Title: SARMC Institutional Review Board: Emergency Use of a Test Article (Drug, Device, Biologic)

Policy Statement: The use of an investigational drug, biologic, or device in either an unplanned or a planned emergency situation must be evaluated by the IRB. The IRB must review and approve procedures, informed consent and information to be used with subjects or their legally authorized representatives in situations in which use of such procedures and documents is feasible. The IRB must also review and approve procedures and information to be used when providing an opportunity for a family member to object to a subject’s participation in the clinical investigation.

Procedure:

I. Definitions
   A. Unplanned Emergencies: An individual emergency in which the participant is in a life-threatening situation, there are no standard acceptable treatments available, and there is not sufficient time to obtain IRB approval.
   B. Planned Emergency Research: A research project to be performed with multiple participants in a life-threatening situation. The drug or device must be used before the consent is obtained, and the researcher cannot know in advance who the participants will be. Planned emergency research also requires the researcher to consult with representatives of the communities in which the clinical investigation will be conducted and from which the subjects will be drawn and to conduct a media campaign in those communities.

II. Unplanned Emergencies
   A. The SARMC IRB allows emergency use of an investigational drug (test article), device, or biologic without prior IRB review and approval as permitted under FDA regulation 21 CFR 56.104(c) as long as:
      1. The patient is in a life-threatening situation for which no standard acceptable treatment is available;
      2. No alternative method of approved or generally recognized therapy is available that provides equal or greater likelihood of saving the life of the patient;
      3. Informed consent cannot be obtained because of an inability to communicate with or obtain legally effective consent from the patient or the legally authorized representative (*see below);
      4. There is not sufficient time to obtain IRB approval.

*Note: Even for emergency use, the physician is required to attempt to obtain informed consent of the subject or the subject's legally authorized representative unless both the physician and an independent physician not otherwise participating in the case certify in writing that informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from, the subject and/or time is not sufficient to obtain consent from the subject's legal representative.
B. The use will be initially reported to the IRB office **within one (1) working day** after the emergency use. This initial report needs to specifically address the items noted above, asserting that all four conditions apply, the date of event, the name and contact information of the physician who utilized the drug or device and the diagnosis and nature of the emergency.

C. Required supporting documentation provided to the IRB **within five (5) working days** must include:
   1. Dictated procedure and exam reports;
   2. Product labeling;
   3. The name and contact information of the manufacturer and/or drug/device representative;
   4. Documentation that use of the drug/device was reported to the FDA by the manufacturer or representative;
   5. A follow-up letter to the IRB from the physician that summarizes the nature of the emergency and the rationale for use (the expected benefits from use of the drug/device);
   6. Patient outcomes.

D. A worksheet listing both regulatory and hospital criteria for reporting emergency use of an investigative drug/device is available at [http://www.saintalphonsus.org/forms-and-resources](http://www.saintalphonsus.org/forms-and-resources).

E. A copy of the completed worksheet must accompany the documentation noted above.

F. Further requests by a researcher or physician to utilize the same procedure, drug or device must be presented in accordance with the IRB procedures noted above.

### III. Planned Emergency Research

The IRB may waive or make an exception to the informed consent requirements for a research protocol using FDA regulated drugs, devices and biologics when the research involves participants in a life threatening situation and available treatments are unproven or unsatisfactory. The research will be designed to collect scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, to determine the safety and effectiveness of the test item to treat the life threatening condition. The protocol must show all of the following:

A. The clinical investigation could not practicably be carried out without the waiver

B. The human subjects are in a life-threatening situation

C. Available treatments are unproven or unsatisfactory

D. Obtaining informed consent is not feasible because:
   1. The subjects will not be able to give their informed consent as a result of their medical condition;
   2. The intervention under investigation must be administered before consent from the subjects’ legally authorized representatives is feasible; and,
   3. There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation.

E. If obtaining informed consent is not feasible and a legally authorized representative is not reasonably available then:
   1. The investigator has committed, if feasible, to attempting to contact
within the therapeutic window the subject’s family member who is not a legally authorized representative, and asking whether he or she objects to the subject’s participation in the clinical investigation, and,

2. The investigator will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review. The proposed investigational plan defines the length of potential therapeutic window based on scientific evidence, and the investigator has committed to attempting to contact a legally authorized representative for each subject within that window of time and, if feasible, to asking the legally authorized representative for consent within that window rather than proceeding without consent. The investigator will summarize efforts made to contact legally authorized representatives and make this information available to the IRB at the time of continuing review.

F. Participation in the research holds out the prospect of direct benefit to the subjects because:
   1. Subjects are facing a life-threatening situation that necessitates intervention;
   2. Appropriate animal and other pre-clinical studies have been conducted, and the information derived from those studies and related evidence support the potential for the intervention to provide a direct benefit to the individual subjects; and,
   3. Risks associated with the investigation are reasonable in relation to what is known about the medical condition of the potential class of subjects, the risks and benefits of standard therapy, if any, and what is known about the risks and benefits of the proposed intervention or activity.

G. According to the Food and Drug Administration (FDA), protocols involving an exception to the informed consent requirement must be performed under a separate investigational new drug application (IND) or investigational device exemption (IDE) that clearly identifies that the protocol may include subjects who are unable to consent. The submission of those protocols in a separate IND/IDE is required even if an IND for the same drug product or an IDE for the same device already exists. Department of Health and Human Services (DHHS) regulations allow physicians to provide emergency medical treatment outside of research, and any data collected is not allowed as part of a research study. Saint Alphonsus Regional Medical Center has agreed to abide by DHHS regulations, but if the research involves the use of an investigational drug, biologic or device, the research also falls under the jurisdiction of the FDA and regulations for both must be followed.

H. Public Disclosure: the IRB will prospectively review and approve the public disclosure materials, which must include:
   1. A clear statement that informed consent will not be obtained for most research subjects as well as, a clear statement that explains what is typically done during consent and that this study is a clear departure from the norm;
   2. Information about the test article or medical device, the use, description of the risks and expected benefits;
   3. A synopsis of the research protocol and study design;
   4. Information about how potential study subjects will be identified;
5. A physical sample of the experimental device and demonstration of the use, if feasible and appropriate;
6. A list of the sites and/or locations where the study population will be drawn prior to study initiation;
7. The disclosure(s) should be presented in language(s) and formats (hard copy, electronically, and available through public establishments) that is understandable to the community from which the research subjects are drawn and in which the research will take place.

Related Policies: Informed Consent - Waiver of Authorization

Related Forms: Checklist for Emergency Use of an Investigational Drug/Device


http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html
