INDIRA GANDHI INSTITUTE OF MEDICAL SCIENCES,

SHEIKHPURA, PATNA – 800 014 Bihar

RESEARCH CELL

SUBMISSION & APPROVAL OF

PROJECTS

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

VERSION-1.1 Dated 03.05.2017

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 Scientific Advisory Committee (SAC) for review (The PI will have to make a presentation of their project before SAC).

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

After IEC approval, the PI provides SAC 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 notify Accounts Section for disbursement of funds.

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 Research Advisory Committee (RAC), IGIMS, Patna for review (The PI will have to make a presentation of their project before RAC).

After SAC approval, the Research Cell forwards the documents along with SAC 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 SAC 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 Scientific Advisory Committee (SAC) for review (The PI will have to make a presentation of their project before SAC).

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

After IEC approval, the PI provides SAC 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 – 800 014 Bihar

SECTION-A: FOR INFORMATION OF THE RESEARCH CELL

01. Title of the Research Project :

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

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

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

05. Is the study interventional? :

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

07. Research Questions; Hypotheses :

08. Objectives :
(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 standardizations, 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 :

SECTION-B: DISCLOSURE FOR ETHICAL REVIEW

Serial No of IEC Management Office*: _____/_____/_____/_____ File name YYYY MM/DD Sr. No

*** to be filled by IEC secretariat**

1.Type of Study : Cross sectional ☐ Case control ☐ Cohort ☐ Clinical Trial ☐ Review ☐

Participating Centre : Single center ☐ Multi-centric ☐ Others (Specify) ☐

Whether any work on this project has started or not? ☐ (mark √ if yes, X if no)

(Please enclose a separate certificate to this

2. **TYPE OF REVIEW:**

☐ **Initial Review**

☐ **Resubmission Review**

☐ **Amendment Review**

☐ **Expedited Review**

☐ **Emergency Review**

☐ **Continuing Review**

☐ **Report Review**

☐ **Protocol Termination**

3 Sponsor Information:

1. Indian **a) Government** ☐ **Central** ☐ **State** ☐ **Institutional** ☐

b) Private ☐ **(c) Self-funded** ☐

2. International **Government** ☐ **Private** ☐ **UN-Agencies** ☐

3. Industry **National** **Multinational** ☐

Contact Address of Sponsor:

Financial Disclosure	**YES (please break-up)**	**NO, Why not?.....**

Who will bear the cost of investigation /implants drugs/contrasts.	**1.** ☐ **Patient 2.** ☐ **Project 3.** ☐ **Exempted 4.** ☐ **Other Agencies (Name)_____**

- **Has the principal investigator ever been involved in or convicted of a crime, disciplined by a public or private medical organization, or by a licensing authority?**

  ☐ No ☐ Yes,

  Explain……..

- **Does the PI, the study colleagues or their families have any financial relationship with the sponsor other than payment for theconduct of the study?**

  ☐ No ☐ Yes, describe the relationship…….

Note: Financial disclosure includes speaking fees, consultation fees, stock ownership or other equity interest,patents, trademarks, copyrights, licensing agreements. Report interests valuing over $10,000 and interests representing a greater than 5% ownership in an enterprise.

- **For this study, how many of the following will the PI supervise?** Sub-investigators……. Study sites…….

- **How many (in total) of the following does the PI currently supervise?** Open studies…… Location…….Sub-investigators…… . Study staff……

Essential Enclosures based on standard formats

Item	Status (encircle right response)	Page no.
☐ **Informed Consent Form** Provide Informed consent form (clearly identified and dated) in the language(s) understood by the potential research participants and, when required, in other languages too.	**Yes/No/NA**	

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	☐
Compensation for study related injury	☐	eg. genetic basis for drug development	

