Annexure 4 – Checklist for PI to Submit for Initial Review of Research Proposal

Check list for Initial Review Submission Form for Research Proposal

Serial No	Type of Document	Check
1	Title of the research proposal	☐
2	Name of the Principal Investigator with qualification and designation	☐
3	Name of the Co-Investigator(s) with qualifications and designation	☐
4	Name of the Institute / Hospital / Field area where research will be conducted	☐
5	Forwarding letter from the Head of the Department / Institution / Guide.	☐
6	Protocol of the proposed research: (includes and is not limited to) clear research objectives, the rationale for undertaking the investigations in human participants in the light of the existing knowledge, inclusion, and exclusion criteria for entry of participants. The Precise description of the methodology of the proposed research, including sample size, type of study design (observational, experimental, pilot, randomized, blinded etc.), intended intervention, dosages of drugs, route of administration, duration of treatment and details of invasive procedures if any, Plan to withdraw or withhold standard therapies during research. Plan for statistical analysis of the study. Ethical issues in the study and plans to address these issues.	☐
7	Proposal should be submitted with all relevant enclosures like proforma, case report forms, questionnaires, follow-up cards, participant recruitment procedures and brochures, if any, Informed consent process, including patient information sheet and informed consent form in English and local language(s). Investigator's brochure for trial on drugs/ devices/ vaccines/ herbal remedies and statement of relevant regulatory clearances.	☐
8	Source of funding and financial requirements for the project.	☐
9	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.	☐
10	Usefulness of the project / trial	☐
11	Expected 'benefits' to volunteers / community. 'Benefits' to other categories if any	☐
12	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. Description of the arrangements for indemnity, if applicable in study-related injuries and description of the arrangements for insurance coverage for research participants, if applicable.	☐
13	Agreement to report all Serious Adverse Events (SAE) to IHMRB -IRB.	☐
14	Other financial issues including those related to insurance.	☐
15	An account of storage and maintenance of all data collected during the trial.	☐
16	Research proposals approval by scientific advisory committee	☐

17	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)	☐
18	For exchange of biological material in international collaborative study a MoU/ Material	☐
19	Transfer Agreement between the collaborating partners.	☐
20	Statement of conflicts of interest, if any.	☐
21	Agreement to comply with the relevant national and applicable international guidelines, Good Clinical Practices (GCP) protocols for clinical trials.	☐
22	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 the modification(s) to the protocol made on that account. The reasons for negative decisions should be provided	☐
23	A statement on, probable ethical issues and steps taken to tackle the same as justification for washout of standard drug, or the use of placebo control.	☐
24	Curriculum vitae of all the investigators with relevant publications in last five years.	☐
25	Plans for publication of results / positive or negative / while maintaining the privacy and confidentiality of the study participants.	☐
26	Any other information relevant to the study.	☐
27	Signature of the Principal Investigator with date.	☐

Note: The above information and enclosures should be furnished wherever necessary depending upon the nature of the study proposal

Annexure 5 – IRB SUBMISSION FORM

Form to be filled by the Principal Investigator (PI) for submission to Institutional Review Board (IRB), IHMR B

Serial No of IRB application (*for office use only)*	

Declaration by the PI team

	Name, Designation and Department	Qualifications	Address, Tele, Email	No of projects already with Investigator	Signature
PI					
Co.PI/Collaborators 1.					
2.					
3.					
4.					
5.					

Please attach detailed Curriculum Vitae of all Investigators (with subject specific publications limited to previous 5 years).

1. Funding agency or Sponsor Information *(tick appropriately)*	
a) Government of India and undertaking agencies	☐
b) Private for profit	☐
c) Private not for profit	☐
d) Self-sponsored	☐
e) Academic	☐
f) International donor agency	☐
1.1 Name and Contact details of the sponsor/ funding agency	
1.2 Approximate budget (in rupees)	
2. Type of Study design *(tick appropriately)*	
a) Cross Sectional Survey	☐
b) Case Control Study	☐
c) Cohort Study	☐
d) Randomised Controlled Trial	☐
e) Systematic Review	☐
f) Literature Review	☐
g) Other (specify)_____	☐
3. Type of Centres *(tick appropriately)*	
a) Single Centre	☐
b) Multi Centric	☐
4. Type of Review *(tick appropriately)*	Applicable
c) New	☐
d) Revision	☐

5. Further information for clinical trials *(tick appropriately)*	Applicable
a) Drug trail	☐
b) Vaccine trail	☐
c) Device trail	☐
d) Alternative Medicine trail	☐
5.1 Is the intervention already approved or marketed *(tick appropriately)*	Not Applicable
a) Approved for India	☐
b) Approved for USA	☐
c) Approved for EU	☐
d) Marketed in India	☐
e) Marketed in USA	☐
f) Marketed in EU	☐
g) Approved for Other Markets (specify) _____	☐
h) Marketed for Other Markets (specify) _____	☐

