1. PURPOSE

This policy establishes requirements for reporting unanticipated problems involving risks to participants or others (including adverse events) to the Creighton University Institutional Review Board (IRB).

During the course of a research study, unanticipated problems involving risks to participants or others may occur. The IRB shall review these problems and reassess the balance between the risks and benefits to the subjects. The Principal Investigator has the primary responsibility of evaluating each problem for severity, likelihood of occurrence, and relationship, and reporting unanticipated problems involving risks to participants and others.

2. IRB REVIEW OF UNANTICIPATED PROBLEMS INVOLVING RISKS TO PARTICIPANTS OR OTHERS

2.1. The IRB Chair or designee considers whether: 1) the problem was foreseen OR (2) no participants or others were harmed AND (3) participants or others are not at increased risk of harm. If no further action is required, the Principal Investigator shall be notified. A summary report of all reported events shall be attached to the minutes for review at a convened meeting.

2.2. If the IRB Chair or designee determines that further action is required, the report, plan of action, and supporting material (e.g., revised protocol or consent) shall be sent to a convened IRB meeting for review.

2.3. The IRB shall review the report and the Principal Investigator’s plan of action and consider the following actions:

2.3.1. Modification of the protocol
2.3.2. Modification of the information disclosed during the consent process
2.3.3. Providing additional information to current participants (this shall be done whenever the information may relate to the participants’ willingness to continue participation)
2.3.4. Providing additional information to past participants
2.3.5. Requiring current participants to re-consent to participation
2.3.6. Alteration of the frequency of continuing review

2.3.7. Observation of the research or consent process by Quality Assurance Monitor

2.3.8. Requiring additional training of the investigator

2.3.9. Notifying investigators at other site(s)

2.3.10. Termination or suspension of the project (see IRB Policy 135, “Suspensions and Terminations”)

2.3.11. Obtaining addition information.

2.4. The Principal Investigator shall be notified immediately in writing of action taken by the board. The Principal Investigator shall also be contacted should additional information be required at any stage of the IRB review process or if changes need to be made to the protocol or informed consent document.

2.5. The Principal Investigator shall report back to the IRB within the timeframe required by the IRB that all conditions of the action plan have been met. If the conditions have not been met by the end of that timeframe, the IRB shall consider this to be noncompliant conduct (see IRB Policy 131, “Noncompliant Conduct”).

2.6. The convened IRB shall make the final determination of whether there is an unanticipated problem posing risks to participant or others based on the materials compiled during the inquiry. The IRB shall communicate this action to the Office of Research and Compliance.

2.6 The Associate Vice Provost for Research and Compliance, in consultation with the IRB and the General Counsel's Office, shall determine whether any government or private funding agency must be notified prior to, during, or after any investigation. If the unanticipated problem is to be reported to a federal regulatory agency and appropriate organizational officials, the Associate Vice Provost for Research and Compliance, in consultation with the IRB and the General Counsel’s Office, shall report the unanticipated problem to the appropriate federal regulatory agency and the organizational officials in the timeframe required by the agency or within 30 days, whichever is shorter.