



IRB Policy Number: 2201 Version: 3.0 Effective Date: 08/15/25	Protocol Deviations and Noncompliance	Supersedes Document Dated: 12/01/16, 07/26/19
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Section 22: Protocol Deviations and Noncompliance

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22.1 Reporting to the IRB

When a protocol deviation or incident of noncompliance (See [Section 2 – Definitions](#)) becomes known to a researcher, they must complete and submit a Reportable New Information Form (Adverse Events, Unanticipated Problems, Protocol Deviations) to the DU IRB. Upon receipt, an IRB Compliance Analyst will review the report and bring it to the attention of the Research Integrity and Education Director. Initial review of the report will be conducted to determine the seriousness of the deviation and whether the deviation is an incident of noncompliance. A consultation with the IRB Chair will also occur before any action is requested from the PI. The PI will be notified of the results of the review and if further action is necessary (e.g., a protocol amendment).

Allegations of protocol deviations and incidents of noncompliance may also be reported by someone other than the researcher through the DU Ethics Hotline (866-780-0002), telephone calls to the Office of Research & Sponsored Programs (ORSP), letters, e-mails, or directly to the ORIE Director, IRB Chair, or Institutional Official. Additionally, reporting of non-compliance by research participants or a third party (i.e. news media), could trigger an inquiry by the IRB. However, it is expected that researchers and research staff promptly self-report protocol deviations or incidents of noncompliance regardless of whether the incident is minor, sporadic, serious, or continuing. All reports and allegations of noncompliance will be thoroughly investigated by the IRB.

22.2 Response to Report

22.2.1 Inquiry

Upon receipt of a report or allegation of noncompliance, the ORIE Director and IRB Chair will be notified. An IRB Compliance Analyst will prepare an email or letter to the researcher responsible for the research in question, informing them of the allegation and requesting a response to the allegation within 5-7 workdays. Upon receipt of the researcher's response, the allegation and response will be discussed with the ORIE Director and IRB Chair. The ORIE Director and IRB Chair will then determine whether the allegation has a basis in fact or whether further information is needed. If it appears that the allegation has a basis in fact or if it cannot be determined if there is a basis in fact, an IRB investigation is initiated as described in [Section 22.2.2](#). If the allegation has no basis in fact, no further action is taken under this policy.

If the noncompliance is clearly neither serious nor continuing, and there is a corrective action plan that can be readily implemented to prevent recurrence, then the matter may



be handled as a protocol deviation.

22.2.2 IRB Investigation

Reported protocol deviations or incidents of noncompliance with a basis in fact, or if it cannot be determined if there is a basis in fact, may be the subject of further inquiry. If deemed necessary by the IRB Chair, an *ad hoc* subcommittee of the IRB may be appointed and may include any or all of the following: IRB Chair, ORIE Director, IRB Compliance Analyst(s), and other IRB members whose presence is deemed essential. It will be determined whether anyone assigned to the *ad hoc* subcommittee has a conflict of interest with the investigator or the research that is the subject of the inquiry and if a conflict exists, assign other members to replace those with the conflict. The *ad hoc* subcommittee investigation will be accomplished as soon as possible, but should be concluded within 30 days. The IRB Chair may elect to immediately suspend the research, pending results of the investigation, to protect the safety, rights, or welfare of subjects.

In the event that the investigation finds evidence that federal, state, or local regulations or policies and/or any restrictions, requirements, stipulations, or determinations of the IRB have not been adhered to, the ORIE Director or IRB Chair shall brief the IRB at the next scheduled convened meeting or at a specially convened meeting regarding the details of noncompliance. Applicable documents (may include the study protocol, consent form(s), initial application, description of alleged noncompliance, and results of the investigation) pertaining to the incident and the investigation will be sent to IRB members prior to the meeting. Members are expected to review all documents prior to the meeting.

