14.2 Appendix 2: IERC MGMDCH Application Form

Title of the project

	Name	*Designation*	*Department & Institution*
Principal Investigator			
Co-Investigator			
Co-Investigator			
Co-Investigator			

Non-sponsored study•Sponsored study•

If Non-Sponsored Study

Thesis/dissertation • ICMR student ship • Other Academic •

Please mention approx. date of submission of thesis/dissertation (month & year)_____

If Sponsored studywhether

1. Indian • a) Government • b) Industry • c) Institutional •

2. International • a) Government • b) Private • c) UN agencies•

3. Industry •

Address of Sponsor:

Total Budget : Rs._____

*Research Fund will be deposited in: DJST • DDF • Research Society • Other •*If other, please specify_____

Please give details of allocation of budget in attachment.

1.Type of Study :

Prospective • Retrospective • In vitro •

Single center • Multicentric • If multicentric, how many centres

_____

2. Does the study involve use of : Drug / Vaccine • Device • Alternative Medicine •

Any other • Not Applicable • If other, please specify_____

i) Is the test drug/ dental material/ device marketed inIndia **Yes** • **No** •

Is it marketed in other countries: **Yes** • **No** •Specify _____

If **marketed** in India, please **attachpackage insert**

If **not marketed** in India, please **attach Drugs Controller General (India) [DCG (I)] permission**.

ii)Is the test drug/dental material an Investigational New Drug (IND)? Yes • **No** •

If yes, please submit Investigator's Brochure which contains data of pre-clinical studies.

If IND, please also **attach DCG (I) permission**.

iii) Does the test drug/dental material involve a change in use, dosage, route ofadministration?

Yes • **No** • **If yes, pleaseattach copy of DCG (I) permission**.

3. Clinical Study is : Phase I • Phase II • Phase III • Phase IV •

4. Subject selection:

i) Number of subjects at this centre ☐ multicentric, total number of subjects ☐

ii) Vulnerable subjects Yes • No •***(If yes, tick the appropriate boxes)***

pregnant women • children • elderly • fetus • illiterate • handicapped •

seriously/terminally ill • mentally challenged • economically/socially backward •

any other • If other, please specify_____

iii) Special group subjects Yes • No •***(If yes, tick the appropriate boxes)***

employees •students • nurses/dependent staff • any other •

If other, please specify _____

4. Does the study involve use of		
i) Fetal tissue or abortus	Yes	No
ii) Organs or body fluids	Yes	No
iii) Recombinant/gene therapy **If yes, please submit a copy of Genetic Engineering Advisory Committee (GEAC) permission**.	Yes	No
iv) Ionising radiation/radioisotopes **If yes, please submit a copy of Bhabha Atomic Research Centre (BARC)permission.**	Yes	No

v) Infectious / biohazardous specimens	Yes	No
vi) Will pre-existing/stored/excised tissue samples/ Extracted tooth be used?	Yes	No
vii) Will samples be collected for banking/future research	Yes	No
viii) Will any sample collected from patient be sent abroad? **If yes, please submit a copy of Director General of Foreign Trade (DGFT) permission.**	Yes	No
ix) Is there any collaboration with any foreign lab., clinic or hospital ? **If yes, please submit a copy of Health Ministry Screening Committee (HMSC) approval.**	Yes	No
5. Will any advertising be done for recruitment of Subjects? (Posters, flyers, brochures, etc.) **If yes, kindly attach a copy for IERC MGMDCH review.**	Yes	No
6. Data Monitoring i) Is there a Data & Safety Monitoring Board/Committee (DSMB)?	Yes	No
ii) Is there a plan for interim analysis of data?	Yes	No
iii) For how long will the trial data be stored? _____years		
7. Is there compensation for participation? If Yes, Monetary • In kind • Specify amount / type: _____	Yes	No
8. Are there any arrangements for compensation of trial related injury? **Yes • No •** **Please submit a copy of the insurance policy if it is available.**		

We hereby declare the information given above is true and that we do not have any financial or non - financial conflict of interest.

