

Emergency Treatment

The contact list for Emergency Treatment authorization can be found here in [RSS](#).

Under certain circumstances, a physician may treat a patient with an investigational (non-FDA approved) drug, biologic or device, or treat a patient utilizing a non-IRB approved protocol; Pursuant to FDA regulations, the patient must be suffering from a serious, life-threatening or debilitating illness for which there is no satisfactory treatment alternative(s) and there must not be sufficient time to obtain full IRB review and approval. Emergency treatment as defined here is not research. The FDA regulations do not provide for expedited IRB approval in emergency situations.

UNMC/Nebraska Medicine policy requires the IRB be notified prior to such use, by contacting the IRB office. This notification is not IRB approval. The IRB will only state it is aware of the proposed use and considers the use to meet the requirements of 21 CFR 56.102(d), 21 CFR 56.104(c), and the criteria in [HRPP 6.4 Emergency Use of a Test Article](#), section 5.0 of the full policy.

The investigator is still required to obtain informed consent of the patient or the patient's legally authorized representative. The consent form must contain appropriate elements structured to reflect that consent is for treatment purposes as opposed to research. View a sample [Consent Form for Emergency Treatment](#)

A useful guide can be found here: [Emergency Use vs Expanded Access](#)

The UNMC Emergency Use of a Test Article Report form can be found in RSS and a signed copy of the consent form must be submitted to the IRB within 5 business days following the treatment.

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