

## Policies and Procedures

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### 1. PURPOSE

- 1.1. All members of Creighton University involved in human subject research are expected to comply with federal, state, and Creighton University policies governing the conduct of research at or through Creighton.
- 1.2. For information on reporting noncompliance, follow Creighton University Policy, "Reporting Noncompliant Conduct in Research or Sponsored Programs."
- 1.3. The Institutional Review Board (IRB) shall review all instances of noncompliance involving human participants to determine whether they constitute serious or continuing noncompliance, as defined below.

### 2. DEFINITIONS

- 2.1. **Noncompliance** is failure to follow the regulations, requirements, or determinations of the Creighton University IRB.
- 2.2. **Serious Noncompliance** is noncompliance that adversely affects the rights and welfare of participants or places participants at increased risk of harm. Serious noncompliance is a failure to follow any of the regulations, policies, or determinations of the IRB, and that, in the judgment of a convened IRB, increases risks to participants, decreases potential benefits, or compromises the integrity of the research. The IRB shall review instances of research conducted without prior approval and determine whether it constitutes serious noncompliance.
- 2.3. **Continuing Noncompliance** is a pattern of noncompliance that indicates an unwillingness to comply with regulations and policies or a lack of knowledge that may lead to an adverse effect on the rights and welfare of participants or may place participants at an increased risk of harm. In the judgment of the IRB, continuing compliance is that which will continue unless intervention occurs. Examples of continuing noncompliance include:
  - 2.3.1. Repeated violations of study protocol and institutional policies
  - 2.3.2. Repeated instances of failure to renew an active study prior to expiration date
  - 2.3.3. Repeated failure to respond to the IRB's inquiries or requests for documentation

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2.3.4. Repeated failure to respond to and resolve any study contingencies

2.3.5. Repeated instances of failure to respond to IRBs inquiries and contingencies

### 3. IDENTIFYING NONCOMPLIANCE

3.1. Noncompliance (serious and continuing) may be identified in a number of ways, including but not limited to:

3.1.1. A report by an individual made directly to the IRB Office, which can include reports by research staff or others involved in a study. See Creighton University Policy, "Reporting Noncompliant Conduct in Research or Sponsored Programs," for more information on reporting noncompliance.

3.1.2. An investigator-initiated report made via IRB titled, "Application for Reportable New Information."

3.1.3. IRB continuing review of ongoing research. IRB Document "Continuing Review or Project Termination IRB-01 Biomedical Research," or "Report for Continuing Review or Project Termination IRB-02 Social-Behavioral Research," used to assess all instances of noncompliance throughout the life cycle of a study.

3.1.4. Compliance reviews (audits) conducted by the Office of Research Compliance.

3.1.5. A report by a participant who directly contacts the IRB office.

3.1.6. A report by another committee, department, or official.

3.1.7. A report from the study sponsor or sponsor's monitoring entity.

4. Annual report that summarizes IRB activities and a cumulative report of violations, patient compliance, and noncompliance. **PROCEDURE FOR NONCOMPLIANCE IDENTIFIED BY OR REPORTED DIRECTLY TO THE IRB**

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- 4.1. For an allegation of noncompliance identified by or reported directly to the IRB(s), the IRB Chair or designee is responsible for initially reviewing reports or allegations of noncompliance and taking appropriate action (including no action).
- 4.2. When an allegation of noncompliance has been identified, the IRB Chair or designee, in collaboration with the Director of Research Compliance or designee, shall gather information pertinent to the review of the allegation. This may include:
  - 4.2.1. The initial noncompliance report
  - 4.2.2. The research protocol
  - 4.2.3. Informed consent forms
  - 4.2.4. Other documentation related to the report
- 4.3. Based upon this investigation, the IRB Chair or designee shall decide whether:
  - 4.3.1. The allegation is not substantiated or confirmed and no further review is needed.
  - 4.3.2. Further information is needed to make a determination.
  - 4.3.3. The allegation is substantiated or confirmed and is noncompliance.
- 4.4. If further information is needed to make a determination, the IRB Chair or designee shall contact the Director for Research Compliance and request a comprehensive review of the project and/or investigator. This investigation will follow the process outlined in Creighton University Policy, "Reporting Noncompliant Conduct in Research or Sponsored Programs." Upon completion of this investigation, the report shall be forwarded to the IRB Chair or designee and will be reviewed at a convened meeting of the IRB.
- 4.5. If the IRB Chair or designee determines the allegation is substantiated or confirmed and noncompliance has occurred, but it is neither serious nor continuing, the IRB Chair or designee shall forward the report to the IRB for informational purposes only. The IRB administrator shall file this report in the general compliance files and in a project file, if appropriate. The investigator shall be notified of the board review by letter after the meeting.

