

GENERAL INFORMATION AND FORMAT

**FOR ONLINE SUBMISSION OF PROJECT PROPOSALS
FOR FINANCIAL ASSISTANCE**

BIOMEDICAL DEVICE AND TECHNOLOGY DEVELOPMENT PROGRAMME



**GOVERNMENT OF INDIA
MINISTRY OF SCIENCE & TECHNOLOGY
DEPARTMENT OF SCIENCE & TECHNOLOGY
TECHNOLOGY BHAVAN, NEW MEHRAULI ROAD,
NEW DELHI – 110 016**

GENERAL INFORMATION

Department of Science and Technology has initiated a programme on **Biomedical Device and Technology Development (BDTD)** during 2016. Department was earlier supporting development of instruments for Medical and Healthcare applications through Instrumentation Development Programme. BDTD has been evolved considering the concern of medical device industry for R&D to develop new innovative products as per global standards. The mandate of BDTD is to evolve and support projects for design & development of devices for:

- a) **Early-Stage Prototype Development:** (The integration and testing of basic components in a laboratory environment)
- b) **Late-Stage Prototype Development** (Fabrication of compact prototype for testing and validation)
- c) **Pilot Scale Testing and validation:** (Upon completion of the technology's design, fabrication final testing with limited number of prototypes) with mandatory (manufacturer) industry participation.

The focus of DST- BDTD will be on development of devices and related technologies. The targeted categories include screening, diagnostic, surgical and life support equipments for clinical applications in healthcare sector.

WHO CAN SUBMIT PROJECT PROPOSALS

The Project Proposal could be submitted for financial support by scientist/ engineers/ technologists working in Universities and other academic institutions; R&D institutions/ laboratories having adequate infrastructure and facilities to carry out R&D work.

Financial support is provided only for temporary staff salaries, equipment, consumables, domestic travel and other miscellaneous items. No support is provided towards basic infrastructure and building and International travel.

The investigators/ R&D Group should have adequate experience and expertise in the relevant area of proposal. **A Clinician should be involved with investigating team as Co-PI.**

PROCEDURE FOR SUBMISSION OF PROJECT PROPOSALS

Only soft copy should be submitted online in the enclosed format. Please ensure that following documents have been completed and attached in original with one copy of the proposal.

- i. Certificate from the investigator (given on page 1 of the format); and

- ii. Endorsement from Head of the institution on Letter Head (given on page 2 of the enclosed format).

Application received without above documents/with incomplete information will not be entertained.

POINTS TO BE KEPT IN MIND WHILE SUBMITTING PROJECT PROPOSALS

1. Involvements of clinician and industries

The mandatory participation of clinician as a Co-PI is required to understand the users perspective.

It is envisaged that the end product of development shall be transferred to industries for commercial production. Hence it is desirable that industry (s) may be associated with project right from the beginning with defined participation in technical terms.

As far as possible the proposed device should have sufficient users in the country and there should be adequate demand for the product.

2. Project Duration

The projects should be time-bound normally for duration of 2-3 years depending upon the device/technologies to be developed.

3. Monitoring of the Project

Implementation of the projects is monitored regularly through Progress Reports, Financial Statements and Committee of Experts in Group review meetings and onsite as well.

GENERAL TERMS AND CONDITIONS FOR THE GRANT

1. The Institution where project will be implemented, will assume financial and other administrative responsibilities of the project.
2. In case of multi-institutional project, the Principal Investigator has to obtain formal agreement from the collaborating institutions/scientists.
3. International travel is normally not permissible under the project.

4. The manpower recruited for the project should be paid as per the rules of the institute and guidelines of the Government of India. The posts which are not covered under the guidelines but permissible under projects at host institute are also permitted.

The temporary staff employed for the project by the organization is not treated as employees of Government of India and the deployment of such staff at the time of termination of the project will not be the concern / responsibility of the Government of India.

