

Appendix 9:

Policy on non-compliance

NON-COMPLIANCE GUIDANCE TO IRB AND RESEARCHERS

It is the institutional policy to conduct research projects in accordance with the approved IRB protocol, federal regulations, state law, and University policy. Failure to do so will constitute noncompliance in the research endeavor. Noncompliance can be minor or significant.

Minor noncompliance is those actions that deviate from the approved research plan and generally they are unintentional. Examples include changing study personnel without IRB approval, altering the plan of study or minor wording changes in the protocol and study questionnaire without IRB approval.

Serious noncompliance includes the following:

- failure to obtain informed consent or inadequate procedures for obtaining informed consent from subjects
- conducting human subjects research without IRB approved protocol or exemption
- inadequate supervision of research that involves potential risks to subjects and others
- conducting research, including enrollment of subjects, when IRB approval has expired or has been suspended or terminated
- making substantive changes to a previously approved protocol without prior IRB approval unless the change is necessary to eliminate apparent immediate hazards to the subject
- failing to adhere to the conditions of approval of a protocol as specified by Rowan's IRB
- starting research under a protocol before meeting the conditions required by an IRB and receiving an IRB notification of approval
- failing to take IRB or institutionally required human subjects protection training; enrolling more subjects than approved by an IRB
- failing to have research participants sign a new consent form when new and relevant risks are discovered or failing to provide this new information to participants
- altering an IRB-approved consent process or an IRB-approved recruitment process without prior IRB approval
- misrepresentation of information related to human subjects research or performance of the research
- Conducting exempt research without IRB approval

Noncompliance could also be continuous involving multiple or repeated instances of non-compliance involving a single or multiple protocols.

Federal regulations require the reporting of serious and continuing noncompliance to the IRB, institutional officials and certain federal agencies and department heads.

IRB Review: Whether the noncompliance was inadvertent, careless or reckless or intentional, the IRB will determine the seriousness of noncompliance and take appropriate actions.

Appropriate actions may include the following:

- Requesting the investigator make modifications to the protocol

- Requiring more frequent review of the protocol (e.g., more often than the minimal of annual review)
- Requesting the investigator modify the consent process or consent documents
- Requiring the investigator to provide additional information to current and/or past participants or re-consenting to participation
- Requiring additional training of the investigator and/or study staff
- Reconsideration of IRB approval
- Implementation of monitoring of the research
- Implementation of monitoring of the consent process
- Suspension of the research
- Termination of the research
- Refer the matter for further consideration by the Institutional Official.

If IRB actions are serious, the IRB may make recommendations to the Institutional Official to report such serious noncompliance to the OHRP or FDA or any other funding agency that funds or supports the particular research activity. A copy of such report will also be communicated to the investigator, coinvestigator(s), department heads/chairs and the Deans of investigator's or coinvestigator's college or school and Vice President for Research.

The IRB has the right to suspend the research study, but individual's privilege to conduct human subject research can only be decided by the Institutional Official or the Vice President for Research.

Responsibilities of Investigators

1. Make yourself familiar with the University policies and federal regulations governing human subject's research. The primary responsibility as an investigator is the protection of the human subjects who have volunteered to participate in your studies.
2. IRBs may conduct random reviews of approved protocols to improve the quality of research and record keeping. In such cases, IRB will provide sufficient notice to the investigator to prepare for the review and advise the investigator that the review is conducted for quality improvement and for education purposes. During the audit the IRB representatives may talk with research staff, tour the facility, review study records, and IRB records. This process is collaborative and helpful with the end goal of facilitating the research and the protection of participants.
3. The most important way to stay in compliance is to follow the protocol as it has been approved by the IRB. If there is a need to change the protocol or any other IRB-approved documents, it MUST be approved by the IRB before implementing those changes.
4. Investigators, research personnel, or other individuals who believe that an incident of non-compliance has occurred must report the incident to the IRB as soon as they become aware of the incident as required by regulatory and institutional policies for the protection of human subjects.
5. When IRB requests to conduct a review of noncompliance, cooperate with the IRB providing documents and other information requested by the IRB. IRB or IRB subcommittee may conduct interviews of investigators, co-investigators study staff and

other individuals who may be associated with the noncompliance activity. Be available to meet with the IRB when such requests are made by the IRB.

