



SOP: Compliance Review Committee					
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**1 PURPOSE**

This procedure defines the process by which the Compliance Review Committee (CRC) determines if identified noncompliance in the conduct of human subject research by University of Miami researchers constitutes serious and/or continuing noncompliance.

**2 REVISIONS FROM PREVIOUS VERSION**

- 2.1 Editorial changes to reflect electronic implementation and Single IRB Review mandate.
- 2.2 Revised to apply to CRC Review
- 2.3 Revised to apply this SOP solely to non-compliance by University of Miami investigators.

**3 DEFINITIONS**

- 3.1 Conflict of interest - a relationship between a member of the CRC and any key personnel on a study being considered by the CRC, if that relationship biases or appears to bias the ability of the committee member to make objective decisions regarding the noncompliance. Such conflicts may include, but not be limited to, membership in the same department or division as the study team member, or a collaboration on publications or research studies.
- 3.2 Continuing noncompliance - a recurring pattern of behavior or noncompliance that, if not remediated, may compromise subject welfare/safety, subject rights, or data integrity.
- 3.3 HSRO – Human Subject Research office
- 3.4 IRB – Institutional Review Board
- 3.5 Quorum – 50% plus one of committee members must be present
- 3.6 Non-compliance – Failure to follow the regulations, university policies or the requirements or determinations of the IRB
- 3.7 PI – Principal Investigator
- 3.8 RCQA – Research Compliance and Quality Assurance
- 3.9 Serious Non-Compliance - failure to comply with regulations, university policies, or the requirements/determinations of the IRB, when, in the judgment of the institution, such failure substantially increases risks to subject welfare/safety, subject rights, or data integrity. Serious noncompliance may also involve compromising the effectiveness of UM's human subject research protection program.

**4 RESPONSIBILITIES**

- 4.1 The Institutional Official or designee:
  - 4.1.1 Appoints a Chair of the CRC (voting member)
  - 4.1.2 Appoints a Vice Chair of the CRC (voting member) who may act in lieu of the Chair in the Chair's absence
  - 4.1.3 Appoints the members of the CRC in consultation with the CRC Chair. Each member will be appointed for a renewable term of 3 years.
  - 4.1.4 Appoints the members of the CRC in consultation with the CRC Chair. Each member will be appointed for a renewable term of 3 years.
  - 4.1.5 Submits identified noncompliance issues to the CRC
  - 4.1.6 Reports determinations of serious and/or continuing noncompliance to institutional leadership, the IRB, and to applicable federal agencies
  - 4.1.7 Reserves the right to determine that an issue constitutes serious and/or continuing noncompliance even if the CRC does not make this determination
  - 4.1.8 Provides training to the CRC members in collaboration with the CRC Chair and other members of the Human Subject Research Protection Program



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- 4.2 CRC Chair:
  - 3.2.1 Convenes and directs meetings
  - 3.2.2 Advises the Institutional Official on CRC membership
  - 3.2.3 Provides training to the CRC members in collaboration with the Institutional Official
  - 3.2.4 Reviews meeting minutes
  - 3.2.5 Serves as part of the Initial Review Committee
- 4.3 CRC Voting Members:
  - 4.3.1 Attend convened meetings
  - 4.3.2 Review, as determined by CRC Initial Review Committee, internal and external audit reports and PI responses to such audits, as well as any other supporting documents provided.
  - 4.3.3 Review alleged noncompliance issues identified or brought forth to the IRB Institutional Official, or others
  - 4.3.4 Vote based on definition of serious and/or continuous noncompliance defined herein as to whether the noncompliance is serious and/or continuing
  - 4.3.5 Attend required training
- 4.4 CRC Administrator:
  - 4.4.1 Attends convened meetings
  - 4.4.2 Ensures quorum is met
  - 4.4.3 Notifies CRC members of upcoming meetings
  - 4.4.4 Invites PIs of studies being considered to meeting
  - 4.4.5 Creates meeting minutes
  - 4.4.6 Communicates determinations of serious and/or continuing noncompliance to the HSRO/IRB
  - 4.4.7 Provides meeting minutes to CRC Chair and Institutional Official
  - 4.4.8 Maintains meeting minutes
  - 4.4.9 Drafts letters to external officials (OHRP, FDA) as necessary
- 4.5 CRC Non-Voting Members:
  - 4.5.1 Attend convened meetings
  - 4.5.2 May request clarification/ provide consultation, as needed
  - 4.5.3 Leave CRC meetings prior to deliberations
- 4.6 CRC Initial Review Committee
  - 4.6.1 Comprises CRC Chair and Executive Director, Human Subject Research Office
  - 4.6.2 Reviews of internal and external audits to determine if meeting of the CRC is warranted, as serious and/or continuing noncompliance may be identified

