

7. NON-COMPLIANCE

Non-compliance is defined as conducting research involving human subjects in a manner that disregards or violates federal regulations governing such research. This can include, but is not limited to, failure to obtain CPHS approval for research involving human subjects, inadequate or non-existent procedures for informed consent, inadequate supervision in research involving experimental drugs, devices or procedures, failure to follow recommendations made by the CPHS to insure the safety of subjects, failure to report unanticipated problems or proposed protocol changes to the CPHS, and failure to provide ongoing progress reports.

7.1 Investigation of Allegations of Non-compliance

45 CFR 46.113 states, “An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB’s requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB’s actions and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head.” To exercise this statutory authority, the IRB shall review all allegations of non-compliance with human subjects regulations and review any study that has been associated with unexpected serious harm to research subjects. The IRB will follow these policies and procedures for conducting an inquiry and investigation into allegations of non-compliance and in reviewing incidents of unexpected serious harm to subjects.

CPHS will take appropriate action to insure the safety and welfare of human research subjects. These actions may range from corrective or educational measures for the researcher to terminating CPHS approval for all active studies of a research. Further, the CPHS may suspend approval of research projects at any time during an inquiry or investigation to assure the protection of human subjects.

This policy includes written procedures for reporting actions to appropriate University and federal government officials as required by federal regulations.

Application

These policies and procedures apply to all research activities of faculty, staff, students and others who are involved in research that falls under the jurisdiction of the CPHS.

7.2 Reporting Allegations of Non-compliance

The Research Compliance Specialist has primary responsibility for receiving allegations (anonymous or otherwise) or evidence of non-compliance involving human research participants, particularly possible serious or continuing non-compliance

Allegations may also be reported to:

- the principal investigator;
- the Vice President for Research;
- the Executive Director of Research Services; or
- any CPHS staff member.

The CPHS itself may initiate a complaint based on information available to the CPHS (e.g., deficiencies noted in CPHS files, media or scholarly reports of research activity subject to CPHS jurisdiction).

7.3 Review of Allegations of Non-compliance

Purpose

In the inquiry stage, factual information is gathered and expeditiously reviewed to determine if an investigation of the complaint is warranted. An inquiry is not a formal hearing or an in-depth analysis of the allegations; it is designed to separate allegations deserving further investigation from those that are frivolous, unjustified or related to minor infractions.

Process

Whenever an allegation or complaint of non-compliance is made, the Director of Research Compliance will forward the allegation to the Vice President for Research who will appoint an inquiry panel. Written notice of the allegations will also be sent to the researcher and a response will be requested within 10 working days. If the complaint raises issues of safety and welfare for research subjects that are apparent upon initial review, the researcher will also be given notice of an opportunity to address in his/her response the possible summary suspension of the researcher's project(s).

The inquiry panel will review the allegation of non-compliance, the response from the principal investigator and any other information necessary to determine whether an investigation is warranted. The inquiry panel may interview the researcher and others, but is not obligated to do so. It may be necessary to secure critical data or materials at the outset of an inquiry to protect the integrity of those data or materials or records. The CPHS maintains the authority to secure such materials at any time during an inquiry or investigation.

Recommendations and Outcomes

At the conclusion of the inquiry phase, the inquiry panel will make a recommendation to the Vice President for Research. Possible recommendations include: 1) dismissal of the allegation or complaint as unjustified; 2) referral of the matter to another more appropriate system within the University for resolution (e.g., Grievance, Academic Misconduct; Student Conduct Code); 3) resolution through corrective or educational measures where the violation of human subjects regulations is minor or inadvertent; and 4) a formal CPHS investigation where the allegation or complaint appears founded and is of a serious nature.

The Vice President for Research will promptly act upon the recommendation of the inquiry panel and notify the researcher in writing of the outcome of the inquiry phase. This notice will include a statement of the reasons for the decision. Depending on the nature of the allegations and the extent of the review required, the inquiry phase is expected to be completed within thirty working days. The Vice President for Research may grant an extension of this time frame if warranted.

