OFFICE OF REGULATORY COMPLIANCE · OFFICE OF THE VICE CHANCELLOR FOR RESEARCH

Human Research Protection Program

Emergency Preparedness and Response Standard Operating Procedure

Version Number: 001

Effective Date: June 5, 2026

Applies to: All COMIRB Staff, Panel members, and Chairpersons for all human subjects research overseen by the Colorado Multiple Institutional Review Board (COMIRB).

Approval Authority: Assistant Vice Chancellor for Regulatory Compliance.

Approved by: John Heldens, June 5, 2026

1. Purpose and Scope

This SOP describes how the University of Colorado Anschutz (CU Anschutz) and the University of Colorado Denver (CU Denver) protect human research participants and sustain the oversight activities of the Human Research Protection Program (HRPP) and the Colorado Multiple Institutional Review Board (COMIRB) when an emergency disrupts the normal conduct of human subjects research.

This SOP is specific to human research protections and supplements—but does not replace—the University's comprehensive emergency plans. These include the CU Anschutz Comprehensive Emergency Management Plan (CEMP) and its Continuity of Operations (COOP) Annex, departmental and building COOP plans, and the CU Denver | Anschutz Preparedness Planning Handbook. As stated in the CEMP, The University Crisis Leadership Team (UCLT) is the strategic leadership team during complex and non-complex emergency responses. The CEMP describes activation of the campus Emergency Operations Center (EOC). In any emergency, faculty, staff, students, and research personnel first follow direction from University Police, the Emergency Management Division, and the CU Alerts! / CU Anschutz Alerts! notification systems.

2. Types of Emergencies

The appropriate response depends on the nature, severity, and expected duration of the event and on whether a study offers participants the prospect of direct benefit or can continue by alternative means (e.g., remotely). Consistent with the all-hazards approach of the CEMP, covered emergencies include:

Widespread infectious disease, such as pandemics or regional outbreaks;

Severe weather and natural or human-caused disasters, such as tornadoes, blizzards, flooding, or fire;

Power, utility, network, or website outages and cyber incidents;

Damage to buildings or other infrastructure;

Chemical, biological, radiological, or nuclear (CBRN) incidents; and

Acts of violence or civil disturbance that may pose a general threat to individuals on or around campus.

3. Roles and Responsibilities

a) **Vice Chancellor for Research (Institutional Official).** Coordinates with University leadership and the University Crisis Leadership Team (UCLT), to set institutional research priorities during an emergency.

b) **Assistant Vice Chancellor for Regulatory Compliance and COMIRB Leadership.** Direct HRPP and IRB continuity, assess the event's impact on human subjects research, and communicate with the Institutional Official, UCLT and research community as necessary.

c) **COMIRB Chairs and IRBs.** Prioritize and conduct IRB reviews, convene additional or ad hoc meetings as volume requires, and issue the determinations needed to protect participants.

d) **Principal Investigators.** Protect enrolled participants, adapt their studies as necessary in response to campus emergency alerts and directives under CEMP, and communicate with COMIRB, sponsors, and participants as necessary.

e) **HRPP staff.** Sustain essential operations, shift duties as needed to maintain capacity, and support education of the research community.

4. Assessing Impact and Determining Actions

The Institutional Official, COMIRB Leadership, and COMIRB Chairs—in coordination with the UCLT—assess the event's impact on human research and determine appropriate actions. The University prioritizes continuity of research and maintains activities to the extent it is safe to do so. Depending on the event, actions may include:

a) Continuing studies that pose minimal risk to participants (e.g., research conducted remotely or off-site);

b) Postponing initiation of certain studies, such as in-person studies with little-to-no prospect of direct benefit;

c) Pausing recruitment or enrollment while continuing necessary activities for already-enrolled participants;

d) Converting in-person interactions to remote alternatives—e.g., telehealth, telephone, or video visits—where scientifically and clinically appropriate;

e) Prioritizing continuing reviews, emergency-related research, and therapeutic studies when review capacity is limited; and

f) In extreme circumstances, temporarily suspending some or all human subjects research.

