

Expanded Access Template Document

Individual Patient Expanded Access IND Annual Report

Template should be utilized to meet the requirement to submit annual reports to FDA under an effective IND for an individual patient.



Note: This page should be sent on University or Department letterhead.

[Date]

Food and Drug Administration
Center for Drug Evaluation and Research
[Specify applicable CDER Review Division]
Central Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

RE: **IND [XXXXXX], Serial [YYYY]**
IND Annual Report

To Whom It May Concern:

Please find enclosed the annual report for expanded access IND [XXXXXX]. *[Provide a brief summary of the patient here, if applicable and/or any pending questions].*

If there are any questions regarding this submission, please contact me or *[second contact]* at *[second contact phone number]* or at *[second contact email address]*. *[Second Contact]* can act on my behalf on any issue relating to this IND.

Sincerely,

[Physician name]
[Relevant title]
[Relevant department]
[Clinic or institution physical address]
[Physician phone number]
[Physician e-mail address]

Cc: *[if you have listed anyone above as an additional contact, include full contact information here]*

Expanded Access Template Document

Individual Patient Expanded Access IND Annual Report

Template should be utilized to meet the requirement to submit annual reports to FDA under an effective IND for an individual patient.



IND [xxxxxx]

Serial [yyyy]: Annual Report

Reporting Period: [mm dd yyyy] to [mm dd yyyy]

[Date]

[Name of Sponsor Investigator]

[X Professor, Department]

[University of XXX]

Confidential

Expanded Access Template Document

Individual Patient Expanded Access IND Annual Report

Template should be utilized to meet the requirement to submit annual reports to FDA under an effective IND for an individual patient.



1. Study Information

Please include a brief summary of the status of the patient treatment plan. Specify which 12 months are covered by your report such as “the reporting period for this submission is from June 1, 2010 to May 31, 2011.”

General Note: Maintain all headings throughout this document. If a particular section doesn't apply to your IND – state so!

Expanded Access Title: [IRB APPROVED TITLE]

Expanded Access Identifiers: [IRB Approved Protocol Number]

Expanded Access Treatment: [DRUG (GENERIC NAME) DOSAGE]

Expanded Access Purpose: This is an Expanded Access protocol to provide [DRUG] to [ONE] patient to treat [CONDITION].

Enrollment Update

[ONE] patient has been enrolled for Expanded Access treatment of [CONDITION]. The first treatment date was [DATE]. [Please include demographic information for this patient, including ethnic category, racial category, and age range, as feasible, along with the status of the patient (ex still on drug)].

Brief Description of Results

[Please provide a clinical update on the patient].

2. Summary Information

Serious Adverse Events

No adverse events have been reported by the patient during this reporting period. No patient deaths or dropouts due to adverse experiences have occurred during this reporting period.

[If serious AEs have been reported, please note those here and below in the table, as applicable.]

TABLES CAN BE DELETED AS APPROPRIATE.

Table X: Summary of the serious adverse experiences by system organ class

Body System	N (total)
Blood and lymphatic system disorders	0
Cardiac disorders	0
Congenital, familial and genetic disorders	0
Ear and labyrinth disorders	0

Expanded Access Template Document

Individual Patient Expanded Access IND Annual Report

Template should be utilized to meet the requirement to submit annual reports to FDA under an effective IND for an individual patient.



Body System	N (total)
Endocrine disorders	0
Eye disorders	0
Gastrointestinal disorders	0
General disorders and administration site conditions	0
Hepatobiliary disorders	0
Immune system disorders	0
Infections and infestations	0
Injury, poisoning and procedural complications	0
Investigations	0
Metabolism and nutrition disorders	0
Musculoskeletal and connective tissue disorders	0
Neoplasms benign, malignant and unspecified (including cysts and polyps)	0
Nervous system disorders	0
Pregnancy, puerperium and perinatal conditions	0
Psychiatric disorders	0
Renal and urinary disorders	0
Reproductive system and breast disorders	0
Respiratory, thoracic and mediastinal disorders	0
Skin and subcutaneous tissue disorders	0
Social circumstances	0
Surgical and medical procedures	0
Vascular disorders	0

Summary of IND Safety Reports

No IND safety reports have been submitted during this reporting period.

3. Overall Treatment Plan

Please provide an update on the treatment plan for the patient. See examples below.

The patient will continue to receive treatment with [DRUG] at this dosage [DOSAGE] until [SHE/HE] no longer benefits or until she can no longer tolerate it.

OR [UPDATED TREATMENT PLAN]

4. Investigator Brochure

If the investigator's brochure has been revised, a description of the revision and a copy of the new brochure. In this case, this section applies to commercial sponsors – just state:

Not Applicable

Expanded Access Template Document

Individual Patient Expanded Access IND Annual Report

Template should be utilized to meet the requirement to submit annual reports to FDA under an effective IND for an individual patient.



5. Treatment Plan Amendments

[Please note if there have been any treatment plan changes for this patient that were not yet submitted to the FDA and IND. Since these should be submitted in real time, ideally, a statement can be made indicating that there are no amendments or new changes during this reporting period.]

6. Foreign Marketing Developments

[A brief summary of significant foreign marketing developments with the drug during the past year, such as approval of marketing in any country or withdrawal or suspension from marketing in any country.] This section applies to commercial sponsors therefore likely just state:

Not Applicable

7. Outstanding Regulatory Business

[If true, please note that "There is no outstanding regulatory business for this IND." If there are any pending questions for the Agency, they can be noted here.]