



CMH LAHORE MEDICAL COLLEGE & INSTITUTE OF DENTISTRY

Protocol Code	

Registration and Application Form
For Initial Review and Resubmission
(Please fill in or tick whenever appropriate)

Please print in A4 size paper

SECTION I: APPLICATION INFORMATION	
1. Study Title	
2. Type of Submission	<input type="checkbox"/> Initial Review <input type="checkbox"/> Resubmission [<i>Version and date of version must be inserted as a document footer for all resubmissions</i>]
3. Date of Submission:	<dd/mm/yyyy>
4. Study Category	<input type="checkbox"/> Research involving human participants <input type="checkbox"/> Research involving non-human living vertebrates <input type="checkbox"/> Others (indicate):
5. Type of study:	<input type="checkbox"/> Specify based on FOR/SEO : _____ <u>http://mrdcs.mastic.gov.my/assets/downloads/v6.pdf</u> <input type="checkbox"/> Clinical Trial Phase I <input type="checkbox"/> Clinical Trial Phase II <input type="checkbox"/> Clinical Trial Phase III <input type="checkbox"/> Clinical Trial Phase IV (Post Marketing Surveillance) <input type="checkbox"/> Whole-Genome Study (submit appropriate Informed Consent Form for Whole-Genome Study) <input type="checkbox"/> Interventional Study <input type="checkbox"/> Non-interventional Study <input type="checkbox"/> Combination of Interventional and Non-Interventional Study <input type="checkbox"/> Others, please indicate:

<p>6. Category of Principal Investigators <i>Please refer to Sections II-IV</i></p>	<p><input type="checkbox"/> 6.1 CMH Lecturer/Researcher (<i>This category requires completion of SECTION IIB: SCIENTIFIC REVIEW APPROVAL and SECTION III: PTJ ENDORSEMENT</i>)</p> <p><input type="checkbox"/> 6.2 CMH Post/Graduate Student (Master/Doctorate) (<i>This category requires completion of SECTION IIA: SUPERVISOR APPROVAL and SECTION IIB: SCIENTIFIC REVIEW APPROVAL</i>)</p> <p><input type="checkbox"/> 6.3 Other CMH staffs (Nurse, Administrative Staff, etc.) (<i>This category requires completion of SECTION IIB: SCIENTIFIC REVIEW APPROVAL and SECTION III: PTJ ENDORSEMENT</i>)</p> <p><input type="checkbox"/> 6.4 Non-CMH (<i>This category requires completion of SECTION IV: AUTHORIZATION AND ACKNOWLEDGEMENT OF REVIEW below</i>)</p> <p><input type="checkbox"/> 6.5 Others, please specify:</p>
<p>7. Purpose of study</p>	<p><input type="checkbox"/> Academic requirement (Thesis, Dissertation, Training Requirement)</p> <p><input type="checkbox"/> Independent research work</p> <p><input type="checkbox"/> Multi-institutional or multi-country collaboration</p> <p><input type="checkbox"/> Others (indicate):</p>
<p>8. Study Duration</p>	
<p>9. Involvement of special populations or vulnerable groups</p>	<p><input type="checkbox"/> Not involving special populations or vulnerable groups</p> <p><input type="checkbox"/> Children (under 18)</p> <p><input type="checkbox"/> Indigenous People</p> <p><input type="checkbox"/> Elderly</p> <p><input type="checkbox"/> People on welfare/social assistance</p> <p><input type="checkbox"/> Poor and unemployed</p> <p><input type="checkbox"/> Homeless persons</p> <p><input type="checkbox"/> Refugees or displaced persons</p> <p><input type="checkbox"/> Prison Inmate or other institutionalized individuals</p> <p><input type="checkbox"/> Subordinates</p> <p><input type="checkbox"/> Patients currently under your care</p> <p><input type="checkbox"/> Patients in emergency care</p> <p><input type="checkbox"/> Patients with incurable diseases</p> <p><input type="checkbox"/> Others (indicate): _____</p>
<p>10. Hosting Institution <i>(University/School/Department/Unit/Center where the PI is employed)</i></p>	<p>NAME OF HOSTING INSTITUTION :</p> <hr/> <p>TYPE OF HOSTING INSTITUTION</p> <p><input type="checkbox"/> CMH</p> <p><input type="checkbox"/> Non-CMH Pakistan</p> <p><input type="checkbox"/> Non-CMH outside Pakistan</p>
<p>11. Study site (where the study will be)</p>	<p>NAME OF STUDY SITE :</p>

conducted. Please list ALL sites)	TYPE OF STUDY SITE <input type="checkbox"/> CMH School/Department/Unit/Center/Premise/Hospital <input type="checkbox"/> Non-CMH with local IRB/ERB/ERC <input type="checkbox"/> Non-CMH without local IRB/ERB/ERC
12. Status of Funding	<input type="checkbox"/> In process <input type="checkbox"/> Approved <input type="checkbox"/> No funding (skip 13 and 14)
13. Funding :	NAME OF FUNDING/GRANT : TYPE OF FUNDING AGENCY <input type="checkbox"/> CMH <input type="checkbox"/> Investigator (Self-funding) <input type="checkbox"/> Pakistan Government agency/office/entity <input type="checkbox"/> External Government agency/office/entity <input type="checkbox"/> Multilateral Agency (UN agencies and other intergovernmental agencies) <input type="checkbox"/> Private company or Non-governmental organization (NGO) <input type="checkbox"/> Others (indicate): _____
14. Amount of Study Budget	PKR _____ (Other currency, please specify: _____)
15. Previous ethics approval or clearance issued by other sites	<input type="checkbox"/> Name of Institutional Review Board or Ethics Review Committee: <u>CMH Lahore Medical College and Institute of Dentistry</u> Date of ethics approval: Date of expiration of ethics approval: _____ <input type="checkbox"/> In process <input type="checkbox"/> Not applicable
16. Principal Investigator	Name: NIC/Passport Number : Address: Office Phone : _____ Facsimile : _____ Hand phone : Email :

