

The Carle Foundation

IRB Policy 410

Subject	Research in Emergency Settings				
Approval	Dec 2006	Review	Sep 2010	Revision	Jun 2009
Scope	These policies and procedures apply to all research conducted in emergency settings or on an emergency basis under the Carle Foundation Hospital Federal Wide Assurance.				
Purpose	To provide guidance for research in emergency settings.				

Statement of Policy

- As a rule, all research conducted under the Carle Foundation Hospital (CFH) Federal Wide Assurance must be submitted for prior IRB review and approval before any contact with a participant, and must satisfy regulatory requirements for informed consent. This policy describes special cases of emergency research conducted without prior IRB review or informed consent. Failure to comply with this or any Carle IRB policy can result in termination of research privileges; see [IRB General Administration Policy 101 Compliance with Policies and Procedures Mandate](#).

Definitions

Emergency use means the use of a test article on a human subject 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.

Life-threatening means diseases or conditions where the likelihood of death is high unless the course of the disease or condition is interrupted; and diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival. These criteria do not require the condition to be immediately life-threatening, rather, the subject(s) must be in a life-threatening situation requiring intervention before review at a convened IRB meeting is feasible.

Specific Policies

- Emergency Use of a Drug or Biological Product** The FDA allows the use of investigational drugs or biological products outside the standard research setting under (1) a treatment IND or (2) an emergency use exemption. [21 CFR 56 and FDA Information Sheets]
 - See [IRB Review of Research Policy 409 Clinical Investigation Involving Drugs, Devices and Biological Products](#) for standard research setting requirements and treatment IND information.
 - Exemption from prior IRB approval for emergency use of an unapproved drug or biologic.
 - The emergency use of an unapproved drug/biologic requires an IND.** If the prospective subject does not meet the criteria of an existing protocol, or if an approved study protocol does not exist, the usual procedure is to contact the manufacturer and determine if the drug or biologic can be made available for emergency use under the company's IND. If the emergent need for the drug/biologic does not allow time for submission of an IND, the FDA may authorize shipment of the article in advance of the IND submission. Contact the FDA directly or call the Carle IRB for assistance.
 - The FDA allows for one emergency use (per institution) of a drug/biologic without prior IRB review and approval** if the definition of emergency use is met and the use is reported to the IRB within 5 working days. If possible, the investigator should notify the IRB prior to the emergency use. This notification should not be construed as IRB approval.
While acknowledging that it would be inappropriate to deny treatment to a second individual if the only obstacle is that the IRB has not had sufficient time to convene a meeting and review the issue, FDA regulations require that any subsequent use of an unapproved drug or biologic have prior IRB review and approval. Contact the IRB for specific guidance in these situations.
 - Even for an emergency use, the investigator is required to obtain informed consent** of the subject or the subject's legally authorized representative unless both the investigator and a physician who is not otherwise participating in the clinical investigation certify in writing that all of the following conditions are met. [21 CFR 50.23(a)]
 - The subject is confronted by a life-threatening situation necessitating the use of the agent.
 - Informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from the subject.
 - There is not sufficient time to obtain consent from the subject's legal representative.
 - No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the subject's life.

Specific Policies (cont.)

If, in the investigator's opinion, immediate use of the drug or biologic is required to preserve the subject's life, and if time is not sufficient to obtain an independent physician's determination that the four conditions mentioned above apply, the clinical investigator should make the determination and, within 5 working days after the use of the article, have the determination reviewed and evaluated in writing by a physician who is not participating in the clinical investigation. The investigator must notify the IRB within 5 working days after the use of the test article [21 CFR 50.23(c)].

