SOP Title	**EMERGENCY USE NOTIFICATION AND REPORTING PROCEDURES**	SOP No.	**UWS-HP-607**
		Version	.02
Effective Date	04 February 2021	Page	1 of 9

Signatures and Dates:

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Approving Authority:	

Review/Approval for unchanged documents

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1. Purpose and Applicability

This Standard Operating Procedure (SOP) documents the process used by the Walter Reed Army Institute of Research (WRAIR) HSPB to review submissions regarding WRAIR's participation on the Emergency Use of a drug, biologic, device, or combination product and the corresponding reporting procedures.

The U.S. Food and Drug Administration (U.S. FDA) and reviewing IRBs recognize that situations arise in which there could be a need to use an investigational drug, biologic, device, or combination product in a manner inconsistent with the approved protocol/Investigational New Drug (IND) Application/Investigational Device Exemption (IDE) or by a physician who is not an investigator on the clinical study. The criteria for emergency use are defined in the Code of Federal Regulations (CFR) and must be followed. The emergency use provision in 21 CFR 56.104(c) is an exemption from prospective IRB review and approval and may not be used unless all conditions of 21 CFR 56.102(d) are met. This exemption allows one use without prospective IRB review; any subsequent use requires prospective review. The emergency use of an unapproved investigational drug, biologic, device, or combination product requires an IND or IDE application. Should conditions require the use of such for a subject who does not meet inclusion/exclusion criteria for a protocol, the investigator must contact the Sponsor to determine if the drug, biologic, device, or combination product can be made available for emergency use under the IND/IDE. U.S. FDA may also authorize shipment of the test article in advance of an IND/IDE submission. When emergency use of a test article is initiated without IRB review or approval, the patient may not be considered a research subject. Such emergency care may not be claimed as research, and data from an emergency use may not be reported in a way that implies that the activity was a prospectively planned systematic investigation designed to develop or contribute to generalizable knowledge.

Recognizing that the WRAIR is not a military treatment facility (MTF) but that WRAIR personnel may participate (i.e. as an investigator, subject matter expert, supplier of the investigational product or other support) in the emergency use of the investigational product at Department of Defense (DoD) medical centers (MEDCENs), the WRAIR Institutional Official (IO) will rely upon the IRB that has jurisdiction of the MTF or patient care facility at which the emergency use of the product will occur. This must be a well-coordinated effort to ensure the patient's access to the best available care.

2. Responsibilities

a. The WRAIR IRB Administrative Director (or Designee) is responsible for:

1) Receiving the notification of WRAIR's participation on the emergency use of a test article, ensuring that the WRAIR Commander has received the notification of WRAIR's participation on the emergency use request, and providing a recommendation regarding WRAIR's participation on the request.
2) Reviewing documentation of WRAIR's participation on the emergency use of a test article and ensuring that the request is being reviewed by a fully convened and Health and Human Services (HHS)-registered IRB.
3) Reminding the WRAIR investigator/point of contact (POC) to file appropriate reports.
4) Ensuring that the emergency use of a test article is appropriately tracked in all correspondence and documentation.

b. The IO or Designee is responsible for:

1) Receiving and reviewing the emergency use request and issuing initial concurrence for WRAIR's participation on the request, at the recommendation of the WRAIR IRB Administrative Director/Designee.
2) Reliance on the appropriate reviewing IRB for review of the emergency use request.
3) Issuing the Commander Approval Authorization once the reviewing IRB approval has been received for the emergency use request.

c. The HSPB Staff are responsible for:

1) Verifying that the submission for the emergency use is complete, to include the approval by the full reviewing IRB.
2) Ensuring that the appropriate Institutional Agreement for IRB review (IAIR) is in place between WRAIR and the reviewing Institution, when appropriate.
3) Preparing and sending communications/memoranda to the WRAIR investigator/POC regarding the emergency use request on behalf of the WRAIR IRB Administrator and IO.
4) Preparing the regulatory file for the emergency use request, archiving all documentation corresponding to the request in the regulatory file and updating the HSPB database.

d. The participating Branch/Directorate Director is responsible for notifying the WRAIR HSPB when the emergency use request has been made and for reporting the results to the WRAIR HSPB in real time once the emergency use has been completed.

3. Materials and Equipment

Not Applicable

4. Investigator Guidance:

The WRAIR Investigator or POC is expected to:

a. Provide documentation (memorandum for record) that outlines how authorization of the emergency use was obtained from the U.S. FDA via expedited means by the requesting physician in real time. The U.S. FDA emergency use authorization can be obtained either over the phone or via other rapid means of communication to the appropriate U.S. FDA review division.

b. Obtain a copy of the Full Board reviewing IRB concurrence for emergency use, or, if the conditions of 21 CFR 56.102(d) are met, the reviewing IRB Chair may concur with the emergency use and the use may proceed without Full Board IRB acknowledgment, but will need to be obtained later.

c. Report to the WRAIR Commander/IO and the Administrative IRB Director, any intent of emergency use of a test article and receive Commander initial concurrence for WRAIR to participate in the request. This includes reporting the provision of a WRAIR product, even when the WRAIR IRB is not the IRB of Record.

d. Within five days of the use, submit a copy of the follow-up report on the patient's condition, per 21 CFR 56.104(c) to the reviewing IRB and HSPB.

