LSU Health NEW ORLEANS

Human Research Protection Program

Institutional Review Board (IRB) Researcher Education Series

EXPANDED ACCESS TO A TEST ARTICLE

LSU Health NEW ORLEANS
Human Research Protection Program

What is Expanded Access?

Expanded Access allows a physician to use an investigational drug, biologic, or device to treat a patient who does not have a comparable alternative therapy or who has exhausted all options to treat their disease or condition.

The intent of expanded access is treatment, not research

LSU Health NEW ORLEANS
Human Research Protection Program

Expanded Access Categories

<u>DRUGS & BIOLOGICS</u>

Emergency Use of Drugs or Biologics

Single Patient Only

Non-Emergency Use of Drugs or Biologics

Single Patient or Intermediate Group

<u>DEVICES</u>

Emergency Use of a Device

Single Patient Only

Compassionate Use of a Device

Single Patient Only

LSU Health NEW ORLEANS
Human Research Protection Program

Expanded Access: Drugs & Biologics

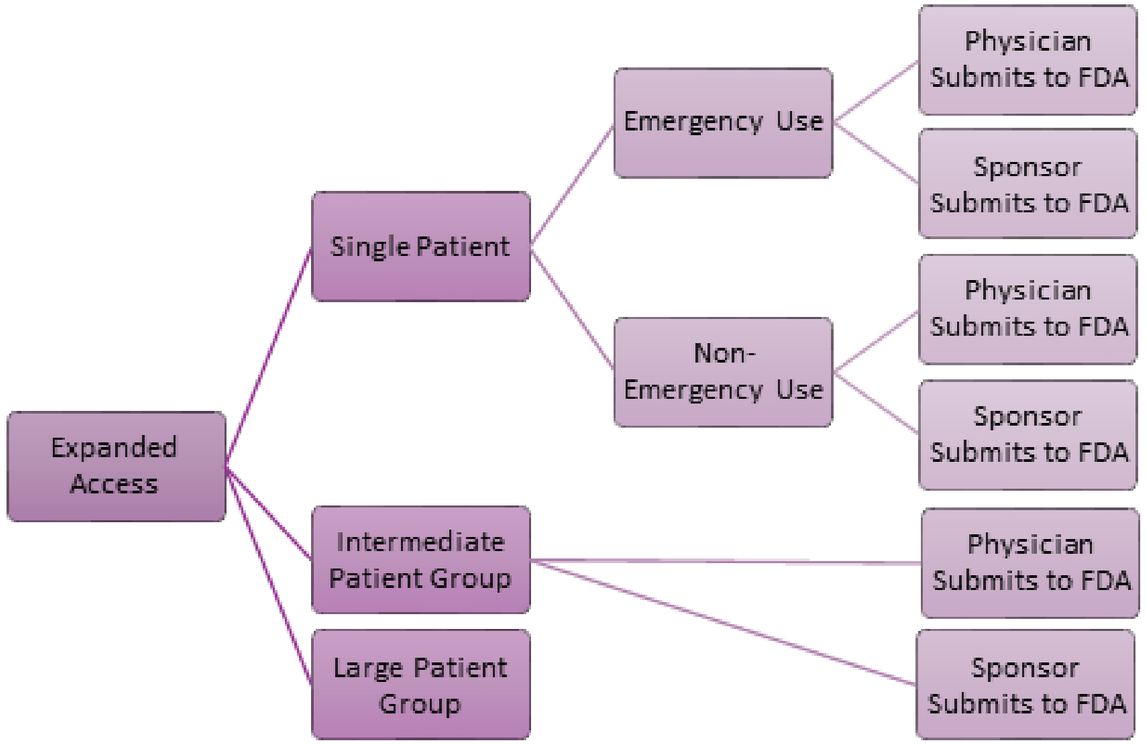
Expanded access allows for the use of unapproved drugs and biologics outside of a clinical trial for patients with serious diseases or conditions when there is no satisfactory alternative therapy to treat the patient's disease or condition.

