

Florida State University Policy 7-IRB-15

Title of Policy: Reporting of Unanticipated Problems Involving Risk or Adverse Events

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

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Revised _____

I. INTRODUCTION

This policy describes the responsibility and authority of the IRB for reviewing unanticipated problems involving risk and adverse events reported by the Investigator. The policy outlines the responsibility the Investigator has in reporting unanticipated problems involving risk and adverse events.

II. POLICY

1. The IRB is charged with the responsibility of reviewing reported unanticipated problems involving risks to subjects and adverse events in accordance with this policy. The IRB may elect to vote to suspend or terminate the study or direct the Investigator to contact subjects for re-consenting or to provide additional information regarding subject safety.
2. Investigators must address risks to subjects in the initial IRB application. Plans for safety monitoring, reporting of adverse events and/or unanticipated problems involving risks to subjects, and procedures for transmitting information to the IRB must be described in the initial application.
3. The Investigator shall be responsible for submitting to the IRB any independent data safety monitoring reports in a timely manner.
4. Investigators shall be responsible for informing governmental and/or other sponsors of any adverse event and/or unanticipated problems involving risks to subjects in accordance with the sponsors' policies and regulations.
5. Investigators are responsible for informing the appropriate institutional committees and federal agencies (such as the FSU Biosafety Committee, OHRP, FDA) of any adverse events and/or unanticipated problems involving risks to subjects in accordance with FSU policies and federal regulations.

6. Prior to, and at the time of IRB continuing review of an approved research study, it is the Investigator's responsibility to keep the IRB office informed of any unanticipated problems involving risks to subjects or adverse events that were serious, unanticipated, and resulted in a change to the risk/benefit ratio, even if the event occurred at a location for which the FSU IRB is not the IRB of record. The Investigator shall be responsible for the documentation, investigation, and follow-up of all possible study-related adverse events and unanticipated problems involving risks to subjects.
7. The level and promptness of an IRB review of adverse events and unanticipated problems involving risks to subjects depends upon the following:
 - a) the seriousness of the event,
 - b) the relationship of the event to study participation,
 - c) whether the event is described in the study procedures, investigator's brochure and/or the informed consent documents,
 - d) whether the event occurred to a subject enrolled at a location for which an FSU Investigator is involved in the conduct of the research or is responsible for the reporting of unanticipated problems or adverse events to a regulatory agency, and
 - e) whether the event changes the risk/ benefit ratio.
8. The FSU IRB has identified three categories of adverse events and/or unanticipated problems involving risks to subjects and manner of response:
 - a) Level I – For events or problems occurring to the subject enrolled at an FSU site or at a site in which an FSU Investigator is involved in the conduct of the research or is responsible for the reporting of adverse events and/or unanticipated problems involving risks to subjects to a regulatory agency, the response shall be as follows:
 - All **SERIOUS** and **UNANTICIPATED** adverse events or problems involving risks to subjects that may possibly be or are known to be related to the research activity must be reported promptly to the IRB office utilizing the FSU IRB Adverse Event Report Form for each event. The report and underlying events shall receive a full committee review.
However, if there is no change to the risk/benefit ratio, or the research proposal or consent form, then an expedited review shall be utilized. (Note that the Chair or designee, at the time of the expedited review, may refer any adverse event to the full committee for review).
 - All **NON-SERIOUS** and **UNANTICIPATED** adverse events or problems involving risks to subjects that may possibly be or are known to be related to

the research activity must be reported promptly to the IRB office utilizing the IRB Adverse Event Report Form. An expedited review shall be utilized provided there is no change in the risk/benefit ratio, the research proposal or the consent form. (Note that the Chair or designee, at the time of the expedited review, may refer any adverse event to the full committee for review).

- b) Level II – For events occurring to the subject not enrolled at an FSU site or a site in which an FSU Investigator is not involved in the conduct of the research and the Investigator is not responsible for the reporting of unanticipated problems or serious adverse events to a regulatory agency, the response shall be as follows:
- All SERIOUS and UNANTICIPATED adverse events or problems involving risks to subjects that may possibly be or are known to be related to the research activity and the Principal Investigator has determined that there is a change to the risk/benefit ratio of the research, then an amendment request must be submitted to the IRB. An expedited review shall be utilized, unless the Chair or designee refers the matter to a full committee for review.
 - All NON-SERIOUS and UNANTICIPATED adverse events or problems involving risks to subjects that may possibly be or are known to be related to the research activity and the PI has determined that there is a change in the risk/benefit ratio of the research, require the submission of an amendment request to the IRB. An expedited review shall be utilized, unless the Chair or designee refers the matter to a full committee for review.
 - Events not resulting in changes to the risk/benefit ratio yet are of importance to the study or the IRB should be included in a summary format submitted with the Application for Continuing Review (renewal). Individual reports of such adverse events or unanticipated problems involving risks to subjects are not required to be submitted to the IRB, but must be retained in the PI's files for reference.
- c) Level III – All adverse events and/or unanticipated problems involving risks to subjects occurring in a human gene transfer protocol, regardless of relation to the study, must be reported promptly to the IRB, the FSU Biosafety Committee, and NIH Office of Biotechnology Activities, and other applicable regulatory agencies, such as the OHRP, and the FDA. The phrase “Human Gene Transfer” is defined as the deliberate transfer of recombinant DNA, DNA or RNA derived from recombinant DNA, into human subjects.
9. A Serious Adverse Event is defined as any experience that suggests a significant hazard, contraindication, side effect, or precaution, and includes any experience that is a:
- a) Death;
 - b) Life-threatening emergency;
 - c) Persistent or significant disability/incapacity;
 - d) Inpatient hospitalization or prolongation of existing hospitalization;
 - e) A congenital anomaly/birth defect;
 - f) Any other experience that suggests a significant hazard, contraindication, side effect or precaution that may require medical or surgical intervention to prevent one of the outcomes

listed above.

10. An Unanticipated Problem Involving Risks to Subjects, as referenced in 45 CFR 46.103(b)(5) may be an undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention (such as a headache following a spinal tap, intestinal bleeding associated with aspirin therapy, a loss of confidentiality, protocol deviation possibly effecting risk to the subject).
11. The FSU IRB has the authority to suspend or terminate approval of research that has been associated with unexpected serious harm to participants and/or others. When an IRB elects to take such action, the Chair shall promptly report this action, in writing, to the Investigator, including the rationale for the decision. Such action shall also be promptly reported to the Vice President for Research, the Associate Vice President for Research, the Department Head, and the Dean of the Investigator's School. Regulatory authorities such as the OHRP, FDA, NIH, or other federal sponsoring departments or agencies shall also be promptly notified by the IRB Office or any terminations for cause or suspensions for cause.

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

BOG 1.001(3)(m), 45 CFR 46.103,113