THE TOP-TEN INVESTIGATOR RESPONSIBILITIES

UCLA DEPARTMENT OF MEDICINE
CLINICAL RESEARCH

As Principal Investigator, you are responsible for making sure that the following occur:

1. A **prospective** review and approval of all human subject research protocols by the UCLA IRB (or certification of exemption).
   - *IRB approval is required for all human subject research before it can start.*
   - *If there is a lapse in the annual renewal, research must be put on hold until an up-to-date approval is provided by the IRB.*
2. An investigator named on the IRB-stamped consent form provides and documents the process of written informed consent.
   - *Responsibility for the consent process cannot be delegated to a nurse or coordinator.*
   - *An investigator cannot sign-off on consent that was obtained by others.*
   - *A named investigator must personally assure that the subject understands what is described in the consent, their alternative options, the risks, and that they may revoke their consent at any time without jeopardizing their care.*
3. Subjects receive a copy of the IRB-stamped informed consent, the State of California Subject's Bill of Rights (for medical research), and the IRB-approved HIPAA Research Authorization form (when applicable) as part of the consent process.
   - *Subjects must get a copy of all of their signed consent documents.*
   - *You must retain a signed copy of all documents with your study records.*
4. Study visits and procedures are carried out exactly as described in the IRB-approved consent forms and any proposed changes to the protocol are **prospectively** submitted to the IRB for review and approval. The only exception is when changes are needed to eliminate an immediate hazard to the subject.
   - *No changes to the study procedures, investigators, or protocols are allowed without first submitting them to the IRB and obtaining IRB approval.*
   - *Additional studies/tests, the collection/storage of additional samples, or changes in drug administration may not be implemented without IRB review and approval.*
5. Protocol violations/deviations are reported to the IRB, as well as any injuries or unanticipated problems involving risks to human subjects.
   - *Anything that is not "working" with the study should be reported to the IRB along with suggestions for changes/corrections.*
6. Good clinical practice guidelines are followed when performing clinical research.
   - *Maintain source documents for all visits, procedures and tests in order to provide independent verification of the information recorded on the case report forms.*
   - *Maintain a comprehensive regulatory binder that includes copies of all correspondence with the IRB, FDA and sponsor, as well as protocols and amendments, etc.*
   - *All tests used for clinical decision-making must be performed in CLIA-certified laboratories or in a similarly certified manner.*

- *All study drugs and investigational agents must be maintained and dispensed by the Investigational Drug Section (IDS) of the Ronald Reagan UCLA Medical Center Department of Pharmaceutical Services according to an approved pharmacy protocol.*
- *All information recorded onto the case report form will be reviewed by a study investigator, with documentation of approval or corrective action for abnormal values and/or protocol violations. You are directly responsible for the integrity of the study data and the safety of the subjects.*

7. Serious adverse events are immediately reported according to the UCLA IRB Decision Tree for internal or external events and FDA guidelines.
   - *Report first – obtain and report follow-up details later.*
   - *It does not always matter if the SAE is related to the study, it must be immediately reported if required by the UCLA IRB Decision Tree guidelines.*
8. All of the investigators/staff involved in human subject research are knowledgeable of the research protocol and IRB polices and appropriately trained and/or certified for the research that they are conducting including Human Research Subject Protection, HIPAA, blood drawing, biosafety, sample shipping, etc.
   - *You should personally verify certificates of training.*
   - *Offer additional training to your staff when their responsibilities increase.*
   - *Foreign-trained physicians that lack a valid California medical license may not perform medical procedures, medical evaluations or in any way act in the role of a treating physician.*
9. The privacy and confidentiality of personally identifiable information for all human subjects participating in research is maintained, except as required by law or if release of this information is requested in writing by the subject.
   - *No personal identifiers should appear on case report forms.*
10. All aspects of research funding and expenditures are handled in a manner consistent with University and/or funding agency guidelines.
    - *Limit and supervise all petty cash distributions.*
    - *Meet regularly with fund managers to review expenditures.*

The opportunity to carry out research involving human subjects is an honor and a privilege that carries with it a number of responsibilities. As the Principal Investigator, you will be responsible for these Top-Ten responsibilities as well as many others that are mandated by the University, the funding agency, the FDA, the IRB, University Contracts and Grants, and the Department.

I have read these responsibilities and agree to apply them to my research study entitled:
Various

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Sponsor Name Various _____

_____ _____ _____

Signature Print Name Date