Criteria as determined by the FDA:

1. Patient must have a serious or immediately life-threatening disease or condition for which there is no comparable alternative
2. Patient must be unable to participate in a clinical trial for the investigational product
3. Potential benefits must justify potential risks of the treatment use and those potential risks are not unreasonable in the context of the disease or condition being treated
4. Providing the investigational drug for the requested use will not interfere with the initiation, conduct, or completion of clinical investigations that could support marketing approval of the expanded access use or otherwise compromise the potential development of the expanded access us

LSU Health NEW ORLEANS
Human Research Protection Program

Types of Expanded Access: Drugs & Biologics



LSU Health NEW ORLEANS
Human Research Protection Program

Emergency Use of Drug or Biologic

1. Obtain Letter of Authorization/Approval from Medical Developer/Manufacturer/Sponsor
2. Notify the IRB, if time permits, by submitting Expanded Access to a Test Article (EATA) application in Kuali
3. Physician or Sponsor requests Emergency Use Authorization from the FDA
4. Obtain Informed Consent or Independent Physician Certification
5. If authorized, proceed with treatment
6. Notify or follow-up with the IRB using the EATA application in Kuali
7. Physician or Sponsor will submit appropriate documentation to FDA within 15 business days
8. Physician or Sponsor submits follow-up reports to FDA, as necessary

Emergency use of a drug or biologic is only allowed for single patient use.

If you intend to use the drug or biologic again, a Full Board application must be submitted.

LSU Health NEW ORLEANS
Human Research Protection Program

Non-Emergency Use of Drug or Biologic

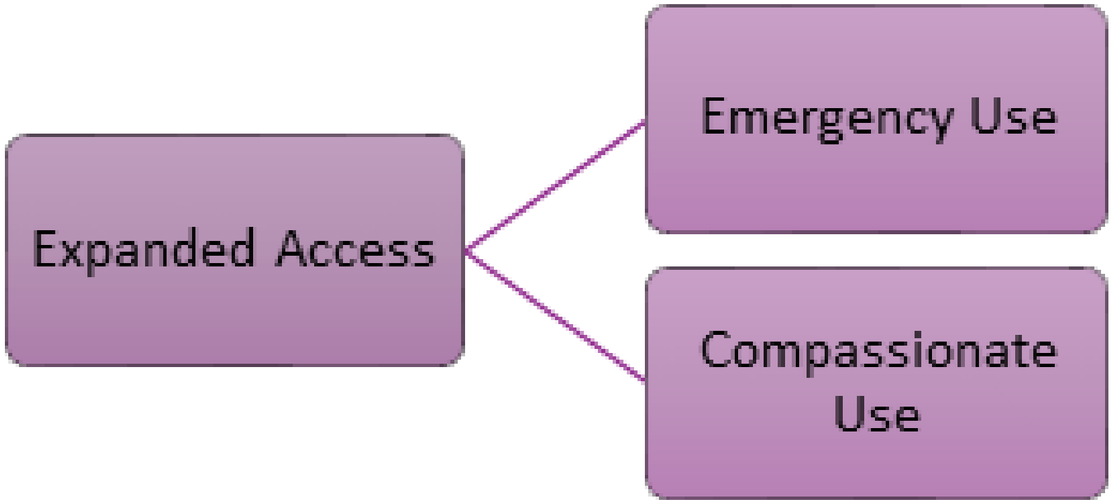
1. Obtain Letter of Authorization/Approval from Medical Developer/Manufacturer/Sponsor
2. Physician or Sponsor requests Non-Emergency Use Authorization from the FDA
3. Submit an EATA application in Kuali to obtain IRB approval or concurrence from the Chair/Designated Member (must have approval or concurrence prior to use)
4. Obtain Informed Consent
5. If authorized, proceed with treatment
6. Follow-up with the IRB using the EATA application in Kuali
7. Physician submits follow-up reports to FDA or Sponsor

Non-Emergency use of a drug or biologic is allowed for a single-patient or an intermediate-size group. An intermediate-size group is considered a small group of people receiving the treatment at the same either in the same hospital or at various hospitals.

