BASAVESHWARA MEDICAL COLLEGE AND HOSPITAL,

CHITRADURGA - 577502

SYNOPSIS

RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES
BANGALORE, KARNATAKA

"TITLE OF DISSERTATION"

Name of the candidate **:** Dr.

Professor & Guide **:** Dr.,

Professor & HOD **:** Dr. .

Course and Subject **:**

DEPARTMENT OF

BASAVESHWARA MEDICAL COLLEGE AND HOSPITAL,

CHITRADURGA – 577502

2019

RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES,
BANGALORE, KARNATAKA

ANNEXURE II

PROFORMA FOR REGISTRATION OF SUBJECTS FOR DISSERTATION

1.	**NAME OF THE CANDIDATE AND ADDRESS (in block letters)**	**Dr.** .
2.	**NAME OF THE INSTITUTION**	BASAVESHWARA MEDICAL COLLEGE AND HOSPITAL, CHITRADURGA – 577502.
3.	**COURSE OF STUDY AND SUBJECT**	**MEDICAL –**
4.	**DATE OF ADMISSION TO COURSE**	
5.	**TITLE OF THE TOPIC**	**"TITLE OF THE STUDY"**

6.	**BRIEF RESUME OF THE INTENDED WORK:** **6.1 Need for the study :** **6.2 Review of literature :**

	1) **6.3 Objectives of the study**: ○
7	**MATERIALS AND METHODS** **7.1** **7.2. Method of data collection (including sampling procedure if any):** **Inclusion criteria :** **Exclusion criteria :** **7.3 Does the study require any investigations or interventions to be conducted on patients or other humans or animals? If so, please describe briefly.** **7.4 Has ethical clearance been obtained from your institution in case of 7.3?**

8.	**LIST OF REFERENCES :**

9.	**SIGNATURE OF CANDIDATE**	
10.	**REMARKS OF THE GUIDE**	
11	**NAME AND DESIGNATION OF GUIDE** **(in block letters)** **11.1SIGNATURE**	
	11.2CO- GUIDE(If Any)	
	11.3SIGNATURE	
	11.5 HEAD OF THE DEPARTMENT **11.6SIGNATURE**	
12.	**12.1 REMARKS OF THE CHAIRMAN AND PRINCIPAL** **12.2 SIGNATURE**	

BASAVESHWARA MEDICAL COLLEGE AND HOSPITAL, CHITRADURGA

DEPARTMENT OF

INFORMED CONSENT

I _____ the undersigned hereby give my consent for the investigations carried upon me. I am satisfied with the information given about this clinical study titled **"NAME OF TITLE"**being conducted by **Dr. NAME OF POST GRADUATE** under the guidance of **Dr. NAME OF GUIDE** Professor, Department of . I have been informed and explained about the risks involved in my local language and I hereby voluntarily give my consent without any fear or pressure, in a mentally sound and conscious state to participate in this study. I have been informed about the confidentiality of my records and my right to withdraw from the study at any time I choose and that I am not liable for any compensation.

PLACE:

DATE : PATIENT'S/GUARDIAN SIGNATURE

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PROFORMA

"TITLE OF THE STUDY"

From,

Dr.
Postgraduate in ,
BASAVESHWARA MEDICAL COLLEGE AND HOSPITAL,
CHITRADURGA.

To,

The Principal,
BASAVESHWARA MEDICAL COLLEGE AND HOSPITAL,
CHITRADURGA.

THROUGH PROPER CHANNEL

Respected sir,

SUBJECT:- Acceptance of registration and forwarding of dissertation topic

*****

In accordance with the above cited subject, I undersigned studying Post graduate course in (SUBJECT) have been allotted the dissertation topic **"TITLE OF THE STUDY"**under the guidance of **NAME OF GUIDE**, Professor, Department of, Basaveshwara Medical College and Hospital, Chitradurga.

I request you to kindly forward the dissertation topic in the prescribed form to the University for approval.

Thanking you,

Yours faithfully,

(Dr.)

Signature of the Guide

PROFESSOR,
DEPARTMENT OF ,
BASAVESHWARA MEDICAL COLLEGE AND HOSPITAL,
CHITRADURGA – 577502

From,

The Professor and Head of the Department,
Department Of,
BASAVESHWARA MEDICAL COLLEGE AND HOSPITAL,
CHITRADURGA.

