1. PURPOSE
To delineate all the steps required for permitting emergency use of a test article.

2. POLICY
All uses of a test article on a human subject in a life-threatening or severely debilitating situation in which no standard acceptable alternative treatment is available and which there is not sufficient time to obtain prospective full IRB review and approval or FDA approval for the use must be reported to COMIRB.

3. SPECIFIC POLICIES

3.1. Definitions
3.1.1. Test article: Industry-sponsored investigational drug or biologic obtained under an IND (Investigational New Drug) or device obtained an IDE (Investigational Device Exemption).
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: University of Colorado at Denver, and each of its affiliates are considered to be separate institutions.

3.2. Procedures

3.2.1 Initial Queries
3.2.1.a All questions for possible emergency use should be forwarded to the Director or designated senior staff.
3.2.1.b Emergency Use Query Log, Form CF-054 must be completed.
3.2.1.c Person entering information into the log must check Emergency Use Tracking Log, Form CF-061, to determine if this is a first use.
3.2.1.d Follow-up on query log with contact to determine if emergency use occurred. If it did not occur, enter such in query log. If emergency use occurred, document date of use and remind the physician that written notification has to be sent to COMIRB within 5
days. Review with the physician the required documentation to be submitted (i.e., emergency use report, consent document used, and any other necessary supporting letters).

3.2.2 Written Notification

3.2.2.a. An physician must submit a report of emergency use of a test article within five working days of its occurrence using the Emergency Use of Investigational Drug / Device Request Form, CF-049, and all requested supporting documentation.

3.2.2.b. Emergency use reports for adult subjects will be directed to an Adult Panel Coordinator for review by an appropriate Adult Chair.

3.2.2.c. Emergency use reports for pediatric subjects will be directed to the Pediatric Panel Coordinator for review by the appropriate Pediatric Chair.

3.2.2.d. Emergency use reports will be logged in “Emergency Use Tracking Log”.

3.2.2.e. A spreadsheet for “Emergency Use Tracking,” Form CF-061, is kept in Excel in the K Drive under “Administration” in a folder titled “Emergency Use.” The Director or Senior IRB Staff will document on the spreadsheet, the date received, PI name, study agent, patient initials, and institution.

3.2.2.f. The Director or Senior IRB Staff determines if 1st or subsequent use of test article based on the “Emergency Use Tracking Log,” Form CF-061. Director/Senior IRB Staff indicates the number of use for this emergency test article at the designated institution on the checklist, Form CF-061.

3.2.2.g. Chair reviews the notification and completes checklist, Form CF-056.

3.2.2.h. These documents submitted for emergency use are dated and signed by a COMIRB Chair as “meets criteria for emergency use”.

3.2.2.i. An “emergency use notification letter,” CF-055-1, is generated from the template, located on the K Drive in the emergency use folder. The emergency use letter is sent out by the Director or Senior IRB Staff.

3.2.2.j. The emergency use documents are placed in a dark blue file folder and filed in the emergency use file drawer.

3.2.3. Subsequent uses of emergency test article at same institution

3.2.3.a. Chair reviews and completes checklist as per Emergency Use Chair Checklist, Form CF-056.

3.2.3.b. If appropriate, generates second use letter, CF-055-2 or subsequent use (3rd or more) letter, CF-055-3. Physician will be notified that submission of a protocol for full board review is required within 90 days. The Director or Senior IRB Staff is responsible for ensuring that the required protocol is submitted or documenting on the tracking sheet that additional action is required.

3.2.3.c. Subsequent submission of documents for prospective IRB approval will be managed in accordance with COMIRB Policies and Procedures for full board submission and review.
3.2.3.d. If a protocol has not been submitted within 90 days, then the Director or Senior IRB Staff will notify the Compliance Board. The Compliance Board will determine if a warning letter or other action should be taken in accordance with COMIRB Policies and Procedures regarding continued non-compliance. If the Board determines that it is appropriate, a warning letter will be sent by the Director on behalf of the Compliance Board to the PI, the Head of Department and the Institutional Compliance Officer for the site.

3.2.3.e. Failure to comply within a further 30 days will be deemed non-compliance and reported to the FDA.

4. RESPONSIBILITY
It is the responsibility of the COMIRB Director, Assistant Director, all COMIRB Chairs and Senior IRB Staff to implement this SOP.

The COMIRB Director and Senior IRB Staff are responsible for review and implementation of the SOP. The COMIRB Director or Assistant Director will approve and ensure implementation of 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” 2010
- FDA Information Sheets “Emergency use of unapproved medical devices” 1998
- FDA Information Sheet guidance for IRBs, clinical investigators, and sponsors: “Frequently asked questions about medical devices” 2006

6. ATTACHMENTS
- CF-054 Emergency Use Query Log, Form
- CF-061 Emergency Use Tracking Log, Form
- CF-049 Emergency Use of Investigational Drug / Device Request Form, Form
- CF-056 Emergency Use Chair Checklist, Form
- CF-055-1 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)
- Instructions to Clinical Investigators

7. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

<table>
<thead>
<tr>
<th>Who</th>
<th>Task</th>
</tr>
</thead>
<tbody>
<tr>
<td>Director</td>
<td>Instruct investigators to submit appropriate Emergency use of Investigational Drug / Device request form with appropriate supporting documentation as outlined. Complete phone log and follow-up if documentation not submitted. Once submitted to COMIRB enter in Emergency Use tracking log. Determine if 1st or subsequent use at that institution. Enter information on checklist. Follow-up per the instruction of the Chair.</td>
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<tr>
<td>Senior IRB Staff</td>
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<tr>
<td>Chair</td>
<td>Reviews notification and completes checklist</td>
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