



MAHATMA GANDHI MISSION'S DENTAL COLLEGE & HOSPITAL

Junction of NH-4 and Sion Panvel Expressway,

Sector-1, Kamothe, Navi Mumbai- 410 209

E-Mail ID :mgmdch@mghmmumbai.ac.in

IRRC 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 study whether

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 • Any other.....			
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 in India Yes • No •			
Is it marketed in other countries: Yes • No • Specify _____			
If marketed in India, please attach package 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 of administration?			
Yes • No • If yes, please attach 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 <input type="text"/> multicentric, total number of subjects <input type="text"/>			
ii) Vulnerable subjects Yes • No • <i>(If yes, tick the appropriate boxes)</i>			
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 • <i>(If yes, tick the appropriate boxes)</i>			
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	NA
ii) Organs or body fluids	Yes	No	NA
iii) Recombinant/gene therapy If yes, please submit a copy of Genetic Engineering Advisory Committee (GEAC) permission.	Yes	No	NA
iv) Ionising radiation/radioisotopes If yes, please submit a copy of Bhabha Atomic Research Centre (BARC) permission.	Yes	No	NA

v) Infectious / biohazardous specimens	Yes	No	NA
vi) Will pre-existing/stored/excised tissue samples/ Extracted tooth be used?	Yes	No	NA
vii) Will samples be collected for banking/future research	Yes	No	NA
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	NA
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	NA
5. Will any advertising be done for recruitment of Subjects? (Posters, flyers, brochures, etc.) If yes, kindly attach a copy for IRRC MGMDCH review.	Yes	No	NA
6. Data Monitoring			NA
i) Is there a Data & Safety Monitoring Board/Committee (DSMB)?	Yes	No	NA
ii) Is there a plan for interim analysis of data?	Yes	No	NA
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	NA
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.)			
<p>We hereby declare the information given above is true and that we do not have any financial or non - financial conflict of interest.</p> <p>Signature of Principal Investigator: _____</p> <p>Signatures of Co- investigators: 1. _____ 2. _____ 3. _____</p> <p>Forwarded by Heads of Department(s) _____</p> <p>Stamp/Seal of the Department(s)</p>			

