

University of California, San Diego  
Human Research Protections Program  
Institutional Review Board  
Standard Operating Policies and Procedures

Section 5.2  
Communications, Sanctions, Appeals, and Disciplinary Actions

***Policy***

The mandate of the IRB and its authority to require changes in research procedures developed by investigators has the potential to generate adversarial reactions and negative responses. It is the policy of this program that all communications by HRRP staff to and about faculty, staff, students, and their research activities will be conducted in a respectful and courteous manner.

The IRB has the authority to suspend or terminate protocols that are found to be non-compliant with institutional policies and procedures, state laws, and/or federal laws or regulations or have been associated with unexpected serious harm to subjects.

The suspension of a protocol is the temporary cessation of some or all research activities. The termination of a protocol is a permanent cessation of all research activity.

Regulatory Noncompliance

Potential occurrences of regulatory noncompliance in research may be revealed by a complainant or through formal and informal monitoring activities. Non-compliance is a failure to follow the regulations or the requirements and determinations of the IRB. The Chair or his/her designee will initially review allegations of noncompliance and determine whether the alleged are non-compliance in fact. If so, a further determination will be made about whether the non-compliance may (1) cause injury to subjects and rise to the level of an unanticipated problems involving risks to subjects or others or (2) constitute serious or continuing noncompliance with IRB regulations. The Chair may initiate further investigation or other measures as necessary to protect the safety of research subjects.

Minor Noncompliance

Minor noncompliance are those where it can be determined that the investigator unintentionally missed or omitted a requirement defined by the IRB that has not affected subject safety, rights, or welfare. If a minor occurrence is found, the IRB Administrator and/or Chair will notify the investigator of the error and define corrective action that needs to be taken. The IRB Administrator will maintain documentation of any telephone or written communications. The Administrator and/or Chair will confirm that corrective action has been taken.

Whenever possible, investigators will be assisted to achieve compliance without the need for sanctions. However, if the investigator fails to cooperate with the IRB requests to correct minor noncompliance, this inaction will be treated as continuing noncompliance.

### Serious Noncompliance

Serious violations are those where the investigator was non-compliant with his/her federally regulated responsibilities as an investigator, placing a subject at increased risk of injury. Failure to take corrective action of a minor instance of noncompliance after being notified by the IRB may also be considered a significant noncompliance. When suspected serious noncompliance is brought to attention, the Chair may temporarily suspend active enrollment of subjects and/or remove ongoing subjects from the study pending a timely investigation and review by the full IRB. If the IRB Chair suspends research on an urgent basis, the suspension must be reported to and reviewed by the convened IRB.

Depending upon the situation, a study or investigator audit may be initiated by the IRB or the Chair, per procedures outlined in the section on Protocol Audits. The IRB or the Chair may temporarily suspend approval of research at any time during this process.

The Chair and HRPP Director will provide IRB members with sufficient information to review noncompliance, which may include an investigator audit if necessary. Generally, all materials relevant to a review of noncompliance would be provided on the HRPP database. The IRB will review the audit report to determine whether a serious violation has occurred or whether the investigator has engaged in a pattern of disregard for research regulations, policies or procedures. The review may be performed by the full IRB, or by a subcommittee of IRB members selected by the Chair, which then reports to the full IRB. However, the final determinations and actions will be made by the full IRB at a convened meeting.

Upon completion of the review, the IRB may dismiss the allegations, confirm that compliance was achieved with the cooperation of the investigator, establish a plan for corrective action. If the IRB determines that non-compliance occurred, a determination of whether non-compliance was serious or continuing must also be considered. When the IRB determines that non-compliance was serious or continuing in nature, the IRB may impose or recommend sanctions as described below. All determinations of serious or continuing non-compliance must be reported to appropriate federal agencies and organizational officials in accordance with the reporting requirements detailed below.

Whenever possible, technical assistance will be recommended to investigators to assist them with achieving compliance without the need for imposition of sanctions. However, in cases where cooperation does not occur, or when it is determined that the safety or welfare of subjects or the integrity of the institution are or have been placed at risk, sanctions may be imposed.

Sanctions that may be imposed by the IRB include, but are not limited to: a) suspension or termination of project(s); b) more frequent review of project(s); c) compliance audits; d) letters of censure; e) restrictions on serving as an investigator on human subjects protocols;

f) research privilege probation; g) suspension or termination of research privileges; h) requiring additional education and training of the investigator or their research staff; i) embargo or retraction of publications, j) reporting of noncompliant activities to governmental entities; k) or reclassification as possible scientific misconduct.

