1. PURPOSE
   1. This procedure establishes the process to review notifications of:
      1. Emergency uses of test articles in a life-threatening situation.
      2. Non-emergency individual patient/small group expanded access for an unapproved medical device (commonly known as Compassionate Use).
      3. Non-emergency individual patient expanded access use of an investigational drug for which an IRB waiver is requested
   2. The process begins when the IRB receives a notification of a proposed or actual emergency use of a test article in a life-threatening situation.
   3. The process ends when a Designated Reviewer has
      1. Determined whether the proposed or actual emergency use of a test article in a life-threatening situation will or has followed FDA-regulation; and
      2. Notified the physician and IRB staff of the determination.
2. POLICY
   1. Whenever possible physicians are to notify the IRB of a proposed emergency use of a test article in a life-threatening situation in advance of the use.
   2. Physicians are to notify the IRB of a proposed compassionate use of an unapproved device, for the purpose of obtaining concurrence from an IRB Chair.
   3. In order to meet the criteria for emergency uses of a test article, data obtained from such uses cannot be used in a non-exempt systematic investigation designed to develop or contribute to generalizable knowledge.
   4. Investigators are to notify the IRB of a non-emergency individual patient expanded access use of an investigational drug “Request for Authorization to Use Alternative IRB Review Procedures” identified on FDA Form 3926 (field 10.b.) or a separate waiver request included with FDA Form 1571 for the purpose of obtaining concurrence from an IRB Chair or designee.
3. RESPONSIBILITIES
   1. A Designated Reviewer carries out these procedures.
4. PROCEDURE
   1. For a proposed emergency use of a test article in a life-threatening situation, review the information in CICERO or speak with the physician and use the “WORKSHEET: Emergency Use of a Test Article” to determine whether the circumstances will meet the regulatory criteria.
      1. If met, remind the physician that:
         1. If the use involves a drug or biologic, under FDA regulations the emergency use is Research and the patient is a Human Subject;
         2. If the use involves a device, FDA expects IRB oversight similar as if the use were Human Research.
      2. If not met, inform the physician orally that if the physician proceeds with the use, the IRB will consider that action to be Non-Compliance.
   2. For notifications after the emergency use of a test article in a life-threatening situation use the “WORKSHEET: Emergency Use of a Test Article” to determine whether the circumstances met the regulatory criteria.
      1. Compassionate use of a device. If so, use “WORKSHEET: Compassionate Use of a Device to determine whether the circumstances will meet the regulatory and guidance criteria and indicate the results of this determination to the physician.
      2. Non-emergency individual patient expanded access use of an investigational drug for which an IRB waiver is requested. If so, use “WORKSHEET: Criteria for Approval (HRP-311)” to determine whether the proposed use meets the requirements under 21 CFR 50 and 56.111[[1]](#footnote-1) and indicate the results of this determination to the IRB staff.
         1. Execute the “Submit Designated Review” activity. In the “Notes” section document that the decision is to concur (or not) is in lieu of review and approval at a convened IRB meeting at which a majority of the members are present per the request for a waiver under 21 § 56.105 of the requirements in § 56.108(c).
   3. Inform IRB staff of the results of the evaluation.
5. MATERIALS
   1. HRP-001SOP: Definitions
   2. HRP-024 SOP: New Information
   3. HRP-311WORKSHEET: Criteria for Approval
   4. HRP-318 WORKSHEET: Emergency Use
   5. WORKSHEET: Compassionate Use of a Device
6. REFERENCES
   1. 21 CFR §50.23; 21 CFR §50.24; 21 CFR §56.102(d); 21 CFR §56.104(c).
   2. 21 CFR §812.36; 21 CFR §812.47.
   3. 21 CFR § 56.105; 21 CFR § 56.108(c).
   4. (FDA Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors) Frequently Asked Questions About Medical Devices: <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127067.pdf>.
   5. Individual Patient Expanded Access Applications: Form FDA 3926 Guidance for Industry; https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm432717.pdf

1. *“The IRB chairperson (or designated IRB member) would consider the same information that the full IRB would consider to determine whether to approve the treatment when reviewing and concurring for individual patient expanded access use.”* Per FDA correspondence dated 10/10/17 [↑](#footnote-ref-1)