APPLICATION FORM FOR BOS RESEARCH FUND COMITTEE (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 1

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

APPLICATION FORM FOR BOS RESEARCH FUND COMITTEE (BOSRFC)

BOMBAY ORTHOPAEDIC SOCIETY

☐ 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:

APPLICATION FORM FOR BOS RESEARCH FUND COMITTEE (BOSRFC)

BOMBAY ORTHOPAEDIC SOCIETY

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.

1. 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, pleaseattach copy of DCG(I) permission.

APPLICATION FORM FOR BOS RESEARCH FUND COMITTEE (BOSRFC)

BOMBAY ORTHOPAEDIC SOCIETY

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

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.

APPLICATION FORM FOR BOS RESEARCH FUND COMITTEE (BOSRFC)

BOMBAY ORTHOPAEDIC SOCIETY

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: **Attach File**

Signatures of Co-investigators: 1) **Attach File** 2) **Attach File** 3) **Attach File**

Forwarded by Heads of Department(s):

APPLICATION FORM FOR BOS RESEARCH FUND COMITTEE (BOSRFC)

BOMBAY ORTHOPAEDIC SOCIETY

Check List of Documents:

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