LOYOLA UNIVERSITY HEALTH SYSTEM

LOYOLA UNIVERSITY CHICAGO

INSTRUCTIONS and NOTIFICATION:
Single Patient IND, including Emergency Use, Drug and Biologic

PURPOSE

1. Guidance document to assist physicians through procedures required by the FDA, LUC and LUMC for a Single Patient IND, including emergency use. This document is supplemental to SOP PRO-019.
2. Notification Document for CRO/ CCTO/ IRB

INSTRUCTIONS

- Follow the steps outlined below. Many of them can be done concurrently.
- The form itself is at the end of this document. Please complete and send to the CRO (Non-Cancer Related Investigational agents) or CCTO (Cancer related investigational agents).

STEP 1. Evaluate whether the use meets the FDA criteria for a single patient emergency use.

All of the following criteria must apply.

☐ The patient has a **serious or immediately life-threatening disease or condition**. 21 CFR 312.305(a)(1)

Immediately life-threatening: Means a stage of disease in which there is reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment. 21 CFR 312.300(b)

Serious disease or condition: Means a disease or condition associated with morbidity that has substantial impact on day-to-day functioning. Short lived and self-limited morbidity will usually not be sufficient, but the morbidity need not be irreversible, provided it is persistent or recurrent. Whether a disease or condition is serious is a matter of clinical judgement, based on its impact on such factors as survival, day-to-day function, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one. 21 CFR 312.300(b)

☐ There is **no comparable or satisfactory alternative** therapy. 21 CFR 312.305(a)(1)

☐ The **potential patient benefit** justifies the potential risk of the use and those potential risks are not unreasonable in the context of the disease or the condition. 21 CFR 312.310(a)(1)

☐ The **probable risk to the patient** from the investigational item is not greater than the probable risk from the disease or the condition. 21 CFR 312.310(a)(1)

☐ The emergency use **will not interfere with the initiation, conduct, or completion of any clinical investigations** of the item that could support marketing approval of expanded access to the item or otherwise compromise the potential development of expanded access use of the item. 21 CFR 312.305(a)(3)

☐ There is not sufficient time to obtain IRB review and approval of the use. 21 CFR 56.102(d), 21 CFR 56.104(c)

Not sufficient time: The FDA does not define this term.

☐ The use of the drug or biologic is not already available to the physician through an ongoing clinical investigation at Loyola University Medical Center.

STEP 2. Obtain authorization from the Manufacturer and the FDA.

FDA authorization must be obtained before the use can occur.

Contact the manufacturer (or other source of the item) to determine whether the investigational item can be made available for the emergency use.

- Request permission to use the drug or biologic under the emergency use mechanism;
- Determine whether the manufacturer has an existing IND (Investigational New Drug approval) that they will allow to be amended or referenced for this emergency use.
    - If YES, ask whether they are willing to submit the amendment to the FDA or whether they want you (the physician) to prepare and submit the amendment to the FDA. If they want you to submit the amendment, ask them for permission to refer to the existing IND documents. To summarize:
        - The IND holder is willing to submit the amendment to the FDA, or
        - The IND holder wants you (the physician) to submit the amendment to the FDA.
    - If NO, you will need to submit an application to the FDA for an Emergency IND. Ask the manufacturer for permission to refer to the manufacturer's IND and supporting documents.
- You will need to arrange for shipping of the drug or biologic to LUMC Investigational Drug Pharmacist- see Step 3
- Determine if the manufacturer requires a letter from the IRB before entertaining your request or shipping the item.,

FDA Instructions on applying for an Emergency IND:
http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm107434.htm

Contact information for the FDA:

	FDA Office/Division	Phone	Email
Drug	Division of Drug Information	301-796-3400 888-463-6332	druginfo@fda.hhs.gov
Biological blood products	Office of Blood Research and Review	301-827-3518	
Biological vaccine products	Office of Vaccines Research	301-827-3070	
General biologics	CBER, Office of Communication, Outreach & Development	301-827-4081	ocod@fda.hhs.gov
After working hours	Office of Crisis Management & Emergency Operations	301-796-8240 866-300-4374	Emergency.operations@fda.hhs.gov

STEP 3. Coordinate with Investigational Drug Pharmacist.

Contact LUMC Investigational Drug Pharmacist as soon as possible to inform them of the planned use and shipment of the drug or biologic. Do not wait until you have obtained authorization from the FDA and/or the manufacturer. Provide the following information:

- Name of the drug or biologic.
- The source from which you are obtaining it (for example, the drug company's name).
- Drug Shipment contacts
- Any information regarding administration, preparation instructions, and dispensing instructions (dose, route, frequency, etc.).
- Estimated date and time of use.

