RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR

It is the role of the Institutional Review Board (IRB) to assist and ensure researchers discharge their responsibilities.

Principles to Follow:
The principal investigator and co-investigators are responsible for the full conduct of this study and especially to insure compliance of this protocol with federal regulations for the protection of human research subjects (FDA 45 CFR, Part 46, Federal Register, June 19, 1992; Helsinki Declaration.

These principles include special attention to the following:

- The risks to the subject must be reasonable in relation to the benefit to be gained. The study must be well designed; the results to be achieved must be significant.
- Risks to the subject must be minimized; safeguard to the subject's well being must be maintained.
- There must be equitable selection of the subjects. No discrimination or undue pressure can be brought to bear. Example: students, prisoners.
- There must be a truly informed consent. Subject, parent, or guardian must understand it. There can be no coercion. The subjects must be able to withdraw at any time without penalty. This would include even subtle changes such as relationship to doctor.

IT IS THE RESPONSIBILITY OF THE INVESTIGATOR TO:

- Insure that all procedures in approved protocols are performed and supervised by the listed principal investigator (PI) or co-principal investigator (co-PI) (not unlisted investigators, technicians, residents, fellows or nurses).
- Notify the IRB in writing if the investigator or list of co-Principal investigators has changed.
- Provide the IRB with the appropriate information on the research protocol including initial information, notification of subsequent modifications, terminations, and adverse reactions, etc.
- Insure that no research will be initiated (except emergency or compassionate) until IRB approval is received.
- Obtain appropriate [signed] informed consent from subject(s) and signed HIPAA Authorization form. Both forms must be signed and copies given to the subject.
- Carry out the protocol, as approved. Initiate modifications only after the IRB has approved the amendment, except where necessary to eliminate apparent immediate hazards to the subject.
- Complete requests for continuing review timely and accurately.
- Maintain confidentiality of all protocol records.
- Report in writing to the IRB (within 5 working days) any severe adverse reaction, unanticipated problem, death, or injury arising during the conduct of an IRB approved protocol.
- Keep appropriate records including names and access information for all research subjects.
- Note subject's participation in a research protocol in the medical record, establish a medical record if none exists, and ensure that a copy of the signed informed consent document is inserted.
- The principal investigator should provide his or her own research assistant or technical support, to assist with the preparation of the protocol submission. The IRB cannot provide technical or clerical support to principal investigators.
- Complete the OHRP Human Subject Assurance Training and upon completion, submit a copy of the certificate to the IRB. All principal and co-investigators and study coordinators must complete this module and have a copy on file in the IRB office. OHRP Human Subject Assurance Training Link: http://phrp.nihtraining.com/users/login.php

If the protocol involves an investigational drug, device or biologic, the principle investigator must also report adverse events to either the sponsoring company or directly to the FDA in the case of investigator – initiated research.

The IRB will mail original correspondence only to the principal investigators, unless special circumstances require the IRB to contact other parties. It is the responsibility of the investigator to insure that copies of IRB letters are distributed to appropriate individuals (e.g. grant and contract administrators, department administrators, granting agencies or pharmaceutical sponsors, co-PIs, etc.)