1. PURPOSE
To delineate steps required for permitting and reporting emergency use of an unapproved investigational drug, biologic or medical device.

2. POLICY
Emergency use of an unapproved investigational drug or biologic requires an emergency IND from the FDA, or authorization for shipment from the FDA if there is not time for an IND submission, and must be reported to the IRB within 5 working days of use.

Emergency use of an investigational device should only take place under an existing IDE, and must be reported to COMIRB within 5 working days.

(COMIRB Policies and Procedures for the Protection of Human Subjects, 22.7 Emergency Use).

3. SPECIFIC PROCEDURES
3.1 Definitions
3.1.1 Emergency Use: the use of an unapproved investigational drug, biologic or medical device for the treatment of a patient with a life threatening or severely debilitating condition.
3.1.2 Life Threatening: disease or condition where the likelihood of death is high unless the course of disease is interrupted, and where the endpoint of a clinical trial is survival. The criteria for ‘life-threatening’ do not require the condition to be immediately life-threatening or to immediately result in death; rather the subject must be in a life-threatening situation requiring intervention before review at a convened meeting of the IRB is feasible.
3.1.3 Severely Debilitating: disease or condition that causes major irreversible morbidity (e.g., blindness, loss of arm, leg, hand or foot, loss of hearing, paralysis or stroke).
3.1.4 Institution: The University of Colorado Denver | Anschutz Medical Campus, and each of its affiliates are considered to be separate institutions.
3.1.5 COMIRB Management: The COMIRB Director, Assistant Director, or IRB Manager.

3.2 Initial Queries
3.2.1 All questions for possible emergency use should be forwarded to the Director, Assistant Director or IRB Managers.
3.2.2 Drugs and Biologics: COMIRB leadership will notify physicians of the requirement for an Emergency IND, direct them to contact the FDA to obtain an Emergency IND, and to notify COMIRB within 5 days of the use of the test article.
3.2.3 Medical Devices: Physicians will be advised to complete CF-049 and submit it to COMIRB.
4. COMIRB Records
4.1.1 COMIRB Management will create a submission record in the IRB electronic system for record keeping for the emergency use. The Emergency Use and the name of the drug, biologic or medical device will be included in the submission title. The involved physician will be named in the PI field for the record.
4.1.2 COMIRB Management will follow-up with the physician within 5 days to determine if the emergency use occurred.

4. Written Notification to COMIRB
4.2.1 Physicians are required to provide the following to COMIRB within 5 working days of emergency use of an unapproved investigational drug, biologic or medical device:
- Completed COMIRB Form CF-049 or equivalent information provided to the FDA
- Emergency IND approval from the FDA
- FDA Form 3926 (if used)
- Protocol (if any)
- Consent form
- Documentation of emergency use waiver of consent if applicable
- Investigator’s Brochure (if any)
4.2.2 COMIRB Management will create a study record in the electronic IRB system and upload these documents to that study record, and verify they have been uploaded correctly.
4.2.3 Emergency use notifications will be directed to an IRB Chair. If the Emergency Use is for a pediatric patient, the notification will be directed to a Chair for an IRB that reviews pediatric research.
4.2.4 The IRB Chair will review the notification. If the FDA has not already confirmed that the use qualifies as emergency use, the Chair will complete checklist CF-056.
4.2.5 If the sponsor requires a letter from the IRB prior to shipment, an Emergency Use letter will be sent by COMIRB management (CF-055a).
4.2.6 The notification to the IRB will be acknowledged with letter CF-055b for the first use of the drug at the institution. Notifications for second and third uses will be acknowledged with letters CF-055-2 and CF-055-3 respectively, edited as appropriate.

4. Tracking and Reporting
4.3.1 A report of Emergency Uses is be available through the IRB electronic system.
4.3.2 Emergency use documents are stored in the IRB electronic system.

4. Subsequent emergency uses
4.4.1 If the FDA issues subsequent Emergency INDs for the same drugs or biologics at the same institution, the emergency use is allowed under the same process described above. Subsequent uses of the same drug at the same institution would be subject to IRB review, in which case the electronic study record noted above would also be scheduled for review at a convened meeting by an appropriate COMIRB panel.
4.4.2 If the FDA refuses to issue additional emergency use INDs at the same institution, the physician will be obligated to pursue different strategies to continue to use the test article (e.g., single patient IND, intermediate size IND, etc.) with full board review and approval.

4. Full Board Reviews
4.5.1 Reports of UAPs or potential Serious or Continuing Noncompliance involving the emergency will be reported to COMIRB and reviewed in accordance with COMIRB Policies and Procedures for full board submission and review.
4.5.2 Emergency Use of an unapproved investigational drug or biologic without an Emergency Use IND or authorization to ship from the FDA shall be reported to the IRB as potential serious noncompliance.

4.5.3 Failure to report Emergency Use of an unapproved investigational drug, biologic or medical device to COMIRB within 5 business days shall be reported to the IRB as potential serious noncompliance.

4. RESPONSIBILITY
4.1. The COMIRB Director is responsible for implementing this SOP.

5. APPLICABLE REGULATIONS AND GUIDELINES
- 21 CFR 50.23
- 21 CFR 56.102(d)
- 21 CFR 56.104(c)
- 21 CFR 312.36
- FDA Information Sheets “Emergency Use of an Investigational Drug or Biologic”
- FDA Information Sheet: “Individual Patient Expanded Access Applications: Form FDA 3926”
- FDA Information Sheets “Expanded Access for Medical Devices”
- FDA Information Sheet Guidance For IRBs, Clinical Investigators, and Sponsors Frequently Asked Questions About Medical Devices

6. ATTACHMENTS
- CF-049 Emergency Use of Investigational Drug / Device Request Form, Form
- CF-056 Emergency Use Chair Checklist, Form
- CF-055a Emergency Use Letter Template – Pre-Shipment
- CF-055b Emergency Use Letter Template (1st use)
- CF-055-2 Emergency Use Warning Letter (2nd use)
- CF-055-3 Emergency Use Letter Template (3rd or subsequent use)
- CG-21 Emergency Use of an Investigational Drug Guidance for Investigators

**PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY**

<table>
<thead>
<tr>
<th>Who</th>
<th>Task</th>
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<tbody>
<tr>
<td>Director</td>
<td>Provide instruction to physicians, COMIRB staff and Chairs on compliance with FDA regulations and guidance on emergency use, and COMIRB policies and procedures. Collect all necessary records to document compliance.</td>
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<tr>
<td>Assistant Director</td>
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<tr>
<td>IRB Managers</td>
<td>Reviews notification, completes checklist, signs letter</td>
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<td>Chair</td>
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