



FACULTY ADVISOR RESPONSIBILITIES

For the study entitled _____, led by _____

_____, I agree to the Faculty Advisor Responsibilities outlined below.

- Meets with the student investigator on a regular basis to monitor study progress;
- Should problems arise during the course of the study, the Faculty Advisor agrees to be available, personally, to supervise the student investigator in solving them;
- Ensures that all investigators and key study personnel have completed the VU IRB required human subjects training program in CITI;
- Ensures that the project is performed only by qualified personnel according to the approved IRB application;
- Ensures that the student investigator does not implement any changes to the approved IRB application or informed consent document without prior IRB approval (except in an emergency, if necessary to safeguard the well-being of human participants, and will report to the IRB within 5 days of such change);
- If children are included in research activities, ensures that the student investigator follows the [Vanderbilt University Protection of Minors Policy](#), which includes appropriate provisions for background clearance checks, training and education, Codes of Conduct, external and mandatory reporting.
- Ensures that the student investigator only obtains legally effective informed consent from human participants or their legally authorized representative, only the currently approved date stamped informed consent documents for human participants are used; and a copy of the informed consent is provided to the participant.
- Ensures that the student investigator promptly reports any unanticipated problems involving risks to participants or others, or any serious adverse events (whether anticipated or not) to the IRB;
- Assumes responsibility for the accurate documentation, investigation and follow-up of all possible study-related adverse events and unanticipated problems involving risks to participants.
- If unavailable to supervise this research personally, as when on sabbatical leave or vacation, the Faculty Advisor arranges for an alternate Faculty Advisor to assume direct responsibility in his or her absence and advises the IRB in advance of such arrangements;
- Ensures that the student investigator promptly provides the IRB with any information requested relative to the project;
- Ensures that the student investigator promptly and completely complies with an IRB Decision to suspend or withdraw approval for the project; and
- Ensures that the student investigator obtains continuing review approval prior to the date approval for the study expires. Further, the Faculty Advisor understands that if the student investigator fails to apply for continuing review, approval for the study will automatically expire and the Faculty Advisor must ensure that all study activity ceases until IRB approval is obtained.

Name:

Signature:

Date: