

**PROTOCOL APPLICATION FORM FOR INSTITUTIONAL HUMAN ETHICS COMMITTEE
PSG INSTITUTE OF MEDICAL SCIENCES & RESEARCH,
PEELAMEDU, COIMBATORE - 641 004.**

(Please ensure that the form is TYPED, not handwritten. Please do not leave any section blank)

Project Title:

Principal Investigator's Name
Educational Qualifications

Department
Phone
Fax
E-mail

Other Personnel:

Name	Qualifications	Role	Department
1			
2			
3			

Summary Information

1	Is this study a Pilot project <input type="checkbox"/> or a Full project <input type="checkbox"/> ?
1.1	If full project, has pilot study been done? Yes <input type="checkbox"/> No <input type="checkbox"/>
1.1.1	If no, state reasons
1.1.2	Was ethical clearance obtained for the pilot study? Yes <input type="checkbox"/> No <input type="checkbox"/>
1.1.2.1	If no, state reasons

2.1	Does your study involve ONLY data review / collection and analysis? Yes <input type="checkbox"/> No <input type="checkbox"/>
2.2	Subject Populations (Please check all applicable):
	<input type="checkbox"/> Minors (Under18) <input type="checkbox"/> Pregnant women
	<input type="checkbox"/> Fetuses <input type="checkbox"/> Abortuses
	<input type="checkbox"/> Mentally impaired <input type="checkbox"/> Laboratory personnel
	<input type="checkbox"/> Healthy volunteers <input type="checkbox"/> Students
	<input type="checkbox"/> None of the above <input type="checkbox"/> Others, specify
2.3	Study location
	PSG IMS & R <input type="checkbox"/> PSG Hospitals <input type="checkbox"/>
	Others <input type="checkbox"/> , (specify)
2.4	Does this study involve Collaborating with other institution(s)? Yes <input type="checkbox"/> No <input type="checkbox"/>
2.4.1	If yes, provide
	<ul style="list-style-type: none"> • Name of each institution, • Contact person's name, designation and contact details:
	Role / Terms of reference

3	Funding source: PSG <input type="checkbox"/> Others <input type="checkbox"/> , (specify)
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4	Budget (a) Itemized		

5	Budget (b) Total		

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6	Do the investigators have financial interests/obligations to sponsor?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	If YES to 6 above, then specify the nature of such interests / obligations.	
6.1	Does your study involve any of the following:	
6.1.1	Radioisotopes/radiation - producing machines	Yes <input type="checkbox"/> No <input type="checkbox"/>
6.1.2	Human blood or body fluids?	Yes <input type="checkbox"/> No <input type="checkbox"/>
6.1.3	Human embryos and embryonic cells	Yes <input type="checkbox"/> No <input type="checkbox"/>
6.1.4	Medical equipment used for human patients/subjects, also used on animals?	Yes <input type="checkbox"/> No <input type="checkbox"/>
6.1.5	Potentially addicting drugs?	Yes <input type="checkbox"/> No <input type="checkbox"/>
6.1.6	Collection of health or medical information of individuals, including from medical records, billing records, any clinical or research databases?	Yes <input type="checkbox"/> No <input type="checkbox"/>

(An Investigational New Drug (IND) is one which is NOT commercially available but is undergoing clinical trials with the approval of appropriate drug authorities of India. A Commercially available drug is one that is marketed. Clinical trials may be undertaken for these drugs in case of a new indication or new formulation etc.)

7.1	Is the drug being studied an Investigational new Drug?	Yes <input type="checkbox"/> No <input type="checkbox"/>
7.1.1	If it is an IND, provide the Name IND #	
7.1.2	Is the IND held by the sponsor <input type="checkbox"/> investigator <input type="checkbox"/> ?	
7.1.2.1	If held by sponsor, please provide the Sponsor's name:	
7.2	Is the drug being studied a Commercially Available Drug?	Yes <input type="checkbox"/> No <input type="checkbox"/>
7.2.1	If Commercially available drug, please provide the name of the manufacturer:	

8	Does the study involve an Investigational Device?	Yes <input type="checkbox"/> No <input type="checkbox"/>
8.1	If so, grade the risk: Non - Significant risk <input type="checkbox"/> Significant risk <input type="checkbox"/>	
8.2	Please provide the name of the manufacturer:	

9	Type of review requested :	REGULAR <input type="checkbox"/> EXPEDITED <input type="checkbox"/> EXEMPT <input type="checkbox"/>
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Detailed Information

The suggested headings must precede the explanatory comments.
 If a heading is not relevant write 'Not Applicable'.

