

Standard Operating Procedures		
SOP #402.4 Revision 4	TITLE: Research Noncompliance	Effective Date: 3/1/2019
Approved By: OIRB Director	Signature 	Date 3/1/2019
Approved By: IRB Chair	Signature 	Date 3/1/2019

PURPOSE

To describe the policies and procedures the Institutional Review Board (IRB) and the Office of the IRB (OIRB) follow for handling allegations and findings of noncompliance.

REVISIONS FROM PREVIOUS VERSION

Corrections to board actions, addition of forwarding to research misconduct, and administrative corrections

POLICY

The ethical conduct of research is a shared responsibility. It requires cooperation, collaboration, and trust among the institution, researchers and their research staff, the participants who enroll in research, IRB members, and OIRB staff. The primary responsibility of the IRB is to ensure protection of the rights and welfare of research participants. In performing that responsibility, the IRB addresses allegations of noncompliance with IRB requirements and/or federal regulations governing the conduct of human research. OIRB staff, IRB members, or IRB consultants do not participate in alleged noncompliance reviews if they have a conflict of interest (see the IRB Member and Consultant Conflict of Interest SOP).

Definitions

Noncompliance is defined as conducting research in a manner that disregards or violates federal regulations or institutional policies and procedures applicable to human research. Noncompliance with IRB policies and/or federal requirements may involve a range of issues from relatively minor, administrative, or technical violations to more serious violations that pose risk to participants and/or violations of participants’ rights and welfare.

Continuing noncompliance is a persistent failure to adhere to the laws, regulations, or policies governing human research.

Serious noncompliance is a failure to adhere to the laws, regulations, or policies governing human research that may reasonably be regarded as:

- (1) Involving substantive harm, or a genuine risk of substantive harm, to the safety, rights, or welfare of participants, research staff, or others; or
- (2) Substantively compromising the effectiveness of a facility’s human research protection or human research oversight programs.

RESPONSIBILITIES

Execution of SOP: Researchers, IRB, OIRB

PROCEDURE

Submission and Screening of Allegations of Noncompliance

1. Anyone may submit allegations of noncompliance or continuing noncompliance involving human research to the OIRB verbally or in writing. Allegations of noncompliance can also be made through the UNM Compliance Hotline at 1-888-899-6092. OIRB staff or the IRB may also identify concerns during the review process. The OIRB/IRB maintains confidentiality regarding the identity of the person submitting the allegation to the extent possible.
2. The OIRB Director or designee (hereafter OIRB Director refers to OIRB Director or designee) screens the allegation/concern of noncompliance to determine whether the protocol(s) affected is supported by federal funds.
3. The OIRB Director also determines whether the protocol has issues pertinent to other research review committees, e.g. Institutional Biosafety Committee, Conflict of Interest, etc. and notifies these units of any pertinent issues as appropriate.

Assessment of Allegations

1. The OIRB Director reviews allegations/concerns to determine whether the facts justify the allegation (i.e. there are supporting documents or statements).
2. If the OIRB Director deems an allegation/concern unsubstantiated (i.e. finds no supporting documents or statements), they consult with the IRB Chair or their designee. The IRB Chair or OIRB Director may decide no additional action is needed, further inquiry is necessary, or the issue should be presented to a convened IRB.
3. If the OIRB Director determines that an allegation/concern is substantiated but the concerns are minor or administrative issues, the OIRB Director manages the concern through communications with the PI or the complainant. The OIRB Director reports the minor issue to the IRB Chair or designee. The IRB Chair or designee may determine that the noncompliance does not meet serious or continuing noncompliance and no additional action is needed, or determine further inquiry is necessary, or determine the issue should be presented to a convened IRB.
4. If the OIRB Director determines the allegation/concern may be substantiated and may involve an unanticipated problem or serious or continuing noncompliance, they forward applicable materials to the IRB Chair or designee.
5. At the completion of the assessment, when appropriate, the OIRB Director communicates (by phone, email, or letter) the IRB Chair's or designee's decision to the complainant (if the identity of the person is known) and, if applicable, to the individual against whom the allegation/concern was raised (respondent).
6. If it is determined that the allegation may involve research misconduct (as defined in Faculty Policy E40), the matter will be referred to the Research Integrity Officer.

Inquiries into Serious Violations

1. If the allegation/concern involves more serious human protections issues than administrative or minor concerns, the convened IRB and/or the IRB Chair decides whether to initiate an inquiry. The convened IRB or IRB Chair bases the decision on the seriousness and/or the frequency of violations and/or disregard for the federal regulations or the institutional policies and procedures applicable to human research.
2. If the OIRB Director, IRB Chair, or convened IRB determines that an allegation/concern is substantiated and suggests that participants are at immediate risk, the IRB Chair, in consultation

with the OIRB Director, considers whether to immediately suspend IRB approval in accord with the Termination and Suspension SOP.

