University of Ghana Medical Centre
Medical and Scientific Research Centre (MSRC)
Standard Operating Procedure and Policy on Investigator Reporting Requirements and IRB Review of Reportable Events

Investigator Reporting Requirements and IRB Review of Reportable Events

A. Definitions

1. Problems not anticipated in the IRB submission, related to participation in the research and places participants or others at risk of harm.
2. Unexpected adverse drug event: Any adverse drug experience which is not consistent with the risk information provided to the participants and the IRB.
3. Unexpected adverse device effect: Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that problem was not anticipated in the IRB submission.
4. Non-compliance to IRB regulations whether it is due to ignorance or deliberate choice to ignore regulations.
5. Serious non-compliance: Noncompliance that materially increases risks, that results in substantial harm to subjects or others, or that compromises the rights or welfare of participants.
6. Continuing non-compliance: A pattern of repeated non-compliance that compromises the rights and welfare of participants, the validity of the study or the mission or operation of MSRC.
7. Report of non-compliance: An instance of non-compliance that does not require further information to confirm. Allegation of non-compliance: An assertion made by a second party that must be proven or supported with evidence to either confirm or deny.

B. PI Reporting Requirements

1. The PI is required to notify the IRB promptly of:
   a. Unexpected adverse drug events, unexpected adverse device effects, and other unanticipated problems
   b. Noncompliance with national regulations or the requirements or determinations of the IRB
   c. Receipt of new information that may impact the willingness of participants to participate or continue participation in the research study.
2. Changes in approved research initiated without IRB approval to eliminate an immediate hazard.
3. Timeframe for reporting: all reported events should be reported to the IRB within five (5) working days unless it is unanticipated deaths which should be reported within one (1) working day of the occurrence of the event.
4. Audits/Inspections/Inquiry: The PI should immediately report to MSRC any audit from regulatory agencies or study sponsors. A report of the audit should be furnished to the MSRC.

5. Reports of problems determined to represent unanticipated problems involving risks to participants or others, noncompliance determined to represent serious or continuing non-compliance, and suspensions and terminations of IRB approval should be reported to study sponsor, as required.

C. Procedures for Review of Reports of Unanticipated Problems

1. The Chairperson (or designee) will review reports of submitted events to determine whether the event represents an unanticipated problem involving risks to participants or others.
2. If the report is determined to constitute no more than a minimal risk of harm, the Chairperson (or designee) will acknowledge such in myUGMC-IRB system. The Chairperson (or designee) should always declare and excuse themselves if they have any conflict of interest.
3. If the report is determined by the Chairperson (or designee) to possibly constitute an unanticipated problem involving risks to participants or others and the event represents more than a minimal risk of harm to participants or otherwise significantly impacts participants the event will be reviewed by the fully convened IRB.
4. If the event requires full board review, the convened IRB will review the report and determine if it represents unanticipated problems or risks to participants or others and determine if additional actions are required. If the determination made by the convened IRB differs from that made by the Chairperson (or designee), the determination of the convened IRB supersedes that made by the Chairperson (or designee).
5. The Chairperson (or designee) or convened IRB may take the following actions to protect the rights and welfare of participants. These actions may include, but are not limited to:
    a. No action necessary
    b. Modification of the protocol, consent process/documents or provision additional information to current and past participants or myUGMC-IRB application
    c. Requiring current participants to re-consent to participation
    d. Alteration of the frequency of continuing review
    e. Requiring additional training of the PI
    f. Referral of the PI to the research integrity committee.
    g. Suspension of the research pending a more thorough review.
    h. Terminate the research
6. The IRB sends written notification of determinations and actions taken to the PI through the myUGMC-IRB system. Reports to other entities may also be made.

D. Allegations and reports of Non-Compliance

The Chairperson (or designee) will respond to allegations and reports of violations of regulations and policies related to human research according to the procedures described below. The Chairperson (or designee) will self-identify conflicts of interest and will not participate in the investigation or review if a conflict exists.

1. Reports of non-compliance or suspected non-compliance:
   a. Reports/allegations of non-compliance or suspected non-compliance may be submitted to MSRC by a PI, study team, MSRC staff, IRB members, the research integrity committee, other auditing groups, a research participant or anyone else with a concern.
   b. Such reports/allegations may be made to the MSRC office, to the Direct of medical and scientific research, or through other UGMC offices. When human research related reports/allegations are received by other offices, MSRC is notified promptly. Reports/allegations should include as much information as possible regarding the event(s) or action(s).
   c. The identity of the informer will be kept confidential unless he/she provides permission to disclose identifying information.
2. Handling allegations of non-compliance:
   a. The individual staff member who first learns of the event or action will refer to the Chair of the IRB for further investigation and information gathering.
   b. If the Chair (or designee) determines that the allegation has no basis in fact, no further action will be taken under this Policy. If the Chair (or designee) determines that the allegation involves non-compliance in fact, the remainder of this procedure for non-compliance is followed. If, in the course of handling the allegation of noncompliance, the Chair (or designee) is unable to resolve whether the allegation has a basis in fact, the matter will be referred to the Research Integrity Committee (RIC) for further investigation.
   c. If the RIC determines that the allegation has no basis in fact, no further action will be taken under this Policy. If the RIC determines that the allegation involves non-compliance in fact, the remainder of this procedure for a report of noncompliance is followed.
3. Handling reports of non-compliance:
   a. The chair or the RIC upon determining that a report of non-compliance needs further investigations, will follow the procedure below.
   b. Will make contact with the PI and, when appropriate, consult the director of MSRC, UGMC legal office, or other organizational office as appropriate.
   c. PIs may voluntarily initiate suspension or termination of their research until the allegation or report of noncompliance has been investigated and resolved. If deemed necessary by the IRB Chair (or designee), the matter will be referred to the RIC for possible suspension or termination.