10	PURPOSE	Briefly describe the purpose of the study in non-technical language
(Type here)		
11	BACKGROUND	Describe past experimental and/or clinical findings leading to the formulation of the study.
(Type here)		
12	RATIONALE	This is based on the belief in the need for additional or completely new research on a unique problem in a given field. Explain, defend, and/or prove that the current literature (if any) and current findings (if any) on the given problem are inadequate, outdated, and/or inaccurate.
(Type here)		
13	MATERIALS AND METHODS	
13.1	Study population and methodology	
	(i) Describe the <u>procedures</u> that the human subject must undergo in the research project (e.g., drug administration, device implantation, biopsies, blood drawing, MRI, etc.) Explain why human subjects must be used for this project.	
	(ii) Describe the <u>mode of recruitment</u> of subjects for the study e.g., charts review, referral from physicians, response to advertisement etc.	
	(iii) Please provide a sample of any advertising or other <u>materials to be used to recruit subjects</u> for your study. Any and all future advertisements should be submitted as a revision for Human Ethics Committee approval prior to being used.	
	(iv) Are you <u>withholding any standard treatment</u> ? If so please include this information in the ethics committee protocol AND consent form.	
	(v) Type and number of experimental subjects and controls.	
	<ul style="list-style-type: none"> • Identify inclusion criteria. • Identify exclusion criteria. • Indicate how many subjects will be involved. Justify your sample size, inclusion and exclusion criteria. • Indicate the number of potentially vulnerable subjects to be entered into the study, including minors, pregnant women, economically and educationally disadvantaged, and decisionally impaired. Also explain the rationale behind them being included. • Indicate the number, if any of subjects who are laboratory personnel, employees, and/or students. They should render the same written informed consent. If compensation is allowed, they should also receive it. 	
(Type here)		
13.2	Use of drugs, reagents, or chemicals	
	(a) If you are using an IND, please enclose a copy of the investigator's brochure and the sponsor's protocol.	
	(b) If commercially available drugs, reagents, or chemicals are being administered list name(s), source of supply, and if not premixed, whether material will be mixed and by whom.	
	(c) Is this a new or different use of this commercially available drug, reagent, or chemical?	
	(d) Provide details of dosages, routes and frequency of administration, dose escalation plans, and relevant data on toxicity and reactions.	
(Type here)		
13.3	Use of human blood or body fluids	
	State the provisions that you have for following universal precautions while using human blood or body fluids	
(Type here)		
13.4	Use of patient-related equipment	
	If medical equipment used for human patients/subjects is also used on animals, describe such equipment and disinfection procedures.	
(Type here)		
13.5	Use of investigational devices	
	(a) Describe the device to be used. If a non-significant risk device study is indicated, provide rationale for the device being non-significant risk.	
(Type here)		
13.6	Must be completed if "YES" to the relevant sub-section of 6.1	
13.6.1	State whether the procedures (e.g., extra CT scans, more X-rays, etc. involving the use of radioisotopes or radiation machines) are performed as	
	<ul style="list-style-type: none"> • A normal part of clinical management for the medical condition that is under study • being performed because the research subjects are participating in this project 	Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/>

