SOP

Indira Gandhi Institute of Medical Sciences, Patna-800014

RESEARCH CELL

SUBMISSION & APPROVAL OF

INTRAMURAL, EXTRAMURAL & COLLABORATIVE PROJECTS

AT IGIMS PATNA

PROCEDURE OF SUBMISSION & APPROVAL OF EXTRAMURAL/COLLABORATIVE PROJECTS

Principal investigator (PI) submits Concept proposal to funding agency (if applicable) and also informs the research cell.

After acceptance of Concept proposal by funding agency, PI submits the complete Extramural/Collaborative Project proposal along with Informed Consent Documents (in case of human studies) to Research Cell. The PI is also required to submit the filled Project information form (given below).

After receiving hard and soft copies of the documents, the Research Cell provides a Provisional Project code and forwards to Committee for review (The PI will have to make a presentation of their project before Committee).

After the Research Cell approval, Research Cell forwards the documents along with approval letter to the Institute Ethics Committee (IEC) for review.

After IEC approval, the PI provides Committee and IEC approval letters and other relevant documents and obtains permission from Head of Institute (including signing of MOU in case of collaborative projects).

Submission of project proposal to funding agency for review and approval

Following acceptance of the project, the PI provides sanction letter from funding agency to Research Cell for issuance of a Permanent Project code, and the Research Cell notifies Accounts Section for disbursement of fund.

PROCEDURE OF SUBMISSION & APPROVAL OF INTRAMURAL PROJECTS (FUNDED)

Call for intramural projects notified by Research Cell to Faculty members

Interested Faculty member (i.e. Principal Investigator [PI]) submits complete Intramural Project proposal in the prescribed format along with Informed Consent Documents (in case of human studies) to Research Cell. The PI is also required to submit the filled Project information form (given below).

After receiving hard and soft copies of the documents, the Research Cell provides a Provisional Project code and forwards to Committee for review (The PI will have to make a presentation of their project before Committee).

After the Research Cell approval, the Research cell forwards the documents along with approval letter to the Institute Ethics Committee (IEC) for review.
After IEC approval the Research Cell facilitates the short-listing of projects for institute research grant .

After IEC approval, the PI provides Committee and IEC approval letters and other relevant documents and obtains permission from Head of Institute.

After permission from Head of the institute, PI informs the Research Cell which issues a Permanent Project code and notifies Accounts Section for disbursement of the grant.

PROCEDURE OF SUBMISSION & APPROVAL OF NON-FUNDED PROJECTS

Principal Investigator [PI]) submits complete Intramural Project proposal along with Informed Consent Documents (in case of human studies) to Research Cell. The PI is also required to submit the filled Project information form (given below).

After receiving hard and soft copies of the documents, the research cell provides a Provisional project code and forwards to Committee for review (The PI will have to make a presentation of their project before Committee).

After the research cell approval, the research cell forwards the documents along with approval letter to the Institute Ethics Committee (IEC) for review.

After IEC approval, the PI provides Committee and IEC approval letters and other relevant documents and obtains permission from Head of Institute.

After permission from Head of the institute, PI informs the Research Cell which issues a Permanent Project code for the record.

INDIRA GANDHI INSTITUTE OF MEDICAL SCIENCES,
SHEIKHPURA, PATNA, BIHAR, PIN-800014

SECTION-A: FOR INFORMATION OF THE RESEARCH CELL

1. . Title of the Research Project :

2. . Type of Project
(Intramural/extramural/collaborative) :

3. . Name, Designation & Address of the :
Principal Investigator with email & mobile number

4.Name(s), Designation(s) & Address(es) :
of the Co-Investigator(s) with email & mobile numbers

5.Is the study interventional? :

6.Background Information & Justification (100–200 words). :
(State the reasons for undertaking the study & include
6-10elevant references)

7.Research Questions; Hypotheses :

08. Obiectives
(a) Primary :
(b) Secondary :

09.Was statistical expert consulted? If yes, Name, Designation :

10. Material and Methods
(a) Whether the study involves humans, :
animals or both?
(b) Type of study :
(Randomized controlled trial/cohort
study/case control study/record review/
prospective clinical study/others)

(c) In case of human study mention the
(i) Inclusion criteria :
(ii) Exclusion criteria :
(d) Number of groups to be studied, :
their names and definitions
(Name the groups as control, treatment I,
treatment II, etc.)
(e) Sample size in each group and sample :
size determination methods
(Sample size must be estimated using
standard scientific/statistical methods)
(f) Interventions (including drugs) to be used, if any :

11.Are the drugs and doses to be used, approved for these :
indications by Drugs Controller General of India (DCG-I)? :
(Enclose the approval letter from DCG-I for the trial on humans)

12. Methodology (include sampling method, randomization
:
technique, interventions and their standardization,
variables to be studied, proposed statistical methods, etc.)

