



## Annexure I - Application Form for Initial Review

Pt. Deendyal Upadhyaya National Institute for Persons with Physical Disabilities  
(Institutional Ethics Committee)

EC Ref.No. (For office use):

**General Instructions:** a) Tick one or more as applicable. Mark NA if not applicable  
b) Attach additional sheets if required  
c) May select more than one option

### SECTION A - BASIC INFORMATION

#### 1. ADMINISTRATIVE DETAILS

(a) Name of Organization:

.....

(b) Name of Ethics Committee:

.....

(c) Name of Principal Investigator:

.....

(d) Department/Division: ..... (e) Date of submission: 

dd	mm	yy
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(f) Type of review requested<sup>1</sup> :

Exemption from review  Expedited review  Full committee review

(g) Title of the study:

.....

Acronym/ Short title, (If any):

.....

(h) Protocol number (If any): ..... Version number: .....

(i) Details of Investigators:



Name	Designation and Qualification	Department and Institution	Address for communication <sup>2</sup>
Principal Investigator/Guide			
Co-investigator/student/fellow			

(j) Number of studies where applicant is a:

- i) Principal Investigator at time of submission
- ii) Co Principal Investigator at time of submission:

.....

(k) Duration of the study:

**2. FUNDING DETAILS AND BUDGET**

(a) Total estimated budget for site:

.....  
 .....

(b) Self-funding  Institutional funding  Funding agency (Specify)

.....  
 .....

<sup>1</sup>Refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017 on Page 36 Table 4.2. for types of review

<sup>2</sup>Include telephone/mobile, fax numbers and email id



## SECTION B - RESEARCH RELATED INFORMATION

### 3. OVERVIEW OF RESEARCH

(a) Lay summary<sup>3</sup> (within 300 words):

.....

.....

.....

.....

.....

.....

(b) Type of study:

- |                |                          |                               |                          |                   |                          |
|----------------|--------------------------|-------------------------------|--------------------------|-------------------|--------------------------|
| Basic Sciences | <input type="checkbox"/> | Clinical                      | <input type="checkbox"/> | Cross Sectional   | <input type="checkbox"/> |
| Retrospective  | <input type="checkbox"/> | Epidemiological/              | <input type="checkbox"/> | Case Control      | <input type="checkbox"/> |
| Prospective    | <input type="checkbox"/> | Public Health                 | <input type="checkbox"/> | Cohort            | <input type="checkbox"/> |
| Qualitative    | <input type="checkbox"/> | Socio-behavioural             | <input type="checkbox"/> | Systematic Review | <input type="checkbox"/> |
| Quantitative   | <input type="checkbox"/> | Biological samples            | <input type="checkbox"/> |                   |                          |
| Mixed Method   | <input type="checkbox"/> | Any others ( <i>Specify</i> ) | <input type="checkbox"/> |                   |                          |
- .....

### 4. METHODOLOGY

(a) Sample size/ number of participants (*as applicable*)

At site..... In India..... Globally .....

Control group..... Study group .....

Justification for the sample size chosen (100 words); In case of qualitative study, mention the criteria used for saturation

.....

.....

.....

.....

.....

(b) Is there an external laboratory/outsourcing involved for investigations?<sup>4</sup>

Yes  No  NA

(c) How was the scientific quality of the study assessed?

- |   |                          |                          |                          |                                |                          |
|---|--------------------------|--------------------------|--------------------------|--------------------------------|--------------------------|
| Independent external review               | <input type="checkbox"/> | Review by sponsor/Funder | <input type="checkbox"/> | Review within PI's institution | <input type="checkbox"/> |
| Review within multi-centre research group | <input type="checkbox"/> | No review                | <input type="checkbox"/> |                                |                          |

Date of review:

dd	mm	yy
----	----	----



Comments of scientific committee, if any (100 words)

.....

.....

.....

<sup>3</sup>Summarize in the simplest possible way such that a person with no prior knowledge of the subject can easily understand it.

<sup>4</sup>If participant samples are sent outside for investigations, provide details of the same and attach relevant documentation such as an MTA / MoU



## SECTION C: PARTICIPANT RELATED INFORMATION

### 5. RECRUITMENT AND RESEARCH PARTICIPANTS

(a) Type of participants in the study:

- Healthy volunteer  Patient  Vulnerable persons/ Special groups   
Others  (Specify) .....
- Who will do the recruitment? .....

Participant recruitment methods used:

- Posters/ leaflets/Letters  TV/Radio ads/ Social media/ Institution website  Patients / Family/Friends visiting hospitals  Telephone   
Others  (Specify) .....

(b) i. Will there be vulnerable persons / special groups involved ? Yes  No  NA

ii. If yes, type of vulnerable persons / special groups

- Children under 18 yrs  Pregnant or lactating women   
Differently abled (Mental/Physical)  Employees/Students/Nurses/Staff  Elderly   
 Institutionalized  Economically and socially disadvantaged   
Refugees/Migrants/Homeless   
Terminally ill (stigmatized or rare diseases)   
Any other (Specify):  .....

iii. Provide justification for inclusion/exclusion .....

iv. Are there any additional safeguards to protect research participants? .....