2. **Emergency Use of Unapproved Devices.** The FDA and Carle recognize that emergencies arise where an unapproved device may offer the only possible life-saving alternative, but an investigational device exemption (IDE) for the device does not exist, or the proposed use, physician, or institution is not approved under an existing IDE. Using its enforcement discretion, the FDA has not objected if a physician chooses to use an unapproved device in such an emergency, provided that the physician later justifies to the FDA that an emergency actually existed. These policies and the FDA require that physicians follow subject protection procedures specified by the FDA, both before and after any emergency use of an unapproved medical device. Contact the Carle IRB for specific guidance.
3. **Planned Emergency Research—Informed Consent Exception** Research may be planned for a medical emergency setting, as described in 21 CFR 50.24. This federal regulation allows the conduct of research studies to test emergency treatments on patients with specific life-threatening medical conditions (head trauma, cardiac arrest, stroke) when patients cannot give informed consent because of their conditions, and their family is not available to provide consent. On rare occasions and under carefully regulated circumstances, a person in a life-threatening situation may be enrolled in an emergency research study before arriving at a hospital (and may be treated in an ambulance) or in the emergency room of a hospital without being able to give his or her informed consent because of his or her medical condition. Such emergency research has been allowed by the FDA under very restricted circumstances with a narrow exception to informed consent requirements.
 - a. The conduct of planned research in life-threatening emergent situations, where obtaining prior informed consent has been waived, must be approved in advance by the FDA and the Carle IRB, and publicly disclosed to the community in which the research will be conducted. Subjects in these cases represent a vulnerable population for which additional protections are required.
 - b. The informed consent exception in this limited set of circumstances is conditional upon documented findings of the Carle IRB with the concurrence of a licensed physician, who is not participating in the clinical investigation, according to FDA regulations at 21 CFR 50.24 and related guidance. Contact the Carle IRB for assistance with the requirements for this research.
 - c. The following findings are required for approval of planned emergency research. Additional information is provided in the FDA Information Sheet entitled "Exception from Informed Consent for Studies conducted in Emergency Setting: Regulatory Language and Excerpts from Preamble."
 - The human subjects are in a life-threatening situation, available treatments are unproven or unsatisfactory, **and** (i) the collection of valid scientific evidence is necessary to determine the safety and effectiveness of particular interventions.
 - It is not feasible to obtain informed consent because (i) the subjects will not be able to give consent due to their medical condition, (ii) the intervention must be administered before consent from the subjects or their legal representatives is feasible, **and** (iii) there is no reasonable way to identify the individuals likely to become eligible for the research.
 - Participation in the research holds out the prospect of direct benefit to the subjects because (i) the subjects are in a life-threatening situation requiring an intervention; (ii) appropriate animal or preclinical studies have been conducted and the evidence supports the potential for the intervention; **and** (iii) risks are reasonable in relationship to what is known about the medical condition and the risks and benefits of both the standard therapy and the proposed intervention.
 - The research could not practicably be carried out without an informed consent waiver.
 - The research protocol defines the length of the potential therapeutic window based on scientific evidence; the investigator has committed to attempting to contact a legally authorized representative for each subject within that window of time and to asking that representative for consent; **and** the investigator will summarize efforts made to contact representatives and make this information available to the IRB at the time of continuing review.
 - The IRB has reviewed and approved informed consent procedures and an informed consent document in accordance with application regulations; these procedures and this document will be used with the subjects or their legal representatives where feasible; **and** the procedures include IRB-approved information to be used when providing a family member the opportunity to object to a subject's participation in the research.

Specific Policies (cont.)

- Additional protections for the rights and welfare of the subjects will be provided, including at least (i) consultation with community representatives where the research will be conducted; (ii) advance public disclosure of the research plan, risks, and benefits, to the communities where the research will be conducted; (iii) public disclosure of research results to the communities where the research will be conducted, after the research is complete; and (iv) establishment of an independent data monitoring body to oversee the research.
- The IRB is responsible for assuring that procedures are in place for informing (i) each subject at the earliest feasible opportunity, or (ii) if the subject remains incapacitated, the subject's legal representative, or (iii) if such a representative is not reasonably available, a family member, of the subject's inclusion in the clinical investigation, the details of the investigation, and other information contained in the approved consent document, and will provide the subject or their representative an opportunity to discontinue participation at any time.
- The IRB determinations made for planned emergency research shall be documented according to applicable regulations and retained by the IRB for at least three years after completion of the clinical investigation.
- Protocols involving an exception to informed consent for planned emergency research must be performed under a separate IND or IDE that clearly identifies the protocols as including subjects who are unable to consent.
- If the IRB determines that it cannot approve a clinical investigation involving planned emergency research without informed consent, the IRB must document its findings and provide the findings promptly in writing to the clinical investigator and the sponsor of the clinical investigation. The sponsor must promptly disclose this information to the FDA and to other investigators and other IRBs that have been asked to participate in or approve the clinical investigation.

Reference

21 CFR 50.24, and 45 CFR 46 Emergency Research Consent Waiver

Approval On File

*Approved by IRB Board Aug 2010

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