7.4 Suspension and Reporting

At any time during the inquiry or investigation process, the CPHS may determine that it is necessary to suspend the accrual of research subjects or suspend approval of research project(s) to assure the protection of human subjects. The authority to suspend research rests with the CPHS; both the inquiry and investigation panels may recommend suspension to the CPHS. If suspension is warranted, it normally will occur at the end of the inquiry phase. Except in cases of imminent harm to research subjects, the CPHS will not suspend approval of research studies until the researcher has had an opportunity to respond to the initial allegation of non-compliance.

When the CPHS makes a decision to suspend approval of research, it will notify the Vice President for Research and other appropriate University officials. These may include the researcher's department head, dean of the college, and senior administrative officers. The Vice President for Research, who

serves as the authorized institutional official, will send written notice on behalf of the CPHS to the following entities, as required under federal regulations:

1. the Federal Office for Human Research Protections (OHRP);
2. the Federal Food and Drug Administration (FDA) if the suspension of research approval involves an investigation drug or device;
3. the OHRP and FDA as applicable, if the matter involves the non-submission of a project which should have been reviewed by the CPHS, and the researcher's failure to do so has resulted in unanticipated risks to human subjects or serious or continuing non-compliance with CPHS requirements; and
4. external and internal sponsors funding a study under suspension. Reports will be filed within five working days of suspension.

In some cases reporting to professional licensing boards or state agencies may also be required. These reports will be made by the Vice President for Research or other appropriate University officials.

7.5 Investigation of Allegations of Non-compliance

Purpose

The purpose of the investigation is to explore the allegations by assembling and examining relevant information. The investigation panel's charge is to generate a report that summarizes the information it considered, its conclusions as to whether there was non-compliance with human subjects regulations and recommendations for action. During an investigation, additional information may emerge that justifies broadening the scope of the investigation beyond the initial allegations. The researcher shall be informed if new and different allegations are discovered during the course of the investigation.

Process

The investigation will be conducted by an ad hoc panel of at least three CPHS members established by the Vice President for Research. One of the panelists shall be a member of the inquiry panel. All other members will be CPHS members whose areas of expertise are suited to reviewing the complaint and area of study. Depending on the nature and scope of the complaint, CPHS members may be relieved of their regular CPHS duties during the investigation so as not to be overburdened.

The investigation panel may use any and all materials and reports gathered during the inquiry phase, but is not limited by actions or conclusions of the inquiry panel. The investigation panel may obtain documents and other records relevant to the investigation, such as researcher records, medical charts, grant applications and other scientific or scholarly data. The investigation panel may interview any persons who may have information relevant to the complaint. All interviews will be tape recorded. The panel may draw on the resources of the institution or external consultant to assist in the review of issues which require expertise beyond or in addition to that available on the investigation panel.

The researcher under investigation will be given an opportunity to submit written comments and appear before the panel on at least one occasion prior to the panel issuing its report. The researcher may offer relevant information to the panel and suggest other individuals to be interviewed. The researcher also may be accompanied by an advisor, including an attorney, at any time the researcher appears before the panel. The researcher shall give the panel notice of the advisor's participation at least 48 hours prior to any interview.

At the conclusion of its investigation, the investigation panel will prepare a report summarizing the information it considered and outlining its conclusions and recommended actions. The investigation panel will forward a copy of this preliminary report to the researcher and give the researcher ten working days in which to submit comments to the report. The investigation panel will review any comments received from the researcher and decide, based on these comments, whether to modify its preliminary

report. When finalized, the investigation panel will send the Vice President for Research its report with any comments received from the researcher. Depending on the case, the investigation phase is expected to be completed within 60 working days. The Vice President for Research may grant extensions if warranted and may request interim reports.

