LSUHSC IRB Presents:

LUNCH & LEARN

EMERGENCY USE & EXPANDED ACCESS

MAY 3, 2023

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Objectives

- To provide guidance for investigators and study teams on types of Expanded Access for drugs and biologics.
- To provide guidance to investigators and study teams on types of Expanded Access for Devices
- To provide guidance for investigators and study teams on IRB resources for both Expanded Access of drugs or devices and Kuali submission.

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What is Expanded Access

Expanded Access allows for the use of an **unapproved investigational drug, biologic, or device** (test article) to **treat a patient** who does not have a **comparable alternative therapy** or has **exhausted all options** to treat a disease or condition.

The intent is treatment, not research.

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Criteria for Expanded Access

All of the following conditions must exist to justify the expanded access of an unapproved investigational drug, biologic, or device:

- The patient has a life-threatening or serious disease or condition;
- There is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition; and
- Potential patient benefit justifies the potential risks of the investigational device.
- Patient taking the investigational medical product will not affect the investigational trials (drugs/biologics only).

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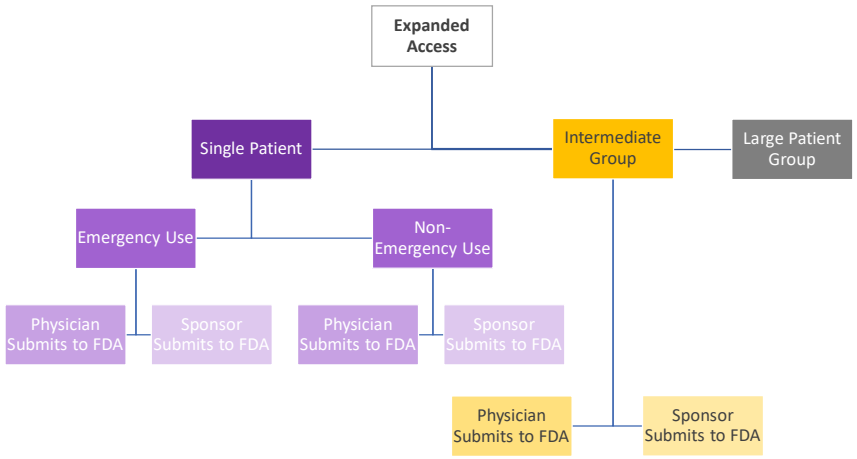
Types of Expanded Access for Drugs & Biologics



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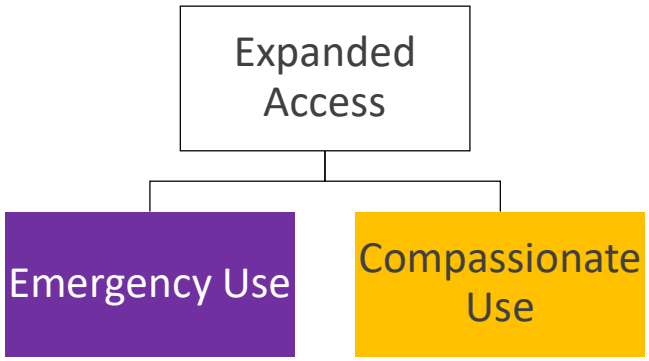
Types of Expanded Access for Devices



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Submitting a EUTA

Expanded Access Categories

Use of an Unapproved Drug or Biologic:

- Emergency Use for a Single Patient
- Non-Emergency Use for an Individual Patient
- Non-Emergency Use for an Intermediate-Size Patient Group

Use of an Unapproved Medical Device:

- Emergency Use for a Single Patient
- Compassionate Use for a Single Patient

All requests for expanded access should be submitted via Kuali; select Expanded Access to a Test Article as the protocol type.

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Resources

- Guidance on Expanded Access to Test Articles
- FDA Introduction to Expanded Access
- EXPANDED ACCESS TO TEST ARTICLES website link: https://www.lsuhsc.edu/administration/academic/ors/irb/expanded_access.aspx

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Save the Date!

Date	Time	Topic
06/07/2023	12:00PM	Non-Human Subjects Research Determinations
07/05/2023	12:00PM	Reliance

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