5. Protecting Research Participants

Investigators are responsible for protecting enrolled participants during an emergency. These responsibilities include but are not limited to the following:

a) Investigators may implement changes to approved research without prior IRB approval when necessary to eliminate an apparent immediate hazard to participants; such changes are reported to COMIRB promptly and in accordance with COMIRB reporting requirements.

b) Where in-person research is restricted, investigators assess what is needed to protect participant safety and well-being and follow University guidance regarding alternative activities (e.g., using alternate sites, home administration by qualified personnel, or shipment of investigational product) and consult with COMIRB and their sponsors on how to proceed.

c) Investigational drugs, biologics, and devices are stored, handled, dispensed, and accounted for in accordance with FDA requirements throughout the emergency.

d) Investigators plan in advance for the protection of biospecimens and research data, and take proactive measures to ensure preservation of these materials (e.g., by securing backup power for freezers and repositories).

e) Protocol deviations, such as missed in-person visits, are tracked and reported to COMIRB, sponsors, and regulators as applicable.

f) Investigators keep participant and study-team contact information current, particularly for long-term studies, so participants can be provided with emergency information.

g) Investigators are encouraged to build flexibility (such as remote enrollment, electronic consent, and remote visits) into protocols in advance of any emergency.

6. Continuity of IRB Review and HRPP Operations

COMIRB and the HRPP rely on the University's existing emergency-preparedness, continuity, and information-technology infrastructure rather than maintaining separate systems. Continuity of IRB review and HRPP operations is supported by:

a) **The campus emergency and continuity framework.** The CU Anschutz CEMP and its Continuity of Operations (COOP) Annex, in conjunction with the CU Denver | Anschutz Preparedness Planning Handbook, govern facilities, communications, data backup, and recovery. Continuity of the electronic submission system (InfoEd/eRA) and related research systems is managed by the Office of Information Technology (OIT) under University standards; the details are addressed in those plans and are not duplicated here.

b) **Remote operations.** HRPP staff have hybrid work schedules and all day-to-day work and meetings are conducted through electronic systems. HRPP telephone systems are fully accessible remotely. If facilities are inaccessible or at the direction of the UCLT, HRPP staff and COMIRB members can easily transition to fully remote operations.

c) **Cross-coverage.** If personnel are unavailable, duties shift to other trained staff to preserve essential functions.

d) **Surge capacity.** COMIRB may add ad hoc or additional meetings to manage volume and may prioritize reviews as described in Section 4.

e) **Interim safety measures.** COMIRB may identify alternative activities that investigators can implement immediately to protect participants—to be documented in a subsequent amendment—and communicate them through OVCR Newsletters, ad-hoc town hall meetings, and the "Announcements" page on the COMIRB website.

7. Reliance on External IRBs

To preserve review capacity during an emergency, COMIRB may cede oversight to qualified external IRBs. COMIRB participates in national reliance consortia, including the SMART IRB master reliance agreement, and maintains reliance agreements with private IRBs, allowing review to be ceded to another qualified IRB when appropriate.

8. Notification, Education, and Training

Notification

To supplement campus communication plans described in the CEMP, the AVC for Regulatory Compliance and COMIRB Leadership will distribute HRPP specific updates and guidance to investigators, COMIRB members, HRPP staff, and key institutional contacts. This will be done through

town halls, COMIRB's regular weekly office hours, newsletters, email and announcements on the COMIRB website. During an emergency, investigators contact COMIRB regarding active studies that must continue (such as therapeutic clinical trials), continuing reviews, amendments, and reportable events.

Education and Training

COMIRB members and HRPP staff review this policy to understand their roles during an emergency. Investigators and study teams review this policy together with the campus emergency plans applicable to their site and enroll in CU Alerts! / CU Anschutz Alerts!. Incident-specific guidance may be issued at the onset of an emergency.

Review

HRPP and COMIRB Leadership reviews this policy after each EOC activation that impacted human subjects research, incorporates lessons learned, and coordinates updates with the UCLT.

8. Record of Changes

Initials	Date	Section	Summary of Change