

NONCOMPLIANCE

1.1. Overview

Investigators and their research staff, the IRBs, Office of Responsible Research Practices (ORRP), and the organization share responsibility for the ethical conduct of human subjects research and for compliance with federal regulation, applicable state and local law, and University policy. The Ohio State University encourages all faculty, staff, students, and volunteers, acting in good faith, to report suspected or actual wrongful conduct associated with human subjects research.

1.2. Definitions

Noncompliance: Failure (intentional or unintentional) to comply with applicable federal regulations, state or local law, the requirements or determinations of the IRB, or University policy regarding research involving human subjects. Noncompliance can result from action or omission. Noncompliance may be non-serious (minor) or serious, and may also be continuing (see below).

Non-serious or minor noncompliance: Noncompliance that does not increase risk to research participants, compromise participants' rights or welfare, or affect the integrity of the research/data or the human subjects protection program. Examples of minor noncompliance may include, but are not limited to: lapses in continuing IRB approval, failure to obtain exempt determination before exempt research involving human subjects is conducted, minor changes in or deviations from an approved protocol, or administrative errors.

Serious noncompliance: Noncompliance that has the potential to increase risk to research participants, compromise participants' rights or welfare, or affect the integrity of the research/data or the human subjects protection program. Examples of serious noncompliance may include, but are not limited to: conducting or continuing non-exempt human subjects research without IRB approval; lack of legally effective informed consent from research participants; failure to report or review serious adverse events, unanticipated problems, or substantive changes in research; or inappropriate oversight of the research to insure the safety of human subjects and the integrity of the research/data.

Continuing noncompliance: Noncompliance (serious or non-serious) that has been previously reported, or a pattern of ongoing activities that indicate a lack of understanding of human subjects protection requirements that may affect research participants or the validity of the research and suggest the potential for future noncompliance without intervention. Examples of continuing noncompliance may include, but are not limited to: repeated failures to provide or review progress reports

resulting in lapses of IRB approval, inadequate oversight of ongoing research, or failure to respond to or resolve previous allegations or findings of noncompliance.

Allegation of noncompliance: An unconfirmed report of noncompliance.

Finding of noncompliance: An occurrence or determination of noncompliance that does not require further confirmation or investigation (e.g., failure to respond to the IRB within established deadlines, allegation of noncompliance determined by the IRB to be true).

1.3. Handling Allegations and Findings of Noncompliance

Allegations of noncompliance should be forwarded to the Office of Responsible Research Practices. ORRP will process all allegations and findings of noncompliance, whether these reports arise internally (e.g., from OSU faculty, staff, ORRP, the IRB, or investigator self-reports) or from outside the University (e.g., research participants or regulators). Allegations of noncompliance will remain confidential to the extent permitted by Ohio law, consistent with the need to conduct an adequate investigation. The University will take reasonable steps to protect persons who file reports in good faith from retaliatory actions based on such filing, in accordance with the [OSU Whistleblower Policy 1.40](#).

Actions undertaken in response to an allegation or finding of noncompliance will be completed in a timely manner, based on the circumstances or seriousness of the potential noncompliance. Under federal regulations, the IRB has the 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. The IRB Chair or Vice-Chair, Investigative Subcommittee, IRB Policy Committee (IPC), or IRB may suspend or terminate approval of an investigator's research and/or secure critical documents at any time during or following an inquiry or investigation if necessary to assure the protection of research participants. The Office of Research will assure that the necessary resources are available to conduct a thorough review of all noncompliance.

1.3.1. Initial Inquiry

ORRP staff will consult with the Chair or Vice-Chair of the IRB responsible for reviewing the research or members of the IPC, and as necessary University counsel, on all allegations or findings of noncompliance. Any individual with a potential conflict of interest may not participate in the initial inquiry. The Principal Investigator (PI) and Co-Investigator(s), as applicable, may be informed of an allegation of noncompliance or contacted for a response during the initial inquiry, depending on available information and the nature of the potential noncompliance.

Possible outcomes of the initial inquiry include:

- Dismissal of the allegation (i.e., unsubstantiated),
- Referral to other appropriate University process (e.g., misconduct review),
- No further action required (i.e., for minor violations),
- Corrective action(s) recommended (i.e., for minor violations),
- Review by convened IRB required (i.e., noncompliance may be serious and/or continuing but further investigation is not needed), or
- Further investigation required.

Further investigation will be undertaken when the results of the initial inquiry indicate that additional fact-finding is required to assess the alleged or reported noncompliance.

