Guidelines for submission of Research Project/protocol for PhD/ M.D thesis to Institutional Ethics Committee-Human Research (IEC-HR) for its consideration.

1. All projects/protocols submitted for the consideration of the Institutional Ethics Committee (IEC-HR) for its clearance must be accompanied by the proforma duly filled in by the investigator. **A copy of the proforma is enclosed.**

2. No research project/protocol will be considered by the IEC-HR until it has been assessed by the RPAC of the College and the changes suggested by the RPAC, if any, have been incorporated. And the project is found suitable for forwarding to the funding agency. The project in its final form should be submitted to the IEC-HR for its consideration.

3. Protocols for MD and Ph.D. requiring IEC-HR clearance should be submitted only in its final form after the plan of work has been approved by the PG committee of the college/approval of the Departmental Research Committee of Faculty of Medical Science, University of Delhi for Ph.D. candidate. PhD protocol should be accompanied by a letter of permission from the College authority suggesting that the work can be pursued in the institution.

4. No project of the Investigator/guide shall be considered in future if they fail to comply with the advice of the IEC-HR with regard to submission of the periodic progress report and/or report on completion of the project/thesis to the Committee while clearing that project. Further on non-compliance the stipend of the post-graduate student from the month of May/October after submission of thesis may be withheld. Permission to utilize the subsequent installment of research/project grant shall be subject to submission of interim/periodic report to IEC-HR. Such restrictions shall also be applicable to the Ph.D. students.

5. In the case of Short-term Research Studentship (STRS) of ICMR, the project will have to be submitted for ethics committee clearance before sending it to ICMR but the ethics clearance certificate shall be issued only on the submission of summary of the work done.

UNIVERSITY COLLEGE OF MEDICAL SCIENCES, DELHI_-110 095

PROFORMA FOR INSTITUTIONAL ETHICS COMMITTEE (HR)
CLEARANCE OF RESEARCH PROJECTS

Note : 1. All columns should be clearly filled up. Use additional sheets, if necessary.
2. Send five copies of the proforma duly signed by the applicant.

1.	Title of the Research Project	
2.	Name, designation and address of the Principal Investigator/Supervisor	
3.	Name, designation and address of the Co-Investigator/Co- supervisor	
4.	Name(s) and designation of Investigator(s)/supervisor(s)/ co-supervisor(s) etc,.if any, not belonging to UCMS & GTB Hospital	
5.	Name of the department(s) where research is proposed to be carried out	
6.	Name of the department(s) that would collaborate in the project.	
7.	Name of outside institution(s) that would collaborate in the study.	
8.	In case the study is multi-centric give details of all other centers, investigators etc.	
9.	Name and address of agency proposed to fund the project and whether any such grant is already available.	

10.	Duration of the proposed study with phasing and limitations, if any.	

11. Brief description of work to be undertaken, material methods etc. :		
12.	Anticipated risks involved in the implementation of the project and remedies suggested (This needs to be given in full details) **RISKS** • Procedural • Adverse drug reaction due to investigational drug treatment • Invasive investigation • Any other risk Explain measure to counter/compensate the above risk factors	
13.	Are the necessary facilities available in the department where the research is proposed to be carried out? If so, give details thereof. Will patient/subject be sent to other places? Give reasons thereof. (letter of permission/willingness to	

	cooperate from other department(s)/institution(s).	
14.	Details of facilities which are not available in the department and are proposed to be sought from other Department. (letter of permission/ willingness to cooperate from other department(s).	
15	Details of facilities which are not available in UCMS &GTB Hospital are to be availed of from other institution(s) (letter of permission/ willingness to cooperate from other institution(s).	
16.	Details of any fees/honorarium payable to investigators/collaborators/patient/others, if any	
17.	A) Consent is necessary from the participating subject. A copy of proposed Consent Form in English and Hindi be enclosed. **Consent form** • Does it have the name of the institution at the top • Does it also have the name, address and telephone No. of the Guide/Investigator etc B) Patient Information Sheet informing patient about • Freedom of individual to withdraw from research. • Publication, if any including photograph and pedigree chart • Duration of participation in study • Benefit that may be expected as an outcome of research to the subject • Alternative procedure or treatment if available. • His right to prevent use of his/her biological sample(s) at any time during the conduct of research	

	• Foreseeable discomfort or risk to the subject • Extent to which confidentiality of record could be maintained • Responsibility of investigator • Provision of compensation of risk C) Case Record Form	
18.	Whether clearance has been obtained from any other agency related to the proposed project, if so details thereof.	
19.	Whether clearance is necessary from any other agency? If so, details thereof	
20.	Is there any provision to compensate the investigators/victims in case of mishaps? If so, details thereof.	
21.	In case the project is sponsored by a private agency, particularly a multinational agency having business interest in India, whether prior approval of the competent authority has been obtained?	
22.	Full justification of Project keeping in view the policies and programmes of the Government including details of current knowledge on the subject and therein.	
23.	Has the project been sent to any other Institution/Body for Ethical Clearance? If yes, give details.	
24.	Any other information which may be useful for consideration of the project by the IEC(HR)	