Annexure: C: Research / Study –Protocol

(More points & more space in this proforma can be added if required, *but no point to be deleted*. Each page to be signed by the applicant)

Name and address of Applicant: Mobile No:			
Designation:		Department:	
Title of research /dissertation protocol			
is this research for your dissertation..?		write: YES / NO	
Signature of applicant with date:			
For office use only: Research Protocol Application No:			
Remark of Scientific committee	Approved / Not Approved		
Signature/s of Scientific committee with date			
Remark IEC subcommittee or IEC member secretory; and signature/s with date	**Type of review:Exemption from review/Expedited review/Full committee review:** Approved / Not Approved		

1.	Title of the study-protocol:	
2.	Name, Designation & Postal-Address with Mobile number, e-mail of: UG/PG-student / Investigator / Research worker Write or attach your (researchers) brief curriculum vitae. Have you completed research methodology or Good Clinical Practice or similar research training/workshop in last five years..? Attach its certificate.	
3.	Name, Designation & Postal-Address with Mobile number, e-mail of: UG/PG-Guide / Co-Investigator / Co-Research worker Write or attach your (researchers) brief curriculum vitae. Have you completed research methodology or Good Clinical Practice or similar research training/workshop in last five years..? Attach its certificate.	
4.	For PG Student Only (To be written on IEC approval certificate)	
	Full Name of PG-Student (Capital; Start With Surname)	
	Name of Department	
	Candidate admitted year	
	Course (MD or MS) & Subject	
	College Name & Address	
	Name of PG Teacher:	
	PG Teacher MUHS recognition letter, vide letter no and date:	

5.	is this research sponsored (Funded) by government/private agency? If yes, give details of authentic sponsorer information like : Name, Designation & Address with Telephone, Fax, e-mail, website, etc And mention Protocol number / version :	
6.	For sponsored (Funded) research by private/govt- agency/institute; 1. Give all details of financial budget of the research project. 2. If applicable; give DCGI-approval, Patients insurance, tripartite agreement, IEC-approval of other institutes, protocol with all details, investigators' brochure, investigators CV etc 3. Any other relevant documents as per current guidelines by concerned government agencies.	
7.	Introduction / Justification / rational for the study / study background: Also mention why a human study is needed to answer the research question	
8.	If applicable; Mention justification of inclusion / exclusion of ***vulnerable populations*** in your research.	
9.	Aim and Objectives: Also mention about primary research question, secondary research question, primary hypothesis, other hypothesis.. (also mention about end points if applicable)	

10.	Research Study- design	
11.	Research study- Centre	
12.	Research Study- population source	
13.	Research Study- Sample size (No of patients / subjects for study) :	
14.	Mention Proposed method for study subject recruitment/ enrollment.	
15.	Material and Methods	
16.	Review of Literature With minimum 15 references to be quoted in Vancouver style	
17.	Justification for placebo, benefit–risk assessment, plans to withdraw. If standard therapies are to be withheld, justification for the same;	
18.	Inclusion criteria	
19.	Exclusion criteria	

20.	Details of new investigational product (eg Drugs/surgicals, etc) if any: (Name, dose, route of administration, frequency of administration, efficacy & safety parameters, procedure, etc) If applicable, attach investigator's brochure/package insert/product information.	
21.	Whether Case record form (CRF)/Data Collection form attached..? Yes/No	
22.	Patient instruction card, diary, etc if applicable.	
23.	Do you need exemption from obtaining Informed Consent form (ICF) from study subjects? if yes give justification	
24.	Have you attached sample format / proforma for patient information sheet (PIS) & Informed Consent Form (ICF) in patient,s language as per Schedule-Y of THE DRUGS AND COSMETICS RULES, 1945 ..? **If yes, mention procedure for seeking and obtaining informed consent**. (very imp) Audio-Video recording if applicable;	1. PIS & ICF- Marathi: yes or No 2. PIS & ICF- Hindi: yes or No 3. PIS & ICF- English: yes or No 4. any other language: yes or No

24.	Statistical analysis	
25.	**Are there any likely adverse effects / complications / risks/ injuries related to this clinical study, if any?** **In addition, mention measures for its management.** **(very important)**	
26.	**Give details of: Proposed compensation & reimbursement of incidental expenses and management of research related and unrelated injury / illness during and after research period.** **(very important)**	
27.	Provision of ancillary care for unrelated illness during the duration of research.	
28.	Is there any financial burden to the patient due to this research project..? eg investigation, medications, surgicals, etc	
29.	Facilities available / infrastructure requirement for your research:	
30.	Criteria for protocol violation.	
31.	Study subjects drop-out criteria	

32.	Probable Duration for the study completion: -Period that may be required for data collection : -Deadline for collecting data : -Period that may be required for analysis of data : -Deadline for analysis of data	
33.	REVIEW OF RESEARCH WORK PROGRESS	

Reviews	**1st quarter**	**2nd quarter**	**3rd quarter**	**Final quarter**
Review of progress of project				
Review of collection of data				
Review of analyzed data				

34.	plans to maintain the privacy and confidentiality of the study participants	
35.	Write name of persons responsible for Privacy, Confidentiality, Archival of data (data / record keeping)..?	
36.	Mention about plans for publication of results – positive or negative– while maintaining confidentiality of personal information/identity Who is/are Authorized for publication of data?	