Outcome

The Vice President for Research will base his decision on the report of the investigation panel and any comments submitted by the researchers. Actions the Vice President may take with respect to the investigation include, but are not limited to: 1) dismissal of the complaint as unjustified; 2) remediation or educational measures; 3) increased reporting by the researcher of his/her human subjects research activities; 4) restrictions on research practice, such as limiting the privilege to minimal risk or supervised projects; 5) suspension of approval for one or more the researcher's studies; 6) termination of approval for one or more of the researcher's studies; 7) withdrawal or retraction of publications/presentations; and 8) referral to other University officials or committees for possible further review and action by those bodies.

7.6 Appeals/Reconsideration

Purpose

The purpose of an appeal is to give the researcher an opportunity to request reconsideration of the Vice President's decisions under certain limited circumstances. Grounds for appeal are limited to: 1) new information not reasonably available during the investigation; 2) material failure to follow these policies and procedures; and 3) sanction exceeds the severity of the violation. No other grounds will be considered.

Process

The appeals panel will be comprised of three CPHS members who have not served on any other panel involved in the process (i.e., inquiry or investigation panels). The appeals panel will review the written statement of appeal by the researcher and make a recommendation as to whether the Vice President for Research should reconsider any aspect of his decision based on the ground outlined above. In reaching this recommendation, the appeals panel may seek a response from the investigation panel. The decision whether to forward a request for reconsideration should be made within 10 working days.

If the appeals panel denies the appeal, the Vice President's prior decision becomes final. If the appeals panel recommends reconsideration, the Vice President re-opens the case. When the Vice President re-opens the case, he may choose to reconvene the investigation panel or reconsider the matter on his own. The Vice President (or the investigation panel, if reconvened) will offer the researcher the opportunity to appear personally to present the appeal.

Upon reconsideration, the Vice President determines whether to modify or uphold his original decision. This action is final. The reconsideration phase is expected to be completed within 30 working days.

7.7 Dissemination of Findings

At the stage when the Vice President's decision becomes final (i.e., 5 working days after his original decision if there is not appeal; upon a decision by the appeals panel to deny the appeal; or upon the Vice President's final determination if the case is forwarded for reconsideration), the findings will be released to the researcher and to appropriate University and governmental officials as required under federal regulations. The same guidelines as set forth above for reporting suspensions will apply. Further, it may be necessary to inform these same officials of the status of the proceedings while they are pending.

Coordination with other Investigative Processes

Some complicated cases require review by other institutional or external entities. The CPHS will cooperate in the review of allegations of academic misconduct, financial mismanagement, FDA inspections, etc. In cases that appear to involve academic misconduct, the investigation panel may report allegations of such misconduct to appropriate institutional officials. Where academic misconduct and CPHS investigations are pending against the same researcher, the CPHS will participate in a close coordination of processes to avoid duplication of effort and minimize competing use of resources.

Conflict of Interest/Commitment

As with all CPHS processes, any CPHS committee member who has a conflict of interest or commitment relating to the matter under review will excuse himself/herself from the proceedings and an alternate will be designated by the senior chair. It is permissible to allow substitution of non-CPHS members for conflict of interest/commitment concerns at any stage in the establishment of an inquiry or investigative review panels.

Confidentiality for Complainants and Witnesses

Generally, the researcher under review should have access to the identity of complainant(s) and others who provide information. However, if such individuals are in a status subordinate to the researcher and wish to maintain their anonymity, the CPHS will make every effort to protect their identities while at the same time affording the researcher access to the substance of the allegations and information presented against him/her. The CPHS cannot guarantee absolute anonymity.

Retaliation

Reviewing complaints and allegations of non-compliance is critical to the CPHS's ability to protect human subjects. A climate free of sanction is required to foster appropriate reports and ensure a fair review of allegations. Retaliation against good faith "whistle blowers" is illegal and will not be tolerated at this institution. Whistle blowers who report CPHS related concerns may utilize other mechanisms at the University for protection from retaliation.