

DEPARTMENT: INSTITUTIONAL REVIEW BOARD
POLICY NUMBER: 023
SECTION: GENERAL IRB POLICIES
REVIEW RESPONSIBILITY: IRB
EFFECTIVE DATE: AUGUST 13, 2003
REVISION DATE:
LAW IMPLEMENTED: 45 CFR 46.103

SUBJECT: Investigator Checklist

1. The Principal Investigator agrees to abide by the federal regulations for the protection of human subjects.
2. The Principal Investigator (“PI”) agrees to maintain raw data (including audiotapes and videotapes) and completed consent forms available for 3 years beyond the completion of the study for Human Subjects Committee verification at any time.
3. If the data collection or testing of subjects is to be performed by persons other than the PI (i.e. student assistants), the P.I. will assume full responsibility for supervising those persons to ensure that human subjects are adequately protected.
4. The PI is encouraged to have all existing and future key personnel complete the FSU Human Subjects training before they are involved in this study.
5. The PI agrees to report all changes of key personnel, protocols, and informed consent regardless of review status.
6. The IRB shall not grant final approval of NIH projects until the PI and key personnel working on the project have completed the NIH human subjects training. Proof of such completion of training shall be included in the application file.
7. Nature and Purpose of Research:
 - a) Is it research?
 - b) Controversial/Sensitive areas
 - c) Importance/Value
8. Scientific Background:
 - a) Background/Rationale
 - b) Previous animal/clinical trials
 - c) Literature support
9. Subject Population:

- a) Appropriate to goals of study
- b) Number of subjects
- c) Special subject characteristics: “special populations”
- d) Inclusion/exclusion criteria
- e) Justification for “vulnerable population”
- f) Methods used to identify potential subjects
- g) Recruitment process
- h) Selection process

10. Research Design:

- a) Design will enable valid conclusions
- b) Special problems/risks imposed by design: randomization, pre-randomization, placebo control, blinded, etc.
- c) Can design be modified to decrease risks and still yield valid data?
- d) Need for monitoring of study (i.e. safety monitoring board)

11. Risk/Benefit Ratio:

- a) What are the potential risks/discomforts?
- b) What are inconveniences and/or burdens: cost to subject, time, visits, travel, etc.?
- c) Risk classification category: less than minimal, greater than minimal, life-threatening
- d) Probability of risk/harm
- e) Safeguards adopted to minimize risk/harm
- f) How will injury/harm be detected?
- g) Benefits to subject (if any intended or anticipated)
- h) Benefit to population of patients with subject’s condition
- i) Benefit to society
- j) Have efforts been made to maximize possibility of benefit?
- k) Are risks/discomforts/burdens balanced by potential benefits?
- l) Is risk/benefit ratio comparable to that of alternatives to participation?
- m) If no benefit to subject, can risks, discomforts and burdens be justified on basis of generalizable knowledge to be obtained?
- n) Risk/benefit ratio in research involving special subjects – i.e. children

12. Processing of Research Data:

- a) How will data be recorded and maintained?
- b) Sensitive data? Need for special protections?
- c) Provisions to protect anonymity or confidentiality
- d) To whom will data be disclosed? Will data contain identifiers or be coded?
- e) Will proposed statistical treatment of data yield valid results?

13. Monitoring:

- a) Any need for special monitoring or reporting?

14. Informed Consent Process:

- a) Who will solicit consent?
- b) Will subjects have the capacity to provide consent?
- c) Timing/Setting in which consent will be solicited
- d) Should subject advocate or other individual be present during consent process?
- e) Verbal vs. written consent; request for waiver

15. HIPAA applicability:

- a) Are you requesting/accessing protect health information from a covered entity?
- b) If you need authorization or other forms to access PHI, are the forms acceptable to the covered entity?

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LW IMPLEMENTED: 45 CFR 46.204 – 207

SUBJECT: Research Involving Pregnant Women, Human Fetuses and Neonates

1. This policy applies to all research, development, and related activities involving pregnant women, the fetus, and neonates. The requirements within this policy are in addition to those imposed under existing IRB policies and other applicable federal, state, or local laws.
2. Definitions as used in this policy shall mean as follows:
 - a) “Pregnancy” encompasses the period of time from implantation until delivery. A woman shall be presumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.
 - b) “Fetus” means the product of conception from implantation until delivery.
 - c) “Neonate” means a newborn.
 - d) “Viable” as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration. If a neonate is viable then it may be included in research only to the extent permitted and in accordance with the requirements of subparts A and D of 45 CFR 46.
 - e) “Dead fetus” means a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.
 - f) “Nonviable neonate” means a neonate after delivery that, although living is not viable.
3. Pregnant women or fetuses may be involved in research if all of the following conditions are met:
 - a) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;