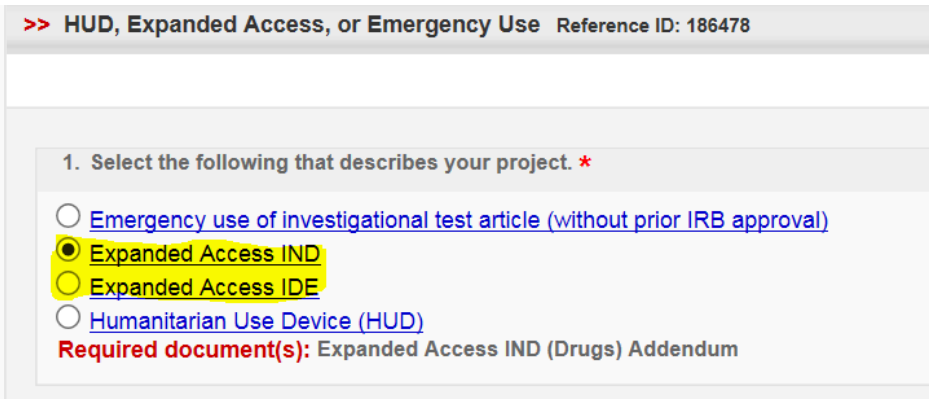
How to complete an Expanded Access Drug or Device Application

Expanded access provides a pathway for patients to gain access to investigational drugs, biologics and medical devices for serious diseases or conditions. The purpose is not research but treatment for a patient or patients with an unapproved drug or device. Although it is not research the FDA requires review and approval by a convened IRB. Expanded Access includes **compassionate use, treatment, single subject, etc IND or IDEs.**

1. Create a "New Study"
2. The "Project Title" should say "Expanded Access...".
3. Screening questions: Answer "No" to #1.
    - Answer "Yes" to #1.A.
4. NHSR Activities:
    - Select "Expanded Access IND" for drugs
    - Select "Expanded Access IDE" for devices



5. Required Attachments:
    - Complete the Expanded Access Drug OR Expanded Access Device Addendum, found here, and upload to the attachments section of the online application.
    - Other required documents are listed in the addendum.
    - Informed Consent Templates are generated by the IRBIS or available for use.
6. Cover memo: Please use the cover memo to identify your submission as a request for Expanded Access Use of a Drug or Device.

References:

- http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm351261.pdf
- http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm051345.htm

For more information, please call the IRB office at 919-966-3113.

Version date: April 20, 2017