**5. PROCEDURE**

- 5.1 The CRC administrator notifies the CRC Initial Review Committee and the Institutional Official of potentially serious or continuing noncompliance issues by providing them with copies of all internal Quality Review Reports (audit reports) from the Office of Research Compliance and Quality Assurance (RCQA) or with any other identified or reported allegations of noncompliance issues obtained by the convened IRB, expedited review, Reportable New Information, Institutional Official or others. The CRC Initial Review committee determines whether any of the information received could qualify for reporting to OHRP/FDA or other federal agencies. Internal Quality Review Reports with no "Immediate Action Required" items will not be considered by the Initial Review Committee.



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- 5.2 The Initial Review Committee will review these items within 5 working days. Upon review, members of the Initial Review Committee will make determinations if the issue does not qualify as serious/continuing non-compliance. The CRC administrator will document this determination in the system (eProst) obtain acknowledgement from the reviewing IRB of record, and notify the Institutional Official.
- 5.3 Either member of the CRC Initial Review Committee may direct potential non-compliance issues to a convened meeting of the CRC. When potential non-compliance issues are directed to the CRC, the CRC Administrator will:
  - 5.3.1 Set a date and time for the CRC convened meeting.
  - 5.3.2 Create an agenda for the meeting
  - 5.3.3 Forward internal and external audit reports, PI responses and/or any other relevant documentation or information to all members of the CRC.
  - 5.3.4 Invite the PI of the human research under review to attend the meeting
- 5.4 Reports of noncompliance will not be reviewed by the CRC:
  - 5.4.1 If the study is not funded through the Public Health Service (PHS) and if it is not otherwise regulated by the Food and Drug Administration.
  - 5.4.2 If the study is overseen by an external IRB or if the UM CIRB is the reviewing IRB for external sites. In these cases the IRB of record will make determinations regarding serious and/or continuing noncompliance.
- 5.5 Convened CRC Meeting
  - 5.5.1 Establish whether any CRC member has a conflict of interest with any of the issues presented.
  - 5.5.2 Conflicted members will be recused during discussion of the item and will not vote on that item.
  - 5.5.3 The CRC Chair will open the meeting.
  - 5.5.4 If the potential issues were discovered during an internal Quality Review/audit, the RCQA Auditor will present the issues and answer any questions the CRC members might have. The RCQA Executive Director (ED) or QA Manager will be present for this presentation and to answer any questions. The RCQA Auditor and ED/QA Manager will leave the meeting prior to deliberations but will be available for further questions.
  - 5.5.5 The PI will be afforded the opportunity to attend the CRC convened meeting during its consideration of noncompliance in his/her study. He/she may present additional relevant information and answer questions, and will leave the meeting prior to deliberations.
  - 5.5.6 The CRC will discuss the identified noncompliance issues.
  - 5.5.7 Each CRC voting member will determine whether the issues presented constitute serious and/or continuing noncompliance and will vote accordingly.
  - 5.5.8 The CRC determination is made by majority vote of the members present.
  - 5.5.9 The CRC Administrator will record the votes and maintain meeting minutes.
- 5.6 Issuing a CRC Determination Letter
  - 5.6.1 Once a determination is made, the CRC will provide a written document with the final determination (serious and/or continuing noncompliance or neither) to the IRB and the Institutional Official.
  - 5.6.2 The Institutional Official will summarize in a letter, the findings of serious and/or continuing noncompliance and report the findings to the applicable federal agencies, as warranted, within 30 days of CRC Initial review. Exceptions to this timeline must be documented in eProst and the reasons for the delay stated.



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**6 DOCUMENTATION**

6.1 The CRC will maintain meeting minutes, including the final determination

**7. REFERENCES**

- 7.1 21 CFR §56.108(b)
- 7.2 45 CFR §46.103(b)(5), 45 CFR §46.108(a)
- 7.3 SOP: New Information (HRP 024)