Standard Operating Procedures for Expired Protocols

Notifications

1. All investigators shall receive via eIRB notices of pending expiration of his/her research study approximately 90, 60, 30 days prior to the expiration date.
2. Within 30 days of expiration a letter will be sent via eIRB to the PI, all co- investigators, and the Department Chair from the RowanSOM-IRB Office notifying them of the expiration.
3. Within 30 to 60 days of expiration a letter will be sent via eIRB to the IRB Chair notifying them that the study is being referred to the RowanSOM Institutional Review Board. A copy of this letter will be sent to the PI, and the Depart Chair, or the Research Dean if the PI is a Department Chair. This letter will include the deadline for submission of required documents and the Institutional Review Board meeting date at which the protocol will be reviewed. The date of the meeting to which investigators will be referred will be identified by determining the next deadline that provides the PI will at least 15 business days to respond.
 - a. Investigators who do not submit an application for continuation or closure prior to their expiration date will be referred to the Institutional Review Board. The study will be reviewed by the IRB Committee for continuation or closure at the request of the principal investigator if it is received by the meeting deadline. The study will be referred for administrative termination if no application is received by the meeting deadline.
 - b. Investigator submit a continuation or closure request prior to expiration, but whose protocols expire during the review process:
 - i. Before assignment to an IRB Committee meeting date, a careful review of the study file will be conducted to access the timeliness of submission, the turn- around time of IRB reviews, and the amount of time IRB staff have taken to provide comments and/or other necessary materials and guidance to the investigators.
 1. In case where expiration of the protocol is due to IRB reviewer turn-around and/or IRB staff time, the protocol will not be assigned an IRB Committee review date. The file will be reviewed again for inclusion on an Institutional Review Board Committee agenda in the following month if the study status is still at that time "Expired." No notice will be generated.
 2. In cases where expiration of the protocol is due to the principal investigator's failure to submit a response to an IRB debriefing memorandum, the protocol will be included on the Institutional Review Board Committee agenda for administrative termination. If the principal investigator responds to the debriefing memorandum prior to the submission deadline, the protocol will be included on the Institutional Review Board agenda for closure or continuation at the request of the principal investigator.
 - c. Investigators who have left the institution: Following administrative closure of protocols of investigators who have been found to have left the institution, notification of the closure and referral for future follow-up will be made to the appropriate school research dean.

Any exception to these procedures will be made through special permission by the IRB Chair and/or the IRB Office.

IRB Committee Actions:

1. The IRB shall take action based on the following Categories of Expired Protocols:

Category 1: Unfunded minimal risk protocols – no submission of continuation application.

1. Protocols in this category may be voted upon as a group.
2. Protocols will be administratively closed.
3. Investigator is placed on probation.

Category 2: Funded minimal risk protocols – no submission of continuation application.

1. Protocols in this category may be voted upon as a group.
2. Protocols will be administratively closed.
3. Sponsors will be notified of protocol status.
4. Investigator is placed on probation.

Category 3: Unfunded greater than minimal risk protocols – no submission of continuation application.

1. Protocols in this category will be voted upon individually.
2. All these studies present greater than minimal risk to participants, the IRB will make a determination as to whether a for-cause audit will be required.
3. Investigator is placed on probation.

Category 4: Funded greater than minimal risk protocols – no submission of continuation application.

1. Protocols in this category will be voted upon individually.
2. As these studies present greater than minimal risk to participants, the IRB will make a determination as to whether a for-cause audit will be required.
3. Sponsors will be notified of protocol status.
4. Investigator is placed on probation.

Category 5: Unfunded minimal risk protocols with submission of continuation application.

1. Protocols in this category will be voted upon as a group.
2. Principal Investigators will be issued a warning letter requiring that they submit a response to the IRB addressing all outstanding issues within 15 days of notice.
3. Failure to provide adequate response by the stated deadline will result in administrative closure.
4. Investigator is placed on probation.

Category 6: Funded minimal risk protocols with submission of continuation applications.

1. Protocols in this category will be voted upon as a group.

2. Principal Investigators will be issued a warning letter requiring that they submit a response to the IRB addressing all outstanding issues within 15 days of notice.
3. Failure to provide adequate response by the stated deadline will result in administrative closure.
4. Sponsor will be notified of protocol status.
5. Investigator is placed on probation.

Category 7: Unfunded greater than minimal risk protocols with submission of continuation application.

1. Protocols in this category will be voted upon individually.
2. Principal Investigators will be issued a warning letter requiring that they submit a response to the IRB addressing all outstanding issues within 15 days of notice.
3. All these studies present greater than minimal risk to participants, the IRB will also make a determination as to whether a for-cause audit will be required.
4. Investigator is placed on probation.

Category 8: Funded greater than minimal risk protocols with submission of continuation application.

1. Protocols in this category will be voted upon individually.
2. Principal Investigators will be issued a warning letter requiring that they submit a response to the IRB addressing all outstanding issues within 15 days of notice.
3. All these studies present greater than minimal risk to participants, the IRB will also make a determination as to whether a for-cause audit will be required.
4. Sponsors will be notified of protocol status.
5. Investigator is placed on probation.

4. Continuing non-compliance:

An investigator who has been brought before the IRB more than once for expired protocols will be considered for a determination of continuing non-compliance, subject to reporting to OHRP.

5. Exceptions may be granted by the IRB Committee on a case by case basis.

Designation of Investigator-on-probation:

1. Implications of designation as Investigator-on-probation:
 - a. Investigators-on-probation may not submit new protocols for review to RowanSOM IRB or Western IRB, nor can they be added as study personnel to other existing or new protocol submissions.
 - b. Investigators-on-probation may submit review requests for continuation of other protocols.
 - c. IRB members who are determined to be investigators-on-probation may be suspended from membership on the IRB until they have complied with the conditions set forth to return to good-standing.
2. **Steps investigators-on-probation must take to regain good standing.**
 - a. Investigators-on-probation must present a final report for each study that has been administratively closed by the Executive Committee of the IRB.

b. Investigators-on-probation must present a detailed corrective action plan addressing the reasons why protocols were allowed to fall out of review and explaining what steps will be taken to prevent future occurrences.

c. Once administratively closed by the IRB, Principal Investigators may not resume study activity on that protocol. The protocol must be submitted and reviewed as a new submission, and new approval granted prior to the initiation or continuation of research activities.