Signature of Principal Investigator: _____

Signatures of Co- investigators: 1._____

2._____3._____

Forwarded by Heads of Department(s) _____

_____

Stamp/Seal of the Department(s)

14.3 Appendix 3: Check List of Documents

Sr. No.	Document	Yes	No
1	IERC MGMDCH application form		
2	Summary of protocol		
3	Protocol		
4	Amendments to protocol		
5	Informed consent document in English		
6	Informed consent documents in Regional languages (Total No.:)		
7	Back translations of Informed consent documents		

8	Amendments to the informed consent document		
9	Case Record Form / Questionnaire		
10	Principal investigators Current Curriculum Vitae		
10	Subject recruitment procedures: advertisement, letters to doctors, notices		
11	Investigator Brochure		
12	Ethics Committee clearance of other centres (Total No.)		
13	Insurance policy if any		
14	Drugs Controller General (India) [DCG(I)] clearance if applicable		
15	Investigator's agreement with sponsor if applicable		
16	Investigator's undertaking to DCG(I) if applicable		
17	Health Ministry Screening Committee (HMSC)approval if applicable		
18	Bhabha Atomic Research Centre (BARC) approval if applicable		
19	Genetic Engineering Advisory Committee (GEAC)approval if applicable		
20	Director General of Foreign Trade (DGFT) approval if applicable		
21	FDA marketing/manufacturing license for herbal drugs. if applicable		
22	Other Documents		

14.5 Appendix 5: Checklist For Submission of Serious Adverse Event Report (SAE) Occurring in ClinicalTrial

Sr. No.	Details		
1.	Country (Name of the country should be specified)		
2	SAE report of death or other than death, Please tick	Death ☐	Other Than ☐

			De ath
3	In case of serious adverse event(SAE), please specify if there is any injury to the subject (please specify Yes/ No) in the box		
4	Protocol Title		
5	Protocol Study No./ ID/ Code		
6	Copy of Clinical Trial permission obtained from CDSCO		
7	CTRI Registration No. (Mandatory for Clinical Trial Permitted after 15/06/09)		
8	Sponsor(Address with contact no and Email)		
9	CRO (Address with contact no and Email)		
10	Initial / Follow-up (FU)		
11	In case of follow-up : dae & duary no of intial or recently submmitted report information		
12	**Patient Details**		
a)	Initials & other relevant identifier (hospital/OPD record number etc.)		
b)	Gender		
c)	Age and/or date of birth		
d)	Weight		
e)	Height		
13	**Suspected Drug(s)**		
a)	Generic name of the drug.		
b)	Indication(s) for which suspect drug was prescribed or tested.		
c)	Dosage form and strength		
d)	Daily dose and regimen (specify units - e.g., mg, ml, mg/kg)		
e)	Route of administration		
f)	Starting date and time of day		
g)	Stopping date and time, or duration of treatment		
14	**Other Treatment(s)**		
	Provide the same information for concomitant drugs (including nonprescription/OTC Drugs/dentalmaterial) and non drug therapies , as fo the suspected drug(s).		
15	Details of the events		
	Full description of event (s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious.		

	In addition to adescription of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the reaction .		
	Start date (and time) of onset of reaction.		
	Stop date (and time) or duration of reaction		
	Dechallenge and rechallenge information		
	Setting (e.g., hospital, out-patient clinic, home, nursing home).		
16	**Outcome**		
a)	Information on recovery and any sequelae; results of specific tests and/or treatment that may have been conducted .		
b)	For a fatal outcome, cause of death/cause of failure and a comment on its possiblerelationship to the suspected reaction; any post-mortem findings.		
c)	Other information: anything relevant to facilitate assessmentof the case,such as medical history including allergy, drug or alcohol sabuse; familyhistory; findings from special investigations etc.		
17	**Details about the Investigator**		
a)	CT Site Number, if any		
b)	Name		
c)	Address		
d)	Telephone/Mobile Number & Email		
e)	Profession (speciality)		
f)	Date of reporting the event to Licensing Authority:		
g)	Date of reporting the event to Ethics Committee overseeing the site:		
h)	Signature of the Investigator		
18	**Details about the Ethics Committee**		
a)	Name & Address		
b)	Name of Chairman & Address		
c)	Telephone/Mobile Number		
d)	Email		
19	**Adverse Event Term / Details of SAE**		
20	Causality Assessment (Related/Unrelated) by Investigator.		
21	Causality Assessment (Related/Unrelated) by Sponsor/CRO		
22	Details of compensation provided for injury or death. In case no compensation hasbeen paid, reason for the same :		

a)			
b)	Duly filled SAE Form as per Appendix XI of Schedule Y		
c)	Laboratory investigations report /Discharge summary (if available and applicable)		

Note: inofrmation not relevant to a particular SAE should be marked with NA

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