



RESEARCHER RESPONSIBILITIES LIST

The following are the minimum responsibilities of Principal Investigators as stated in the formal agreement between New York University School of Medicine and the federal Office of Protection from Research Risks (the "Assurance"). Please check each item to indicate that you have carefully read and understand your responsibilities.

- 1. Principal Investigators acknowledge and accept their responsibility for protecting the rights and welfare of human research subjects and for complying with all applicable provisions of the Assurance.
- 2. Principal Investigators who intend to involve human research subjects will be responsible for obtaining IBRA review and approval prior to the initiation of research.
- 3. Principal Investigators are responsible for providing a copy of the IBRA-approved and signed informed consent document to each subject at the time of consent, unless the IBRA has specifically waived this requirement. All signed consent documents are to be retained in a manner approved by the IBRA.
- 4. Unless otherwise authorized by the IBRA, Principal Investigators are responsible for obtaining and documenting informed consent in accord with applicable federal regulations at 45 CFR §46.116 and 45 CFR §46.117.
- 5. Principal Investigators shall be responsible for promptly reporting proposed changes in previously approved human subject research activities to the IBRA. The proposed changes may not be initiated without IBRA review and approval, except where necessary to eliminate apparent immediate hazards to the subjects. See **Request Form for Approval of Amendment**.
- 7. Principal Investigators will report to the IBRA any unexpected and serious events or other unanticipated problems involving risks to subjects or others within 15 calendar days. See **Adverse Event Report Form**.
- 8. Principal Investigators will submit a progress report (**Request Form for Reapproval or Study Closure**) at least four weeks prior to the date at which the IBRA has determined continuing review is required. If the progress report is not received by the due date, it cannot be guaranteed that a study will be reviewed before the expiration of your approval date. If a study is not reviewed prior to the expiration date, new enrollment is suspended and you may not continue with the study for previously enrolled subjects except as approved by the IBRA.
- 9. Principal Investigators will complete an educational program on the protection of human research participants.

Note: Investigators conducting research subject to FDA jurisdiction and who are also the sponsors of the research ("Sponsor-investigators") have additional responsibilities and should consult the Investigator Guide for a more detailed discussion of their responsibilities. Sponsor-investigators will comply with these additional requirements.

I HAVE READ AND UNDERSTAND MY RESPONSIBILITIES AND AGREE TO COMPLY WITH EACH OF THESE REQUIREMENTS.

Signature

Date

Name (print)