Florida State University Policy 7-IRB-34

Title of Policy: Basic Elements of Consent

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

Effective Date: Readopted –January 1, 2015

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Revised _____

I. INTRODUCTION

This policy states that according to 45 CFR 46.116, specific elements must be included in all informed consent documents unless waived by the IRB.

II. POLICY

1. 45 CFR 46.116 requires that specific elements be contained in all informed consent documents unless waived by the IRB. Required elements of informed consent may not be omitted and there shall be no inconsistencies between the IRB application and the informed consent document regarding the purpose, risks, and benefits of the research.

2. In seeking consent, the following information shall be provided to each subject and are the fundamental basic elements of consent:

    a) a clear statement that the study involves "research";
    b) an explanation of the purposes of the research;
    c) the expected duration of the subject's participation;
    d) a complete description of the procedures to be followed;
    e) an identification of any procedures which are experimental;
    f) a description of any reasonably foreseeable risks or discomforts to the subject;
    g) a description of any benefits to the subject or to others which may reasonably be expected from the research;
    h) a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
    i) a statement describing the extent, if any, to which confidentiality of

records identifying the subject will be maintained;

j) for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

k) an explanation of whom to contact for answers to pertinent questions about the research and the research subjects' rights (such as the IRB office); and

l) a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

3. Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

   a) a statement that the particular treatment or procedures may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

   b) anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

   c) any additional costs to the subject that may result from participation in the research;

   d) the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

   e) a statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

   f) the approximate number of subjects involved in the study.

4. The informed consent document should not contain any unproven claims of effectiveness or certainty of benefit, either express or implied.

5. The informed consent document must be communicated in a language that is understandable to the subject, and should not be complex, so that it can be comprehended by all subjects. Technical and scientific terms should be adequately explained using common or lay terminology.

6. The informed consent document shall not contain any exculpatory language through which the subject is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the University, or its agents from liability for negligence.

7. If research involves test articles regulated by the US Food and Drug Administration (FDA), the informed consent document must include a statement that the purpose of the study includes evaluation of both the safety and the effectiveness of the test article.

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

BOG 1.001(3)(m), 45 CFR 46.116