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.
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.*

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).
Types of Expanded Access for Drugs & Biologics

- Expanded Access
  - Single Patient
    - Emergency Use
      - Physician Submits to FDA
      - Sponsor Submits to FDA
  - Non-Emergency Use
    - Physician Submits to FDA
    - Sponsor Submits to FDA
  - Intermediate Group
    - Physician Submits to FDA
    - Sponsor Submits to FDA
  - Large Patient Group

Types of Expanded Access for Devices

- Expanded Access
  - Emergency Use
  - Compassionate Use
**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.lsuhs.edu/administration/academic/ors/irb/expanded_access.aspx](https://www.lsuhs.edu/administration/academic/ors/irb/expanded_access.aspx)
## Save the Date!

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