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13.6.2	Radiation – related information <ul style="list-style-type: none"> Identify the radionuclide and chemical form. For each dosage, provide the route of administration and the amount administered. Please provide dosimetry information and reference the source documents (package insert, MIRD calculation, peer reviewed literature). 	
13.6.3	Radiation-machine related information <i>(i) Diagnostic procedures</i> <ul style="list-style-type: none"> For well-established radiographic procedures, identify the procedures and the numbers of times each will be performed on a single research subject. For each radiographic procedure, provide the setup and technique sufficient to permit dose modeling For radiographic procedures that are not well-established, provide information sufficient to permit dose modeling. <i>(ii) Therapeutic Procedures</i> <ul style="list-style-type: none"> For radiographic procedures that are not well-established, provide information sufficient to permit dose modeling. For a well-established therapeutic procedure, identify the area treated, dose per fraction and number of fractions. State whether the therapeutic procedure is being performed as a normal part of clinical management for the research subject's medical condition or whether it is being performed because the research subject is participating in this project. For a therapeutic procedure that is not well-established, provide basis for dosimetry, area treated, dose per fraction and number of fractions. 	
14	Would subjects undergo these or similar procedures (medical, psychological, educational etc.) if they were not taking part in this research? If 'NO', then describe how the study procedures differ from what subjects would otherwise undergo.	Yes <input type="checkbox"/> No <input type="checkbox"/>
15	RISKS and BENEFITS Specify any <u>potential/known risks/hazards</u> to which they may possibly be exposed. Please also address any risks related to psychological, social or economic well-being. For a known drug/device/procedure etc., please review literature and indicate frequency, and reversibility of potential risks. If possible <u>include statistical incidence of complications</u> and mortality rate of proposed procedures.	
15.1	Indicate the level of risks. Low (innocuous procedures, e.g., phlebotomy; no therapeutic agent) Medium ("Safe" therapeutic agent) High	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
15.1.1	Therapy with (select all that apply): Chemotherapy Antibody Potential toxic drug Risky procedure (e.g., organ biopsy) Vulnerable subjects (e.g., minors, pregnant women, Economically and educationally disadvantaged, decisionally impaired)	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
15.2	Detail the measures being taken to minimize all the above risks.	
15.3	Describe the <u>anticipated benefits</u> of this research for individual subjects in each subject group. If none, state "none" .	
15.4	Describe the <u>anticipated benefits</u> of this research for society. If none, state "none" .	
15.5	Explain how the benefits outweigh the risks.	
16	If men/women/children or any religious/social groups are NOT included, please provide a rationale.	
17	Is your subject participating in other protocols? Yes <input type="checkbox"/> No <input type="checkbox"/> If NO, please ensure that you will be kept informed by the subject. If YES, please list them.	
18	COMPENSATION and INCENTIVES The amount of payment, if any that will be paid for participation in the study must be expressly included in the ethics committee protocol AND consent form.	

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19	COSTS and FINANCIAL BURDEN borne by participants Any costs that will be charged to the patient must be expressly included in the Ethics committee protocol AND consent form	
20	STUDY RELATED RISKS and INJURIES Specify your indemnity type and coverage; Specify patient compensation mechanism/insurance and the amount.	
21	PROBABLE DURATION Include an estimate of the probable duration of the entire study as well as an estimate of the total time each subject is to be involved.	
21.1	Study endpoint Have you established guidelines or endpoints by which you can evaluate the alternative treatments during the study? If one treatment proves to be clearly more effective than another, will study be terminated before the projected total patient population has enrolled? When will the study end if no important differences are detected?	
22	Tissue sampling or banking for research (a) Are you taking samples of tissues, cells, blood or body fluids (b) Will they be stored for research purposes not specified in this protocol?	Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/>
22.1	If yes to (b), explain below the rationale and details. Please include the same in the consent form.	
23	Potential Conflicts of Interest There are two types of assistance that one can receive during the course of the study. <ul style="list-style-type: none"> You may receive personal payment for conducting the study - this will have to be recorded as conflict of interest. It is desirable that you document this fact. Payment for cost of the study 	Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/>
24	Consent Process Is a consent form (with translations into the local languages) included with this application? (Permission from the owner of the data must be appended if the project is a retrospective data mining study). *Forms for minors (Upto 18 yrs of age) All studies done on minors must be accompanied with a consent form signed by the subjects parents or guardians.	Yes <input type="checkbox"/> No <input type="checkbox"/>
24.1	If YES to 16 (above), then: Who is obtaining consent? The person obtaining consent must be knowledgeable about the study.	
24.2	How is consent being obtained?	
24.3	What steps are you taking to determine that potential subjects are competent to participate in the decision-making process?	
25	Confidentiality Please give a brief description as to how the confidentiality of the subjects is being maintained in your study. Even if the study is a retrospective data mining project, confidentiality needs to be maintained.	
25.1	Will you record any direct subject identifiers (names, patient, hospital, laboratory or claim numbers, addresses, telephone numbers, locator information, etc.) If yes, explain why this is necessary and describe the coding system you will use to protect against disclosure.	Yes <input type="checkbox"/> No <input type="checkbox"/>

