

## Expanded Access Template Document

### *Individual Patient Summary of Expanded Access and IND Withdrawal Cover Letter*

*This template should be used as the cover letter in support of an IND amendment/submission to provide a summary of expanded access use as well as request IND withdrawal to the FDA.*



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

*[Date]*

Food and Drug Administration

*[FDA Review Center]*

*[FDA Review Division]*

*[Address Line 1]*

*[Address Line 2]*

Attn: *[Name of FDA Division Director and Credentials]*  
*[Title/Appointment, Name of Division]*

RE: Summary of Expanded Access Use; Request for IND Withdrawal  
IND XXXXXX, Serial 00XX

Dear *[Name of FDA Division Director]*:

I am writing to provide a summary of expanded access use for IND XXXXXX and a request to withdraw the IND since treatment is complete. The IRB has been notified and remaining drug has been properly disposed.

*Please also include a paragraph with the following information in this letter:*

- Reason for conclusion of patient treatment and IND withdrawal*
- Duration of treatment and summary of results*
- Adverse effects (must be included)*
- Synopsis of treatment final outcome (survived, discharged to other care facility, died)*
- Disposition of any remaining drug*

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]*