At a convened meeting, the IRB will then determine if the incident of noncompliance was serious or ongoing and what restrictions, conditions, or other remedial actions are necessary to resolve the noncompliance and the procedures required to prevent future occurrences. Within 7 days of the IRB's determination, the researcher is notified in writing of the requirements necessary to assure compliance with the restrictions and/or determinations of the IRB and the IO and other organizational officials are also notified of the IRB's determination. Notification of regulatory agencies, as applicable, will be accomplished according to [HRPP 2701](#). All documents relating to the investigation will be retained by the IRB Office in a secure location and will be made available to authorized individuals for further reference. Records are held for at least three years.

22.2.3 Examples of Serious and Ongoing/Continuing Noncompliance

1. Serious noncompliance affects or will likely affect the rights and welfare of subjects. Examples of serious noncompliance include:
 - a. Initiation of human research related activities without IRB review and approval.
 - b. Modifications to an IRB-approved study without prior IRB approval except to eliminate immediate hazards to the subjects.
 - c. Continuation of research activities after the expiration date of IRB approval.
2. Ongoing/Continuing noncompliance is a repeated pattern of noncompliance that is likely to continue without intervention. Examples of
 - a. Multiple reports of an investigator failing to follow regulations and/or IRB procedures.
 - b. The investigator frequently allows studies to lapse.
 - c. Multiple instances of an investigator using invalid or unapproved documents.
 - d. The investigator fails to follow a directive or corrective action established by the IRB.



22.2.4 Possible IRB Actions

1. **Research Suspension:** Suspension is when research activities are suspended due to serious concerns regarding investigator noncompliance. For example, subjects may be at increased risk due to inappropriate investigator actions. The investigator will be notified in writing of such a determination and any other actions required. The suspension will be reported to appropriate individuals and agencies as described in [HRPP 2301](#).
2. **Research Termination:** Termination of research activities occurs when the issues of noncompliance cannot be resolved. The investigator will be notified in writing of such a determination, and the termination will be reported to appropriate individuals and agencies as described in [HRPP 2301](#).
3. **Other possible IRB actions include:**
 - a. Notification of current subjects when the information may relate to subjects' willingness to continue to participate in the research.
 - b. Modification of the protocol.
 - c. Modification of the information disclosed during the consent process.
 - d. Providing additional information to past subjects.
 - e. Requiring current subjects to re-consent to participate.
 - f. Modification of the continuing review schedule.
 - g. Monitoring of the research or the consent process.
 - h. Referral to other organizational entities.

Note: If an IRB suspends or terminates a protocol, the IRB must:

1. Consider whether procedures for withdrawal of enrolled subjects, taking into account their rights and welfare.
2. Consider whether current subjects should be informed of the suspension or termination.
3. Require any adverse events or outcomes of withdrawal to be reported to the IRB.

Another possible outcome of an investigation may determine that data obtained as a result or in the context of a non-compliance investigation could be determined invalid. The investigator will be notified in writing of such determination.

22.2.5 Noncompliance that is Not Serious or Ongoing

If the IRB determines at a convened meeting that the incident of noncompliance was neither serious nor ongoing, the IRB may establish a corrective action plan that requires the researcher and/or research staff to attend specialized training. Additionally, the PI may be requested to assist in arranging specialized training for a wider departmental audience to address possible misunderstandings of policies and procedures that led to or could lead to similar incidents of noncompliance. Incidents of noncompliance that were not found to be serious or ongoing will be in the IRB minutes and reported to the Institutional Officer (IO), but will not be reported to federal regulatory agencies.

22.2.6 Reporting to IO and Others

If the incidents of noncompliance are serious or ongoing, and/or the IRB determines that a protocol must be suspended or terminated, the incidents and IRB actions must be reported to the IO and the applicable regulating agency. (See [HRPP 2701](#)). Using their discretion, the IO may also report the incident to the Provost, Dean, or Chair regarding the noncompliance incident.