5. It is the policy of DST to maximize the use of equipment. In this light, investigator shall permit the use of spare or idle capacities of equipment procured under the project by bona fide users (research workers in other DST funded projects or other projects of the institute).
6. All the assets including equipment acquired and prototypes fabricated from the grant will be the property of Government of India and should not be disposed of, or utilized for purposes other than those for which the grant has been sanctioned, without the prior sanction of the Department of Science & Technology.
7. The Principal Investigator/ organization will be required to furnish progress reports every six months on the progress made on all aspect of the project including expenditure incurred on various approved items during the period.
8. The Comptroller and Auditor General will have the right to access to the books and accounts of the organization for Grants received from the Government.
9. The organization would maintain separate account for the project. The grant should be kept in an interest earning bank account and the interest earned should be reported to the Department of Science & Technology. The interest thus earned will be treated as a credit to the organization and will be adjusted towards further installments of the Grant.
10. Grant can be terminated by DST at any stage if it is convinced that the Grant has not been properly utilized or appropriate progress is not being made.
11. If the Principal Investigator wishes to leave the organization where the project is based, the organization/investigator will inform the same to DST and with its consultation evolve steps to ensure successful completion of the project, before relieving the Principal Investigator. The Investigator should submit three copies of complete and detailed report of the work done by them on the project before leaving the organization.
12. Sale proceeds, if any, of the components, prototypes, pilot plants etc. fabricated as a result of the development of the project arising directly from funds granted by the Department of Science & Technology shall be remitted to the Government of India.

The Government of India, may, at its discretion allow a portion of such receipt to be retained by the organization.

13. The know-how generated from the project would be the property of the Government of India and any receipts by way of sale of know-how, utilization of know-how for production, royalties etc. shall belong to the Government of India. The Government of India, may, at its discretion, allow a portion of such receipts to be retained by the organization.
14. The Principal Investigator / organization will prepare all the documents that would be required for the transfer of know-how to the production agency/agencies and submit them of DST as and when required. The organization will be responsible to transfer the know-how developed to the production agency/ agencies and supply all the needed information to the production agency/ agencies as and when required.

DEPARTMENT OF SCIENCE AND TECHNOLOGY
POLICY ON CONFLICT OF INTEREST
FOR REVIEWER & COMMITTEE MEMBER or APPLICANT or DST OFFICER
ASSOCIATED/ DEALING WITH THE SCHEME/ PROGRAM OF DST

Issues of Conflicts of Interest and ethics in scientific research and research management have assumed greater prominence, given the larger share of Government funding in the country's R & D scenario. The following policy pertaining to general aspects of Conflicts of Interest and code of ethics, are objective measures that is intended to protect the integrity of the decision making processes and minimize biasness. The policy aims to sustain transparency, increase accountability in funding mechanisms and provide assurance to the general public that processes followed in award of grants are fair and non-discriminatory. The Policy aims to avoid all forms of bias by following a system that is fair, transparent and free from all influence/ unprejudiced dealings, prior to, during and subsequent to the currency of the programme to be entered into with a view to enable public to abstain from bribing or any corrupt practice in order to secure the award by providing assurance to them that their competitors will also refrain from bribing and other corrupt practice and the decision makers will commit to prevent corruption, in any form, by their officials by following transparent procedures. This will also ensure a global acceptance of the decision making process adopted by DST.

Definition of Conflict of Interest:

Conflict of Interest means "any interest which could significantly prejudice an individual's objectivity in the decision making process, thereby creating an unfair competitive advantage for the individual or to the organization which he/she represents". The Conflict of Interest also encompasses situations where an individual, in contravention to the accepted norms and ethics, could exploit his/her obligatory duties for personal benefits.

1. **Coverage of the Policy:**

- a) The provisions of the policy shall be followed by persons applying for and receiving funding from DST, Reviewers of the proposal and Members of Expert Committees and Programme Advisory Committees. The provisions of the policy will also be applicable on all individuals including Officers of DST connected directly or indirectly or through intermediaries and Committees involved in evaluation of proposals and subsequent decision making process.
- b) This policy aims to minimize aspects that may constitute actual Conflict of Interests, apparent Conflict of Interests and potential Conflict of Interests in the funding mechanisms that are presently being operated by DST. The policy also aims to cover, although not limited to, Conflict of interests that are Financial (gains from the outcomes of the proposal or award), Personal (association of relative / Family members) and Institutional (Colleagues, Collaborators, Employer, persons associated in a professional career of an individual such as Ph.D. supervisor etc.)