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4.6. All instances of noncompliance that potentially constitute serious or continuing noncompliance shall be referred to a convened IRB meeting for review and vote as to whether the instances constitute serious and/or continuing noncompliance. If the IRB decides the noncompliance is serious and/or continuing, the IRB shall follow the steps outlined in Section 7 of this policy.

### **5. PROCEDURE FOR NONCOMPLIANCE IDENTIFIED BY AN IRB ADMINISTRATOR**

- 5.1. For an allegation of noncompliance identified by an IRB administrator, the Research Compliance Director or designee shall gather information pertinent to the review of the allegation. This may include:
- 5.1.1. Interviews with the Principal Investigator and/or research staff
  - 5.1.2. The research protocol
  - 5.1.3. Informed consent forms
  - 5.1.4. Other documentation related to the report
- 5.2. Based upon this investigation, the Research Compliance Director or designee shall initiate a report. In collaboration with the Director for Research Compliance, the IRB Administrator or designee shall decide whether:
- 5.2.1. The allegation is not substantiated or confirmed and no further review is needed.
  - 5.2.2. Further information is needed to make a determination.
  - 5.2.3. The allegation is substantiated or confirmed and is noncompliance.
- 5.3. If further information is needed to make a determination, the IRB Chair or designee shall contact the Director for Research Compliance and request a comprehensive review of the project and/or investigator. This investigation will follow the process outlined in Creighton University Policy, "Reporting Noncompliant Conduct in Research or Sponsored Programs." Upon completion of this investigation, the report shall be forwarded to the IRB Chair or designee and will be reviewed at a convened meeting of the IRB.

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- 5.4. If the IRB Chair or designee and the Director for Research Compliance determine the allegation is substantiated or confirmed and noncompliance has occurred, but it is neither serious nor continuing, the IRB Administrator shall forward the report to the IRB for informational purposes only. The IRB administrator shall file this report in the general compliance files and in a project file, if appropriate. The investigator shall be notified of the board review by letter after the meeting.
- 5.5. All instances of noncompliance that potentially constitute serious or continuing noncompliance shall be referred to a convened IRB meeting for review and vote as to whether the instances constitute serious and/or continuing noncompliance. If the board decides the noncompliance is serious and/or continuing, the board shall follow the steps outlined in Section 7 of this policy.

## 6. PROCEDURE FOR NONCOMPLIANCE IDENTIFIED BY THE DIRECTOR FOR RESEARCH COMPLIANCE

- 6.1. For allegations of noncompliance identified by the Director for Research Compliance, the process outlined in Creighton University Policy “Reporting Noncompliant Conduct in Research or Sponsored Programs,” shall be followed.
- 6.2. If the Director for Research Compliance determines the allegation is substantiated or confirmed and noncompliance has occurred, but it is neither serious nor continuing, the Director for Research Compliance shall forward the report to the IRB Administrator or designee, who shall present to the IRB for informational purposes only. The IRB Administrator shall file this report in the general compliance files and in a project file, if appropriate. The investigator shall be notified of the board review by letter after the meeting
- 6.3. All instances of noncompliance that potentially constitute serious or continuing noncompliance shall be referred to a convened IRB meeting for review and vote as to whether the instances constitute serious and/or continuing noncompliance. If the board decides that the noncompliance is serious and/or continuing, the board shall follow the steps outlined in Section 7 of this policy.