The pharmacist will process the electronic record for the BEACON treatment plan for Oncology drugs and Therapy Plans for non- oncologic drugs.
LUMC Investigational Pharmacy Service: 708-216-6225 bmuneer@lumc.edu
You must comply with Investigational product policies and procedures regarding receipt, storage, and dispensing of the item SOP

STEP 4. Institutional Clearance: determine the financial arrangements.

Follow LUMC Financial counseling/Pre-authorization processes to determine who will be responsible for paying for the drug or biologic and any associated procedures, monitoring, and follow-up (including after the drug or biologic has been used).

STEP 5. Institutional Clearance: independent concurrence for use.

Emergency use without prior IRB approval.

Obtain concurrence by the Institutional Review Board (IRB) chairperson or by a designated IRB member, before the treatment use begins, in order to comply with FDA's requirements for IRB review and approval. This concurrence would be in lieu of review and approval at a convened IRB meeting at which a majority of the members are present.

STEP 6. Informed Consent

The FDA's informed consent requirements for emergency use are described here. If you will be able to obtain consent, begin the consent process as soon as possible by discussing the situation with the patient and/or patient's legal representative, even if you don't yet have a consent form ready.

- The consent form is not the same as a standard clinical consent form.
- The FDA requires the consent process to include all of the standard elements of a research consent. The LUC **TEMPLATE: Consent for Emergency or Single Patient Use** meets this requirement.

In order of preference:

- Whenever possible, obtain consent from the patient or the patient's legally authorized representative.
  You must complete and use the **TEMPLATE: Consent for Emergency or Compassionate Use**. Retain a copy to send to the IRB after the emergency use, and place a copy in the patient's medical record.
  If it is not possible to obtain consent, the emergency use may still proceed if the treating physician and an independent physician agree that all of the following four conditions apply (21 CFR 50.23.(a)):
  1. The patient is confronted by a life-threatening situation necessitating the use of the investigational drug or biologic.
  2. Informed consent cannot be obtained from the patient because of an inability to communicate with, or obtain legally effective consent from, the patient.
  3. Time is insufficient to obtain consent from the patient's legal representative.
  4. There is no available alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the patient.

STEP 7. Notification of the FDA.

This is an FDA requirement. If the manufacturer submitted an amendment to the FDA or obtained the emergency IND, you should provide the report to the manufacturer, who will then report to the FDA. Otherwise, you report directly to the FDA (see contact information in the table in Step 2).

The report must contain:

- A summary of the conditions constituting the emergency.
- Patient outcome and results, including any adverse effects.
- Patient protection measures that were followed, which might include:
  - Obtaining informed consent from the patient or a legal representative;
  - Involvement of Investigational Drug Services;
  - Authorization from the manufacturer;
  - An independent assessment from a physician (the Medical Director or designee) who is not conducting any research using the drug/biologic.

Outcome information is not considered to be research data and may not be used, presented, or published as research.

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STEP 9. Notification of the IRB.

This is an FDA requirement.
Complete the form below and send to the IRB within 5 business days after the use.

In addition to completing and submitting this form, consider the probability of possible future use of the investigational drug or biologic at LUMC. If likely, you should initiate efforts to obtain IRB approval and FDA approval for those future uses.

Physician Information

Treating Physician's (your) Name (first, last):	Department or Division:	

Phone number(s):	Email address(es):

Investigational Drug/Biologic Information

Name of the drug/biologic:	IND #:	Manufacturer:

Use of the Drug/Biologic

Facility in which the drug/biologic was used:	Date and time the investigational drug/biologic was used:		Patient Age:
	Date:	Time:	Description of dosing (# of doses, route, duration, etc.)

Submit this form to the following Research Offices to assist with internal reviews and approvals.

Cancer Clinical Trials Office: (Cancer Related Investigational Agents): Ceil Petrowsky RN MSN cpetrow@luc.edu 708-327-3306

Clinical Research Office: (Non-Cancer Related Investigational Agents): Jessica Shore RN PhD jshore@luc.edu 708- 216-2027

Printed Name_____ Signature_____

Date_____

Your physician's signature_____ Date_____

For IRB Use Only

I have reviewed this Notification and (if necessary) obtained additional information from the physician. In my opinion, this emergency use:

Met the FDA requirements for emergency use

Did not meet the FDA requirements for emergency use

IRB Chair Name	IRB Chair Signature	Date