Expanded Access Application Quick Guidance for Investigational Device

Does my patient fit EAP Criteria?

My patient(s) has a life-threating **or** serious disease **or** condition requiring immediate use

No

Yes

My patient(s) has no comparable **or** satisfactory alternative therapy to diagnose, monitor or treat the disease or condition

Yes

No

Potential patient benefit justifies the potential risks of the investigational device

Yes

Yes

Your patient (s) fits Expanded Access Criteria according to FDA regulations

Consultation

Schedule a free one-on-one consultation to get started with your EAP application to FDA today!

EA IDE maybe not eligible for your circumstances. Contact RSO

Expanded Access Programs

What?

Expanded Access (EA) is a program in which the FDA allows a qualified physician to access investigational medical products to treat patient(s) who has a serious condition, have exhausted standard of care therapies and be ineligible for a clinical trial

Why?

Required by FDA Regulation
21 CFR 812.35(a)(2), 812.36
21 CFR 812.150(a)(4)

***Failure to comply may result in termination of IDE, Warning Letters, Disqualifications/ Restrictions/ Debarments (posted on FDA website), Criminal prosecutions, prison, fines.**

Types?

- **Emergency Use (single patient)**
- **Compassionate Use (single Patient)**
- **Compassionate Use (small group)**
- **Treatment Use**

How?

Emergency Use (single patient)

- Physician contacts product manufacture & obtain agreement to provide product
- Physician obtains informed consent & begin treatment*
- Physician notifies IRB & files written request to FDA retrospectively
- Physician closes or withdraws IDE

Compassionate Use (single Patient)

- Physician contacts Regulatory Support Office — Book a one-on-one consultation today!
- Physician contacts product manufacture and obtain agreement to provide product
- Sponsor/ physician submits IDE supplement Per 21 CFR 812.150(a)4
- Sponsor/ Physician submits New IDE
- Sponsor/ physician obtains IRB Chair Concurrence
- Physician obtains informed consent after IRB & begin treatment
- Sponsor/physician submits follow-up report, progress reports, final reports, adverse events (AE) to FDA and IRB (submit AEs)

*FDA does not need to be notified prior to the emergency use of a device when a patient meets the criteria for emergency use

At a GLANCE

Use EA Application Template

FDA Review Phase
30 days for Response for non-emergency EA

Sponsor will be notified the date FDA receives original application

Possible Responses
Approval of treatment IDEs
Disapproval or withdrawal of approval of treatment IDEs

Contents of an IDE Supplement to FDA requesting approval of compassionate use

Description of patient's condition circumstances necessitating treatment	☐
Discussion of reasons why alternative therapies are unsatisfactory	☐
Discussion of why probable risk of using investigational device is no greater than probable risk from disease or condition	☐
Describing any deviations in the approved clinical protocol that may be needed to treat the patient	☐
The patient protection measures that will be followed: **1. Draft of the informed consent to be used** **2. Concurrence by the IRB chairperson** **3. Independent assessment by uninvolved physician** **4. Authorization from device manufacturer on the use of the device**	☐

Requirement for Compassionate Use Follow-up Report

- Must be submitted within 45 days of device use
- Must include summary of patient outcome
- Must report Unanticipated Adverse Device Effect

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