

Expanded Access Template Document

Physician Training

This email template can be used to train a physician using an investigational drug under expanded access on the roles and responsibilities of being a sponsor-investigator.



Dear Physician,

This email will fulfill the sponsor-investigator training requirement for physicians holding an expanded access IND. Please read the following email in its entirety and reply to this email to indicate that you have read and understand the materials.

Under [21 CFR 312.305\(c\)](#), the individual or entity that submits an expanded access IND is considered a sponsor and the physician under whose immediate direction an investigational drug is administered is considered an investigator. A physician serving in both roles is considered a sponsor-investigator by the FDA and is responsible for complying with the regulatory requirements for both sponsors and investigators to the extent they are applicable to the expanded access use. The responsibilities of sponsors and investigators are described in Title 21 of the Code of Federal Regulations Part 312 [Subpart D](#) and in related FDA guidance documents.

The following are requirements for physicians fulfilling the role of a sponsor-investigator of an expanded access IND:

- Protect the rights, safety, and welfare of patients.
- Ensure that the treatment follows the treatment plan or protocol and all applicable regulations. Adequate and accurate case histories of the observations of patients should be maintained.
- Safety Reporting: Promptly inform FDA in a written IND Safety Report of serious, unexpected adverse events that are related to the investigational drug within 15 calendar days after receipt of information. If fatal or life threatening – notify FDA (via phone or fax) as soon as possible but no later than 7 calendar days after receipt of information. If follow-up information is received, this must be submitted in a Follow-Up to a Written IND Safety Report, within 15 calendar days. Additionally, safety reports should be sent to the Institutional Review Board (IRB) overseeing the expanded access use.
- Annual Reporting: A brief report must be submitted within 60 days of the anniversary date of the IND each year that the IND is in effect. The content of an annual report should include the content described in [21 CFR 312.33](#). An annual report is not required if treatment was completed and FDA was notified before one year passed.
- Changes in Treatment Plan/Protocol: If a change to the treatment plan or protocol is needed, a submission describing the change should be submitted to the FDA prior to implementation.
- Maintain control of the investigational drug and administer only to patients authorized to receive it. Records must be kept of the disposition of the drug such as the dates, quantity, and use by patients. Any unused supply must be returned to the manufacturer or disposed of

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according to the manufacturer's instructions. An investigational pharmacy may assist with this responsibility.

- Maintain accountability records of the investigational drug including shipment, receipt, and inventory. An investigational pharmacy can assist with receipt, preparation of the drug, and accountability records, but these are ultimately the responsibility of the sponsor-investigator.

Individual Patient Expanded Access:

- Summary of Expanded Access Use (treatment completed): For individual patient expanded access, the sponsor must provide to FDA a written summary of the expanded access use, including any adverse events, at the conclusion of treatment.

Form FDA 3926 may be used for certain follow-up submissions to an individual patient IND, including the Initial Written IND Safety Report; Follow-up to a Written IND Safety Report; Annual Report; Summary of Expanded Access Use (treatment completed); Change in Treatment Plan; General Correspondence or Response to FDA Request for Information; and Response to Clinical Hold.

In addition to the FDA requirements for sponsor-investigators, the physician must also comply with IRB requirements. These include, ensuring IRB review and approval of the treatment as well as changes to the treatment plan prior to implementation, obtaining the patient's informed consent, and reporting serious and unanticipated adverse events that are related to the study drug to the IRB. Check local policies for IRB timelines on reporting.