2. **Specifications as to what constitutes Conflict of Interest.**

Any of the following specifications (non-exhaustive list) imply Conflict of Interest if,

- (i) Due to any reason by which the Reviewer/Committee Member cannot deliver fair and objective assessment of the proposal.
- (ii) The applicant is a directly relative# or family member (including but not limited to spouse, child, sibling, parent) or personal friend of the individual involved in the decision making process or alternatively, if any relative of an Officer directly

- involved in any decision making process / has influenced interest/ stake in the applicant's form etc.
- (iii) The applicant for the grant/award is an employee or employer of an individual involved in the process as a Reviewer or Committee Member; or if the applicant to the grant/award has had an employer-employee relationship in the past three years with that individual.
 - (iv) The applicant to the grant/award belongs to the same Department as that of the Reviewer/Committee Member.
 - (v) The Reviewer/Committee Member is a Head of an Organization from where the applicant is employed.
 - (vi) The Reviewer /Committee Member is or was, associated in the professional career of the applicant (such as Ph.D. supervisor, Mentor, present Collaborator etc.)
 - (vii) The Reviewer/Committee Member is involved in the preparation of the research proposal submitted by the applicant.

 - (viii) The applicant has joint research publications with the Reviewer/Committee Member in the last three years.
 - (ix) The applicant/Reviewer/Committee Member, in contravention to the accepted norms and ethics followed in scientific research has a direct/indirect financial interest in the outcomes of the proposal.
 - (x) The Reviewer/Committee Member stands to gain personally should the submitted proposal be accepted or rejected.

The Term "Relative" for this purpose would be referred in section 6 of Companies Act , 1956.

3. **Regulation:**

The DST shall strive to avoid conflict of interest in its funding mechanisms to the maximum extent possible. Self-regulatory mode is however recommended for stake holders involved in scientific research and research management, on issues pertaining to Conflict of Interest and scientific ethics. Any disclosure pertaining to the same must be made voluntarily by the applicant/Reviewer/Committee Member.

4. **Confidentiality:**

The Reviewers and the Members of the Committee shall safeguard the confidentiality of all discussions and decisions taken during the process and shall refrain from discussing the same with any applicant or a third party, unless the Committee recommends otherwise and records for doing so.

5. **Code of Conduct**

5.1 To be followed by Reviewers/Committee Members:

- (a) All reviewers shall submit a conflict of interest statement, declaring the presence or absence of any form of conflict of interest.
- (b) The reviewers shall refrain from evaluating the proposals if the conflict of interest is established or if it is apparent.
- (c) All discussions and decisions pertaining to conflict of interest shall be recorded in the minutes of the meeting.
- (d) The Chairman of the Committee shall decide on all aspects pertaining to conflict of interests.
- (e) The Chairman of the Committee shall request that all members disclose if they have any conflict of interest in the items of the agenda scheduled for discussion.

- (f) The Committee Members shall refrain from participating in the decision making process and leave the room with respect to the specific item where the conflict of interest is established or is apparent.
- (g) If the Chairman himself/herself has conflict of interest, the Committee may choose a Chairman from among the remaining members, and the decision shall be made in consultation with Member Secretary of the Committee.
- (h) It is expected that a Committee member including the Chair-person will not seek funding from a Committee in which he/she is a member. If any member applies for grant, such proposals will be evaluated separately outside the Committee in which he/she is a member.

5.2 To be followed by the Applicant to the Grant/Award:

- (a) The applicant must refrain from suggesting referees with potential Conflict of Interest that may arise due to the factors mentioned in the specifications described above in Point No. 2.
- (b) The applicant may mention the names of individuals to whom the submitted proposal should not be sent for refereeing, clearly indicating the reasons for the same.

5.3 To be followed by the Officers dealing with Programs in DST:

While it is mandatory for the program officers to maintain confidentiality as detailed in point no. 6 above, they should declare, in advance, if they are dealing with grant applications of a relative or family member (including but not limited to spouse, child, sibling, parent) or thesis/ post-doctoral mentor or stands to benefit financially if the applicant proposal is funded. In such cases, DST will allot the grant applications to the other program officer.