*If written consent is not obtained, give reasons:

ii. Who will obtain consent ? PI/Co-PI Nurse/Counsellor

Research staff Any other (specify

☐ **Participant Information Sheet** 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 too.	**Yes/No/NA**	
☐ **Case report forms, diary cards, and other questionnaires** intended for research participants;	**Yes / No/ NA**	
☐ **Study budget and budget justification**	**Yes / No/ NA**	
☐ **A statement of agreement** to comply with ethical principles set out in relevant guidelines, Good Clinical Practices (GCP) protocols for clinical trials	**Yes / No/ NA**	
☐ **Curriculum Vitae** (CV) of investigators (updated, signed, and dated)	**Yes / No/ NA**	
☐ **Investigators' Brochure***	**Yes / No/ NA**	
* when 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 etc.) has to be provided. For any drug / device trial, all relevant pre-clinical animal data and clinical trial data from other centres within the country / other countries, if available should be provided.		
☐ Material to be used (including advertisements) for the recruitment of potential research participants	**Yes / No/ NA**	
☐ All significant previous 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	**Yes / No/ NA**	

previous negative decisions should be provided. ·		
☐ · CPCSEA clearance, if any	**Yes / No/ NA**	
☐ HMSC/DCGI/DBT/BARC clearance if obtained	**Yes / No/ NA**	
☐ In case of multi-centric study, IEC clearance of other centres must be provided	**Yes / No/ NA**	
☐ In case an insurance cover is intended, Insurance certificate must be provided (as per ICMR guidelines)	**Yes / No/ NA**	
☐ Permission to use copyrighted Questionnaire/proforma	**Yes / No/ NA**	
☐ Definite undertaking as to who will bear the expenditure of injury related to the project	**Yes / No/ NA**	
☐ Institutional Animal Ethics Committee clearance	**Yes / No/ NA**	
☐ **Agreement to report all Serious Adverse Events (SAE) to AIIMS BBSR -IEC.**	**Yes / No/ NA**	

Essential Descriptions

A. Provide a description of the ethical considerations involved in the research and plan to address this issue.

Also include information on following items as mentioned in the box below

Subject selection: i. Number of Subjects :		
ii. Duration of study :		
iii. Will subjects from both sexes be recruited	Yes	No
iv. Inclusion / exclusion criteria given	Yes	No
v. Types of subjects Volunteers ☐ Patients ☐		
vi. Vulnerable subjects Yes ☐ No ☐ (Tick the appropriate boxes) Pregnant women ☐ children ☐ elderly ☐ Fetus ☐ illiterate ☐ handicapped ☐ terminally ill ☐ seriously ill ☐ mentally challenged ☐ economically & socially backward ☐ any other ☐		
vii. Special group subjects Yes ☐ No ☐ (Tick the appropriate boxes) Captives ☐ institutionalized ☐ employees ☐ Students ☐ nurses/dependent ☐ armed ☐ any other ☐ staff ☐ forces ☐		
Privacy and confidentiality **i Study involves -** Direct Identifiers ☐ Indirect Identifiers/coded ☐ Completely anonymised/ delinked ☐		
ii. Confidential handling of data by staff	Yes	No
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
If Yes, the study has been reviewed by ….. ¡ None ¡ Bio-safety ¡ Recombinant DNA Advisory Bio-safety ¡ Recombinant DNA Advisory Committees		
iv. Use of pre-existing/stored/left over samples	Yes	No
v. Collection for banking/future research	Yes	No
vi. Use of ionizing	Yes	No

radiation/radioisotopes **If yes,** has Bhaba Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained?	Yes	No
vii. Use of Infectious/bio hazardous 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…		
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 ☐ Benefit to Society ☐		
Is there compensation for participation? (including expenses and access to medical care) If yes, Monetary ☐ In Kind ☐ Specify amount and type:	Yes	No
Is there compensation for injury? **If yes,** by Sponsor ☐ by investigator ☐ by Insurance Company ☐ by any other (give details) ☐	Yes	No

14. Do you have conflict of interest? (financial/nonfinancial) **If Yes, specify :**	Yes	No
Conflict of interest for any other investigator(s) (if yes, please explain in brief	1_____Yes No 2_____Yes No 3_____Yes No 4_____Yes No	

B. Provide a description of the process used to obtain and document consent

C. A description of the arrangements for indemnity, if applicable.

D. A description of the arrangements for insurance coverage for research participants, if applicable.

E. Explain all anticipated 'risks' (adverse events, injury, discomfort) of the project. Efforts taken to minimize the 'risks'. Proposed compensation and reimbursement of incidental expenses and management of research related and unrelated injury/ illness during and after research period.

