

Approved by IRB executive committee: DRAFT  
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AAHRPP Element I.3.D and I.5.C

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## **POLICY**

The University of Utah IRB requires investigators to follow the federal regulations for the emergency use of a test article and planned emergency research.

## **PROCEDURES**

### **1. Procedures for Exemption from IRB Review Requirements for Emergency Use of a Test Article**

FDA regulations [21 CFR 56.104(c)] permit the emergency use of a test article without prospective IRB review. Emergency use is defined as the use of a test article on a human participant in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval [21 CFR 56.102(d)]. FDA regulations require that any subsequent use of the investigational product at the institution have prospective IRB review and approval. 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.

- 1.1. Investigators must notify the IRB before the test article is administered. The investigator submits a Report of Emergency Use of a Test Article Form. The IRB Chair or designee reviews the report using the Emergency Use Checklist to determine whether the FDA requirements for emergency use of a test article are met.
  - 1.1.1. If the IRB Chair or designee determines that it meets the FDA requirements for emergency use of a test article in a life-threatening situation, notification is sent to the investigator through the ERICA system. This determination must not be construed as an approval for emergency use by the IRB.
  - 1.1.2. If the IRB chair or designee determines that it does not meet the FDA requirements for emergency use of a test article in a life-threatening situation, the research will be referred to a convened IRB meeting.
- 1.2. If immediate use of the test article is required to save the life of the participant and there is not sufficient time to contact the IRB, the investigator may proceed with the emergency use. In this case, the investigator must submit a Report of Emergency Use of a Test Article Form within 5 working days of the emergency use of a test article. The IRB Chair or designee reviews the report using the Emergency Use Checklist to determine whether the FDA requirements for emergency use of a test article are met.
  - 1.2.1. If the IRB Chair or designee determines that the reported activity meets the FDA requirements for emergency use of a test article, notification is sent to the investigator through the ERICA system.

This determination must not be construed as an approval for emergency use by the IRB.

- 1.2.2. If the IRB Chair or designee determines that the investigator failed to comply with the regulatory requirements for emergency use of a test article, appropriate corrective action will be taken according to SOP 903, HRPP Requirements and Non-Compliance.

## **2. Procedures for Exception from Informed Consent Requirements**

The investigator must obtain informed consent of the subject or the subject's legally authorized representative for emergency use of a test article. However, the FDA provides an exception from the requirements of informed consent [21 CFR 50.23].

- 2.1. The investigator must submit required documentation to the IRB for review within 5 working days after use of the test article using the Report of Emergency Use of a Test Article Form.
- 2.2. The IRB Chair or designee will review the documentation using the Emergency Use Checklist (Exception from Informed Consent portion).
  - 2.2.1. If the IRB Chair or designee determines that the documentation meets the FDA requirements for exception from informed consent before the use of a test article, notification is sent to the investigator through the ERICA system.
  - 2.2.2. If the IRB Chair or designee determines that the investigator failed to comply with the regulatory requirements for exception from informed consent before the use of a test article, appropriate corrective action will be taken according to SOP 903, HRPP Requirements and Non-Compliance.

## **3. Procedure for Exception from Informed Consent Requirements for Planned Emergency Research**

The IRB may review and approve applications for planned use of a test article in an emergency setting. The IRB may approve a request for a waiver of informed consent for planned emergency research in accordance with the exception in FDA regulation [21 CFR 50.24] and under DHHS regulation [45 CFR 46.101(i)].

VA researchers are not permitted to use these provisions. However, VASLCHCS researchers may petition the Under Secretary for Health for a waiver of informed consent in emergency situations.

- 3.1. If an investigator wishes to waive consent under this policy, the investigator must complete a Request for Waiver of the Informed Consent for Planned Emergency Research.
- 3.2. For research subject to FDA regulations - If the IRB approves a request for a waiver of informed consent for planned emergency research, all of the required determinations under 21 CFR 50.24 and in Federal Register, Vol. 61, No. 192, pp. 51531-51533, October 2, 1996 (<http://www.hhs.gov/ohrp/humansubjects/guidance/hcdc97-01.htm>) will be made by a convened IRB.

- 3.3. For research not subject to FDA regulations - If the IRB approves a request for a waiver of informed consent for planned emergency research that is not subject to FDA regulations, all of the required determinations in Federal Register, Vol. 61, No. 192, pp. 51531-51533, October 2, 1996 (<http://www.hhs.gov/ohrp/humansubjects/guidance/hcdc97-01.htm>) will be made by a convened IRB.
- 3.4. If an IRB determines that it cannot approve the proposed waiver of informed consent because the investigation does not meet the criteria in the exception provided in the federal regulations (as cited above) or because of other relevant ethical concerns, the IRB will document its findings and provide these findings promptly in writing to the investigator and to the sponsor.