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| **Instructions** | | |
| * Complete this template when the submission involves expanded access to the use of investigational new drug(s). * Complete this template in addition to the HRP-513 - Template - External IRB Request, HRP-503 - Template – Protocol, or HRP-508 - Template - Site Supplement to Sponsor Protocol. * Click™ IRB:   + Include the template with a New Study Submission.   + Upload completed template to the Basic Information SmartForm page, Question 10. | | |
| **Complete Questions 1 – 6.** | | |
| 1 | Study title. | |
| 2 | Investigator name. | |
| *NOTE: A licensed physician under whose immediate direction an investigational drug is administered or dispensed for an expanded access use under this subpart is considered an investigator , for purposes of this part, and must comply with the responsibilities for investigators set forth in subpart D of this 21 CFR 312 to the extent they are applicable to the expanded access use.* | |
| 3 | Sponsor name. | |
| *NOTE: There are additional requirements if this is a sponsor-investigator. A licensed physician under whose immediate direction an investigational drug is administered or dispensed, and who submits an IND for expanded access use under this subpart is considered a sponsor-investigator , for purposes of this part, and must comply with the responsibilities for sponsors and investigators set forth in subpart D of this part to the extent they are applicable to the expanded access use.* | |
| 3 | Select type of expanded access:  Individual patient, including emergency use  Intermediate-size patient populations.  Treatment IND or treatment protocol | |
| 4 | Reason for expanded access. | |
| *Examples include:*   * *The drug is not being developed, for example, because the disease or condition is so rare that the sponsor is unable to recruit patients for a clinical trial.* * *The drug is being studied in a clinical trial, but patients requesting the drug for expanded access use are unable to participate in the trial.* * *The drug is an approved drug product that is no longer marketed for safety reasons or is unavailable through marketing due to failure to meet the conditions of the approved application.* * *The drug contains the same active moiety as an approved drug product that is unavailable through marketing due to failure to meet the conditions of the approved application or a drug shortage.* | |
| 4 | Sponsor has submitted the expanded access request to the FDA. | No  Yes |
| If yes, complete 4A, 4B, 4C, 4D, and 4E. |  |
| If no, please explain. | |
| 4A | An expanded access submission has been submitted as a:  New IND  Protocol amendment to an existing IND | |
| 4B | IND#: | |
| 4C | Who holds the IND? | |
| 4D | Is the expanded access in effect? | No  Yes |
| 4E | Is the expanded access subject to a clinical hold? | No  Yes |
| 5 | The investigator confirms that they accept expanded access responsibilities (check boxes to indicate confirmation):  Reporting adverse drug events to the sponsor.  Ensuring that the informed consent requirements of part 50 of this chapter are met.  Ensuring that IRB review of the expanded access use is obtained in a manner consistent with the requirements of part 56 of this chapter.  Maintaining accurate case histories and drug disposition records and retaining records in a manner consistent with the requirements of 312.62.  Depending on the type of expanded access, other investigator responsibilities under subpart D may also apply. | |
| 6 | Upload to the SmartForm:   * FDA determination or letter (if received) (Supporting Documents SmartForm page) | |