

JJM Medical College, Davangere, Karnataka

**Model form to be filled by the Principal Investigator (PI) for
submission to Institutional Ethics Committee (IEC)
(for attachment to each copy of the proposal)**

Serial No of IEC Management Office:
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Proposal Title:

	Name, Designation & Qualifications	Address Tel & Fax Nos. Email ID	Signature
PI			
Co-PI / Collaborators			
1.			
2.			
3.			
Please attach detailed Curriculum Vitae of all Investigators (with subject specific publications limited to previous 5 years).			

Tick appropriately

Sponsor Information :			
1. Indian	a) Government	<input type="checkbox"/>	Central <input type="checkbox"/> State <input type="checkbox"/> Institutional <input type="checkbox"/>
	b) Private	<input type="checkbox"/>	
2. International	Government	<input type="checkbox"/>	Private <input type="checkbox"/> UN agencies <input type="checkbox"/>
3. Industry	National	<input type="checkbox"/>	Multinational <input type="checkbox"/>

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ii.	Duration of study :			
iii.	Will subjects from both sexes be recruited	Yes	No	
iv.	Inclusion / exclusion criteria given	Yes	No	
v.	Type of subjects	Volunteers <input type="checkbox"/>	Patients <input type="checkbox"/>	
vi.	Vulnerable subjects (Tick the appropriate boxes)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
	pregnant women <input type="checkbox"/>	children <input type="checkbox"/>	elderly <input type="checkbox"/>	
	fetus <input type="checkbox"/>	illiterate <input type="checkbox"/>	handicapped <input type="checkbox"/>	
	terminally ill <input type="checkbox"/>	seriously ill <input type="checkbox"/>	mentally challenged <input type="checkbox"/>	
	economically & socially backward <input type="checkbox"/>	any other <input type="checkbox"/>		
vii.	Special group subjects (Tick the appropriate boxes)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
	captives <input type="checkbox"/>	institutionalized <input type="checkbox"/>	employees <input type="checkbox"/>	
	students <input type="checkbox"/>	nurses/dependent <input type="checkbox"/>	armed <input type="checkbox"/>	
	any other <input type="checkbox"/>	staff <input type="checkbox"/>	forces <input type="checkbox"/>	
6. Privacy and confidentiality				
i.	Study involves -	Direct Identifiers		<input type="checkbox"/>
		Indirect Identifiers/coded		<input type="checkbox"/>
		Completely anonymised/ delinked		<input type="checkbox"/>
ii.	Confidential handling of data by staff	Yes	No	
7. Use of biological/ hazardous materials		Yes	No	
i.	Use of fetal tissue or abortus			
ii.	Use of organs or body fluids	Yes	No	
iii.	Use of recombinant/gene therapy	Yes	No	
	If yes, has Department of Biotechnology (DBT) approval for rDNA products been obtained?	Yes	No	
iv.	Use of pre-existing/stored/left over samples	Yes	No	
v.	Collection for banking/future research	Yes	No	
vi.	Use of ionising radiation/radioisotopes	Yes	No	
	If yes, has Bhaba Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained?	Yes	No	
vii.	Use of Infectious/biohazardous specimens	Yes	No	
viii.	Proper disposal of material	Yes	No	
ix.	Will any sample collected from the patients be sent abroad ?	Yes	No	
If Yes, justify with details of collaborators				

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ii. Is there a plan for reporting of adverse events ? If Yes, reporting is done to : Sponsor <input type="checkbox"/> Ethics Committee <input type="checkbox"/> DSMB <input type="checkbox"/>	Yes	No
iii. Is there a plan for interim analysis of data?	Yes	No
vi. Are there plans for storage and maintenance of all trial database? If Yes, for how long ?	Yes	No
12. Is there compensation for participation? If Yes, Monetary <input type="checkbox"/> In kind <input type="checkbox"/> Specify amount and type:	Yes	No
13. Is there compensation for injury? If Yes, by Sponsor <input type="checkbox"/> by Investigator <input type="checkbox"/> by insurance <input type="checkbox"/> by any other <input type="checkbox"/> company	Yes	No
14. Do you have conflict of interest? (financial/nonfinancial) If Yes, specify :	Yes	No
Checklist for attached documents:		
Project proposal – 20 Copies	<input type="checkbox"/>	
Curriculum Vitae of Investigators	<input type="checkbox"/>	
Brief description of proposal	<input type="checkbox"/>	
Patient information sheet	<input type="checkbox"/>	
Informed Consent form	<input type="checkbox"/>	
Investigator’s brochure for recruiting subjects	<input type="checkbox"/>	
Copy of advertisements/Information brochures	<input type="checkbox"/>	
Copy of clinical trial protocol and/or questionnaire	<input type="checkbox"/>	
Institutional Ethics Committee clearance	<input type="checkbox"/>	
Institutional Animal Ethics Committee clearance	<input type="checkbox"/>	
CPCSEA clearance, if any	<input type="checkbox"/>	
HMSC/DCGI/DBT/BARC clearance if obtained	<input type="checkbox"/>	