Additional sanctions beyond the authority of the IRB may be recommended in writing to the Department Chair, the Dean of the school within which the research activity took place, the UCSD Vice Chancellor for Research, or other appropriate authorities.

The IRB will promptly report any suspension or termination of IRB approval for research and serious instances of noncompliance to appropriate Federal sponsoring agencies, OHRP, the FDA when the study involves a drug or device regulated by the FDA, organizational officials including the Institutional Official and the institution employing the investigator.

In the event that a project is suspended or terminated, the IRB will request from the PI written documentation on how the safety and well-being of subjects currently enrolled in the project will be protected. Unless otherwise stated, a suspended project must cease enrollment of new participants until the suspension is lifted. Currently enrolled subjects may continue to be followed if necessary to ensure subject safety.

If the IRB determines that an investigator may continue his/her project with corrective action, or approval is reinstated after appropriate corrective action, a plan for continuing review will be formulated. Continuing review in this situation may include, but is not limited to audits, Interim Reports, and third party verification. This will be carried out on a periodic basis until the IRB is satisfied that the problem has been adequately resolved. The Investigator will be invited to respond in writing to the results of the review.

#### Notification and Documentation

If the IRB determines that serious or continuing non-compliance has occurred, this must be reported to the UCSD Institutional Official; OHRP, in all cases; the FDA, when research involves drugs and devices regulated by the FDA. For research sponsored by the Department of Defense, serious or continuing non-compliance must be reported to the Department of Defense.

If the IRB has determined that a study must be suspended or terminated, the investigator will be notified by telephone within 24 hours of the decision and in writing within 3 working days. In all other cases, the results of IRB Review will be communicated in writing within 5 working days. A response from the investigator specifying corrective actions will be required within 10 working days of notification. The response should include a formal corrective action plan, the actions to be taken, responsibility, and when the actions will be effective. Where appropriate, the study sponsor and appropriate state and federal authorities will also be notified in writing of the action being taken by the IRB.

When study approval was suspended or terminated, the convened IRBs or IRB chairs considered actions to protect the rights and welfare of currently enrolled participants. The IRBs must notify investigators to submit immediately to the IRB chair, a list of participants

for whom stopping research activities would cause harm, if applicable. Upon IRB Chair approval, the IRB may allow current participants to continue interventions or interactions if the IRB finds an over-riding safety concern or ethical issue involved such that it is in the best interests of individual participants to continue participating.

The IRB should consider whether procedures for withdrawal of enrolled participant took into account their rights and welfare. The IRB needs to consider whether the PI must inform current participants of the termination or suspension including whether such information may relate to the participants' willingness to continue to take part in the research. Upon suspension or termination of IRB approval, the PI is required to report to the IRB updated information on any adverse events or outcomes that have not been previously reported.

#### Expired, Suspended or Terminated Protocols

The HRPP is responsible for promptly notifying the PI when a study has expired, has been suspended or is terminated. The sponsoring agency, private sponsor, or other Federal agencies must also be informed. The PI, not the IRB, is responsible for reporting expired, suspended, or terminated protocols to the sponsor.

#### Scientific and Research Misconduct

Scientific misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results (see Appendix for definitions). If at any time during the investigation the IRB or Chair finds evidence to suggest the possibility of scientific misconduct, the matter will be referred to the Dean for Academic Affairs to pursue according to institutional and University policies.

Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. (a) Fabrication is making up data or results and recording or reporting them. (b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record. (c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. (d) Research misconduct does not include honest error or differences of opinion.

#### Appeals

Investigators who wish to appeal a sanction imposed by the IRB may contact the Research committee of the UCSD Academic Senate. The Academic Senate may, upon review of the issues involved, initiate an inquiry into the process and evidence used by the IRB to arrive at its decision, and issue an opinion on the appropriateness of that process and evidence. In compliance with 45 CFR 46.112, the Academic Senate may not override an IRB decision to disapprove a research project involving human subjects.

### ***Procedures***

1. IRB Chair will make an initial evaluation and initiate suspension or take further action as needed.

2. IRB Member will review files and make determination whether serious noncompliance has occurred, determine if harm to subjects has occurred, and suspend or terminate study as needed, and determine plan of corrective action, sanctions, and monitoring plan, as needed.
3. IRB Administrator will notify investigators of minor instances of noncompliance and prepare correspondence to investigators and distribute to relevant parties, as required.

***Applicable Regulations***

[21 CFR 56.113](#)

[45 CFR 46.113](#)