5. Procedures

3. Procedures:

a. The WRAIR IRB Administrative Director (or Designee) will:

1) Review WRAIR's participation on the emergency use of a test article, ensuring that the initial U.S. FDA's authorization was obtained by expedited means, the reviewing IRB concurrence has been granted, and

verify that all conditions of 21 CFR 56.102(d) are met; this is to be documented in an email or signed memorandum for the WRAIR investigator/POC. A copy is to be retained in the regulatory files held in the HSPB. These conditions include:

a) The patient is in a life-threatening or serious disease condition requiring immediate treatment;

b) There must be no generally acceptable alternative for treatment available;

c) There is not sufficient time to submit a protocol/amendment to the U.S. FDA or full reviewing IRB for prospective approval.

2) Notify the WRAIR IO of his/her action.

3) Verify that the following patient protection procedures are being followed and before the test article is used, require that the WRAIR investigator/POC will:

a) Obtain the reviewing Full Board IRB or Chair's concurrence;

1. Ensure that informed consent is obtained from the patient or his/her legal representative or verify that each situation in which a test article is to be administered an informed consent cannot be obtained, the WRAIR investigator/POC must:

i. Obtain the treating physician's certification in writing regarding the existence of the emergency exception as defined in 21 CFR 50.23;

ii. Obtain the written certification of the existence of the emergency exception from a second physician who is uninvolved in the case;

iii. Ensure that the reviewing IRB has been notified of the intent to use the test article under the exception from informed consent criteria;

iv. Ensure that all requirements for emergency exemption from informed consent are met, as documented in SOP UWS-HP-608.

b) Obtain a copy of the independent assessment by an uninvolved physician;

c) Obtain a copy of the authorization or approval from the Sponsor or manufacturer;

d) Obtain U.S. Army Medical Research and Development Command (USAMRDC) Component Level administrative review concurrence or approval for use, when applicable; and,

e) Obtain WRAIR IO initial concurrence.

4) Verify that the following patient protection procedures are followed and after the test article is used, require that the WRAIR investigator/POC will:

a) Obtain a copy of the written report submitted to the Sponsor for the U.S. FDA that contains a summary of the conditions constituting the emergency, patient protection measures taken (informed consent), and the results (applicable only when a medical device is used which does not have an IDE; the reviewing IRB is to receive a copy of this report);

b) Determine if the test article is likely to be used again; if so, ensure that the reviewing physician has been designated as an investigator and that they are obtaining full reviewing IRB approval of an appropriate protocol (or amendment) prior to subsequent use;

c) Submit all above correspondence and documentation to the WRAIR HSPB as soon as possible, and verify that this documentation has been submitted to the reviewing IRB no later than five days after notification of the use; and

d) Report the status of the emergency use and other relevant information regarding the patient and the test article to the WRAIR HSPB and provide documentation that the report has been provided to the reviewing IRB Chair and their fully convened IRB as appropriate.

b. The HSPB Staff will:

1) Coordinate with the IRB Administrative Director (or Designee) to obtain documentation for the regulatory files;

2) Use the date of the initial reviewing IRB concurrence to initiate tracking to remind the WRAIR investigator/POC to provide a copy of the report filed with the reviewing IRB within the five day time frame required by 21 CFR 56.104(c). Enter the reviewing IRB emergency use concurrence and the WRAIR Commander initial approval of WRAIR's participation in the HSPB database and regulatory file;

3) Include in the WRAIR Investigator/POC communications, a statement that "any subsequent use of the investigational product (test article) requires prospective reviewing IRB review and approval and WRAIR Commander Approval Authorization"; and

4) Maintain a copy of all correspondence and documentation concerning emergency use in the HSPB regulatory files for the study.

c. The Commander, WRAIR will:

1) Review WRAIR's participation on the emergency use request and ensure that all 21 CFR 56 requirements have been met for emergency use;

2) Review the IRB Administrative Director's (or Designee's) recommendation regarding WRAIR's participation in the emergency use request;

3) Issue initial concurrence for WRAIR personnel to participate on the emergency use request; and

4) Issue final Commander Approval Authorization once the emergency use request documentation is complete and the reviewing IRB approval is obtained for the request.

6. Explanation of Abbreviations, Acronyms, and Definition of Terms

Abbreviations and acronyms have been defined in the text at the time of first use.

7. References

Reference Number or Authors	Document Title
AR-40-68	Clinical Quality Management
WRAIR HRPP	Walter Reed Army Institute of Research Human Research Protection Plan
ICH-GCP-E6	Guideline for Good Clinical Practice.
U.S. FDA Guidance	Expanded Access to Investigational Drugs for Treatment Use – Questions & Answers
U.S. FDA Webpage	Expanded Access for Medical Devices: https://www.fda.gov/medical-devices/investigational-device-exemption-ide/expanded-access-medical-devices#treatment
U.S. FDA Guidance	Individual Patient Expanded Access Applications: Form FDA 3926
USAMRDC Policy 21	Administrative Oversight Review and Approval of USAMRDC Conducted and Supported Human Subjects Research
OHRP Guidelines	Guidelines for Formulating Written HURC Policies and Procedureshttp://ohrp.osophs.dhhs.gov/HURC/HURC_guidebook.htm
Titles 21, 32 and 45	Code of Federal Regulations
21 CFR 812.35(a)(2)	IDE Report
Bankert, E. A. and Amdur, R. J.	Institutional Review Board Management and Function, Boston: Jones and Bartlett Publishers.

8. Appendices and Attachments

Appendix or Attachment Number	Title
	None

9. Document Revision History

Version Number	Brief Description of Changes	Effective Date
.00	New	15 July 2007
.01	Biennial review to include updates for consistency with current policies and procedures.	08 April 2011
.02	Review and revisions to incorporate updated guidance, policies and regulations	04 February 2021