F. How long will the research data be stored by the PI? …….years after closing the study

G. **What kind of means will be used to recruit subjects for the study?** (All recruitment materials [copy to be enclosed] must be approved by IRB before use.)

☐ Personal contact
☐ Referrals
☐ From database other than the PI's list
☐ Advertising
☐ Other, specify……

H. Investigator should provide undertaking what they will do with the leftover sample tissue?

I. For international collaborative study details about foreign collaborators and documents for review of Health Ministry's Screening Committee(HMSC) or appropriate Committees under other agencies/ authority like Drug Controller General of India (DCGI)

J. For exchange of biological material in international collaborative study a MoU/ Material Transfer Agreement between the collaborating partners. **(Enclose copy and indicate the enclosure no. and page no. in this document)**

K. Plans for publication of results / positive or negative / while maintaining the privacy and confidentiality of the study participants.

L. Any other information relevant to the study.

Additional Information for Clinical Trials / Experimental Studies

<table>
<tr><td colspan="3">Clinical Trials:
Drug /Vaccines/Device/Herbal Remedies :
i. Does the study involve use of :

Drug ☐ Devices ☐ Vaccines ☐
Indian Systems of Medicine/ ☐ Any other ☐ NA ☐
Alternate System of Medicine.</td></tr>
<tr><td colspan="3">ii. Is it approved and marketed
In India ☐ UK & Europe ☐ USA ☐
Other countries, Specify ☐</td></tr>
<tr><td>iii. Does it involve a change in use, dosage, route of administration?
If yes, whether DCGI’s /Any other Regulatory authority’s Permission is obtained?
If yes, Date of permission :</td><td>Yes

Yes

Yes</td><td>No

No

No</td></tr>
<tr><td>iv. Is it an Investigational New Drug?
If yes, IND/ FDA No:
Name of IND:
Sponsor:
Holder:</td><td>Yes</td><td>No</td></tr>
<tr><td>iv. Is it an Investigational New Device?
If yes, INE/ FDA No:
Name of IDE:
Sponsor:
Holder:</td><td>Yes</td><td>No</td></tr>
<tr><td>Procedure used:</td><td>Invasive</td><td>Non-Invasive</td></tr>
<tr><td>a). Investigator’s Brochure submitted</td><td>Yes</td><td>No</td></tr>
<tr><td>b). In vitro studies data</td><td>Yes</td><td>No</td></tr>
<tr><td>c). Preclinical Studies done</td><td>Yes</td><td>No</td></tr>
<tr><td colspan="3">d). Clinical Study is : Phase I ☐ Phase II ☐ Phase III ☐ Phase IV ☐</td></tr>
<tr><td>e). Are you aware if this study/similar study is being done elswhere ?
If Yes, attach details and give enclosure no. ____ & Page no.____</td><td>Yes</td><td>No</td></tr>
<tr><td>Data Monitoring
i. Is there a data & safety monitoring committee/ Board (DSMB)?</td><td>Yes</td><td>No</td></tr>
</table>

ii. Is there a plan for reporting of adverse events? If Yes, reporting is done to : Sponsor ☐ Ethics Committee ☐ DSMB ☐	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

In case of clinical trials CTRI status Other relevant details	Registered / Not registered No……..

	Name, Designation, Department & Qualifications	**Address Tel & Fax Nos. Email ID**	**No of projects already with Investigator**	**Signature**
PI				
Co-PI / Collaborators **1.**				
2.				
3				
4				
5.				

6.				
7.				

Signature of the Principal Investigator
(Name & Designation)

Signature of Head of the Department
of the Principal Investigator
(Name & Designation)

Signature(s) of the Co-Investigator(s)
(Name & Designation)

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 Member Secretary, Research cell Date:

RESEARCH ADVISORY COMMITTEE BOARD FOR IGIMS

1. Chairperson

Prof. Shyam Sunder
Department of Medicine, IMS, BHU

2. Members

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HOD, Psychiatry, IGIMS

ii) Prof (Dr) Dipendra K Mitra
Department of Immunology,
AIIMS, New Delhi

iii) Dr (Prof) S.K Shahi
HOD, Microbiology, IGIMS

iv) Dr Uday Kumar
HOD, Biochemistry, IGIMS

3. Member Secretary:

Dr P K Sinha
Dean Research, IGIMS