NYU Langone Health

Human Research Protections
Institutional Review Board
1 Park Avenue | 6th Floor | New York, NY 10016
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Expanded Access (EA) to Investigational (non-Food & Drug Administration [FDA] approved) Devices

The purpose of this guidance document is to assist researchers with navigating policy and regulations regarding Expanded Access to **Investigational Devices** and related Institutional Review Board (IRB) submission requirements. Sometimes called "**compassionate use**", expanded access is a potential pathway for a patient with an immediately life-threatening condition or serious disease or condition to gain access to an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available.

Criteria for all categories of Expanded Access submissions: (*Additional criteria described in table below must be met depending on the type of Expanded Access submission)*

- Patient has serious or immediately life-threatening disease or condition
- There are no comparable or satisfactory alternatives to diagnose, monitor, or treat the patient
- Enrollment in a clinical trial is not possible
- The potential benefit to the patient justifies the potential treatment risk(s) – the risk(s) associated with treatment is not greater than the probable risk of the disease or condition
- Providing the investigational product will not interfere with clinical trials that could support the product's development or marketing approval for the treatment indication

Serious Disease or Condition: a disease or condition associated with morbidity that has substantial impact on day-to-day functioning. Short-lived and self-limiting morbidity will usually not be sufficient, but the morbidity need not be irreversible, provided it is persistent or recurrent. Whether a disease or condition is serious is a matter of clinical judgment, based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one.

Immediately Life-Threatening Disease or Condition: a stage of disease in which there is reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment).

This guidance is based on the FDA Regulations 21 CFR 812 for expanded access of devices. For further information and additional resources please visit expanded access resource pages. For guidance on expanded access of drugs, please visit the IRB Template Library. For assistance with submission to the FDA, please contact Research Regulatory Services.

EA Categories	Specific Criteria	IRB Approval Prior to Use?	Required Documents for IRB Submission	Type of Submission in RNav	FDA Approval Prior to Use?
Individual Patient / Small Group Access – *Compassionate Use*	• Treatment for 1 patient or a small group of patients • Patient(s) has serious disease or condition • Sufficient time for IRB and FDA approval prior to treatment • The device is under investigation in a controlled clinical trial for the same use under an approved IDE, or such clinical trials have been completed; ***and*** • The sponsor of the investigation is actively pursuing marketing approval/clearance of the investigational device with due diligence.	**Yes**	• FDA Acknowledgment / Approval Letter • Device Brochure • Instructions for Use (IFU) • Treatment Protocol • Treatment IDE Consent Form*	**New Human Research Study** (select Expanded Access when completing smart form)	**Yes**
Treatment Investigational Device Exemption (IDE)	• Larger population than Small Group • The device is under investigation in a controlled clinical trial for the same use under an approved IDE, or such clinical trials have been completed; **and** • The sponsor of the investigation is actively pursuing marketing approval/clearance of the investigational device with due diligence.	**Yes**	• FDA Acknowledgment / Approval Letter • Device Brochure • Instructions for Use (IFU) • Intermediate-Size Population Access Protocol • Treatment IDE Consent Form*	**New Human Research Study** (select Expanded Access when completing smart form)	**Yes**
Emergency Use of Device	• Treatment for 1 patient • Patient has an immediately life-threatening disease or condition that needs immediate treatment. • There is not sufficient time to obtain IRB approval prior to treatment. • There is no time to use the existing procedures to obtain FDA approval for the use. • Investigational device may be made available for treatment prior to the completion of all clinical trials.	**Yes, contact IRB for clearance to use test article**	• Emergency Use Appendix* • Copy of signed Emergency Use consent form* or certification that the use meets exception from informed consent on the Emergency Use Appendix • Patient's de-identified history and treatment plan/rationale for emergency treatment • Investigator's Brochure (as applicable) • Independent assessment/concurrence from uninvolved physician • Authorization from device manufacturer • Device Brochure • Instructions for Use (IFU) • FDA acknowledgment/correspondence	**Reportable New Information (RNI)** to notify of emergency EA use must be submitted within 5 working days post-treatment.	**Yes**, initial authorization from the FDA is required, and written submission to FDA must be made within 5 working days of the initial authorization.

**Template available on IRB website*

For questions regarding expanded access submissions, contact: Expanded-Access@nyulangone.org