Policy on Noncompliance

Effective date: 04-17-2018

I. Background
As part of protecting the rights and welfare of human subjects participating in UCSC research, the IRB reviews allegations of noncompliance with human research regulations. Noncompliance has the potential to erode trust, harm participants, and jeopardize opportunities for future funding.

II. Definitions
a. 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.
b. Noncompliance: 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.
c. Serious noncompliance: 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.

III. Procedures
a. Anyone may submit allegations of noncompliance to the IRB, or the IRB/ORCA staff may identify potential noncompliance during review. ORCA will maintain confidentiality of anyone reporting the allegation.
b. ORCA will review the allegation and if necessary gather more information from the researchers in order to facilitate a thorough assessment. There should be supporting documents or statements to back up the allegation.
c. ORCA will forward to the Chair or Chair’s designee to determine whether any further action is necessary. The Institutional Official may suspend some or all human research activities if an urgent situation presents itself.
d. The Chair/designee will review the noncompliance form and decide one of the following:
  i. no further action is necessary because either there is no evidence of noncompliance or the evidence is found to be unsubstantiated;
  ii. the issue can be resolved via expedited review because, although noncompliance occurred, it was/is clearly not serious or continuing;
iii. the issue must be reviewed by the convened IRB to determine whether noncompliance was/is serious or continuing, and/or to determine a course of action to address serious or continuing noncompliance; or

iv. more information is needed to make a determination.

e. If the Chair/designee determines that there is no evidence of noncompliance or evidence is unsubstantiated, ORCA will inform the alleger and/or the PI/Faulty Sponsor, as appropriate, that no further action will be taken.

f. If the Chair/designee determines that the noncompliance is minor, ORCA will send the Chair’s/designee’s corrections to PI to acknowledge and address.

g. For noncompliance that needs convened review, the allegation and supporting documents will be reviewed at a full board meeting and the board will vote whether serious or continuing.

h. If the noncompliance is serious or continuing, this will be reported to the PI, the IO, and any required agency (e.g., federal funding agency, FDA, etc.).

i. The convened IRB may take a variety of actions, depending on the outcome of the review, including, but not limited to, the following:

• Approve continuation of research without changes;
• Request formal educational intervention;
• Request minor or major changes in the research procedures and/or consent documents;
• Modify the continuing review schedule;
• Require monitoring of research;
• Require monitoring of the consent process;
• Suspend or terminate IRB approval/disapprove continuation of the study or any activity therein;
• Require auditing of other active protocols of the investigator
• Disqualify the investigator from conducting research involving human subjects at the University;
• Determine that the investigator must tell any publication about the noncompliance related to the study;
• Require that the investigator contact subjects previously enrolled in the study and provide them with additional information and/or re-consent them;
• Request that the investigator inform publishers and editors if he/she has submitted or published manuscripts emanating from the research;

i. The PI should respond to the IRB within thirty days of receipt of the IRB’s correspondence.
IV. References
21 CFR 56.123, 45 CFR 46.112