

N	SOP: Compassionate Use (Device Only), and IRB Waiver for Individual Patient Expanded Access (Drug Only)		
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1 PURPOSE

- 1.1 This procedure establishes the process to communicate the review of:
 - 1.1.1 Non-emergency individual patient/small group expanded access for an unapproved medical device (commonly known as Compassionate Use).
 - 1.1.2 Non-emergency individual patient expanded access use of an investigational drug for which an IRB waiver is requested.
- 1.2 The process begins when the IRB receives a notification of a proposed use.
- 1.3 The process ends when the IRB staff has communicated the determination to the physician.

2 PREVIOUS VERSION

- 2.1 Revised from previous version 08/01/2024.

3 POLICY

- 3.1 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.
- 3.2 Physicians 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.
- 3.3 Device Compassionate Uses and Expanded Access IND use cannot be claimed as research.

4 RESPONSIBILITIES

- 4.1 IRB Office staff carry out these procedures.

5 PROCEDURE

- 5.1 The proposal should be submitted via New Project submission in eIRB+. The Compassionate Use Request for Investigational Devices Form (HRP-1201) should be submitted with all Compassionate Use proposals of medical devices. The proposal will be assigned to a Designated Reviewer (IRB Chair) who determines if the request is one of the following:
 - 5.1.1 If the Designated Reviewer has indicated concurrence of Compassionate Use of a device or IRB waiver for non-emergency individual patient expanded access use of an investigational drug, and that the proposed use will follow FDA regulations:
 - 5.1.1.1.1 Compassionate Use of a device: use "WORKSHEET: Compassionate Use of an Unapproved Medical Device (HRP-325)" to determine whether the circumstances will meet the regulatory and guidance criteria and indicate the results of this determination to the physician.
 - 5.1.1.1.2 Non-emergency individual patient expanded access use of an investigational drug for which an IRB waiver is requested: use "WORKSHEET: Criteria for Approval (HRP-314)" to determine whether the proposed use meets the requirements under 21 CFR 50 and 56.111¹ and indicate the results of this determination to the IRB staff.
 - 5.1.1.1.3 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

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



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requirements in § 56.108(c). For individual patient expanded access use of an investigational drug, an expiration date should be given no more than a year minus a day from the date of determination.

- 5.1.2 If none of the above, stop processing the request and the IRB Office Staff will inform the physician or submitter.
- 5.1.3 Complete a “TEMPLATE LETTER: Compassionate Use Request for Device (HRP-1718)” and send to the physician OR complete a “TEMPLATE LETTER: IRB Waiver For Non-Emergency Individual Patient Expanded Access Use Of An Investigational Drug (HRP-575)” and send to the physician.

6 MATERIALS

- 6.1 WORKSHEET: Compassionate Use of an Unapproved Medical Device (HRP-325)
- 6.2 WORKSHEET: Criteria for Approval (HRP-314)
- 6.3 TEMPLATE LETTER: Compassionate Use Request for Device (HRP-1718)
- 6.4 TEMPLATE LETTER: IRB Waiver For Non-Emergency Individual Patient Expanded Access Use Of An Investigational Drug (HRP-575)

7 REFERENCES

- 7.1 21 CFR §50.23; 21 CFR §50.24; 21 CFR §56.102(d); 21 CFR §56.104(c)
- 7.2 21 CFR §312.305
- 7.3 21 CFR §812.36; 21 CFR §812.47.
- 7.4 (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>.