

APPLICATION FORM FOR BOS RESEARCH FUND COMMITTEE (BOSRFC)



BOMBAY
ORTHOPAEDIC
SOCIETY

Title of the project

Principal Investigator

Name

Designation

Dept. & Inst.

BOS Membership Number

Valid MMC registration number*
(Annexure no.)

CV (Annexure no.)

GCP certificates (Annexure no.)

Co-Investigator I

Name

Designation

Dept. & Inst.

BOS Membership Number

Valid MMC registration number*
(Annexure no.)

CV (Annexure no.)

GCP certificates (Annexure no.)

Co-Investigator 2

Name

Designation

Dept. & Inst.

BOS Membership Number

Valid MMC registration number*
(Annexure no.)

CV (Annexure no.)

GCP certificates (Annexure no.)

Co-Investigator 3

Name

Designation

Dept. & Inst.

BOS Membership Number

Valid MMC registration number*
(Annexure no.)

CV (Annexure no.)

GCP certificates (Annexure no.)

*attach certificate

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Non-sponsored study Co-Sponsored study

Nature of Study

Basic Sciences Sub Speciality General Ortho

Please mention sub speciality

If Co-Sponsored study : Details (use an annexure if necessary)

Address and contact details of Sponsor:

Attached Copy Of MOU (Between BOS, Investigator Institution and Department and Co-sponsoring Institution) Yes No

Annexure no.

How will each of the parties benefit with this project (Use additional appendix/annexure, if necessary)

1.

2.

3.

Total Budget: Rs.

Please give details of allocation of budget in attachment. (give year / phase wise break up of funds required)

Research Fund will be deposited in: DJST DDF Research Society Other

If other, please specify:

Proposed no: of subjects to be accrued:

Proposed date of study start:

Duration of study:

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Statement of Purpose: How will this research contribute to / impact BOS as a body, how will it benefit the subjects being studied. Need and rationale for choosing this particular topic (use annexure or attachment if necessary).Annexure no.

I. Type of Study:

- Prospective Retrospective
 Single center Multi Centric

If multi centric, how many centres with details:

Literature Review on the subject

Detailed Proforma (use annexures) Yes No Annexure no.

Summary of Protocol (use annexures) Yes No Annexure no.

ANY conflict of Interest disclosures Yes No

If yes, details:

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 / 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 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 involve a change in use, dosage, route of administration? Yes No

If yes, please attach copy of DCG(I) permission.

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

4. Subject selection:

i) Number of subjects at this centre:

(If multi-centric, 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:

iv) Animal studies: Yes No

5. Does the study involve use of:

i) Fetal tissue or abortus: Yes No

ii) Organs or body fluids: Yes No

iii) Recombinant / gene therapy: Yes No

If yes, please submit a copy of Genetic Engineering Advisory Committee (GEAC) permission.

iv) Ionising radiation/radioisotopes: Yes No

If yes, please submit a copy of Bhabha Atomic Research Centre (BARC) permission.

v) Infectious / bio-hazardous specimens: Yes No

vi) Will pre-existing/stored/left over samples 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?: Yes No

If yes, please submit a copy of Director General of Foreign Trade (DGFT) permission.

ix) Is there any collaboration with any foreign lab., clinic or hospital? Yes No

If yes, please submit a copy of Health Ministry Screening Committee (HMSC) approval.

6. Will any advertising be done for recruitment of Subjects (Posters, flyers, brochures, etc.)? If yes, kindly attach a copy for BOSRFC review. Yes No

7. Data Monitoring

i) Is there a Data & Safety Monitoring Board / Committee (DSMB) in your institute. Yes No

If not, how will the data and safety be monitored and by whom?

ii) Is there a plan for interim analysis of data? Yes No

iii) For how long will the trial data be stored? Years

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8. Is there compensation for participation? Yes No

If Yes, Monetary in kind,

Specify Amount / Type:

9. Are there any arrangements for compensation of trial related injury? Yes No

Please submit a copy of the insurance policy if it is available.