17. Other Ongoing studies by the Principal Investigator (please add additional row/sheet if necessary)	<input type="checkbox"/> Title: CMH Code (if applicable):	
	<input type="checkbox"/> Title: CMH Code (if applicable):	
	<input type="checkbox"/> Not applicable	
18. Declaration of Conflict of Interest of PI (refer to the CMH website)	<input type="checkbox"/> I have no conflict of interest in any form	
	<input type="checkbox"/> I have personal/family/financial interest in the results of the study NATURE: _____	
	<input type="checkbox"/> I have proprietary interest in the research (patent, trademark, copyright, licensing) NATURE: _____	
19. Other investigators (Co-researchers; including study supervisors) with corresponding task description (please add additional rows/sheet if necessary)	Co-Investigator: Task description:	
	Co-Investigator: Task description:	
20. Submitted by:		
	Designation	
21. PI signature		

Please print your relevant section only

SECTION IIA: SUPERVISOR APPROVAL (for categories 6.2)	
This section should be signed by the appointed Supervisor of the Principal Investigator (Postgraduate Student) that approved the study	
STUDY PROTOCOL TITLE:	<with Version Number and Date>
Principal Investigator:	<Title, Name, Surname, PMDC No.>
I confirm that I have read this Application and that the research will be implemented under my supervision in accordance with the conditions of approval by the CMH. I also confirm that the Principal Investigator is a student under my supervision.	
Supervisor Name	<Title, Name, Surname, Staff No.> ()
Signature and Stamp:	Date of Signature: <dd/mm/yyyy>
SECTION IIB: SCIENTIFIC REVIEW APPROVAL (for categories 6.2, 6.3 and 6.4)	
<i>This section should be signed by the Chair of Research Committee (for categories 6.1 and 6.3) or the Chair of Postgraduate Committee (for category 6.2) that reviewed the scientific merit of the study and issued the appropriate approval. Alternatively, results of Scientific Review disposition may be appended to this application, instead of completing this section, provided that the information required below had been appropriately addressed.</i>	
STUDY PROTOCOL TITLE:	<with Version Number and Date>
Principal Investigator:	<Title, Name, Surname, Staff No.>
I confirm that the (RESEARCH/POSTGRADUATE COMMITTEE) has reviewed and approved the following study protocol-related information: Objectives/Expected output supported by literature review; overall research design; sampling method, sample size, Inclusion/exclusion/ withdrawal criteria; data collection plan and specimen collection, processing, storage and data analysis plan including statistical design/framework, as applicable.	
Issuing committee/office:	
Head of committee/office:	<Title, Name, Surname>
Signature and Stamp:	Date of Signature: <dd/mm/yyyy>
SECTION III: PTJ ENDORSEMENT (for categories 6.1 and 6.3)	
<i>This section should be signed by the head of PTJ (administrative authority legally empowered to sign on behalf the PTJ such as Dean of School, Director of Hospital, Director of Center/Institute and the like) of the Principal Investigator. This section is required only for initial submission, provided there are no changes in study protocol information below.</i>	
STUDY PROTOCOL TITLE:	
Principal Investigator:	<Title, Name, Surname>

I confirm that I have read this Application and that the research will be implemented under the supervision of this School/Department/Institution in accordance with the conditions of approval by the CMH. I also confirm that the Principal Investigator is a staff in this institution.	
Issuing PTJ:	
Head of PTJ:	<Title, Name, Surname>
Signature and Stamp:	Date of Signature: <dd/mm/yyyy>

SECTION IV: AUTHORIZATION AND ACKNOWLEDGEMENT OF REVIEW (for category 6.4 and 6.5) <i>This section should be completed by the signatory official who represents the institution that has supervisory role on the research site. This section is required only for initial submission, provided there are no changes in study protocol information below.</i>	
STUDY PROTOCOL TITLE:	
Principal Investigator:	<Title, Name, Surname>
<p>This is to certify that the <NAME OF RESEARCH SITE>:</p> <p>1) Has no local Institutional Review Board/ Ethics Review Committee; and</p> <p>2) Authorizes and acknowledges the CMH, located at the Center for Research Initiatives – Clinical and Health Sciences, CMH LAHORE MEDICAL COLLEGE & INSTITUTE OF DENTISTRY to perform the ethical review of the abovementioned study protocol in accordance with international ethical standards and national regulatory requirements, and oversee the conduct of the research study which includes progress monitoring, adverse event monitoring, and site visits.</p> <p>OR</p> <p>3) Had received permission from CMH authority to conduct research within CMH premises (attach permission letter)</p>	
Name of Hosting Institution	
Address of Hosting Institution	
Signatory Official	<Title, Name, Surname>
Position of Official	
Signature and Stamp	Date of Signature: <dd/mm/yyyy>