When further investigation or convened IRB review is not warranted (e.g., dismissal of the allegation or minor violations), the Investigator(s) and the IRB responsible for reviewing the research will be notified in writing within 14 days of the allegation/finding of noncompliance and the outcome of the initial inquiry. The Institutional Official, Investigator(s)' Dean, and/or the Department Chair (or equivalent) may also be informed, at the discretion of the IRB Chair or Vice-Chair. Notification will be sent to the person(s) originating the report of noncompliance within 30 days, as applicable. In some cases, the convened IRB or IPC may be asked to recommend corrective actions. Suspended IRB approval may be reinstated, as appropriate, based on the outcome of the initial inquiry and the response of the Investigator(s). Reinstatement of IRB approval(s) will be reported by ORRP within 30 days to those previously informed of the suspension (i.e., Institutional Official, OHRP, any other sponsoring federal Department or Agency, etc.) and others (e.g., Sponsored Programs), as necessary.

If the Investigator(s) is contacted for a response during the initial inquiry, a written response will be requested within 14 days. If the potential noncompliance is reviewed by the convened IRB, the PI and Co-Investigator(s) may respond in person at the meeting during which the review will take place, to be scheduled within 30 days following the receipt of the Investigator(s)' response; or if no response, within 60 days. A personal advisor or legal counsel may accompany the Investigator(s), but the advisor or legal counsel may not participate in the discussion.

Initial inquiries will be completed within 30 days of receipt of the allegation or the finding of noncompliance, depending on the nature of the potential noncompliance.

1.3.2. Investigation and Investigative Subcommittee

An Investigative Subcommittee of the IRB will investigate allegations or reports of noncompliance when the results of the initial inquiry indicate that additional fact-finding is required. Members of the IRB Policy Committee may serve as the

Investigative Subcommittee or a subcommittee including the Vice-Chair, Chair or designee (member or alternate), and at least one additional member/alternate from the IRB responsible for reviewing the research will be formed. Any individual with a potential conflict of interest may not participate in the investigation. At least one IRB member should possess expertise appropriate for review of the potential noncompliance; additional IRB members or external consultants may also be included as determined necessary by the subcommittee Chair. The Chair or Vice-Chair of the IRB responsible for reviewing the research will chair the investigation. The subcommittee will be facilitated by ORRP staff and advised by University counsel. The Investigative Subcommittee will meet as necessary to ensure timely review of pending allegations.

The Investigator(s) will be informed in writing of the allegation and investigation. A written response will be requested within 14 days, depending on the nature of the potential noncompliance, to facilitate review and conclusion of the investigation. The Principal Investigator, other members of the research staff, and/or others may be interviewed and/or an audit of the Investigator(s)' research conducted during the investigation, as necessary.

The Investigative Subcommittee will consider materials and recommendations from the initial inquiry, the Investigator(s)' response, and other information relevant to the investigation (e.g., interviews, audit reports, literature searches, etc.). A summary report that includes the allegation, information considered by the Investigative Subcommittee, and its conclusions and recommendations will be prepared.

Possible outcomes of the investigation include:

- Dismissal of the allegation (i.e., unsubstantiated),
- Referral to other appropriate University process (e.g., misconduct review),
- No further action required (i.e., for minor violations),
- Corrective action(s) required (i.e., minor violations), or
- Review by convened IRB required (i.e., noncompliance is considered to be serious and/or continuing).

When the Investigative Subcommittee believes that serious and/or continuing noncompliance has occurred, the subcommittee's summary report will be forwarded to the Investigator(s) and the IRB responsible for reviewing the research. The Principal Investigator and Co-Investigator(s), as applicable, will be given an opportunity to respond to the subcommittee's findings in writing within 14 days of receipt of the report. The Investigator(s) may also respond in person to the IRB at the convened meeting during which the noncompliance review will take place, to be scheduled within 30 days following the receipt of the Investigator(s)' response; or if no response, within 60 days. A personal advisor or legal counsel may accompany the Investigator(s), but the advisor or legal counsel may not participate in the discussion.

When review by the convened IRB is not warranted (e.g., dismissal of the allegation or minor violations), the Investigator(s) and the IRB responsible for reviewing the research will be notified in writing within 14 days of the results of the investigation. The Institutional Official, Investigator(s)' Dean, and/or the Department Chair (or equivalent) may also be informed, at the discretion of the Chair of the Investigative Subcommittee. Notification will be sent to the person(s) originating the report of noncompliance within 30 days, as applicable. In some cases, the convened IRB or IPC may be asked to recommend corrective actions. Suspended IRB approval may be reinstated, as appropriate, based on the determinations of the Investigative Subcommittee and the response of the Investigator(s). Reinstatement of IRB approval(s) will be reported by ORRP within 30 days of the action to those previously informed of the suspension (i.e., Institutional Official, OHRP, any other sponsoring federal Department or Agency, etc.) and others (e.g., Sponsored Programs), as necessary.