37.	Mention any conflicts of interests if any…	
38.	What are likely Ethical issues involved in the study?	
39.	Whether Investigator/UG/PG-Guide/Research worker is member of Ethics Committee.? If yes mention name	
40.	Write References / Bibliography:	
41.	**Attach / write ONE PAGE EXECUTIVE SUMMARY SHEET** a) Title b) Name of Researchers /Name of P. G. Student & P. G. Guide c) Name of the Department & Institute e) Introduction f) Aim & Objectives g) Material & Methods h) Risks involved i) Expected results	
42.	If involvement of other Department/st; then for permission of research work in that dept ; mention- <u>Name of that dept</u>, <u>sign</u>, <u>name</u> & <u>stamp</u> of Head Of that Dept	
43.	Date	

44. We, the undersigned, have read, discussed, understood and modified accordingly the protocol for the research study entitled above and hereby agree to conduct the research work in accordance with protocol and to comply with all requirements of ICMR, CDSCO guidelines (https://icmr.nic.in/ethical_guidelines.pdf ; http://www.cdsco.nic.in/html/GCP1.html ; https://icmr.nic.in/guidelines/National_Ethical_Guidelines_for_BioMedical_Research_Involving_Children.pdf).

Further, it is stated that to the best of my knowledge there is no ethical dispute in this research protocol and therefore may be approved by the Institutional Ethics Committee, Dr VM Govt. Medical College Solapur.

Also:

i. I have reviewed the clinical protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary Ethics Committee and regulatory approvals have been obtained.

ii. I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol without agreement by the Sponsor (if any) and prior review and documented approval/favorable opinion from the Ethics Committee of the amendment, except where necessary to eliminate an immediate hazard(s) to the trial Subjects or when the change(s) involved are only logistical or administrative in nature.

iii. I agree to conduct and/or supervise this research work at my site personally and/or under supervision of expert in that subject.

iv. I will ensure that the requirements relating to obtaining informed consent and ethics committee review and approval specified in the ICMR/GCP guidelines are met.

v. I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about their obligations in meeting their commitments in the research work.

vi. I have read and understood the information in the Investigator's broacher, including potential risks and side effects of the drug(if applicable).

vii. I agree to maintain adequate and accurate records and to make those records available for audit/inspection by the Sponsor, Ethics Committee, Licensing Authority or their authorized representatives, in accordance with regulatory and ICMR/GCP provisions; I will fully cooperate with any study related audit conducted by regulatory officials or authorized representatives of the Sponsor.

viii. I agree to promptly report to the Ethics Committee all changes in the research work activities and all unanticipated problems involving risks to human subjects or others.

ix. I agree to inform immediately within 24 hour, all unexpected serious and non serious adverse events to the Ethics Committee and/or to Sponsor as well as.

x. I will maintain confidentiality of the identification of all participating study patients and assure security, confidentiality and archival of study data.

	xi. I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical investigators participating in this research work. xii. Wherever required/applicable, I will submit permission from head of the institute to undertake clinical trial/research work, Investigator's Agreement with the Sponsors/head of the institute, Approval / Permission from D.C.G.I., MoU and Approval of Ethics Committee of other Collaborating Center (if available), Any other relevant documents as per regulatory requirements/ guidelines/IEC. xiii. I will inform the IEC of study completion final report, discontinuation, closure, termination of the research work. xiv. PG Teacher student ratio is maintained as per norms laid down by central council/competent authority. xv. The said title of synopsis is not repeated in last 5 years as per MUHS guidelines. xvi. It will be mandatory for me to work on the university approved title only for minimum period of 18 months after its approval. Also it will be mandatory for department to submit six monthly progress report to MUHS as per Annexure : 'E' xvii. Also it is responsibility of the student and guide to inform the ethics committee about completion of the said research work as per instructions/guidelines by MUHS Nashik. xviii. In case of research proposals submitted by undergraduate/postgraduate students, the IEC approval certificate is given by the name of undergraduate/post-graduate students; but in such condition their respective research guide will have all the responsibilities to comply with ICMR guidelines like that of **Principal Investigator (PI).** xix. Also all the information given above is true.	
45.	Signature with name: <u>-UG/PG-Student</u> / Investigator / Research worker /	
46.	Date:	
47.	Signature & Stamp with name of <u>-UG/PG-Guide</u> / Co-Investigator / Co-Research Worker	
48.	Date:	
49.	Signature & Stamp with name of -Prof & Head of the Department	
50.	Date:	