



GUIDANCE FOR LICENSED PHYSICIANS:

Request for Emergency Individual Patient IND Expanded Access Submissions for patients located at CHNOLA

Emergency IND: The Emergency Use of an unapproved Investigational Drug, Agent, or Biologic Products requires an emergency IND. The FDA has established mechanisms and guidance for obtaining an Emergency IND for the use of Investigational Drugs or Biologic Products.

Action	Descriptions and Further Information
1 Request Letter of Authorization (LOA)	<ul style="list-style-type: none">Request a Letter of Authorization (LOA) from the medical product developer.The LOA is typically from the regulatory affairs official of the industry (company). FDA may be able to help identify the contact.If a LOA is not available, submit sufficient information with the FDA Form 3926 for FDA to assure the product's quality.
2 Request FDA Emergency Use Authorization	<ul style="list-style-type: none">Contact the appropriate FDA review division or organization by telephone (or other rapid means of communication).Investigational drugs: 301-796-3400 or druginfo@fda.hhs.gov [CDER's Division of Drug Information]Oncology drugs: 240-402-0004 or ONCProjectFacilitate@fda.hhs.govInvestigational medical devices: 301-796-7100 or DICE@fda.hhs.gov [CDRH's Division of Industry and Consumer Education]Investigational biologics: 240-402-8020 or 800-835-4709 or industry.biologics@fda.hhs.gov [CBER's Office of Communication, Outreach and Development]



3	Obtain Informed Consent	<ul style="list-style-type: none"> Obtain Informed Consent from patient or their legally authorized representative per 21 CFR Part 50. Use a written consent form approved by the IRB. These are located on the CHNOLA Research SharePoint https://lcmchealth.sharepoint.com/Childrens/Research/SitePages/Dept%20-%20Documents.aspx <i>Note: Informed Consent may be obtained prior to requesting FDA emergency use authorization. Industry sponsors may have an approved consent form that can be modified and utilized in emergency cases. If an approved IRB form is not available, and if the patient (or patient agent) is capable of providing informed consent and does not meet the requirements of the exception found in 21 CFR 50.23(a)-(c), then informed consent should be obtained as a patient protective measure and the requirements at 21 CFR 50 should be used as guidelines. Informed consent must be documented in the EMR either (1) uploading of the consent form (2) documentation of required elements of consent according to 21 CFR 50.</i>
4	If authorized by FDA, begin treatment	<ul style="list-style-type: none"> Authorization of the emergency use may be given by an FDA official by telephone (or other means of rapid communication). The investigational drug or biologic may be shipped and treatment of the patient may begin immediately upon FDA emergency use authorization.
5	Notify IRB (Within 5 business days of eIND use)*	<ul style="list-style-type: none"> Tulane Physicians – Log into IRBManager. At the TOP LEFT under “ACTIONS” click “Click to begin the Emergency Use Notification Form.” Complete and submit this form. **** LSUHSC Physicians – Log into Kuali and complete the Emergency Use of a Test Article (EUTA) application. Attach the correspondence from the FDA, letter of authorization from the sponsor (if applicable), and FDA-issued IND number (Contact the IRB staff directly if there is insufficient time to complete a Kuali application). For a detailed SOP of the LSUHSC process of reviewing/approving of an eIND, please visit https://www.lsuhs.edu/administration/academic/ors/irb_sops.aspx.



		<ul style="list-style-type: none"> Send IND number email from the FDA and acknowledgement email from local IRB to CHResearch@LCMCHealth.org. Please also copy Robert.Uddo@lcmchealth.org and Stacy.Drury@lcmchealth.org to have EPIC study account created and link the patient to the study.
6	Submit Form FDA 3926** within 15 business days of FDA emergency use authorization	<ul style="list-style-type: none"> Within 15 business days of FDA emergency use authorization, submit Form FDA 3926 (along with the LOA) to FDA. Instructions for filling out Form FDA 3926 are available online.
7	File Follow-up Report(s)	<ul style="list-style-type: none"> Submit Form FDA 3926 to FDA via mail. For other submission options, contact FDA.

**In an emergency, where there is not sufficient time to secure IRB review prior to beginning treatment, the emergency use of the investigational drug must be reported to the IRB within 5 working days, as required under 21 CFR 56.104(c).*

***FDA Form 3926 is developed specifically for these requests and is easier to complete.*

**** If more than one eIND per institution per medication/biologic is expected a protocol, consent form and IRB submission should be pursued as soon as possible after the first eIND due to FDA requirements*

Important Contacts to assist with eIND issues:

Stacy Drury	Chief Research Officer	Stacy.drury@lcmchealth.org	(504)988-1438
Robert Uddo	Clinical Trials Manager	Robert.uddo@lcmchealth.org	(504)896-2779
Leslie Smitley	Tulane Clinical Trials Manager	lsmitley@tulane.edu	(504)988-9380
Tulane IRB	Tulane IRB	IRBmain@tulane.edu	(504)988-2665
LSUHSC-NO IRB	LSUHSC-NO IRB	IRBoffice@lsuhsc.edu	(504)568-4970
CHNOLA IRB	Emily Moran	CHResearch@lcmchealth.org	(504)896-9401



How to Submit Follow up Report: Submit Individual Patient Expanded Access Applications by mail:

Investigational Drugs:	Food and Drug Administration Center for Drug Evaluation and Research Central Document Room ATTN: [appropriate Review Division] "EXPANDED ACCESS SUBMISSION" 5901-B Ammendale Rd. Beltsville, Md. 20705-1266
Investigational Biologics	Food and Drug Administration Center for Biologics Evaluation and Research Document Control Center 10903 New Hampshire Avenue Bldg. 71, Rm. G112 Silver Spring, MD 20993-0002
For other submission options	contact FDA

******Tulane specific information for the Emergency Use Notification form in IRBManager:**

1. Enter PI name, department, and status (tenure track, etc.)
2. Click- "Other Tulane University Affiliated Site" from location dropdown
3. Local address: enter 200 Henry Clay, NOLA 70118
4. Enter other information: manufacturer/source of medication/biologic, location of supplier of medication/biologic, whether sponsor will receive information, drug/biologic name, chemical formula, route of delivery, FDA eIND letter, investigational brochure, informed consent form, sign form and submit through IRBManager



Follow-up Expanded Access Reports

Submit follow-up reports using the same form as the original expanded access request, either **Form FDA 3926** or **Form FDA 1571**

Action	Timeframe	Descriptions and Further Information
Safety Reports	As soon as possible but in no case later than 15 calendar days	<p>Report unexpected fatal or life-threatening suspected adverse reactions to FDA as soon as possible but in no case later than 7 calendar days after the sponsor's initial receipt of the information.</p> <p>Report serious and unexpected suspected adverse reactions to FDA as soon as possible but in no case later than 15 calendar days after determining that the information qualifies for reporting.</p> <p>Review the Guidance for Industry and Investigators: Safety Reporting Requirements for INDs and BA/BE Studies.</p>
Amendments	Any time	Submit protocol and information amendments to FDA for any changes to the initial Expanded Access IND submission.
Summary	Following completion of treatment	For individual patients, when treatment is complete, submit a summary of expanded access use.
Annual Report	Within 60 days of the anniversary date	<p>For Expanded Access INDs, submit an annual report within 60 days of the anniversary date that the IND went into effect.</p> <p>The Annual Report is not required if treatment was completed and FDA was notified before one year passed.</p>