6. For the Investigational New Drug (IND)	Applicable
Please mention IND No:	

6.1. Additional Information for IND *(tick appropriately)*	Applicable	
a) Investigator's Brochure submitted	YES ◯	NO ◯
b) In vitro studies data	YES ◯	NO ◯
c) Preclinical Studies done	YES ◯	NO ◯

d) Phases of Clinical Study	Phase 1 ◯	Phase 2 ◯	Phase 3 ◯	Phase 4 ◯

e). Are you aware of this study/similar study is being done elsewhere? If yes, attach details

7. **Summary of the proposal** – Introduction, review of literature, aim(s) & objectives, justification for the study, methodology describing the potential risks & benefits, outcome measures, statistical analysis and whether it is of national significance with rationale:

8. Study Participants

1.1. No of subjects		
1.2. Duration of study		
1.3. Will subjects from both sexes be recruited	YES ◯	NO ◯
1.4. Type of subjects	Volunteers ◯	Patients ◯
1.5. Doses Study involve vulnerable subjects	YES ◯	NO ◯
1.5.1. If Vulnerable subjects are involved, please select the appropriate subject		
a) Pregnant women	☐	
b) Children	☐	
c) Elderly	☐	
d) Foetus	☐	
e) Illiterate	☐	
f) Specially Abled	☐	
g) Terminally ill	☐	
h) Seriously ill	☐	
i) Mentally challenged	☐	
j) Others (Specify) _____	☐	
1.6. Does the Study involve special subjects	YES ◯	NO ◯
1.6.1. If Special subjects are involved, please select the appropriate subject		
a) Captives	☐	
b) Institutionalised	☐	
c) Employees	☐	
d) Students	☐	
e) Nurses and Dependent Staff	☐	
f) Armed Forces Members	☐	
g) Others (Specify) _____	☐	

9. Privacy and confidentiality

9.1 Does the data collected from the subjects involved *(tick appropriately)*		
a) Direct Identifiers	☐	
b) Indirect Identifiers/coded	☐	
c) Completely anonymised/ delinked	☐	
9.2 Will the study staff be trained for the confidential handling of data ◯	YES	NO ◯

10. Information on the use of biological/ hazardous materials

Applicable

a) Does the study involve the use of foetal tissue or abortus	YES ◯	NO ◯
b) Does the study involve the use of organs or body fluids	YES ◯	NO ◯
c) If the study involves the use of recombinant/gene therapy, has Department of Biotechnology (DBT) approval for rDNA products been obtained	YES ◯	NO ◯
d) Does the study involve the use of pre-existing/stored/leftover samples	YES ◯	NO ◯
e) Does the study involve the collection for banking/future research	YES ◯	NO ◯
f) If the study involves the use of ionizing radiation/radioisotopes, has Bhaba Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained?	YES ◯	NO ◯
g) Does the study involve the use of Infectious/biohazardous specimens	YES ◯	NO ◯
h) If the use of infectious/biohazardous specimens is involved, are the protocols for proper disposal of the material being prepared	YES ◯	NO ◯
i) Will any sample collected from the patients be sent abroad?	YES ◯	NO ◯
j) If Yes, is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for international collaboration?	YES ◯	NO ◯

11. Informed Consent

11.1 Type of consent to be obtained from the subjects *(tick appropriately)*					
Written	☐	Oral	☐	Audio-Visual	☐
11.2 Who will obtain the informed consent *(tick appropriately)*					
PI or CO-PI	☐	Nurse	☐	Counsellor	☐
Research Staff	☐	Physician	☐	Other _____	
12. Will any advertising be done for the recruitment of Subjects?		**YES** ◯		**NO** ◯	
12.1 If yes, then attach the sample of the promotional material with the proposal				☐	

13. Risks & Benefits

13.1 Is the risk reasonable compared to the anticipated benefits to subjects/community/country?	YES ◯	NO ◯
13.2 Is there physical/social/psychological risk/discomfort?	YES ◯	NO ◯
13.3 Is there any risk for the subjects	YES ◯	NO ◯
13.3.1 If yes, please explain the risk		
13.5 Are there any benefits for the subjects	YES ◯	NO ◯
13.5.1 If yes, please explain the benefits		

14. Information regarding data monitoring

a) Is there a data & safety monitoring committee/ Board (DSMB)?	YES ◯	NO ◯
b) Is there a plan for reporting adverse events?	YES ◯	NO ◯
c) Is there a plan for interim analysis of data?	YES ◯	NO ◯
d) Are there plans for storage and maintenance of all trial databases?	YES ◯	NO ◯
e) Is there compensation for participation? If yes, Monetary ☐ In kind ☐ Specify amount and type:	YES ◯	NO ◯
f) Is there compensation for injury? If yes, by Sponsor ☐ by Investigator ☐ by insurance ☐ by any other company ☐	YES ◯	NO ◯

15. Declaration on Conflict of Interest

Do you have conflict of interest? (financial/nonfinancial)	YES ◯	NO ◯
If Yes, specify:		
Conflict of interest for any other investigator(s) (if yes, please explain in brief)		

16. Please attach the informed consent form in English ☐

17. Please attach the informed consent form in regional language (if any) ☐

Signature of the PI with Date	
Signature of the Head of Institution with Date and Stamp	

----------End of the form----------