## 7. CONVENED IRB REVIEW PROCEDURES FOR NONCOMPLIANCE POSSIBLY SERIOUS OR CONTINUING

- 7.1. The Director for Research Compliance, the IRB Administrator, and the General Counsel shall advise the IRB regarding applicable institutional policies and federal regulations, assist the IRB in documenting its review, answer questions

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about the review process, maintain the records as required by state and federal laws, and serve as a liaison within the Office of Research Compliance with the funding agency or agencies.

- 7.2. The IRB shall review the material related to alleged noncompliance at a convened meeting at which a quorum is present. The convened IRB shall be provided with the summary report, the report of noncompliance (if applicable), and any other pertinent documents. The convened IRB shall determine whether to request additional information or interview additional persons of interest. The IRB may give the respondent the opportunity to meet with the convened IRB before it takes final action.
- 7.3. The convened IRB shall make the final determination of whether the noncompliance is serious or continuing based on the materials compiled during the inquiry. If the noncompliance is serious or continuing, the IRB shall communicate this action to the Director for Research Compliance, Human Resources, the Institutional Official, the Dean of the Principal Investigator's School and Chair of the Principal Investigator's Department/Division.
- 7.4. The convened IRB shall approve a management plan that may include a variety of actions, depending on the outcome of the review, including, but not limited to, the following:
  - 7.4.1. No action
  - 7.4.2. Approve continuation of research without changes but with a cautionary reminder to the PI
  - 7.4.3. Require formal educational intervention
  - 7.4.4. Require minor or major changes in the research procedures and/or consent documents
  - 7.4.5. Modify the current approval period
  - 7.4.6. Require monitoring of research
  - 7.4.7. Require monitoring of the consent process
  - 7.4.8. Suspend the research (temporary cessation of IRB approval of some or all research activities) (see IRB Policy, "Suspensions and Terminations")

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- 7.4.9. Terminate IRB approval/disapprove of continuation of the study (permanent withdrawal of IRB approval) (see IRB Policy, “Suspensions and Terminations”)
- 7.4.10. Require audits of the investigator’s other active protocols
- 7.4.11. Disqualify the investigator from conducting research involving human subjects at the institution
- 7.4.12. Determine the data collected cannot be used for publication
- 7.4.13. Require participants previously enrolled in the study be contacted and provided with additional information and/or be re-consented
- 7.4.14. Request that publishers and editors be informed if manuscripts emanating from the research have been submitted or published
- 7.4.15. Recommend to the appropriate officials of the institutions engaged in the research that further administrative or disciplinary action be taken
- 7.5. The IRB shall communicate the IRB decision to the Principal Investigator in writing.
- 7.6. The IRB shall resolve questions or concerns raised by a PI regarding the outcome of a specific IRB noncompliance review through direct communication with the PI.
- 7.7. The PI may submit a response to IRB concerns in writing within 30 days of the date the IRB issues its final decision. The IRB limits these concerns to a review of the procedures employed to reach the decision (i.e., claims the process was faulty in a way that creates a considerable risk that the outcome was incorrect) or grievances against sanctions imposed as a result of a finding of noncompliance. The PI specifies the nature of any claimed procedural error or the perceived unfairness of sanctions issued. The IRB shall follow up on any PI grievance and/or the completion of the management plan.
- 7.8. The Director for Research Compliance, in consultation with the IRB Administrator 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 noncompliance is to be reported to a federal regulatory

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agency and appropriate organizational officials, the Director for Research Compliance, in consultation with the IRB Administrator and the General Counsel's Office, shall report the noncompliance to the appropriate federal regulatory agency and the organizational officials in the time frame required by the agency or within 30 days, whichever is shorter.