CHRISTUS Health Process for Single Patient Emergency Use Submission

Emergency Individual Patient IND Expanded Access Submissions by a Licensed Physician [21 CFR 312.310]

	Action	Descriptions and Further Information
1.	**Request Letter of Authorization (LOA)**	• 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 (or 1571) for FDA to assure the product's quality. • Letter of Authorization template.
2.	**Request FDA Emergency Use Authorization**	• Contact the appropriate FDA review division or organization by telephone (or other rapid means of communication).
3.	**Obtain Informed Consent**	• Obtain Informed Consent from patient or their legally authorized representative per 21 CFR Part 50. • Use a written consent form approved by the IRB. • *Note: Informed Consent may be obtained prior to requesting FDA emergency use authorization.*
4.	**If authorized by FDA, begin treatment**	• 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 treatment initiation, notify the IRB. • Database for Registered IRB's.
6.	**Submit Form FDA 3926** within 15 business days of FDA emergency use authorization**	• Within 15 business days of FDA emergency use authorization, submit Form FDA 3926 (along with the LOA) to FDA via mail. For other submission options, contact FDA. • Instructions for filling out Form FDA 3926 are available online. Guidance Documents: • Individual Patient Expanded Access Applications: Form FDA 3926 • Expanded Access to Investigational Drugs for Treatment Use—Questions and Answers Other Resources: • Expanded Access Categories for Drugs (Including Biologics)
7.	**File Follow-up Report(s)**	• 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).*

***Physicians will still be able to use FDA Forms 1571 "Investigational New Drug Application (IND)" and Form 1572 "Statement of Investigator" for single patient expanded access submissions; however, Form 3926 is developed specifically for these requests and is easier to complete.*

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If there is time to submit for IRB review before the patient receives treatment, the following process should occur:

Please request an iRIS account at https://christus.imedris.net for each physician that will administer this drug.

Upon the creation of iRIS account(s) for the Physicians, the submission process can commence. To submit, the physician or other staff member will log into iRIS. From the user's iRIS home page:

- Select "Add a new study".
- Select "Research application" and select the appropriate application. (Please answer all applicable questions)

The submission should include:

- Protocol
- Informed Consent (signed and dated) by subject or legally authorized representative
- FDA Form 1571 "Investigational New Drug Application (IND)" and Form 1572 "Statement of Investigator" or Form 3926 "Individual Patient Expanded Access" (signed and dated)
- Letter of Authorization from the medical product developer
- Letter to FDA requesting Compassionate Use
- Expanded Access/Individual Patient IND Cover Letter (FDA) Approval correspondence from the FDA
- Investigators Brochure
- Letter from another Physician or CMO concurring with the PI's plan of treatment
- Curriculum Vitae/Resume (signed and dated)
- Medical Licenses, if applicable
- Any other relevant documents listed in the table for completion of the submission

If you have any questions please contact:

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