6.4 Emergency Use of a Test Article

1.0 Purpose

The purpose of this policy is to describe the requirements for utilization of a test article under emergency circumstances where there is not sufficient time to obtain IRB approval at a convened meeting.

2.0 Policy

It is the policy of the Organization that:

- 2.1. Emergency use of a test article (investigational drug, biologic, or device) must be conducted in full compliance with the requirements of FDA regulations at 21 CFR 56.102(d), 21 CFR 56.104(c).
- 2.2. In an emergency use situation, if time permits, the treating physician who is proposing to use the test article must obtain concurrence from the IRB Chair/designee through the Office of Regulatory Affairs (ORA) that the emergency use meets all FDA requirements.

3.0 Definitions

- 3.1. Emergency Use: The use of a test article on a human patient in a life-threatening or severely debilitating circumstance where no standard medically acceptable treatment is available and there is not sufficient time to obtain full IRB approval for use of the test article to treat the patient [21 CFR 56.102(d)].
  - 3.1.1. Life-threatening: Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted.
  - 3.1.2. Severely debilitating: Diseases or conditions that would likely cause major irreversible morbidity (e.g. loss of a limb, paralysis or stroke).
    Note: A life-threatening and/or severely debilitating condition does not necessarily mean that the condition is immediately life-threatening or may imminently result in death or irreversible morbidity. Rather, the patient must be in a situation requiring prompt administration of the test article before review at a convened meeting of the IRB is feasible and any treatment delay will have a significant deleterious effect on the patient. Consequently, premature death and/or persistent morbidity are likely.

4.0 General Considerations

- 4.1. Emergency Use of a test article (unapproved drug, device or biologic) does not constitute human subject research under HHS regulations. If the administration of the test article is subject to HHS regulations, the data related to such emergency use cannot be included in any report (for example, research article in a journal). However, Emergency use of a test article is considered a clinical investigation under FDA regulations, and data obtained during emergency use of the test

article is subject to FDA inspection and may be required to be submitted to FDA in a marketing application.

- 4.2. Nothing in the policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.
- 4.3. FDA allows physician requests for a single patient IND for compassionate or emergency use in accordance with 21 CFR 312.300. This is referred to as “expanded access use”. The patient or patients to be treated must have a serious or immediately life-threatening disease or condition and there is no comparable or satisfactory alternative therapy, but therapy is not emergent and there is sufficient time for prospective IRB review and approval. Expanded Access Use is subject to HRPP policy 6.5 (Expanded Access to Investigational Drugs and Devices for Treatment Use).
- 4.4. Emergency Use may be appropriate when an IND/IDE does not exist for the test article but there is reason to believe the patient would benefit, or when an IND/IDE exists and either there is no available clinical investigation, or the subject is not eligible for an available clinical investigation.

5.0 IRB Requirements

- 5.1. Physicians intending to use a test article under emergency circumstances should have carefully assessed the potential for therapeutic benefit to the patient and be assured that all of the following criteria are met:
  - 5.1.1. The test article has not been used at the Organization to date under the FDA emergency use provisions, except as noted in section 7.7 below.
  - 5.1.2. The patient is suffering from a life-threatening or severely debilitating condition.
  - 5.1.3. There is no available alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the patient’s life and/or alleviating a debilitating condition.
  - 5.1.4. When possible and/or required, the holder of the IND or IDE (sponsor or device developer) has authorized the emergency use.
  - 5.1.5. When the test article is a medical device, an independent assessment, as appropriate, has been obtained from an uninvolved physician that use of the test article is necessary.
  - 5.1.6. There is not sufficient time to obtain full IRB approval of a protocol.

6.0 FDA Notification

- 6.1. When there is an industry sponsor who is the holder of the IND/IDE, the sponsor will notify FDA as required.
- 6.2. When the investigator is the holder of the IND/IDE, the investigator will notify FDA as required.
- 6.3. When no IND/IDE exists, the treating physician will notify the drug/device developer who, in turn, will notify FDA.