13. (a) If the study is institutional, state whether it is intra-departmental or inter-departmental. :

(b) If the study is inter-departmental, :

(i) State the names of collaborating departments :

(ii) State whether consent/administrative sanction has been obtained from them :

14. (a) If the study is inter-institutional, whether it is national or international. :

(b) State the names of collaborating institutions. :

(c) State whether consent/administrative sanction has been obtained from collaborating institutions. Enclose copies of the same. :

(d) State whether you have enclosed a copy of the original research protocol submitted by the coordinating institution. :

(e) State the responsibilities of each collaborating institution. :

15. Total funds required for the study (in rupees). :

16. Justification for required funds. :

(a) Non-recurring requirements and their costs

(b) Recurring requirements and their costs :

(c) Research project staff requirements & their expenditures :

(d) Overhead charges :

(e) Others (specify) :

17. (a) Source of funding (intramural or extramural) :

(b) If extramural, state the name of funding agency. :

18. Duration of the study :

19. Approval by Institute Ethics committee obtained (Also enclose approvals from other IECs for multicentre studies) :

20. The principal investigator should state

(a) The number of ongoing research projects as principal investigator :

(b) Source and amount of funds in each of his/her research project :

21. Enclosures :

IGIMS,
Sheikhpura, Patna

INFORMED CONSENT FORM FOR PATIENTS PARTICIPATING IN A CLINICAL STUDY

Study Title: _____

Study Number: _____

Patient's Name & Address: _____

Patient Number: _____

Date of Birth/Age: _____

	Please initial box (Patient)
1. I confirm that i have read and understood the information provided dated_____ for the above study and have had the opportunity to ask questions.	[ ]
2. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	[ ]
3. I understand that in the clinical study others working on the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the study. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.	[ ]
4. I agree not to restrict the use of any data or results that arise from this study.	[ ]
5. I agree to take part in the above study.	[ ]

_____	_____	_____
Name of Patient	Signature	Date and Time of Signature

_____	_____	_____
Name of Investigator (Doctor)	Signature	Date and time Signature

(* If a patient has limited ability to read and write, an impartial witness should preferably be present during the entire informed consent discussion and his/her legally acceptable representative should sign on patient's behalf). In these instances the patient places his/her left thumb impression in the place of the signature.

Patient's Legally Acceptable Representative's Statement: ☐ NA

I, as the patient's legally acceptable representative, was present during the consenting procedure and understand the preceding information describing this study. All of the questions regarding the study and the patient's participation in it have been answered to my satisfaction and that of the patient. I state that all aspects of the study were clearly presented during the consent procedure. The patient is willing to participate in the study and I sign below on his/her behalf testifying to this effect.

Name of the Patient: _____

Name of the Legally Acceptable Representative:
_____

Relationship to the Patient: _____

Signature of the Legally Acceptable Representative: _____

Date of Signature: _____

Witness Declaration of Patient's Informed Consent ☐ NA

By signing the consent form I attest that the information was accurately explained to and apparently understood by the patient and the legally acceptable representative (if applicable) and that informed consent was freely given by the patient.

Date and Time _____ **Signature _____**

(Impartial Witness)

Name of the Witness: _____

Address of Witness: _____

_____

_____

Comments: _____

_____

CONSENT FOR MINORS (< 18 YRS)

I, Mr/Mrs_____ being a person aged 18 years and above , and being the Patient/Lawful guardian of_____ herby give my consent to Dr _____ to include _____ in the intended clinical study as explained to and understood by me. I have understood the implications, risks and immediate benefits of the tests and the treatment.
I give consent for the tests to be carried, treatment to be given to _____.

I understand that i have the right to withdraw _____ from the clinical study any time, for any reason without penalty or harm to him/her.
In case of withdrawal, I understand that the doctor will continue to take care of _____in the same way as any other patient.

All the above conditions have been explained to me in the language, which I understand well. (Hindi)

Signature of the Parent/Legally Acceptable Representative: _____

Signatory's Name: _____ Date:____/_____/_____

Signature of Investigator: _____
Investigator's Name: _____ Date:_____/_____/_____

Signature of Impartial Witness: _____
Impartial Witness Name and Address: _____
Date: _____/_____/_____

MINORS ASSENT FORM FOR INCLUSION IN THE CLINICAL STUDY

I confirm that as i give my assent to participate in the study, it is with a clear understanding of the objectives and conditions of the study and with the recognition of my right to withdraw from th study if I change my mind later.

_____
Signature

To be filled by Research cell, IGIMS, Patna only

Checklist:

1. Complete information provided as per format (Yes/ No / Any deficiencies…….)

2. Copy of complete project proposal with signatures of PI, co-PIs and HoD and required documents received (Yes/ No / Any deficiencies…….)

3. Copy of project in digital format (CD/ DVD/ pen drive/email) received (Yes / No / Any deficiencies…….)

4. Category of research project (please tick)

a. Intramural

b. Extramural
- Concept proposal
- Final proposal

c. Collaborative with other institute

Project received on date_____

Provisional project code assigned: _____

Acknowledgement

Received copy of project proposal titled "……" from Dr. ..…… Department of……..,……., IGIMS, Patna on Date…….
Provisional project code assigned……..

Signature of Sub-Dean, Research Cell Date:

Signature of Dean, Research Cell Date: