

Guidance for Submitting Emergency Use Requests Health Sciences IRB • Health Sciences Minimal Risk IRB

Use of an unapproved drug or device can without prior IRB approval can occur in "emergency use" situations that meet specific federal regulatory criteria. The IRB will work with physicians and investigators to make sure patients in critical or novel situations are cared for as soon as possible and in accordance with federal regulations.

Step 1: Obtain Manufacturer or FDA Approval

For emergency use of an unapproved drug or biologic, contact the UWHC Pharmaceutical Research Center for assistance as soon as possible at 608-263-8902.

A physician who wants approval for emergency use of a test article (unapproved drug, biologic or device) must also contact the manufacturer to determine if the product can be made available for use (in one, specific patient) under the company's IND or IDE.

If the company declines or cannot be reached, the physician can contact the FDA for approval.

FDA Contact Information

For Drug Products	301-827-4573
For Biological Blood Products	301-827-3518
For Biological Vaccine Products	301-827-0648
For Biological Therapeutic Products	301-594-2860
For Medical Devices	301-594-1190
For Nights, Weekends, Holidays	301-443-1240

In addition to the Pharmaceutical Research Center, the Office of Clinical Trials (OCT) is very experienced with preparing emergency use requests for unapproved drugs, biologics and devices, and physicians are encouraged to contact OCT for assistance in preparing documentation for the IRB. OCT can be reached at 608-265-6507.

Step 2: Contacting the IRB

During business hours, (Monday through Friday, 8AM-5PM CST), notify the Health Sciences IRB Office of the need to obtain approval for an emergency use situation by calling 608-263-2362. Please specifically state that you are seeking approval for emergency use of an unapproved drug, biologic, or device and, if possible, provide a time frame. You will be referred to either the IRB Office Director or another experienced IRB staff member for assistance with your request.

The IRB Office Director or staff member will ask you to provide an Application for Emergency Use of an Investigational Drug or Device (available at www.medicine.wisc.edu/irb) or a letter or email that contains the following:

- Description of whether the request is for one (1) patient
- Description of whether the situation can be categorized as an emergency (i.e., it is either life threatening or would result in significant debilitation if a delay in treatment occurred)
- Description of whether any other reasonable alternative treatments are available for the patient
- In the case of a device, description of whether concurrence from an independent physician that use of the device is warranted and no other reasonable alternatives are available has been sought
- A draft consent form for review or description of the consent process that will be followed

The IRB Office Director or staff member will communicate any suggested changes to the consent document.

For emergency use requests that occur outside of IRB business hours, see procedures described below.

Step 3: Involving the IRB Chair

After speaking with you, IRB staff will contact the IRB Chair (or other IRB member with medical expertise – “designee”) on your behalf. The IRB Chair (or designee) must assess the request to determine if it meets the criteria for an emergency use. Possible outcomes:

- If it is determined that there is insufficient time for the full IRB to review the request, but the IRB Chair (or designee) agrees that (a) the use meets the criteria for emergency use of a test article, and (b) informed consent will be obtained or the situation meets the requirements allowing an exception from the requirement for informed consent, a letter of acknowledgement is written, which expresses concurrence with the use of the test article but acknowledges that IRB approval has not been granted. In addition, the letter will acknowledge whether a consent document was reviewed and found to be acceptable. The original signed letter is delivered to the treating physician (or designee) and, if an unapproved drug or biologic is used, a copy is sent to the Pharmaceutical Research Center.
- If all criteria for emergency use are not met, but the use appears appropriate and there is time for the request to be added to the next IRB agenda and approved prospectively, the attending physician is referred back to the IRB Office for additional guidance in submitting the request. In such circumstances, the emergency use without prior IRB approval would be allowable only if the patient's condition became more urgent while awaiting IRB action.
- The IRB Chair may also determine that the proposed use does not meet the emergency use criteria and should be submitted to the IRB as an ordinary request.

Step 4: Reporting the Emergency Use

If an Application for Emergency Use of an Investigational Drug or Device and consent document to be used were not received by the IRB Office as part of the original information provided about the emergency use, the application should be submitted to the IRB Office within 5 business days of the emergency use.

The application for emergency use of a test article will be placed on the agenda for the next available HS IRB meeting. The convened IRB will then review the proposal for the emergency use of the test article and determine whether it agreed with the IRB Chair's assessment or additional information should be provided to the recipient of the treatment (or the recipient's representatives).

Emergency Use Requests Outside of IRB Business Hours

When a patient is faced with a life-threatening situation and the physician must employ experimental drugs, biologics, or devices to care for the patient in the most beneficial manner, clinical judgment prevails over administrative procedures. Emergency use of experimental drugs, biologics, or devices outside of IRB business hours may proceed as follows:

- Secure concurrence with the planned treatment from another physician who is not involved in the treatment of this particular patient.
- If an unapproved drug or biologic is being used, notify the Pharmaceutical Research Center.
- Alert the IRB office of the intended use by voice mail at 608-263-2362 or an email to the IRB Office Director.
- Report the action to the IRB office in writing within five business days using the Application for Emergency Use of an Investigational Drug or Device.
- The application is placed on the agenda for the next available IRB meeting for review to determine whether the use (a) met the criteria for emergency use of a test article and (b) that informed consent was obtained or that the situation met the requirements allowing an exception from the requirement for informed consent.