAL INVESTIGATOR RESPONSIBILITIES**

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:

A. Preparation of a research protocol and fulfillment of all subsequent obligations in connection with that protocol and strict compliance with all applicable regulations.

B. 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.

C. 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.

D. Pi will make every effort to minimize risk by using procedures which are consistent with sound research by reducing unnecessary risks using appropriate procedures.

E. PI must ensure that risks to subjects are reasonable in relation to anticipated benefit (if any).

F. Selection of subject population is equitable.

G. Obtain informed consent in advance of research participation.

H. Ensures that privacy and confidentiality is properly maintained.

I. 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).

J. PI is responsible for properly implementing an approved protocol using good clinical and/or human subject research practices.

K. 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.

L. 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.

M. 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.

N. 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.

O. 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.

P. The PI is responsible for complying with all IRB decisions, conditions, and requirements and for ensuring that applicable laws and regulations are observed.

Q. Reporting unanticipated events