If you intend to use the drug or device again, a Full Board application must be submitted.

LSU Health NEW ORLEANS
Human Research Protection Program

Types of Expanded Access: Devices



LSU Health NEW ORLEANS
Human Research Protection Program

Expanded Access: Emergency Use of Device

Normally, an unapproved medical device is only used on Human Subjects through an approved clinical trial that a subject qualifies for and the device is only used in accordance with the approved protocol. However, under the following circumstances, a physician may use an unapproved device to save the life of a patient or to help a patient suffering from a serious disease or condition for which there no other alternative therapy exists:

- An IDE for the device does not exist; or,
- Physician wants to use device in a way not approved under the IDE; or,
- Physician is not an investigator under the IDE.

<u>Criteria for Emergency Use of a Device:</u>

1. Patient must have a serious or immediately life-threatening disease or condition, for which there is no comparable alternative, that needs immediate treatment
2. Physician has substantial reason to believe that benefits exist
3. Because of the immediate need to use the device, there is no time to obtain FDA approval

LSU Health NEW ORLEANS
Human Research Protection Program

Emergency Use of Device

1. Obtain Letter of Authorization/Approval from Medical Developer/Manufacturer/Sponsor
2. Notify the IRB, if time permits, by submitting Expanded Access to a Test Article (EATA) application in Kuali
3. Obtain an independent Physician Assessment
4. Obtain Informed Consent or Independent Physician Certification
5. Notify or follow-up with the IRB using the EATA application in Kuali within 5 business days
6. Physician notifies the FDA or Sponsor of use

Emergency use of a device is only allowed for single patient use.

If you intend to use the device again, a Full Board application must be submitted.

LSU Health NEW ORLEANS
Human Research Protection Program

Expanded Access: Compassionate Use of Device

The Compassionate Use provision provides access to an investigational device for patients who are not eligible for the clinical trial when treating physician believes the device may provide a benefit in treating and/or diagnosing their disease or condition. It may be used only during the clinical trial for which the device is being tested.

Criteria for Compassionate Use of a Device:

1. Patient must have a serious disease or condition that the device is intended to treat or diagnose
2. There is no comparable device or therapy available

LSU Health NEW ORLEANS
Human Research Protection Program

Compassionate Use of Device

1. Obtain Letter of Authorization/Approval from Medical Developer/Manufacturer/Sponsor. *If the developer does not agree to the compassionate use, the Physician cannot move forward.*
2. Developer submits IDE Supplement to FDA
3. Physician devises a Patient Monitoring Schedule
4. Submit an EATA application in Kuali to obtain concurrence from the Chair/Designated Member. *Physician must have concurrence prior to use.*
5. Obtain Independent Physician Assessment
6. Obtain Informed Consent
7. Proceed with Treatment
8. Follow-up with the IRB and report any problems using the EATA application in Kuali within 5 business days
9. Physician notifies Sponsor of use

Compassionate use of a device is only allowed for single patient use.

If you intend to use the device again, a Full Board application must be submitted.

LSU Health NEW ORLEANS
Human Research Protection Program

Resources

GUIDANCE:
HRP-2601 Expanded Access to a Test Article
https://www.lsuhsc.edu/administration/academic/ors/tables_databases.aspx

TEMPLATES:
HRP-2257 Emergency Use of a Test Article Consent Template
HRP-2257CH Emergency Use of a Test Article Joint Consent Template (LSUHSC/CHNOLA)
HRP-2257.1 Non-Emergency or Compassionate Use of a Test Article Consent Template
HRP-2301 Independent Physician Certification: Emergency Use of a Test Article without Consent
HRP-2302 Independent Physician Certification: Emergency or Compassionate Use of an Unapproved Device
HRP-2303 Treating Physician Certification: Emergency Use of an Unapproved Device without Prior Independent Physician Assessment
https://www.lsuhsc.edu/administration/academic/ors/forms_templates.aspx

FDA Videos: *https://www.fda.gov/drugs/information-health-care-professionals-drugs/expanded-access-part-1-introduction-may-2019*