

I'm not robot  reCAPTCHA

Open

Annex I: Clinical trial Application Form

REQUEST FOR AUTHORISATION OF A CLINICAL TRIAL ON A MEDICINAL PRODUCT FOR HUMAN USE TO THE COMPETENT AUTHORITIES AND FOR OPINION OF THE ETHICS COMMITTEES IN THE COMMUNITY

For official use:

Date of receiving the request:	Date of request for additional information:	Grounds for non acceptance/ negative opinion: <input type="checkbox"/>
Date of request for information to make it valid:		Give date:
Date of valid application:	Date of receipt of additional / amended information:	Authorisation/ positive opinion: <input type="checkbox"/>
Date of start of procedure:		Give date:
Competent authority registration number:		Withdrawal of application <input type="checkbox"/>
Ethics Committee registration number:		Give date:

To be filled in by the applicant:

The questions in this form for the request for authorisation from the Competent Authority are also relevant for the opinion from an Ethics Committee (it represents module 1 of the form for applying to an ethics committee) and can be used as part of that application. Please indicate the relevant purpose in a box below.

REQUEST FOR AUTHORISATION TO THE COMPETENT AUTHORITY:
 REQUEST FOR OPINION OF THE ETHICS COMMITTEE:

A TRIAL IDENTIFICATION

A.1	Member State in which the submission is being made:
A.2	EudraCT number
A.3	Full title of the trial:
A.3.1	Title of the trial for lay people, in easily understood, i.e. non-technical, language:
A.3.2	Name or abbreviated title of the trial where available:
A.4	Sponsor's protocol code number, version, and date ¹ :
A.5	Additional international study identifiers (e.g. WHO, ISRCTN ² , US NCT Number ³) if available
A.6	Is this a resubmission? <input type="checkbox"/> yes <input type="checkbox"/> no
A.7	If yes, indicate the resubmission letter ⁴ <input type="checkbox"/> yes <input type="checkbox"/> no
A.8	Is the trial part of a Paediatric Investigation Plan? <input type="checkbox"/> yes <input type="checkbox"/> no
A.8	EMA Decision number of Paediatric Investigation Plan

¹ Any translation of the protocol should be assigned the same date and version as those in the original document.
² International Standard Randomised Controlled Trial Number. Sponsors may wish to use an International Standardised Random Controlled Trial Number (ISRCTN) to identify their trial in addition to the EudraCT number; for instance if their trial is part of a multinational trial with sites outside the Community. They can obtain the number and guidance from the Current Controlled Trials website <http://www.controlled-trials.com/isrctn> to which there is a link from the EudraCT database website <http://eudract.ema.europa.eu/>. When available they should provide it in Section A.5 of the application form.
³ US National Clinical Trial (NCT) Numbers required on the FDA clinical trial application form.
⁴ For a resubmission following previous withdrawal of an application or unfavourable opinion of an ethics committee, or previous withdrawal of an application or refusal of a request by the competent authority, enter a letter in the sequence, A for first resubmission, B for second, C for third et seq.

ANNEXURE -II

FORM B

* Form of affidavit to be made on a non-judicial stamp paper of Rs. 100/- (Rupees One Hundred Only.) before a Notary or an Executive Magistrate or a Metropolitan Magistrate by the Father / Mother / Guardian of the candidate who has not yet completed 18 years of age.

AFFIDAVIT

I, _____ an Indian inhabitant,
 residing at _____

Father / Mother / Guardian of Mr./ Ms. _____
 aged _____ years and _____ months and Indian inhabitant,
 residing at _____

do hereby solemnly affirm and say that I and my son / daughter / ward belong to the Jain Gujarati Religious Linguistic Minority which is a Religious cum-Linguistic minority in the State of Maharashtra.

Solemnly affirmed at _____ this _____ day of _____, 2012.

 (Signature of Father / Mother / Guardian * of the candidate)

Identified by _____ before me.

* Relationship with the Candidate : _____

ANNEXURE -I

FORM A

Form of affidavit to be made on a non-judicial stamp paper of Rs. 100/- (Rupees: One Hundred Only.) before a Notary or an Executive Magistrate or a Metropolitan Magistrate by the candidate, who has completed 18 years of age.

AFFIDAVIT

I, _____ an Indian inhabitant aged _____ years residing at _____

Son / Daughter of Mr. _____
 An Indian inhabitant residing at _____

do hereby solemnly affirm and say that I belong to the Jain Gujarati Religious Linguistic Minority Community which is a Religious cum-Linguistic minority in the State of Maharashtra.

Solemnly affirmed at _____ this _____ day of _____, 2012.

 (Signature of Candidate)

Identified by _____ Before me.

