

IEC approval letter Template

To

Dr.

Dear Dr. _____

The Institutional ethics committee or independent ethics committee (state name of the committee, as appropriate)

reviewed and discussed your application to conduct the clinical trial entitled "....." on.....(date).

The following documents were reviewed:

- a. Trial protocol (including protocol amendments), dated.....version No.(s)
- b. Patient information sheet and informed consent form (including updates, if any) in English or vernacular language version..... And..... date
- c. Investigator's brochure, dated, Version no..... Proposed methods for patient accrual including advertisements etc. proposed to be used for the purpose.
- d. Principal investigator's current Curriculum Vitae.
- e. Insurance policy or compensation for participation and for serious adverse events occurring during the study participation.
- f. Investigator's agreement with the sponsor.
- g. Investigator's undertaking
- h. Clinical trial agreement
- i. Other documents

The following members of the ethics committee were present at the meeting held on (date, time, place).

.....Chairperson of the ethics committee;

..... Member-Secretary of the ethics committee;

..... Name of each member with designation;

Conflict of Interest:

Approval Period: ONE Year

IEC SOP 08: Initial Review Procedures

IEC Decision

- a. Approved – with or without suggestions or comments;
- b. Revision with minor modifications/amendments
- c. Revision with major modifications for resubmission
- d. Disapproved

The ethics committee to be informed about the progress of the study, any Serious Adverse Events (SAE) occurring in the course of the study, any changes in the protocol and patient information or informed consent and to be provided.

Progress of the study periodically [Biannual* and Annual report]

During the course of this investigation, any significant deviations from the approved protocol and/or serious adverse events should immediately be brought to the attention of the Ethics Committee

Submit the continuing letter at least 2 months prior to the end of -the approval period

Yours sincerely,

Member Secretary, Ethics Committee

IEC Decision Letter format

IEC Protocol Code:

Protocol Title:		
Protocol Version and Date:		
Name of the investigator:		
Name of affiliation/Department:		
Status of Review Process		
New Review	<input type="text"/>	Revised Review <input type="text"/> Expedite Review <input type="text"/>
Date of IEC Meeting:		
Venue:		
Decision on the Protocol:		
e. Approved – with or without suggestions or comments;	<input type="text"/>	
f. Revision with minor modifications/amendments	<input type="text"/>	
g. Revision with major modifications for resubmission	<input type="text"/>	
h. Disapproved	<input type="text"/>	
Any suggestion or remarks:		
Approved for the period of _____		

You are requested to report to the Ethics Committee the following:

- › Progress of the study periodically [Biannual* and Annual report]
- › During the course of this investigation, any significant deviations from the approved protocol and/or serious adverse events should immediately be brought to the attention of the Ethics Committee.
- › Submit the continuing letter at least 2 months prior to the end of -the approval period

Signature of Member Secretary