

**University of California, Irvine
Human Research Protections
Standard Operating Policies and Procedures**

Policy Number: 52

Title: Research Non-Compliance

Date of Last Revision: 05/01/2006, 07/07/2010, 10/12/2016, 09/01/2017, 12/19/2019, 09/17/2022

Policy:

It is the policy of the UC Irvine (UCI) Institutional Review Board (IRB) to uphold its role in assuring prompt reporting of any serious or continuing non-compliance with 45 CFR Part 46 or the requirements or determinations of the IRB.

- I. All reports of alleged serious and/or continuing non-compliance or inappropriate involvement of humans in research are investigated. Such reports may come from any source such as an IRB Committee Member, an Investigator, a participant or their family members, institutional personnel, other institutional Committees, UC Irvine Whistleblower Office, UCI Health Affairs Compliance Officer, the media, anonymous sources, or the public. Goals of the IRB, in general, in investigating and managing issues of potential noncompliance include:
 - A. Assuring the safety of human participants;
 - B. Developing action plans to prevent reoccurrence, and promote future compliance;
 - C. Educating research staff to assure the understanding of Food and Drug Administration (FDA) and Office for Human Research Protections (OHRP) guidelines and regulations, and UCI IRB Policy;
 - D. Reporting serious or continuing noncompliance.

- II. Instances meeting the definition of research/scientific misconduct will be reported to the Vice Chancellor for Research.
 - A. Attempts to unduly influence an IRB Committee Member or IRB staff are considered research misconduct.
 - B. IRB members or staff who believe that they have been subject to undue influence must report this to the Assistant Vice Chancellor for Research or utilize the University of California Whistleblower Policy.
 - C. The Assistant Vice Chancellor for Research will report all attempts of undue influence of the IRB process to the Vice Chancellor for Research and the Dean of the Lead Researcher's School.

- III. Definitions of Terms:
 - A. Non-Compliance: Failure to comply with applicable laws, regulations, or institutional policies pertaining to the protection of human subjects, and/or with the requirements or determinations of an IRB.
 - B. Serious Non-Compliance: Failure to comply with applicable laws, regulations, or institutional policies pertaining to the protection of human subjects and/or with the requirements or determinations of an IRB that has a significant adverse impact either on the rights or welfare of participants or on the integrity of the data.
 - C. Continuing Non-Compliance: A pattern of noncompliance that indicates

an inability or unwillingness to comply with applicable laws, regulations, or institutional policies pertaining to the protection of human subjects and/or with the requirements or determinations of an IRB.

References:

45 CFR 46

21 CFR 50 and 56

University of California Policy for Protection of Whistleblowers from Retaliation and Guidelines for Reviewing Retaliation Complaints

IRB Policy 1, "Institutional Oversight of Assurance"

IRB Policy 2, "Activities Subject to IRB Jurisdiction"

IRB Policy 50, "IRB Compliance Activities"

IRB Policy 51, "Administrative Hold, Suspension, or Termination of IRB Approval"

IRB Policy 57, "UCI HRP Policy and Procedure Glossary"

Procedure Number 52.A**Title: Procedure for Investigating and Managing Potential Issues Research Non-Compliance****Procedure:**

This procedure outlines the process for assuring the prompt reporting and management of any serious or continuing non-compliance with 45 CFR Part 46 or the requirements or determinations of the IRB.

I. Lead Researcher (LR) Responsibilities

- A. It is the Lead Researcher's responsibility to adhere to the IRB approved protocol and not to initiate any changes to the protocol prior to IRB review and approval of the change, unless there is an apparent need to minimize risk to the participants. In this case the LR must notify the IRB within 5 working days of the change. (See Policies # 17 and 19.)
- B. The Lead Researcher is responsible for the ethical management, accurate documentation, and the protection of human participants in their research.
- C. The Lead Researcher complies with all requests from the IRB for further information or clarification regarding concerns or issues under investigation.
- D. The Lead Researcher must notify the IRB of potential matters of serious and/or continuing non-compliance.
- E. All incidents of serious and/or continuing noncompliance that occur either at a UCI site, or at a non-UCI site where the UCI IRB is the IRB of record, must be reported to the IRB within 5 business days of the occurrence or within 5 business days from the date in which the LR learned of the occurrence.
- F. If the serious and/or continuing noncompliance meets the definition of an unanticipated problem, the LR must submit a Reportable Event-Unanticipated Problem (UP); otherwise, the LR must submit a Reportable Event-New Information Report (NIR).

