Policy on Noncompliance

Effective date: 9/20/2019

I. Background
In protecting the rights and welfare of human subjects participating in UCSC research, the IRB reviews instances of potential noncompliance with human research regulations, UCSC human subjects research policies, and/or the ethical principles outlined in the Belmont Report. 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. Reporting Noncompliance
a. Anyone may submit allegations of noncompliance to the IRB/ORCA – e.g., someone on the research team, a research subject, Office of Research Compliance Administration (ORCA) staff, or the Institutional Official (IO); or IRB/ORCA staff may identify potential noncompliance during review.
b. The IRB/ORCA will maintain the confidentiality of anyone submitting an allegation.
c. Once potential noncompliance is discovered, the PI must submit a Report of Noncompliance form to ORCA (orca@ucsc.edu). The form provides a summary of the noncompliance and PI corrective actions.
d. Report of Noncompliance forms should be submitted promptly.

IV. Noncompliance Review
a. ORCA does an administrative review of the noncompliance form and gathers more information from the PI or alleger(s) if needed.
b. ORCA may or may not notify the PI immediately of an allegation, depending on the circumstances.
c. When appropriate (e.g. non-anonymous allegation), ORCA keeps the alleger informed of the outcome of review.
d. ORCA will forward the form and any supporting materials to the Chair or Chair’s designee to determine what action is necessary. If the noncompliance is egregious, the issue may be forwarded to the IO and they may suspend or terminate some or all human research activities (see Policy on Suspension and Termination).
e. The Chair/designee will review the potential noncompliance 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.
f. If the Chair/designee determines that there is no evidence of noncompliance or evidence is unsubstantiated, ORCA will inform the PI that no further action will be taken.
g. If the Chair/designee determines that noncompliance occurred, but it is/was not serious or continuing, the Chair/designee may require corrective actions or changes to the protocol, or require no action. ORCA will inform the PI of the determination and any required actions.
h. For noncompliance that is or might be serious or continuing, the form and any supporting materials will be reviewed at a full board meeting and the IRB will determine whether the noncompliance is/was serious or continuing by majority vote and what to do about already enrolled subjects. Only the convened IRB may make a determination of serious or continuing noncompliance.
i. If the IRB determines that noncompliance occurred and is/was serious or continuing, the IRB may require corrective actions or changes to the protocol, or it may suspend or terminate some or all human subjects research activity. ORCA will inform the PI of the determination and send any corrections to the PI to acknowledge and address. The PI must respond in writing. ORCA also notifies the PI’s Department Chair, the IO, and any funding or other agency as required – e.g., OHRP if funded by any Common Rule department or agency (see https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html and https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html) – of the determination. This notification is made within 30 days of the determination.
j. The convened IRB may take a variety of actions 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;
   • Require more frequent continuing review;
   • Require monitoring of research;
   • Require monitoring of the consent process;
   • Suspend or terminate any or all human subjects research activity in the protocol;
   • Require auditing of other active protocols of the investigator;
   • Disqualify the investigator from conducting research involving human subjects at the University;
   • Require that the investigator contact subjects previously enrolled in the study and provide them with additional information and/or re-consent them; and/or
   • Request that the investigator disclose the noncompliance to publishers/editors where they have or will submit manuscripts emanating from the research.

V. Investigator Response to IRB
   The PI must respond to IRB determinations in writing within 30 days of receipt. The PI may acknowledge receipt (if no corrective actions required), agree to the corrective actions, propose additional actions, or appeal the IRB’s determination. The IRB will consider the appeal and decide either to change or not change its determination.

VI. References
   a. 21 CFR 56.123
   b. 45 CFR 46.112