7.0 Procedures for Emergency Use of a Test Article

- 7.1. The treating physician must contact the Executive Chair/designee directly or thru ORA. The IRB Executive Chair/designee must concur that the proposed emergency use has met all the requirements of 21 CFR 56.102(d), 21 CFR 56.104(c), and the criteria in section 5.0 above.
- 7.2. The treating physician will complete section I of the Emergency Use of a Test Article Report and develop a consent form in RSS. The form documents information about the proposed emergency use.
- 7.3. The ORA will issue an acknowledgement that the use of the test article satisfies the

requirements of 21 CFR 56.102(d)
- 7.4. If a test article is an investigational drug or biologic, and there is sufficient time, the treating physician must:
  - 7.4.1. Contact the Chair of the P&T Committee/designee and obtain a P&T emergency use approval.
  - 7.4.2. Notify the Executive Director of the Pharmacy or Investigational Drug Pharmacist of the emergency use, and provide information concerning financial responsibility for the pharmacy costs of the test article.
- 7.5. The treating physician must complete and submit section II of the Emergency Use of a Test Article Report thru RSS within five business days following initiation of the treatment. [21 CFR 56.104(c)].
- 7.6. The Emergency Use of a Test Article Report will be provided to the IRB as a notification at a convened IRB meeting.
- 7.7. Any subsequent use of the test article must have prospective IRB review and approval.
  Note: FDA acknowledges that it would be inappropriate to deny emergency treatment to a second individual if the only obstacle is the IRB has not had sufficient time to convene a meeting to review a protocol (reference "1998 FDA Information Sheets").
- 7.8. If the physician decides not to use the test article the ORA must be promptly notified.

8.0 Informed Consent

- 8.1. The treating physician should be prepared to obtain written informed consent from the patient or the patient's legally authorized representative (LAR) unless conditions in section 8.4 below are met.
- 8.2. The Informed Consent Form (ICF) is generated in RSS based on a modified template as below.
  - 8.2.1. The ICF must comply with the requirements of 21 CFR 50.25 (Basic and Additional Elements of Consent) and HRPP policy 5.1 (Obtaining Informed Consent from Research Subjects), section 4.1 (Basic Elements of Informed Consent).
  - 8.2.2. The elements of informed consent should be worded to reflect the nature of the emergency situation (that is, the patient is being treated for a life-threatening or severely debilitating condition and there are no alternative therapeutic methods that provide an equal or greater likelihood of saving the patient's life).
  - 8.2.3. The ICF must include HIPAA required information and a clear disclosure of the financial obligations of the patient.
- 8.3. Informed consent is not required if both the treating physician and a physician who is not otherwise participating in use of the agent certify in writing all of the following [21 CFR 50.23(a)]:
  - 8.3.1. The subject is confronted by a life-threatening situation necessitating the use of the test article.
  - 8.3.2. Informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from, the subject.
  - 8.3.3. Time is not sufficient to obtain consent from the subject's legal representative.
  - 8.3.4. No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the subject's life.
    Note: The IRB Executive Chair/designee can provide the required certification if they are not participating in any clinical investigation involving the test article. Alternatively, another independent physician can provide certification.
- 8.4. If time is not sufficient to obtain the independent physician determination before use of the test article, the actions of the investigator must be reviewed and evaluated in writing by an independent physician within 5-6 working days. The IRB must be notified within 5 working days when an emergency waiver is used. This notification must not be construed as an approval for the emergency waiver by the IRB. The IRB Executive Chair/designee will review the report to verify that circumstances of the emergency waiver conformed to FDA regulations.

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Revised 1/22/2024 – revised section 4.1 to specify "test article (unapproved drug, device or biologic) rather than just drug or biologic; minor stylistic changes. {Approved Russell McCulloh (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

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