Place:
Date:

Signature & Designation of PI/Co-PI/Collaborator

Appendix D

Proforma for submitting protocols to the Scientific/Institutional Review Board and Institutional Ethics Committee

Kindly submit one copy of protocol and consent forms in 2 parts (in English and local language) and one copy of undertaking by the investigators to the Member Secretary

1. Title of the project:
2. Name of the investigators/co-investigators with designation & department:
 - a). Principal Investigator name
Address
Phone & e-mail
 - b).
 - c).
 - d).
3. Number of projects already with the investigators/co-investigators in hand:
4. Date of approval by Scientific/Institutional Review Board:
5. Sources of funding if any:
6. Objectives of the study:
 - a)
 - b)
 - c)
7. Justification for the conduct of the study:
8. Methodology: It should provide details of number of patients, inclusion criteria, exclusion criteria, control(s), study design, dosages of drug, duration of treatment, investigations to be done, references method of statistical analysis, questionnaire proforma etc:
9. Permission from Drug Controller General of India (DCGI) if applicable
10. Costs involved (Approximate in Rs.)
11. Whether Consent forms part in English and in local language is enclosed?
12. We, the undersigned, have read and understood this protocol and hereby agree to conduct the study in accordance with this protocol and to comply with all requirements of the guidelines given by the apex bodies.

Signature of the Investigators: 1.
2.
3.
4.

Date :

Signature of the Head of the Department

Date:

Appendix E

- 1) Signed and dated application form on prescribed format.
- 2) The protocol of the proposed research (clearly identified, numbered and dated), together with supporting documents and annexes.
- 3) A summary (as far as possible in non-technical language, synopsis, or diagrammatic representation (flowchart) of the protocol.
- 4) A description (usually included in the protocol) of the ethical considerations involved in the research.
- 5) Case report forms, diary cards and other questionnaires intended for research participants.
- 6) In case the research involves a study product (such as a pharmaceutical or device under investigation, an adequate summary of all safety, pharmacological pharmaceutical and toxicological data available on the study product, together with a summary of clinical experience with the study product to date (e.g.: recent investigator's brochure published data, a summary of the product's characteristics); (Product information)
- 7) Investigator(s) curriculum vitae (updated, signed and dated).
- 8) Material to be used (including advertisements) for the recruitment of potential research participants.
- 9) A description of the process to be used to obtain and document consent.
- 10) Written and other forms of information for potential research participants (clearly identified and dated) in the language(s) understood by the potential research participants and, when required, in other languages;
- 11) Informed consent form (clearly identified and dated) in the language(s) understood by the potential research participants and when required in other languages.
- 12) A statement describing any compensation for study participation(including expenses and access to medical care) to be given to research participants.
- 13) A description of the arrangements for indemnity, if applicable.
- 14) A description of the arrangements for insurance coverage for research participants, if applicable.
- 15) A statement of agreement to comply with ethical principles set out in relevant guidelines.
- 16) All previous IEC 's decisions(e.g., those leading to a negative decision or modified protocol) by other ECs or regulatory authorities for the proposed study(whether in the same location or elsewhere) and an indication of modification(s) to the protocol made on that account. The reasons for previous negative decisions must be provided.

Appendix F

UNDERTAKING BY ALL THE INVESTIGATORS

01. Title of the protocol :

02. We the undersigned authors of the above said protocol declare that we do not reveal the identity of the study participants, his/her personal details as well as the treating doctor if any under any circumstances.

03. We further declare that we do not have any conflict in the order of authorship that is submitted for ethical approval. If the necessity arises for change in the order of authorship, we will obtain a written consent from IEC.

Investigators name

Signature with date

1.

2.

3.

4.

5.

Appendix G (Format of approval for clinical trials)

JJMMC, DVG INSTITUTIONAL ETHICS COMMITTEE

Ref No.:- JJMMC/IEC/

Date

To,

Reference: Study Title:

Subject: Ethical Committee approval for conduct of the study-Protocol No.

Dear Dr.

The Institutional Ethics Committee reviewed and discussed your application to conduct clinical trial entitled “.....” ‘on Dated

The Following Documents were reviewed

- a) Trial Protocol No.....version no.....dated.....
- b) Patient information sheet and ICF in English, Kannada and
- c) Investigator's Brochure dated.....version no.....
- d) Proposed methods for patient accrual used for the study.
- e) Principal investigator's current CV
- f) Case Record form with serious adverse event form
- g) Investigators consent/undertaking.
- h) Investigators agreement with sponsors.
- i) Notification to DCGI.
- j) Copy of insurance

The following members of the ethics committee were present at the meeting held on

01.

02.

We approve the trial to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient consent.

You are hereby requested to submit the copy of final study report before publication/presentation.

Yours sincerely,

Member Secretary,

IEC, JJMMC

Chairperson/Vice chairperson

IEC, JJMMC