To,

The Registrar,
Rajiv Gandhi University of Health Sciences,
Bengaluru.

THROUGH PROPER CHANNEL

Respected sir,

As per the regulations of the University of Registration of dissertation topic, the following post graduate student in M.D. Anaesthesiology has been allotted the dissertation topic as follows by the official registration committee of all qualified and eligible guides of the Department of Anaesthesiology.

NAME	TOPIC	GUIDE

Therefore, I kindly request you to communicate the acceptance of the dissertation topic allotted to the PG student at an early date.

Signature of the guide

Yours faithfully,

PROFESSOR,
DEPARTMENT OF
BASAVESHWARA MEDICAL COLLEGE
AND HOSPITAL,
CHITRADURGA – 577502.

ROFESSOR AND H.O.D,
DEPARTMENT OF
BASAVESHWARA MEDICAL COLLEGE
AND HOSPITAL,
CHITRADURGA – 577502.

Basaveshwara Medical College and Hospital, Chitradurga - 577502, 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:

Proposal Title:
"TITLE OF THE STUDY"

	Name, Designation & Qualifications	**Address Tel & Fax Nos. Email ID**	**Signature**
PI			
Co-PI **1.**			
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	☐	Central ☐	State ☐	Institutional ☐		
	b) Private	☐					
2. International	Government	☐	Private ☐	UN agencies ☐			
3. Industry	National	☐	Multinational ☐				
Contact Address of Sponsor:							
Total Budget :							

1.Type of Study :	Epidemiological	☐	Basic Sciences ☐	Animal studies ☐			
Clinical:	Single center	☐	Multicentric ☐	Behavioral ☐			

2. Status of Review: New ☐ Revised ☐

3. Clinical Trials:
Drug /Vaccines/Device/Herbal Remedies :

i. Does the study involve use of :
Drug ☐ Devices ☐ Vaccines ☐

Indian Systems of Medicine/ Alternate System of Medicine ☐ Any other ☐ NA ☐

ii. Is it approved and marketed
In India ☐ UK & Europe ☐ USA ☐

Other countries, specify ☐

iii. Does it involvea change in use, dosage, route of administration?	Yes	No
If yes, whether DCGI's /Any other Regulatory authority's Permission is obtained?	Yes	No
If yes, Date of permission :		
iv. Is it an Investigational New Drug?	Yes	No
If yes, IND No:		
a). Investigator's Brochure submitted	Yes	No
b). *In vitro* studies data	Yes	No
c). Preclinical Studies done	Yes	No
d). Clinical Study is : Phase I ☐ Phase II ☐ Phase III ☐ Phase IV ☐		
e). Are you aware if this study/similar study is being done elswhere ?	Yes	No
If Yes, attach details		

4. Brief description of the proposal – Introduction, review of literature, aim(s) & objectives, justification for study, methodology describing the potential risks & benefits, outcome measures, statistical analysis and whether it is of national significance with rationale (Attach sheet with maximum 500 words):

5. Subject selection:

i.	Number of Subjects : 80		
ii.	Duration of study : 2 years		
iii.	Will subjects from both sexes be recruited	Yes	
iv.	Inclusion / exclusion criteria given	Yes	
v.	Type of subjects Volunteers ☐	Patients ☐	

vi.	Vulnerable subjects (Tick the appropriate boxes)	Yes ☐			No ☐		
	pregnant women	☐	children	☐	elderly	☐	
	fetus	☐	illiterate	☐	handicapped	☐	
	terminally ill	☐	seriously ill	☐	mentally challenged	☐	
	economically & socially backward	☐	any other	☐			
vii.	Special group subjects (Tick the appropriate boxes)	Yes ☐			No ☐		
	captives	☐	institutionalized	☐	employees	☐	
	students	☐	nurses/dependent	☐	armed	☐	
	any other	☐	staff		forces		

6. Privacy and confidentiality

i. Study involves - Direct Identifiers ☐
Indirect Identifiers/coded ☐
Completely anonymised/ delinked ☐

ii. Confidential handling of data by staff	Yes	No
7. Use of biological/ hazardous materials i. Use of fetal tissue or abortus	Yes	No
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 ? **If Yes, justify with details of collaborators**	Yes	No
a) Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration?	Yes	No

b) Sample will be sent abroad because (Tick appropriate box):

