

## Expanded Access Template Document

### Letter of Authorization (LOA)

The template allows the FDA to cross-reference an existing investigational new drug (IND) application in support of an individual patient expanded access request.



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: Letter of Authorization for Expanded Access Use [name of drug] [IND number]

Dear [Name of director for FDA Division that will be reviewing the single patient IND]:

This letter authorizes the Food and Drug Administration to cross-reference IND [IND number] for [drug or biologic name] in support of the following individual patient expanded access use.

Investigator Information:

[Physician name]

[Relevant title]

[Clinic or institution physical address]

[Physician phone number]

[Physician e-mail address]

Protocol Title: [protocol title]

As indicated by my signature below, I am authorized to provide this LOA on behalf of [Company name or Institution name] and my full name, title, address, email address, telephone number, and facsimile number are set out below for verification.

If you have any questions, please contact me at [Physician phone number].

Sincerely,

[Physician name]

[Relevant title]

[Relevant department]

[Clinic or institution physical address]

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*[Physician phone number]*

*[Physician e-mail address]*

DRAFT