II. IRB Committee Responsibilities

- A. When the IRB Committee Chair receives an alleged report of serious and/or continuing non-compliance, the Chair either:
 - 1. Reviews the information, determines the information is not serious and does not meet the definition of continuing non-compliance, the IRB Chair:
 - a) Formulates a corrective action plan;
 - b) Forwards the corrective action plan to the LR; and
 - c) Forwards the information to be included in the IRB agenda as an information item.
 - 2. Reviews the information, determines that more information is needed, and directs an investigation by the HRP Compliance Manager. The LR is notified in writing of the directed investigation (audit); or
 - 3. Reviews the information, determines the information is serious or inhibits the rights or welfare of participants, and forwards the information to the full IRB Committee for review, consideration of

suspension, or consideration of termination. An investigation by the HRP Compliance Manager can occur simultaneously with IRB Committee review for consideration of suspension.

- a) Should the information be forwarded to the full IRB Committee for review, the IRB Chair will present the information to the Committee.
 - b) All members of the full IRB Committee will have access to materials related to the issue for their consideration in advance of the scheduled full Committee meeting.
4. If the allegation involved research misconduct, the IRB Chair will report this to the Vice Chancellor for Research.
- B. The IRB Committee reviews the materials provided at a convened meeting, to determine:
1. There is no issue of non-compliance;
 2. There is noncompliance that is neither serious nor continuing;
 3. There is serious or continuing noncompliance. The IRB office will report this determination according to Policy # 53;
 4. There is insufficient information to make a determination. In this case, the IRB will request additional information from the EQUIP team and defer a determination to a later date.
- C. The IRB Committee considers (required):
1. Suspension of the research (See Policy # 51)
 2. Termination of the research (See Policy # 51)
 3. Notification of current participants when such information may relate to the participants' willingness to continue to take part in the research
- D. The IRB Committee considers the following added protections (optional, as applicable):
1. Dismiss the allegation,
 2. Achieve compliance with the cooperation of the Investigator (and report to the appropriate federal Agency when required) via a modification of the protocol or modification of the information disclosed during the consent process,
 3. Providing additional information to past participants
 4. Requiring current participants to re-consent to participation
 5. Modification of the continuing review schedule
 6. Monitoring of the research, including an increase in monitoring of the research activity via a data safety monitor or board and intervention as necessary through steps such as visits to the activity site and continuing evaluation of the site by the IRB Education and Quality Improvement Team;
 7. Monitoring of the consent process
 8. Referral to other organizational entities
 9. Impose sanctions to achieve compliance (and report to the appropriate federal Agency when required), or
 10. Recommend reclassification as possible scientific misconduct.
 11. Verification that participant selection is appropriate and observation of the actual informed consent process by the IRB Education and Quality Improvement Team;
 12. Request an off-cycle data and safety monitor or board review;
 13. Request a directed audit of targeted areas of concern;

14. Request a status report after each participant receives intervention from the LR;
15. Modify the continuing review cycle;
16. Request additional LR and research personnel education focused on human research protections from the IRB Education and Quality Improvement Team or other available sources (e.g., "CITI", OHRP conferences, NIH tutorial, human research protections seminars);

III. **IRB Administrator Responsibilities**

- A. When the HRP Compliance Manager receives a report of alleged serious and/or continuing non-compliance, they verify whether a detailed explanation from the LR accompanies the report.
 1. If a detailed explanation from the LR accompanies the report it is forwarded to the IRB Chair for review.
 2. If a detailed explanation from the LR does not accompany the report the HRP Compliance Manager contacts the LR to request additional information.
 3. If the report contains no explanation from the LR, or comes from a source other than the LR the HRP Compliance Manager forwards the information to the appropriate IRB Chair for review and determination.
- B. If the report contains an explanation from the LR and comes from a source other than the LR, the HRP Compliance Manager forwards the information to the IRB Chair for review.
- C. If the non-compliance is to be reviewed by the convened IRB, the Administrator prepares the following documents for review by all members of the Committee:
 1. The report (investigation report or KR Reportable Event);
 2. The alleged notification of potential noncompliance, if applicable;
 3. The electronic IRB Database Record which, includes the last approved consent document.
 4. Additionally, the assigned IRB Committee member reviews:
 - a) The last approved Investigator's Brochure, if applicable;
 - b) The Grant, if applicable; and
 - c) Any pertinent information (e.g., questionnaires, DSMB reports, etc.)
 - d) All communication between the Lead Researcher and the IRB Committee.
 5. The LR is notified in writing of IRB determinations.
 6. The Administrator maintains and updates the IRB database as applicable with current study information.