(c) Is there any reimbursement to the participants? Yes  No

If yes, Monetary  Non-monetary  Provide details .....

(d) Are there any incentives to the participants? Yes  No

If yes, Monetary  Non-monetary  Provide details .....

(e) Are there any participant recruitment fees/ incentives for the study provided to the PI / Institution?

If yes, Monetary  Non-monetary  Provide details Yes  No  .....



6. BENEFITS AND RISKS

(a) i. Are there any anticipated physical/social/psychological discomforts/ risk to participants? Yes  No

If yes, categorize the level of risk<sup>5</sup> :

- Less than Minimal risk  Minimal risk   
 Minor increase over minimal risk or low risk  More than minimal risk or high risk

ii. Describe the risk management strategy:

.....  
 .....

(b) What are the potential benefits from the study?	Yes	No	If yes,	Direct	Indirect
For the participant	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
For the society/community	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
For improvement in science	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>

Please describe how the benefits justify the risks

.....  
 .....

(c) Are adverse events expected in the study<sup>6</sup> ? Yes  No  NA

Are reporting procedures and management strategies described in the study? Yes  No

If Yes, Specify .....

.....  
 .....

7. INFORMED CONSENT

(a) Version number and date of Participant Information Sheet (PIS):.....

(b) Version number and date of Informed Consent Form (ICF):.....

- (c) Type of consent planned for :
- Signed Consent
  - Verbal / Oral Consent
  - Waiver of Consent
  - Witnessed Consent
  - Consent from LAR (Specify)
  - Audio-Visual Consent
  - For Parent < 7 years (Parents / LAR)
  - Verbal assent from minor (7-12 years) along with Parental consent
  - Written assent from minor (12-18 years) along with Parental consent
  - Other Consent (Specify)

(LAR = Legally Authorized Representative)



(d) Who will obtain the informed consent?

PI/Co-PI  Research Staff  Other  (Specify) .....

Any tools to be used .....

(e) Participant Information Sheet (PIS) and Informed Consent Form (ICF)

English  Local language  Other  (Specify).....

List the languages in which translations were done.....

If translation has not been done, please justify .....

Are you seeking waiver of consent? If yes, what are the reasons. Yes  No

.....

Provide details of consent requirements for previously stored samples if used in the study<sup>7</sup>

.....

(f) Elements contained in the Participant Information Sheet(PIS) and Informed Consent Form (ICF)

- Simple language  Data/ Sample sharing  Compensation for study related injury
- Risks and discomforts  Need to recontact  Statement that consent is voluntary
- Alternatives to participation  Confidentiality  Commercialization/ Benefit sharing
- Right to withdraw  Storage of samples  Statement that study involves research
- Benefits  Return of research results  Use of photographs/ Identifying data
- Purpose and procedure  Payment for participation  Sponsor contact information
- Others(Specify)

8. PAYMENT/COMPENSATION

(a) Who will bear the costs related to participation and procedures<sup>8</sup>?

PI  Institution  Sponsor  Other agencies  (specify)

(b) Is there a provision for free treatment of research related injuries? Yes  No

If yes, then who will provide the treatment? .....

(c) Is there a provision for compensation of research related SAE? If yes, specify. Yes  No

Sponsor  Institutional/Corpus fund  Project grant  Insurance

(d) Is there any provision for medical treatment or management till the relatedness is determined for injury to the participants during the study period? If yes, specify. Yes  No

.....

9. STORAGE AND CONFIDENTIALITY

(a) Identifying Information: Study Involves samples/data (specify):

Anonymous/Unidentified  Anonymized: Reversibly coded  Irreversibly coded  Identifiable

If identifiers must be retained, what additional precautions will be taken to ensure that access is limited /data is safeguarded? (e.g. data stored in a cabinet, password protected computer etc.).....

.....

(b) Who will be maintaining the data

(c) pertaining to the study? .....



(c) Where will the data be analyzed<sup>9</sup> and by whom? .....

(d) For how long will the data be stored? .....

(e) Do you propose to use stored samples/data in future studies? Yes  No  Maybe

If yes, explain how you might use stored material/data in the future? .....

.....

.....

<sup>5</sup>For categories of risk refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 6 Table 2.1

<sup>6</sup>The term adverse events in this regard encompass both serious and non-serious adverse events.

<sup>7</sup>Information on re-consent requirements can be found at National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 54 in Section 5.8.

<sup>8</sup>Enclose undertaking from PI confirming the same

<sup>9</sup>For example, a data entry room, a protected computer etc.