3. If the convened IRB or the IRB Chair decides to initiate an inquiry to determine the validity of the allegations/concerns, OIRB staff notify the complainant and/or individual/IRB that identified the concern. If the allegation/issue involves a co-investigator or a research assistant, OIRB staff may also contact that individual. The OIRB Director or the IRB Chair notify the PI via telephone and/or e-mail and document such correspondence.
4. The IRB may appoint one or more voting member(s) or OIRB Director to gather information pertaining to the nature of the allegation/concern, the procedures approved in the IRB protocol, and the procedures followed in conducting the research.
5. The IRB representative interviews the complainant or, in cases where the complainant requests anonymity, the individual who received the original allegation/concern interviews the complainant. In some cases, the complainant may have already submitted a written complaint. Either the IRB representative or the OIRB Director may request additional information from the complainant.
6. The convened IRB, the IRB Chair, or a designated IRB representative interviews the respondent and gives them the opportunity to comment on the allegation/concern and provide information. The respondent may submit a written rebuttal to the complaint. Either the IRB or the OIRB Director may request additional information from the respondent.
7. Depending on the nature of the allegation/concern and the information collected during the interviews, the convened IRB or its representative may interview other individuals. In addition, in conducting the inquiry, the convened IRB or its representative may examine research data, both published and unpublished; informed consent/assent forms; inclusion/exclusion criteria; the applicable approved IRB protocol; and any other pertinent information.
8. When appropriate, the IRB member(s) conducting the inquiry prepares, with the assistance of an assigned OIRB staff member, a summary report for the convened IRB. The report may consist of a summary of the allegations/concerns, interview summaries, and copies of pertinent information or correspondence. The report may or may not include recommendations for IRB action. (In some cases, the IRB representative simply provides the IRB with a summary of the allegations/issues, the interview summaries, and copies of pertinent information without an accompanying written report from the review team.)

Review Procedures for Potential Serious or Continuing Noncompliance

1. The OIRB advises the IRB regarding the applicable University and federal regulations, assists the IRB in documenting the review, answers questions about the review process, maintains the records as required by state and federal laws, and serves as a liaison with the funding agency or agencies.
2. The IRB reviews the materials presented by the review team at a convened meeting at which a quorum is present. The materials provided include the summary report of the noncompliance, the protocol and the informed consent document if applicable. The convened IRB determines whether to request additional information or whether to interview additional witnesses. The IRB may give the respondent the opportunity to meet with the convened IRB before it takes final action.

Review Outcomes/IRB Actions

1. After the inquiry, the convened IRB makes the determination whether the allegation/concern is substantiated, and if so, whether the noncompliance is serious or continuing based on the materials compiled during the inquiry. If the noncompliance is serious or continuing and the research federally

funded, the IRB, with the assistance of the OIRB Director, reports the incident(s) to the applicable agency following procedures outlined in the Mandated Reporting to External Agencies SOP.

2. 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 and/or the consent process;
 - Suspend or terminate IRB approval/disapprove continuation of the project;
 - Require inspections of other active protocols of the researcher;
 - Require that the researcher contact participants previously enrolled in the project and provide them with additional information and/or re-consent them;
 - Request that the researcher inform publishers and editors if he/she has submitted or published manuscripts emanating from the research.
3. The IRB informs the following individuals of the allegation/issue, the review process, and the findings of the review, if appropriate, depending upon the outcome of the review, the external sponsor, or the requirements of the applicable regulatory agency:
 - Researcher;
 - Complainant;
 - The Department Chair;
 - Dean or Center Director;
 - Institutional Official;
 - Office for Human Research Protections (see Mandated Reporting to External Agencies SOP);
 - Sponsor, if appropriate;
 - Other administrative personnel as appropriate.
4. The PI submits concerns in writing to the IRB within thirty days of the date the IRB issues the final decision. The IRB limits concerns to three areas: a) review of the procedures employed to reach the decision (i.e. claims that the process was faulty in a way that creates a considerable risk that the outcome was incorrect), b) introduction of additional information that indicates the determination may be incorrect, or c) grievances against sanctions imposed as a result of a finding of noncompliance. The PI specifies the nature of any claimed procedural error or the perceived unfairness of sanctions issued.
5. The IRB resolves questions or concerns raised by a PI regarding the outcome of a specific IRB noncompliance review through direct communication with the PI.
6. The IRB may refer grievous concerns about research faculty to the IO for additional action up to and including barring the individual from conducting human research at UNM.

REFERENCES

45 CFR 46.112

21 CFR 56.112