10. Potential risks and AER reporting provisions

11. Consent form with back translation in regional languages Assent in cases of vulnerable population.

12. If waiver of consent, then why?

13. Confidentiality of subjects: How will it be maintained? In case of video recording, please take separate consent and explain how subject confidentiality will be maintained.

14. Statistical analysis details: Power calculation, tests and time for analysis.

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15. Where will this study be reported?

16. BOS IPR (Intellectual Property Rights) agreement

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):

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Check List of Documents:

- | | | | |
|---|---------------------------|--------------------------|--------------------------------------|
| 1) BOSRFC application form | <input type="radio"/> Yes | <input type="radio"/> No | <input type="radio"/> Not Applicable |
| 2) Summary of protocol | <input type="radio"/> Yes | <input type="radio"/> No | <input type="radio"/> Not Applicable |
| 3) Protocol | <input type="radio"/> Yes | <input type="radio"/> No | <input type="radio"/> Not Applicable |
| 4) Amendments to protocol (if any) | <input type="radio"/> Yes | <input type="radio"/> No | <input type="radio"/> Not Applicable |
| 5) Informed consent document in English | <input type="radio"/> Yes | <input type="radio"/> No | <input type="radio"/> Not Applicable |
| 6) Informed consent documents in Regional languages (Total No.:) | <input type="radio"/> Yes | <input type="radio"/> No | <input type="radio"/> Not Applicable |
| 7) Back translations of Informed consent documents | <input type="radio"/> Yes | <input type="radio"/> No | <input type="radio"/> Not Applicable |
| 8) Amendments to the informed consent document | <input type="radio"/> Yes | <input type="radio"/> No | <input type="radio"/> Not Applicable |
| 9) Case Record Form / Questionnaire | <input type="radio"/> Yes | <input type="radio"/> No | <input type="radio"/> Not Applicable |
| 10) Principal investigators Current Curriculum Vitae | <input type="radio"/> Yes | <input type="radio"/> No | <input type="radio"/> Not Applicable |
| 11) Subject recruitment procedures: advertisement, letters to ---, notices etc. | <input type="radio"/> Yes | <input type="radio"/> No | <input type="radio"/> Not Applicable |
| 12) Investigator Brochure | <input type="radio"/> Yes | <input type="radio"/> No | <input type="radio"/> Not Applicable |
| 13) Ethics Committee clearance of other centers (Total No.) | <input type="radio"/> Yes | <input type="radio"/> No | <input type="radio"/> Not Applicable |
| 14) Insurance policy | <input type="radio"/> Yes | <input type="radio"/> No | <input type="radio"/> Not Applicable |
| 15) Drugs Controller General (India) [DCG(I)] clearance | <input type="radio"/> Yes | <input type="radio"/> No | <input type="radio"/> Not Applicable |
| 16) Investigator's agreement with sponsor | <input type="radio"/> Yes | <input type="radio"/> No | <input type="radio"/> Not Applicable |
| 17) Investigator's undertaking to DCG(I) | <input type="radio"/> Yes | <input type="radio"/> No | <input type="radio"/> Not Applicable |
| 18) Health Ministry Screening Committee (HMSC)approval | <input type="radio"/> Yes | <input type="radio"/> No | <input type="radio"/> Not Applicable |
| 19) Bhabha Atomic Research Centre (BARC) approval | <input type="radio"/> Yes | <input type="radio"/> No | <input type="radio"/> Not Applicable |
| 20) Genetic Engineering Advisory Committee (GEAC)approval | <input type="radio"/> Yes | <input type="radio"/> No | <input type="radio"/> Not Applicable |
| 21) Director General of Foreign Trade (DGFT) approval | <input type="radio"/> Yes | <input type="radio"/> No | <input type="radio"/> Not Applicable |
| 22) FDA marketing/manufacturing license for herbal drugs. | <input type="radio"/> Yes | <input type="radio"/> No | <input type="radio"/> Not Applicable |
| 23) Other Documents -Animal lab permissions (where applicable) | <input type="radio"/> Yes | <input type="radio"/> No | <input type="radio"/> Not Applicable |
| 24) Covering letter | <input type="radio"/> Yes | <input type="radio"/> No | <input type="radio"/> Not Applicable |