Investigations will be completed within 60 days of completion of the initial inquiry, depending on the nature of the potential noncompliance and the complexity of the investigation.

1.3.3. Convened IRB Review

At a convened meeting, the IRB responsible for reviewing the research will review allegations or findings of noncompliance following initial inquiry or further investigation. The IRB will consider the information from the initial inquiry or summary report from the Investigative Subcommittee, the Investigator(s)' response (if any), and any other relevant materials (e.g., research protocol, consent form, etc.) to assess the seriousness of the potential noncompliance and to consider possible corrective action(s). The primary reviewer will lead discussion; materials as described above will be distributed to all scheduled attendees in advance of the meeting. The IRB will make final determinations in closed session by majority vote of a quorum of the members/alternates at the convened meeting.

The Investigator(s) will be notified in writing within 14 days of the final decision of the IRB. Notification will also be sent to the person(s) originating the report of noncompliance within 30 days, as applicable. If not previously reported, any suspension or termination of IRB approval or noncompliance that is determined to be serious or continuing will be reported by ORRP (see below).

1.4. Corrective Actions

Corrective action(s) will be based on the nature of the noncompliance, degree to which research participants were placed at risk, occurrence of previous noncompliance, etc. The range of possible corrective actions that the Chair, Vice-Chair, Investigative Subcommittee, IPC, or IRB may consider includes, but is not limited to:

- Modification(s) of the research or consent form,
- Notification of current and/or past research participants,
- Re-consent of current research participants (when such information may relate to their willingness to continue in the research),
- Monitoring of the research (including audits) or consent process,
- Education or mentoring for the Principal Investigator and/or research staff,
- Additional reporting (e.g., more frequent continuing review),
- Additional resources to support the investigator's research activities,
- Limitations (e.g., restriction to co-investigator status) on research activities or use of research data,
- Suspension of IRB approval for one or more of the Investigator(s)' studies, or
- Termination of IRB approval for one or more of the Investigator(s)' studies.

The Chair or Vice-Chair of the IRB responsible for reviewing the research, Investigative Subcommittee, IPC, or convened IRB may review the Investigator(s)' response to corrective actions. If the Principal Investigator and Co-Investigator(s), as applicable, do not comply with the required corrective action(s) within the time specified in the corrective action plan, additional action may be required, including suspension or termination of IRB approval(s) for ongoing human subjects research activities. The Investigator(s) and the convened IRB will be notified of resolution of corrective actions or the need for additional action(s). If not previously reported, any suspension or termination of IRB approval will be reported by ORRP (see below).

1.5. Appeals

As required by regulation, any decision of the IRB with respect to research involving human subjects is final. However, the convened IRB may review an investigator's request for reconsideration or appeal to a determination regarding noncompliance and/or corrective actions as warranted by the presentation of new information or unusual circumstances. All investigator petitions must be made within 30 days of his/her notification of the IRB's findings. The IRB will review an investigator's request or appeal within 30 days, and the Investigator will be notified in writing of the IRB's decision within 14 days of the review.

1.6. Reporting

Noncompliance determined to be serious and/or continuing or any suspension or termination of IRB approval will be reported by ORRP within 14 days of the finding to the Investigator(s), IRB, Institutional Official, and the Investigator(s)' Dean and Department Chair (or equivalent), and within 30 days to OHRP, FDA (as applicable for FDA-regulated research), any other sponsoring federal Department or Agency, and others (e.g., Sponsored Programs) as necessary, in accordance with The Ohio State University's Federalwide Assurance.

1.7. Record Retention

Records relating to review and investigation of noncompliance will be retained by ORRP for a minimum of three years after completion of the research or any corrective actions (whichever is longer), in keeping federal regulation, applicable state and local law, and University policy.

1.8. Applicable Regulations/Guidance

21 CFR 50.25(b)(5), 21 CFR 56.108(b)(2), 21 CFR 56.112, 21 CFR 56.113, 21 CFR 56.115(b), 45 CFR 46.103(b)(5)(i), 45 CFR 46.111(b)(5), 45 CFR 46.112, 45 CFR 46.113, 45 CFR 46.115(b), "Guidance on Reporting Incidents to OHRP" (05/27/05), OSU Whistleblower Policy 1.40 (03/01/06)