Submit to :

Secretary, Institutional Human Ethics Committee, PSG IMS&R. E-mail: dcrb.psg@gmail.com

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25.2	Will you retain a link between study code numbers and direct identifiers after the data collection is complete? If yes, explain why this is necessary and for how long you will keep this link.	Yes <input type="checkbox"/> No <input type="checkbox"/>
25.3	Describe how you will protect data against disclosure to the public or to other researchers or non-researchers. Explain who (other than members of the research team) will have access to data (e.g., sponsors, advisers, government agencies, etc.).	
25.4	Will you place a copy of the consent form or other study information in the subject's medical or other personal record? If yes , explain why this is necessary.	Yes <input type="checkbox"/> No <input type="checkbox"/>
25.5	Do you anticipate using any data (information, specimens, etc.) from this study for other studies in the future? If yes , explain and include this information in the consent form	Yes <input type="checkbox"/> No <input type="checkbox"/>
26	Other relevant information Include any other documentation that the Human Ethics Committee must possess in order to assist in fulfilling its responsibilities e.g., Protocols from companies (e.g., drug companies), The company's relevant investigator's brochure, List of references etc.	

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Checklist of Documents

S.No	Document	Yes	No
1	Final Protocol with all amendments	<input type="checkbox"/>	<input type="checkbox"/>
2	Investigator's Brochure	<input type="checkbox"/>	<input type="checkbox"/>
3	Informed Consent Form and Patient Information Sheet in English and the relevant translated languages and their back-translations with appropriate translation certificates	<input type="checkbox"/>	<input type="checkbox"/>
4	Case Record Form/ Questionnaire	<input type="checkbox"/>	<input type="checkbox"/>
5	Insurance Policy	<input type="checkbox"/>	<input type="checkbox"/>
6	DCGI clearance	<input type="checkbox"/>	<input type="checkbox"/>
7	Investigator's agreement with sponsor	<input type="checkbox"/>	<input type="checkbox"/>
8	Investigator's undertaking to DCGI	<input type="checkbox"/>	<input type="checkbox"/>
9	Health Ministry Screening committee (HMSC)/ Bhabha Atomic Research Centre (BARC)/ Genetic Engineering Advisory Committee (GEAC) / Director General of Foreign Trade (DGFT) clearance wherever applicable	<input type="checkbox"/>	<input type="checkbox"/>
10	Food and Drug Administration (FDA) marketing/manufacturing license for herbal drugs, where applicable	<input type="checkbox"/>	<input type="checkbox"/>
11	Current CV of the Principal Investigator	<input type="checkbox"/>	<input type="checkbox"/>
12	All relevant pre-clinical animal data	<input type="checkbox"/>	<input type="checkbox"/>
13	All previous data from the clinical trial, if one has taken place	<input type="checkbox"/>	<input type="checkbox"/>
14	Source of funding and financial requirements for the project.	<input type="checkbox"/>	<input type="checkbox"/>
15	Compensation for study participation	<input type="checkbox"/>	<input type="checkbox"/>
16	Any other information relevant to the study	<input type="checkbox"/>	<input type="checkbox"/>

PLEASE NOTE:

APPROVAL FROM THE HUMAN ETHICS COMMITTEE IS VALID FOR THE DURATION INDICATED UPTO A MAXIMUM OF 1 YEAR.

PLEASE RESUBMIT FOR EXTENSION OF THE APPROVAL, if required.

Submit to :

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