d. Once the investigation has been completed, the IRB Chair (or designee) will make an initial determination regarding whether the non-compliance constitutes serious or continuing noncompliance.
   i. If, after investigation, the Chair (or designee) determines that the noncompliance is not serious or continuing non-compliance and the proposed corrective action plan is appropriate, the event and corrective action plan will be documented in the myUGMC-IRB system. No further action is required.
   ii. If the Chairperson (or designee) determines that the noncompliance is not serious or continuing non-compliance, but the proposed action plan does not seem appropriate, the Chairperson (or designee) may work with the PI on a proposed corrective action plan. Once the plan is appropriate, the event and corrective action plan will be documented in the myUGMC-IRB system. No further action is required.
   iii. If the Chairperson (or designee) determines that the report of noncompliance represents serious or continuing noncompliance, the report is referred and reviewed by the RIC

E. Complaints and Concerns to the IRB

1. The PI should work with the research participant to resolve any complaints. MSRC may be contacted for assistance or advice on how to resolve the complaint. All complaints should be reported at the time of continuing review.
2. The Chairperson (or designee) will promptly handle and, if necessary, investigate all complaints and concerns received including those from PIs and research participants.
3. Complaints and concerns may be reviewed by the Chairperson (or designee) and or referred to the RIC
4. Complaints may be reported to the study sponsor or other relevant stakeholders.

F. Suspension and Termination

1. The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with IRB policies or that has been associated with unexpected serious harm to participants.
2. Any fully convened IRB has the right to suspend or terminate research when provided with new information that warrants such action.
3. The Chair or Director of MSRC may suspend research in situations where there is immediate risk of serious harm to participants.
4. Suspensions or terminations by someone other than the convened IRB are reported and reviewed by the convened IRB.
5. Any adverse events or outcomes that result from a suspension or termination must be reported to the IRB.

6. Suspensions and terminations cannot be overturned by organizational officials.

G. New Information

1. The convened IRB or expedited reviewers will review reports of new information that may impact the willingness of participants to participate or continue participation in the research study.
2. If the report of new information represents no more than a minimal risk of harm the event is reviewed in accordance with expedited review procedures.
3. If the report of new information represents more than a minimal risk of harm the event will be reviewed by the fully convened IRB.

H. Reporting

1. Reports of problems determined to represent unanticipated problems involving risks to participants or others, noncompliance determined to represent serious or continuing noncompliance, and suspensions and terminations of IRB approval will include:
   a. The nature of the event.
   b. Name of the organization conducting the research.
   c. Title of the research project and/or grant proposal in which the problem occurred.
   d. Name of the principal investigator on the study.
   e. Number of the research project assigned by the IRB and the number of any applicable grant, contract, or cooperative agreement.
   f. A detailed description of the problem or event including the findings of the IRB and the reasons for the IRB's decision.
   g. Actions the organization is taking or plans to take to address the problem.

2. When appropriate and applicable, copies of the report will be distributed to one or more of the following:
   a. The Dean or head of department of the PI;
   b. The PI Faculty Sponsor;
   c. Officials at the UGMC or affiliate organizations;
   d. MSRC;
   e. Research Integrity committee;
   f. UGMC Legal Office;
   g. The PI is responsible for reporting to the Study sponsor (including Industry Sponsors and Granting Agencies) and must copy MSRC;
   h. Other national agencies, when the research is overseen by those agencies;
   i. Officials, departments or offices from another organization when UGMC serves as the IRB of record for a PI at that organization.

3. Determinations of unanticipated problems involving risks to participants or others, serious or continuing noncompliance or suspension or termination of previously approved research will be reported in writing or via email within 14 days of the final determination.
    a. PIs may appeal a determination that an event represents an unanticipated problem, serious or continuing noncompliance, suspension or termination. The appeal must be received in writing within seven (7) days of the notice of the determination to the PI. Appeals must contain new information that was not previously presented to the board and should not be simply a restatement of information already considered.
    b. Appeals will be reviewed by the IRB and if found to contain new information will be referred to the RIC.
    c. If an appeal is referred to the RIC, reporting of the determination will occur within 14 days of the final RIC determination.