HRP-023 | 03/01/2024 | Author: T. Bechert | Approver: S. Brooks

**SOP: All Emergency Use, Compassionate Use (Device Only) and Individual Patient Expanded Access (Drug Only) Review**

1. **PURPOSE**
	1. This procedure establishes the process to review notifications of:
		1. Emergency use of a drug, biologic, or device 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 use.
	3. The process ends when the IRB has:
		1. Determined whether the proposed or actual use will follow or has followed FDA-regulation and guidance; and
		2. Notified the physician and IRB staff of the determination.
2. **REVISIONS FROM PREVIOUS VERSION**
	1. None
3. **POLICY**
	1. Whenever possible physicians are to notify the IRB of a proposed emergency use of a drug, biologic, or device in a life-threatening situation in advance of the use. Prospective review of emergency use is not required and should never prevent a treating physician from proceeding when all other requirements for use are met. The convened IRB will review all 5-day reports to ensure requirements for emergency use have been met.
	2. Physicians are to notify the IRB of a proposed compassionate use of an unapproved device to obtain full board review and approval prior to use. VCU does not provide Chair concurrence for these submissions.
	3. Emergency uses and device compassionate uses cannot be claimed as research.
	4. VCU does not provide Chair concurrence for proposed uses of non-emergency individual patient expanded access use of an investigational drug via “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. VCU requires full board review and approval of all such submissions.
4. **RESPONSIBILITIES**
	1. The IRB Chair, members, and staff carry out these procedures.
5. **PROCEDURE**
	1. Determine if the notification/request is one of the following:
		1. Emergency use of a drug, biologic, or device in a life-threatening situation. If so, use the HRP-322 - WORKSHEET - Emergency Use to determine whether the circumstances will meet, or if the use described in the 5-day report have met, the regulatory and guidance criteria for emergency use, and indicate the results of this determination to the IRB staff (or directly to the physician if time sensitive).
			1. If the notice is in advance of the use, determine the ability to convene an ad hoc meeting to review the proposed use.
				1. Inform the IRB staff (or physician if time sensitive) that the physician can proceed with the use or work with the physician to identify what additional information/procedures the physician needs to follow. Add to the Full Board Tracking Log and set a 5-day reminder to request the 5-day report.
			2. If the notice involves actual emergency use described in the 5-day report, assign to committee review.
				1. If the actual emergency use did not follow FDA requirements, manage using HRP-024 - SOP - New Information as Non-Compliance.
		2. Compassionate use of a device. If so, assign for committee review and use HRP-325 - WORKSHEET - Device Compassionate Use to determine whether the circumstances will meet the regulatory and guidance criteria and indicate the results of this determination to the physician.
		3. Non-emergency individual patient expanded access use of an investigational drug. If so, assign for committee review and use HRP-314a - WORKSHEET - Criteria for Approval\_Reviewer Summary to determine whether the proposed use meets the requirements under 21 CFR 50 and 56.111 and indicate the results of this determination to the IRB staff.
		4. If none of the above, stop processing the request and inform the physician or submitter.
6. **MATERIALS**
	1. HRP-024 - SOP - New Information
	2. HRP-314a - WORKSHEET - Criteria for Approval\_Reviewer Summary
	3. HRP-322 - WORKSHEET - Emergency Use
	4. HRP-325 - WORKSHEET - Device Compassionate Use
7. **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](https://www.fda.gov/ucm/groups/fdagov-public/%40fdagov-drugs-gen/documents/document/ucm432717.pdf)
	6. AAHRPP element 1.7.C