Facility not available in India ☐
Facility in India inaccessible ☐
Facility available but not being accessed. ☐
If so, reasons…

8. Consent : *Written ☐ Oral ☐ Audio-visual ☐

i. Consent form : (tick the included elements)

Understandable language	☐	Alternatives to participation	☐
Statement that study involves research	☐	Confidentiality of records	☐
Sponsor of study	☐	Contact information	☐
Purpose and procedures	☐	Statement that consent is voluntary	☐
Risks & Discomforts	☐	Right to withdraw	☐
Benefits	☐	Consent for future use of biological material	☐
Compensation for participation	☐	Benefits if any on future commercialization eg. genetic basis for drug development	☐
Compensation for study related injury	☐		

*If written consent is not obtained, give reasons:

ii. Who will obtain consent ? PI/Co-PI ☐ Nurse/Counsellor ☐ Research staff ☐ Any other ☐

9. Will any advertising be done for recruitment of Subjects ? (posters, flyers, brochure, websites – if so kindly attach a copy)	Yes	No
10. Risks & Benefits: i. Is the risk reasonable compared to the anticipated benefits to subjects / community / country?	Yes	No
ii. Is there physical / social / psychological risk / discomfort? **If Yes,** Minimal or no risk ☐ More than minimum risk ☐ High risk ☐	Yes	No
Iii.Is there a benefit a) to the subject ? Direct ☐ Indirect ☐ b) Benefit to society ☐		
11. Data Monitoring i. Is there a data & safety monitoring committee/ Board (DSMB)?	Yes	No
ii. Is there a plan for reporting of adverse events ? **If Yes,** reporting is done to : Sponsor ☐ hics Committee D☐IB ☐	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 ☐ In kind ☐ Specify amount and type:	Yes	No

13. Is there compensation for injury? **If Yes,** by Sponsor ☐ by Investigator ☐ by insurance company ☐ by any other ☐	Yes	No
14. Do you have conflict of interest? **(financial/nonfinancial)** **If Yes, specify :**	Yes	No

Checklistforattacheddocuments:

Project proposal – 20 Copies	☐
Curriculum Vitae of Investigators	☐
Brief description of proposal	☐
Patient information sheet	☐
Informed Consent form	☐
Investigator's brochure for recruiting subjects	☐
Copy of advertisements/Information brochures	☐
Copy of clinical trial protocol and/or questionnaire	☐
Institutional Ethics Committee clearance	☐
Institutional Animal Ethics Committee clearance	☐
CPCSEA clearance, if any	☐
HMSC/DCGI/DBT/BARC clearance if obtained	☐

Place: Signature & Designation of PI/Co-PI/Collaborator

Date:

Appendix D

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

Kindly submit softcopy of protocol along with a hard copy including 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:**" TITLE OF THE STUDY"**

2. Name of the investigators/co-investigators with designation & department:
   a). Principal Investigator name:

   b).Co-Investigator Name :

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: NO

6. Objectives of the study:

   1.

7. Justification for the conduct of the study:Brief synopsis of the study enclosed.

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 – Brief synopsis of the study enclosed.

9. Permission from Drug Controller General of India (DCGI) if applicable: No

10. Costs involved (Approximate in Rs.) - Nil

11. Whether Consent forms part in English and in local language is enclosed: Yes

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. Date:

2.

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. **Dr .**

   Post Graduate in ,
   Basaveshwara Medical College and Hospital,
   Chitradurga.

   Professor,
   Depertment of ,
   Chitradurga.

Appendix G (Format of approval for clinical trials)

INSTITUTIONAL ETHICS COMMITTEE

Ref No.:- BMCH/IEC/ Date

To,

Reference: Study Title: **"TITLE OF STUDY"**

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

Dear **Dr. ,** Postgraduate in

The Institutional Ethics Committee reviewed and discussed your application to conduct clinical trial entitled **"TITLE OF THE STUDY"**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, Chairperson/Vice chairperson

IEC, BMCH IEC, BMCH