IRB Policy Number: 2701 Version: 3.0 Effective Date: 08/15/25	Institutional Reporting Requirements	Supersedes Document Dated: 12/01/16, 07/26/19
Reviewed and Approved by: Tyler Ridgeway, Director, Research Integrity & Education	Reviewed and Approved by: Julia Dmitrieva, PhD, DU IRB Chair	

HRPP POLICY 27: Institutional Reporting Requirements

27.1 Reporting Requirements for the Institution

When the IRB makes any of the following determinations, the decision will be reported within 30 days to applicable regulatory and sponsoring agencies, as required by the institution's FWA.

- Serious and/or continuing noncompliance,
- Unanticipated problem involving risk to subjects or others, or
- Suspension or termination of a study

27.2 Notification of Regulatory and Sponsoring Agencies

IRB determinations of reportable events will be reported to the appropriate regulatory agency or agencies, if applicable under the University's Federal-Wide Assurance and/or FDA regulations. Reports of unanticipated problems involving risks to subjects and others, incidents of serious and/or continuing noncompliance, and suspensions and terminations of research activities should be sent to the following entities within 30 days of the IRB's determination.

27.3 Report Distribution and Content

Federal reports should be copied to the following, as applicable:

1. The Institutional Official
2. OHRP (if the research is federally funded)
3. FDA (if the study is subject to FDA regulations)
4. Any other federal agency that may have oversight of the study
5. The PI
6. PI's Chairperson and/or Dean
7. The faculty sponsor, if applicable
8. The Office of Sponsored Programs (if funded)
9. The sponsor (if funded)
10. The complainant, if known, and request a copy (for allegations of non-compliance)

Reports should contain the following information:

1. The nature of the event (unanticipated problem involving risks to subjects and others, incident of serious and/or continuing noncompliance, or suspension or termination of research activities).
2. Name of the institution conducting the research.
3. Title of the research protocol and/or grant proposal in which the problem occurred.
4. Name of the PI
5. The number assigned to the protocol by the IRB and the number of any applicable federal award, grant, contract, or cooperative agreement.

6. The IND or IDE number associated with the study, if applicable.
7. A description of the problem, including findings of the organization and the reasons for the IRB's determination.
8. A description of any corrective action plan approved by the IRB.

27.4 Requirements for Researchers to Report to the IRB

The following is a comprehensive list of events/issues that must be promptly (within 5 days of becoming aware of them) reported to the IRB:

1. Unanticipated problems involving risks to subjects or others,
2. Protocol deviations,
3. Incidents of noncompliance with the regulations, IRB policies, or determinations of the IRB,
4. Self-imposed or sponsor-imposed protocol suspensions or terminations,
5. Premature study completion,
6. Multi-center safety reports,
7. Study monitor reports,
8. Internal (to the University) or external audit reports,
9. Subject complaints,
10. Any other issue/event that could affect the safety or well-being of subjects.
11. Notifying the IRB does not relieve the researcher from his/her responsibility to notify the sponsor and/or FDA, if applicable.

27.5 Reporting Requirements for the Institution

27.5.1 General

There are several instances when federal regulations require reporting of events to the IO and regulatory and sponsoring agencies. The sub-sections below describe requirements and procedures used to report unanticipated problems involving risks to subjects and others, incidents of serious and/or continuing noncompliance, and suspensions and terminations of research activities. Procedures for determinations of unanticipated problems involving risks to subjects and others, incidents of serious and/or continuing noncompliance, and suspensions and terminations of research activities are described in detail in other sections of this manual. The IRB Chair and/or the Research Integrity and Education Director shall be responsible for preparing and submitting reports of unanticipated problems involving risks to subjects and others, incidents of serious and/or continuing noncompliance, and suspensions and terminations of research activities.

27.5.2 Notification of the IO

Reporting to the IO should be accomplished within five (5) business days after determination by the IRB that an event represents an unanticipated problem involving risks to subjects and others, an incident of serious and/or continuing noncompliance, or a suspension or termination of research activities.

27.5.3 Notification of Regulatory and Sponsoring Agencies

Upon receipt of IRB reports of unanticipated problems involving risks to subjects and others, incidents of serious and/or continuing noncompliance, and suspensions and terminations of research activities, the IO will review the report and forward (or return to the Research Integrity and Education Director for forwarding) it to the appropriate regulatory agency or agencies, if applicable under the University's Federal-Wide Assurance and/or FDA regulations. Reports of unanticipated problems involving risks to subjects and others, incidents of serious and/or continuing noncompliance, and

suspensions and terminations of research activities should be sent to the following entities within 7 days of receipt of the IRB's report:

1. OHRP (if the research is federally funded).
2. FDA (if the study is subject to FDA regulations).
3. The PI.
4. PI's Chair and/or Dean.
5. The faculty advisor, if applicable.
6. The Office of Sponsored Programs (if funded).
7. The sponsor (if funded).
8. The complainant, if known and requests a copy (for allegations of noncompliance).

27.5.4 Contents of the Report

Reports should contain the following information:

1. The nature of the event (unanticipated problem involving risks to subjects and others, incident of serious and/or continuing noncompliance, or suspension or termination of research activities).
2. Name of the institution conducting the research.
3. Title of the research protocol and/or grant proposal in which the problem occurred.
4. Name of the PI.
5. The number assigned to the protocol by the IRB and the number of any applicable federal award, grant, contract, or cooperative agreement.
6. A detailed description of the problem, including findings of the organization and the reasons for the IRB's determination.
7. Actions the institution is taking or plans to take to address the problem (e.g., revise the protocol, suspend subject enrollment, terminate the research, revise the informed consent document, inform enrolled subjects, increase monitoring, etc.).
8. Plans or actions taken to prevent future occurrence of similar problems.