

Stanford

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Emergency Use

The information on this page is only for **Emergency Use of a test article**.

See also [Emergency Use of a Test Article \[GUI-6\]](#) [1].

See the tri-fold [Expanded Access Brochure](#) [2] and the relevant guidances for other types of [Expanded Access](#) [3], or [Humanitarian Use](#) [4].

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Emergency Use

Emergency use: The use of a test article on a human subject in a life-threatening situation in which no standard acceptable treatment is available and where there is not sufficient time to obtain IRB approval.

Test article: Any [investigational] drug, biological product, or medical device for human use.

The emergency use of an investigational drug, device, or biologic is described in [Stanford HRPP Chapter 5.8](#) [5].

Generally, IRB approval is required prior to conducting human subject research. However, an exception to this is the one-time use of an investigational drug or device (test article) for a single participant in a life-threatening (emergency use) situation.

An emergency use of a test article is exempt from prior IRB review and approval, **provided that the emergency use of a test article is reported to the IRB within 5 working days of date of the emergency use**. The IRB may be notified prior to an emergency use; however, this notification should not be construed as an IRB approval.

Any subsequent use of the test article at Stanford is subject to IRB review and approval. **Only one emergency use of the test article is permitted** and any subsequent use needs to be done under an IRB approved protocol. **However**, the FDA acknowledges that it would be inappropriate to deny emergency treatment to a second individual if the only obstacle is that the IRB has not had sufficient time to convene a meeting to review the issue. ([FDA Information Sheet](#) [6], 2003 Update)

The IRB Chair or designated IRB member will review the submission of [Emergency Use of a Test Article ? Notification to the IRB](#) [7] in support of an emergency use of a test article.

Criteria for Emergency Use

All the following must be satisfied:

- Existence of a life-threatening/severely debilitating condition where no standard acceptable treatment is available
- No current IRB approved protocol covering the situation and no time to obtain prior FDA and IRB approval
- Availability of an investigational agent or device which in the opinion of the physician might be beneficial, and
- Availability of an investigational agent or device from a sponsor or elsewhere.
- The Emergency Use of a Test Article is not a systematic investigation designed to develop or contribute to generalizable knowledge.

Consent Requirement

The process of informed consent must meet FDA requirements [21 CFR 50.25]. The investigator is required to obtain legally effective informed consent of the subject or the subject's legally authorized representative, using an appropriate consent document and HIPAA Authorization. The investigator may use the Stanford [consent form and HIPAA](#) [8] Authorization template, or adapt a consent form from a previously approved research study involving the use of the same investigational drug or biologic. Alternatively, the investigator may develop a new consent form that includes all required elements (see [General Requirements for Informed Consent](#) [9]).

Exception from Informed Consent Requirement

Informed consent of the subject or the subject's legally authorized representative is required, **unless both the investigator and a physician (not otherwise participating in the investigation) certify in writing** that:

1. the patient is confronted with a life-threatening situation;
2. informed consent cannot be obtained from the patient (because patient cannot communicate or is incompetent to give consent);
3. consent cannot be obtained from the legally authorized representative (unavailable or unknown); and
4. no alternative approved treatment/therapy is available that provides an equal or greater likelihood of saving the patient's life.

Emergency Use with Drugs and Biologics

The protocol director must submit the following materials to the IRB within five (5) working days, following the use of the test article:

- [Emergency Use of a Test Article ? Notification to the IRB](#) [7] which includes:
 - information about the patient
 - indication of the life-threatening or severely debilitating nature of the situation
 - explanation as to why this drug or treatment was necessary
 - **and**, if the emergency use occurred **without obtaining prior informed consent**, **Section D** on this form must also be completed: Independent Physician Certification - Emergency Use of a Test Article Without Informed Consent
- **Written permission from the manufacturer** for the use of the test article under their IND. Generally the investigator will contact the manufacturer and determine if the drug or biologic can be made available for the emergency use under the company's IND. If the company only allows cross-referencing to their IND, declines permission or cannot be reached, the investigator should contact the FDA for authorization of the shipment of the drug in advance of the IND submission. In such a case the FDA may authorize shipment of the test article in advance of the IND submission. The IRB will request that the investigator contact the FDA to obtain an Emergency Use IND.
- A copy of the signed [Consent Form, with HIPAA](#) [10].

Emergency Use with Devices

The protocol director must submit the following materials to the IRB within five (5) working days following the procedure:

- [Emergency Use of a Test Article ? Notification to the IRB](#) [7] which includes:
 - information about the patient
 - indication of the life-threatening or severely debilitating nature of the situation
 - explanation as to why this device was necessary
 - **and**, if the emergency use occurred **without obtaining prior informed consent**, **Section D** on this form must also be completed: Independent Physician Certification - Emergency Use of a Test Article Without Informed Consent
- Written permission from the manufacturer for the use of the test article under their IDE. Generally the investigator will contact the manufacturer and determine if the device can be made available for the emergency use under the company's IDE. The IRB will request that the investigator contact the FDA to obtain an IDE. If the company only allows cross-referencing to their IDE, declines permission or cannot be reached or an IDE does not exist, the FDA expects the investigator to:
 - Determine whether the criteria for emergency use have been met;
 - Assess the potential for benefits from the unapproved device and to have substantial reason to believe that benefits exist;
 - Assure that the decision of the investigator that an emergency exists is not based solely on the expectation that IDE approval procedures may require more time than is available.
 - Obtain an independent assessment by an uninvolved physician.

In addition, if the device is used and **there is no IDE**:

- The use must be reported to the FDA within 5 working days (to CDRH). This report should contain a summary of the conditions constituting the emergency, patient outcome information, and the patient protection measures that were followed.

- Signed [Consent Form, with HIPAA](#) [10].

FDA Emergency use requests

- For investigational biological products regulated by CBER, call 301-827-1800.
 - For all other investigational drugs, call 301-796-3400.
 - After working hours, call FDA's Office of Emergency Operations at 1-866-300-4374 or 301-796-8240.
 - [CDER website](#) [11] - including Emergency Use
 - [CDER Physician Request for a Single Patient IND for Compassionate or Emergency Use](#) [12]
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Source URL: <https://researchcompliance.stanford.edu/panels/hs/forms/emergency>

Links

[1] <https://stanfordmedicine.box.com/shared/static/5cridy8s1dvs1na2jawanp3b9zcpvdlf.pdf>

[2] <https://stanfordmedicine.box.com/shared/static/w0myy68uz345g2g3df83goifgjj2ih6j.pdf>

[3] <https://stanfordmedicine.box.com/shared/static/zwucoebcma8w5rb4m5dn8ut382829uz5.pdf>

[4] <https://stanfordmedicine.box.com/shared/static/89y403mrzuv784l065ib5jy6cvwm8uuu.pdf>

[5] <https://stanfordmedicine.box.com/shared/static/l2u7ynl9ixc2trf39ku796jjgzkcxsfg.pdf>

[6] <http://www.fda.gov/RegulatoryInformation/Guidances/ucm126491.htm>

[7] <https://stanfordmedicine.box.com/shared/static/zffoz6icql3vb2ccktunhdb9lgs5z3v8.pdf>

[8] <https://rco.sites.stanford.edu/panels/hs/forms/forms-templates>

[9] <https://stanfordmedicine.box.com/shared/static/abnw9zaduffrrj48okqf0bdsue8m83iz.pdf>

[10] <https://researchcompliance.stanford.edu/panels/hs/forms/consent>

[11]

<http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/investigational>

[12]

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/Investigational>