Trinity Health

**Frequently Asked Questions**
**Expanded Access For Treatment Programs of a Test Article**

This Frequently Asked Questions (FAQ) document has been created to provide operational guidance on Expanded Access for Treatment Programs of a test article. This FAQ supports the recommended workflow and informed consent originally posted on March 18 – 19, 2020 (and subsequent updates) for the test article remdesivir (Gilead Sciences).

**Q1. The patient who is to receive remdesivir is in a negative-pressure isolation room. The paper informed consent, once in the room, cannot be taken out of the room. If we follow the patient verbal informed consent process, that requires 2 colleagues to gown/mask up and enter the room (1 to explain and discuss the informed consent, 1 to witness the verbal consent). What logistical / operational recommendations do you have to deliver the informed consent?**

A1. Follow your ministry's normal work instructions for garnering verbal consent as well as the guidance provided in the Collection of Patient Verbal Consent (3/19/20) http://www.trinity-health.org/workfiles/collection-of-patient-verbal-consent.pdf available on COVID-19 Pulse (http://www.trinity-health.org/covid19-pulse) to ensure colleague safety and conservation of supplies.

A. **Verbal Consent with Legally Authorized Representative (LAR) Process** (The patient is unable to give consent and his/her LAR is not able to be physically present in the hospital. This option does not require entering the patient's room.)

    a. **Phone Call with the LAR.**
        i. Physician calls and discusses the informed consent with the LAR. The witness is also on the phone call as a participant.
        ii. LAR verbally gives consent.
        iii. The physician and the witness sign and date the consent with the statement VERBAL CONSENT OBTAINED FROM LAR written on the consent.
        i. Document in the EMR 'Verbal consent obtained' with the names of the physician and witness, time, and date stamp.
        ii. Place (scan) the original signed and dated consent in the EMR.

B. **Emergency Use of Test Article for a Life-Threatening Situation / Exception from Informed Consent Requirements Process** (The patient is unable to consent; the LAR is unavailable to consent; **and** the patient's condition requires immediate intervention. This option does not require entering the patient's room.)

    a. In this instance, the signing of the informed consent is waived and replaced by the ***PERMISSION FOR EMERGENCY USE OF TEST ARTICLE*** form. Complete the form; see Q2 for more information.
    b. FDA regulations permit emergency use of a test article without informed consent by the patient or LAR. Refer to the SJMHS IRB policy/procedure



Sponsored by Catholic Health Ministries | 20555 Victor Parkway • Livonia, MI 48152 • 734-343-1000 • trinity-health.org

"Expanded Access to investigational Drugs and Biologics and Off-Label Use" for further information. https://saml.policymedical.net/policymed/anonymous/docViewer?stoken=f1e162db-50b4-4a1e-a457-797ef23c7500&dtoken=8037a83b-c714-48e8-8ae2-d8096bebebb2

C. **Verbal Consent Process** (The patient is able to give consent.)
   a. Physician enters the room during the normal course of clinical care and*, if allowed per ministry work instructions for negative-pressure isolation rooms,* brings a paper copy of the informed consent to the patient.
   b. Physician discusses the consent with the patient and answers all questions.
   c. Patient gives verbal consent.
   d. Paper copy of the informed consent remains in the room until it can be properly disposed of per ministry work instructions for disposal of used items in a negative-pressure isolation room.
   e. Physician departs room.
   f. On a copy of the consent at the nurses' station:
      i. The physician signs and date the consent with the statement VERBAL CONSENT OBTAINED written on the consent.
      ii. Original signed and dated consent is placed in the medical record.
      iii. Document in the EMR 'Verbal consent obtained' with the physician name, time and date stamp.
      iv. Place (scan) the original signed and dated consent in the EMR.

**Q2. Is Expanded Access of a test article considered research? There are instructions in the recommended workflow about having to report to the IRB, which makes this confusing.**

A2. There are three types of Expanded Access, as described in 21 CFR 312 Subpart I—*Expanded Access to Investigational Drugs for Treatment Use* and FDA Guidance *Expanded Access to Investigational Drugs for Treatment Use—Questions and Answers* (October 2017):

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

**Single Emergency Use**

Single Emergency Use of a test article is NOT considered research, meaning it is NOT a clinical trial/study that must be reviewed and approved prospectively by the IRB. However, the regulations require the physician report the emergent single use to the IRB within five (5) working days of first administration of the test article.

For Single Emergency Use the 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 (the ***PERMISSION*** form) must be completed and filed with the SJMHS IRB No. 1 within five (5) working days of first administration of the test article.

**Expanded Access – Intermediate and Wide-spread Use**

The physician treating a patient with an investigational drug under expanded access is responsible for obtaining IRB review and approval (by a convened IRB meeting) ***before*** treatment with the investigational drug may begin.

This FAQ will be updated once Gilead has garnered FDA approval for either Intermediate and Wide-spread Use.

**Q3. Our ministry has a patient who is being treated with remdesivir under Single Emergency Use; what is the best way to file the *PERMISSION* form with IRB No. 1?**

A3. Each completed, signed and dated ***PERMISSION*** form is to be placed in the EMR, with a copy submitted to: aasjirbsubmissions@stjoeshealth.org

The lead pharmacist may also submit a weekly summary report to IRB No. 1 listing the patients, dosage, adverse events, outcomes, etc. to: aasjirbsubmissions@stjoeshealth.org

**Q4. Who is responsible for managing the data and reporting back to the FDA regarding the EIND?**

A4. The physician who submits the IND is responsible for managing the data and reporting back to the FDA regarding the EIND.

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*."

For more information about FDA's IND safety reporting requirements, see FDA Guidance *Safety Reporting Requirements for INDs and BA/BE Studies* (December 2012).

For more information about how to submit Expanded Access forms (all types): https://www.fda.gov/news-events/expanded-access/expanded-access-how-submit-request-forms