

Florida State University Policy 7-IRB-23

Title of Policy: Investigator Checklist

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

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Revised _____

I. INTRODUCTION

This policy provides an Investigator checklist for completing human subjects research and ensures that the Investigator is in compliance with applicable federal and state laws and local policies and guidelines.

II. POLICY

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?

III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

BOG 1.001(3)(m), 45 CFR 46.103