WHAT'S NEW: Updated Questions and Answers

Expanded Access for Treatment - Frequently Asked Questions

This Frequently Asked Questions (FAQ) document has been created to provide operational guidance on Expanded Access for Treatment, and guidance for informed consent when PPE is in place for droplet, contact or airborne precautions.

Q1. What is Expanded Access for Treatment of a test article? Is it the same as a clinical trial/study of a test article?

A1. There are three types of Expanded Access:

- For individual patients, including Single Emergency Use
- For intermediate-size patient populations
- For wide-spread use

The main distinction between Expanded Access and the 'usual' clinical trial/study of an investigational drug under an IND is that Expanded Access is not primarily intended to obtain information about the safety or effectiveness of a drug. However, these uses are still considered investigational, and, there are activities in each type of expanded access that requires involvement of the Institutional Review Board (IRB).

Single Emergency Use

Single Emergency Use of a test article does NOT require prospective review and approval by the IRB because it is an emergency use of a test article. Informed consent by the patient is required, as is FDA authorization, but it is not necessary to wait for IRB approval to begin treatment. Also, the treating physician is required by regulation to report the emergent single use to the IRB within five (5) working days of first administration of the test article. The physician must also submit to the IRB the outcome of use. If there are any adverse events, these must be reported to the IRB and the FDA.
**Expanded Access – Intermediate and Wide-spread Use**

Intermediate Use and Wide-spread Use Expanded Access requires prospective review and approval by the IRB before treatment with the investigational drug begins. Wide-spread Use Expanded Access typically has a protocol with an informed consent; both documents are to be reviewed (along with all other documents provided by the sponsor) and approved by the IRB before treatment may begin.

**Q2. What form needs to be completed for Single Emergency Use of a test article?**

A2. Single Emergency Use of a test article activities in Trinity Health is overseen by the St. Joseph Mercy Health System (SJMLS) IRB No. 1, as Trinity Health IRB of Record, especially those Single Emergency Use activities during the COVID-19 public health emergency. Complete the SJMLS IRB No. 1 permission form https://www.stjoeshealth.org/assets/documents/irb/sjlms-emergency-use-permission-fillable-word.doc (the PERMISSION form) must be completed and filed with the SJMLS IRB No. 1 within five (5) working days of first administration of the test article.

**Q3. How is Informed Consent obtained for Single Emergency Use when the patient is unable to consent and there is either no Legally Authorized Representative (LAR) / Healthcare Power of Attorney (HPOA) or the LAR/HPOA is unable to consent?**

A3. FDA regulations permit emergency use of a test article without informed consent by the patient or LAR/HPOA. In this instance, the signing of the informed consent is waived and replaced by the PERMISSION FOR EMERGENCY USE OF TEST ARTICLE form that asks for the following:

- **The exception from Informed Consent Requirements** in the FDA regulations permit emergency use of an investigational drug or biologic without informed consent where the investigator and an independent physician, who is not otherwise participating in the clinical investigation, to certify in writing:
  
  a. The patient is confronted by a life-threatening or severely debilitating situation, necessitating the use of an investigational drug or biologic;
  
  b. Informed consent cannot be obtained from the patient (because the patient cannot communicate or is incompetent to give consent);
  
  c. Time is not sufficient to obtain consent from the patient’s legally authorized representative; **AND**
  
  d. No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the patient’s life.

- Physician completes the form and submits it to the IRB for acknowledgment.
- Scan the completed original PERMISSION form into the designated location of the electronic medical record (usually where consents are filed).
- File the original PERMISSION form with the other documents collected for the emergent use.
- The treating physician and the IRB of record retains a copy of the emergent use records and the consent.

**Q4. Our ministry has a patient who is being treated with an investigational drug under Single Emergency Use; what is the best way to file the PERMISSION form with IRB No. 1?**

A4. Submit a copy of the completed PERMISSION form to: aasjirbsubmissions@stjoeshealth.org.

**Q5. How do I obtain signed informed consent from a hospitalized patient who is in isolation when a COVID-19 infection control policy prevents us from entering the patient’s room to collect a traditional handwritten signed informed consent form?**

Q6. Who is responsible for managing the data and reporting back to the FDA regarding the EIND?

A6. The physician who submitted the Expanded Access IND or EIND is responsible for managing the data and reporting to the FDA and the IRB of record regarding the status of the patient and report any serious adverse events that occurred during treatment.

Per FDA Guidance *Individual Patient Expanded Access Applications: Form FDA 3926* (October 2017), “Under individual patient expanded access INDs, the physician who submits an IND is considered a sponsor-investigator (as defined in § 312.3) and is responsible for complying with the responsibilities for both sponsors and investigators to the extent they are applicable to the Expanded Access use, including submitting IND safety reports and annual reports and maintaining adequate drug disposition records. The responsibilities of sponsors and investigators are described in subpart D of 21 CFR part 312 and in related guidance documents, for example, in the guidance for industry *Investigator Responsibilities—Protecting the Rights, Safety, and Welfare of Study Subjects.*"

References and Other Materials:

21 CFR 312 Subpart I — *Expanded Access to Investigational Drugs for Treatment Use*

Expanded Access: [https://www.fda.gov/news-events/public-health-focus/expanded-access](https://www.fda.gov/news-events/public-health-focus/expanded-access)

How to submit Expanded Access forms (all types): [https://www.fda.gov/news-events/expanded-access/expanded-access-how-submit-request-forms](https://www.fda.gov/news-events/expanded-access/expanded-access-how-submit-request-forms)


SJMHS IRB Policy & Procedure *Expanded Access to investigational Drugs and Biologics and Off-Label Use* [https://saml.policymedical.net/policymed/anonymous/docViewer?stoken=f1e162db-50b4-4a1e-a457-797ef23c7500&dtoken=8037a83b-c714-48e8-8ae2-d8096beebbb2](https://saml.policymedical.net/policymed/anonymous/docViewer?stoken=f1e162db-50b4-4a1e-a457-797ef23c7500&dtoken=8037a83b-c714-48e8-8ae2-d8096beebbb2)

SJMHS IRB No. 1 *PERMISSION FOR EMERGENCY USE OF TEST ARTICLE* form [https://www.stjoeshealth.org/assets/documents/irb/sjmhs-emergency-use-permission-fillable-word.doc](https://www.stjoeshealth.org/assets/documents/irb/sjmhs-emergency-use-permission-fillable-word.doc)