6. Sanction for violation

3.1 For a) Reviewers / Committee Members and b) Applicant

Any breach of the code of conduct will invite action as decided by the Committee.

3.2 For Officers dealing with Program in DST

Any breach of the code of conduct will invite action under present provision of CCS (conduct Rules), 1964.

7. Final Appellate authority:

Secretary, DST shall be the appellate authority in issues pertaining to conflict of interest and issues concerning the decision making process. The decision of Secretary, DST in these issues shall be final and binding.

8. Declaration

I have read the above “Policy on Conflict of Interest” of the DST applicable to the Reviewer/ Committee Member/ Applicant/ DST Scheme or Program Officer # and agree to abide by provisions thereof.

I hereby declare that I have no conflict of interest of any form pertaining to the proposed grant *

I hereby declare that I have conflict of interest of any form pertaining to the proposed grant *

* & # (Tick whichever is applicable)

Name of the Reviewer/ Committee Member or Applicant or DST Officer
(Strike out whichever is not applicable)

(Signature with date)

**FORMAT FOR
SUBMISSION OF
PROJECT PROPOSAL**

CERTIFICATE FROM THE INVESTIGATOR

Project Title

1. I/We agree to abide by the terms and conditions of the R&D grant.
2. I/We did not submit the project proposal elsewhere for financial support.
3. I/We have explored and ensured that equipment and basic facilities (enumerated in the proposal) will actually be available as and when required for the purpose of the projects. I/We shall not request financial support under this project, for procurement of these items.
4. I/We undertake that space time on permanent equipment (listed in the proposal) will be made available to other users.
5. I/We have enclosed the following materials :

<u>Items</u>	<u>Number of copies</u>
a) Endorsement from the Head of Institution. (On letter head)	One
b) (This) Certificate from Investigator(s)	One

Name and signature of Investigator

Date

Place

ENDORSEMENT FROM THE HEAD OF THE INSTITUTION

(To be given on Letter Head)

Project Title :

1. Certified that the Institute welcomes the participation of Shri/Smt..... as the Principal Investigator and Shri/Smt.....as the other investigator (s) for the project and that in the unforeseen event of discontinuance by the Principal Investigator, the other investigator (s) will assume the responsibility of the fruitful completion of the project.
2. Certified that the equipment and other basic facilities as enumerated in Section II – Part B and such other administrative facilities as per terms and conditions of the grant, will be extended to the investigator (s) throughout the duration of the project.

Name and signature of the
Head of the Institution

Date :
Place :

PROJECT SUMMARY

Project Title:

Category: Early Stage Prototype/Late Stage Prototype/Prototype testing & validation

PI:

Contact No. Mobile and Office:

Email ID:

Co- PI's:

Total Cost:

Duration:

Manpower:

Equipment proposed:

Industry Partner(if any):

Objectives:

Deliverables:

Budget Details:

Sr. No.	Items	Budget(in Lakhs)			
		1st Year	2nd Year	3rd Year	Total
1.	Salaries/ Wages				
2.	Equipments				
3.	Consumables				
4.	Travel				
5.	Contingencies				
6.	Overhead Expenses*				
	Total				

Novelty (50-100 words):

Details of Proof of Concept/Prototype developed by Investigator/Team (50-100 words):

FORMAT FOR SUBMISSION OF PROJECT PROPOSALS

PART – A

1. PROJECT TITLE:

2. CATEGORY:

- d) **Early-Stage Prototype Development:** (The integration and testing of basic components in a laboratory environment)
- e) **Late-Stage Prototype Development** (Fabrication of compact prototype for testing and validation)
- f) **Pilot Scale Testing and validation:** (Upon completion of the technology's design, fabrication final testing with limited number of prototypes)

3. TOTAL COST OF THE PROJECT:

4. PROJECT DURATION:

5. INSTITUTION / ORGANIZATION:

6. OTHER PARTICIPATING / INTERACTING AGENCIES:

(Please enclose their letter regarding their willingness to participate in the project)

7. PRINCIPAL INVESTIGATOR:

Name :

Designation :

Institution :

Address :

Email:

Mobile:

8. OTHER INVESTIGATOR (S)

- i. Clinician Name (Mandatory) :

Designation :

Hospital :

Address :

Email:

Mobile:

ii. Name :

Designation :

Institution :

Address :

Email:

Mobile:

9. NAME, ADDRESS, EMAIL ID AND MOBILE NUMBER OF EXPERTS WORKING IN THE SUBJECT/AREA(S): (UPTO 10)

10. NAMES AND ADDRESSES OF INDUSTRY/ INSTITUTIONS/HOSPITALS (UPTO 10) INTERESTED IN THE OUTCOME OF THE PROJECT:

11. SUMMARY OF THE PROJECT (MAXIMUM 150 WORDS)

PART – B

1. OBJECTIVES OF THE PROJECT :

2. SIGNIFICANCE OF THE PROJECT:

a) Major applications of the proposed technology

b) Clinical Need

Include significance and estimated patient population/year if known.

c) Technical Solution

Include description along with any prior development..

What is the status of your device idea and provide your own experimental results, if any?

d) Current Practice and Competition.

What are best practices now? How will proposed device be superior to existing devices and practices?

e) Intellectual Property Status

3. REVIEW OF STATUS AND TECHNOLOGY TRENDS IN RESPECT OF DEVICE / INSTRUMENT TO BE TAKEN UP FOR DEVELOPMENT :

a) International status of development.

b) Current status in our country.

c) Status in your organization/Review of expertise available with proposed investigating group in the subject of the project.

d) Gaps to be covered through proposed work with special reference to the proposal.

4. TECHNICAL DETAILS :

- a) Features of the device/instrument proposed to be taken up for development.
- b) Specifications.
- c) Please make a comparison of the system taken up for development with similar products if available in international market indicating similarities of differences.
- d) Description of various techniques and reasons for choosing the particular technique of measurement.
- e) Principle or operation.
- f) Engineering Design of device/instrument
- g) Block/schematic/circuit diagram.
- h) Description of various sub-systems etc.
- i) How calibration, standardization, testing etc. will be achieved? (Please describe in brief procedures/methods for these).
(Please give references wherever applicable).

5. OTHER RELEVANT INFORMATION

- a) Institutional ethical clearance (If needed, enclose a copy)**
- b) Testing/ Calibration**
- c) Third party validation/Limited trials (Detailed Plan and letters from partners)**
- d) Future R&D Prospects**

6. ESTIMATED REQUIREMENT (NO. OF PIECE PER YEAR) OF THE PROPOSED DEVICE / SYSTEM :

(Please mention how the estimated requirement is worked out, i.e. through interaction with users; market survey etc.)

7. ESTIMATED COST OF THE DEVICE /SYSTEM AFTER DEVELOPMENT :

(Please indicate the cost of the components required for making one unit and indicate estimated cost at which device will be available to users after development).

8. THE COST OF SIMILAR IMPORTED DEVICES :

9. PRODUCTION AGENCY / INDUSTRY :

(Please see page 3 of General Information. Please annex willingness/commitment from the production agency to undertake production of device after development and commitment for their contribution for the project).

10. WORK PLAN :

a) Methodology :

Please describe how the work (various steps/activities involved) will be carried out including linkages with production agency & users so that the instrument/ system is development successfully and know – how is transferred to the production agency (s).

b) Time schedule of activities :

Please give bar chart indicating important activities and time duration from start to end :

11. FACILITIES AVAILABLE AT YOUR ORGANISATION WHICH ARE RELEVANT / USEFUL IN IMPLEMENTING THE PROJECT AND WILL BE AVAILABLE TO YOU DURING THE IMPLEMENTATION OF THE PROJECT :

A. Infrastructural facilities (Tick the appropriate box)

Item	Yes	No	NR*	Item	Yes	No	NR*
a) Workshop				g) Transportation			
b) Water & Electricity				h) Administrative & Secretarial support			

- c) Standby power supply
 - d) Laboratory Space & Furniture
 - e) Air Conditioned room for equipment
 - f) Telecommunication
 - i) Library facilities
 - j) Computational facilities
 - k) Any other (Please mention)
-

* NR : Not Required.