## SECTION D: OTHER ISSUES

### 10. PUBLICATION, BENEFIT SHARING AND IPR ISSUES

(a) Will the results of the study be reported and disseminated? If yes, specify. Yes  No

.....  
.....

(b) Will you inform participants about the results of the study? Yes  No

(c) Are there any arrangements for continued provision of the intervention for participants, if effective, once the study has finished? If yes describe in brief (Max 50 words) Yes  No  NA

.....  
.....

(d) Is there any plan for post research benefit sharing with participants? If yes, *specify* Yes  No

.....  
.....

(e) Is there any commercial value or a plan to patent/IPR issues? If yes, please provide details Yes  No

.....

(f) Do you have any additional information to add in support of the application, which is not included elsewhere in the form? If yes, provide details. Yes  No

.....  
.....



**SECTION E: DECLARATION AND CHECKLIST**

11. DECLARATION (Please tick as applicable)	
<input type="checkbox"/>	I/We certify that the information provided in this application is complete and correct.
<input type="checkbox"/>	I/We confirm that all investigators have approved the submitted version of proposal/related documents.
<input type="checkbox"/>	I/We confirm that this study will be conducted in accordance with the latest ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants and other applicable regulations and guide- lines.
<input type="checkbox"/>	I/We confirm that this study will be conducted in accordance with the applicable regulations and guidelines.
<input type="checkbox"/>	I/We will comply with all policies and guidelines of the institute and affiliated/collaborating institutions where this study will be conducted.
<input type="checkbox"/>	I/We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the EC approved protocol.
<input type="checkbox"/>	I/We declare that the expenditure in case of injury related to the study will be taken care of.
<input type="checkbox"/>	I/We confirm that an undertaking of what will be done with the leftover samples is provided, if applicable.
<input type="checkbox"/>	I/We confirm that we shall submit any protocol amendments, adverse events report, significant deviations from protocols, progress reports (if required) and a final report and also participate in any audit of the study if needed.
<input type="checkbox"/>	I/We confirm that we will maintain accurate and complete records of all aspects of the study.
<input type="checkbox"/>	I/We will protect the privacy of participants and assure confidentiality of data and biological samples.
<input type="checkbox"/>	I/We hereby declare that I/any of the investigators, researchers and/or close relative(s), have no conflict of interest (Financial/Non-Financial) with the sponsor(s) and outcome of study.
<input type="checkbox"/>	I/We have the following conflict of interest (PI/Co-PI): 1. .... 2. ....
Name of PI: .....	
Signature: .....	dd mm yy
Name of Co-PI: .....	
Signature: .....	dd mm yy
Name of Co-PI: .....	
Signature: .....	dd mm yy
Forwarded by - Head of the Department .....	
	dd mm yy



12. CHECKLIST						
S. No	Items	Yes	No	NA	Enclosure No	EC Remarks (If applicable)
<b>ADMINISTRATIVE REQUIREMENTS</b>						
1	Cover letter	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
2	Brief CV of all Investigators	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
3	Good Clinical Practice (GCP) training of investigators in last 3 years	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
4	Approval of scientific committee	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
5	EC clearance of other centers*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
6	Agreement between collaborating partners*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
7	MTA between collaborating partners*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
8	Insurance policy/certificate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
9	Evidence of external laboratory credentials in case of an externally outsourced laboratory study QA/QC certification	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
10	Copy of contract or agreement signed with the sponsor or donor agency	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
11	Provide all significant previous decisions (e.g. those leading to a negative decision or modified protocol) by other ECs/Regulatory authorities for proposed study (whether in same location or elsewhere) and modification(s) to protocol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<b>PROPOSAL RELATED</b>						
12	Copy of the detailed protocol <sup>11</sup>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
13	Investigators Brochure (If applicable for drug/biologicals/device trials)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
14	Participant Information Sheet (PIS) and Participant Informed Consent Form (ICF)(English and translated)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
15	Assent form for minors (12-18 years) (English and Translated)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
16	Proforma/Questionnaire / Case Report Forms (CRF)/ Interview guides/ Guides for Focused Group Discussions (FGDs) (English and translated)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
17	Advertisement/material to recruit participants (fliers, posters etc)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<b>PERMISSION FROM GOVERNING AUTHORITIES</b>						
	<b>Other permissions</b>	<b>Required</b>	<b>Not required</b>	<b>Received</b>	<b>Applied dd/mm/yy</b>	<b>EC Remarks</b>
18	CTRI	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
19	HMSC	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
20	Others (Specify)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<b>ANY OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY</b>						
	<b>Item</b>	<b>YES</b>	<b>NO</b>	<b>NA</b>	<b>Enclosure no.</b>	<b>EC remarks</b>
21						
22						

\*For multicentric research.

MTA-Material transfer agreement; CTRI-Clinical Trial Registry-India; HMSC- Health Ministry's Screening Committee;

<sup>11</sup>Refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, section 4 Page no. 35 Box 4.4(b)