B. Available equipment (including test & measuring, calibration etc.) and accessories relevant to the project :

S.No.	Name of equipment and accessories	Model and Make	Remarks
1.			
2.			
3.			

NOTE : Please make sure that the aforesaid facilities and equipment will be available for the project.

C. Available manpower

S. No.	Name & Designation	Area of specialization
1.		
2.		
3.		

12. A. BUDGET ESTIMATES :

Sr. No.	Items	Budget			
		1 st Year	2 nd Year	3 rd Year	Total
1.	Salaries / Wages				
2.	Equipment				
3.	Consumables				
4.	Travel				
5.	Contingencies				

6.	Overhead expenses*				
	Total				

* For the organization of the PI towards meeting their costs for overhead expenses on the project including infra structural facilities etc.

Norms for Manpower, Travel, Contingency & Overheads

Manpower

Nomenclature & Emoluments	Qualification
Junior Research Fellow (₹25,000/- + HRA)	Post Graduate Degree in Basic Science with NET qualification or Graduate Degree in Professional course with NET qualification or Post Graduate Degree in Professional Course
Senior Research Fellow (₹28,000/- + HRA)	Qualification prescribed for JRF with two years of research experience
Research Associate-I (₹36,000/- + HRA)	Ph.D/ MD/ MS/ MDS or equivalent degree or having 3 years of research, teaching and design and development experience after MVSc/ M.Pharm/ ME/ M.Tech with at least one research paper in Science Citation Indexed (SCI) journal. The Research Associate Scale may be decided by the institute/ organization based on the experience of the candidate.
Research Associate-II (₹38,000/- + HRA)	
Research Associate-III (₹40,000/- + HRA)	

Travel & Contingency

₹50,000/- each per annum will be provided for Travel and Contingencies. Higher amount, based on the recommendations of the Expert Committee, to be provided where the research work involves field work or/and project has many investigators/institutions and larger manpower. The contingency amount may also be used for paying Registration Fees for attending international conferences.

Overheads

Overhead amount is towards meeting the cost of academic expenses including infrastructural facilities at the host institutes, and is permissible as given below: :

- For projects costing upto ₹1 crore, 10% of the total cost for educational institutions and NGOs and 8% for laboratories and institutions under Central Government Departments/Agencies;

- b) For projects costing more than ₹1 crore and upto ₹5 crore, overheads of ₹15 lakh or 10% of total cost whichever is less;
- c) For projects costing more than ₹5 crore and upto ₹20 crore, ₹20 lakh will be provided as overheads; and

For projects costing more than ₹20 crore, the quantum will be decided on a case to case basis.

12. B. BUDGET FOR SALARY / WAGES:

Sr. No.	Designation	Scale of pay	Monthly emoluments	Number	1 st Year	2 nd Year	3 rd Year	Total

Justification for manpower required

12. C BUDGET FOR EQUIPMENT :

Sr. No.	Equipment / Accessories	Make & Model	Imported / Indigenous	Estimated Cost	F.E. Component
TOTAL					

Justification for equipment proposed

12. D BUDGET FOR CONSUMABLES MATERIALS :

(Rs. Lakhs)

Sr. No.	Items	Quality	Budget			
			1 st Yr	2 nd Yr	3 rd Yr	TOTAL

Justification for consumable materials giving estimated requirement of consumable for each prototype.

12. E BUDGET FOR TRAVEL :

Please provide estimated number of visits related to the project work and cost per visit along with justification.

13. BIODATA OF INVESTIGATORS :

- a) Name
- b) Date of Birth
- c) Academic qualifications
- d) Areas of expertise
- e) Experience

Sr. No.	Position held (Designation)	Place of work	Duration	Areas of work

- f) Awards received , if any
- g) Technologies Developed/Demonstrated/Transferred**
- h) Publications (Nos.)
 - Books
 - Research papers
 - Patents
- i) List of publications (Paper published during last 10 years)
- j) List of project completed indicating briefly title, sponsoring agency, duration and outcome of project.

14 Research projects currently with the investigator (s):

Please give the following details for each project:-

- Project Title
- Duration
- Date of commencement
- Status
- Cost
- Funding agency