

Call for Pre-proposal on “Creation of Bio-banking facility for Inherited Disorders”

Under Human Genetics and Genome Analysis- UMMID

Access to biological materials is a key prerequisite for scientific research in any medical field and in particular for research on inherited disorders, for which obtaining high-quality samples and the related clinical data remains a major hurdle. Inherited disorder bio-banks can play a pivotal role in making such materials and data available to the scientific community. Considering the high disease burden and a large number of patients, there is a tremendous need for Indian bio-banks to preserve Indian samples; to capture the great diversity of inherited disorders; to spur research into more precise diagnosis and better treatments for these diseases through the utilization of genomics as a part of a cutting-edge approach to promote health and combat disease.

With this aim, Department of Biotechnology (DBT) invites Institution based pre-proposals in the area of Medical Genetics in collaboration with clinicians specifically pathologists in lead role to develop National facility on population-specific/disease-specific Bio-banks for the receipt, storage and distribution of samples for basic, clinical and epidemiological medical research and for the use of future purpose to treat the affected family members.



Scope of the Call

DBT is taking a two-stage, one-application approach to the development of bio-banks that will meet the Medical Research sample storage and distribution needs.

A. Phase I (2 years): During the phase I, the successful awardees will each:

- Create a plan for the organization and development of a full-scale Bio-bank,
- Formulate procedures and equipment needs,
- Ensure all regulatory, ethical and consent issues are addressed.
- Train personnel,
- Identify and provide solutions for any logistical problems that can be foreseen and
- Within the limits of the Phase I budget, test and implement as many of the procedures as possible.

The objective of the Phase I stage will be for the awardees to plan for and demonstrate their ability to fulfill the goal of implementing a full-scale bio-bank in Phase II.

B. Phase II (4 years): In Phase II, the awardees will implement the plans they developed during Phase I to implement a full-scale bio-bank. It is expected that each of the bio-bank will be operating at full scale by no later than the end of the second year of Phase II.

To meet the proposed schedule and to determine whether the questions of feasibility and capability have been adequately addressed, DBT will conduct an administrative and technical review by an expert committee during the second year of the Phase I.

The decision about continued support for Phase II will be based on the accomplishments and progress made in Phase I and the quality of the updated plans for fully functional National facility, which were developed in Phase I. After attaining the stated milestones for the Phase I period, the successful Phase II continuations will be supported to those that are judged to have produced data to demonstrate the feasibility of establishing and sustaining a bio-bank at their site; have the most insight into and experience overcoming the challenges of sustaining a bio-bank in India.

Mode of Submission

Pre-Proposals may be submitted in the prescribed format (**Annexure-I**) clearly stating ‘Proposal against Call for Pre-Proposal on creation of Bio-banking facility under UMMID’ through an email: vinita.chaudhary@nic.in

Instruction Manual (**Annexure-II**) may please be seen before submitting the proposal. Subsequently, two hard copies should also be sent to:

Dr. Vinita N. Chaudhary, Scientist ‘D’, Department of Biotechnology, Block- 2, Room No.816, 8th floor, CGO Complex, Lodhi Road, New Delhi – 110003.

Last date of submission: 30th October, 2017

Annexure-I

PROFORMA FOR SUBMISSION OF PRE-PROPOSAL FOR Creation of Bio-bank under UMMID of Human Genetics and Genome Analysis Programme

PART I: GENERAL INFORMATION

- 1. Project Title: Creation of DBT--“Population-specific/Disorder-specific” Bio-bank**
- 2. Details of Institution (Address and Status of the Institute/University/Hospital/Organization):**
- 3. Details of Coordinator/Principal Investigators/Co-investigators:**

Name:

Address:

Telephone:

Email:

Collaboration with clinicians specifically pathologists in lead role (Please provide Names and Institution Address):

If the project is multi-institutional, please provide the contact details of corresponding person:

- 4. Name and Designation of the Executive Authority of the University forwarding the application:**
- 5. Duration:**
- 6. Total Cost (Rs.)(Excluding contribution from your organization, if any):**

 Phase I (2 years):

 Phase II (4 years):
- 7. *Vision for the proposed Bio-bank in terms of the research and services (150 words):**
- 8. *Significance of the proposed Bio-bank (100 words):**
- 9. *Short term and Long Term goals and strategies to achieve this (100 words):**
- 10. *Innovation content (100 words):**

11. *Feasible approach (100 words):

12. *Plan for sustainability (100 words):

13. *Protection Measures in terms of

(a) Involvement of human subjects:

(Enclose an Informed consent form as outlined in Annexure II and provide the Details of the Institutional Ethical Committee and its Registration number with DCGI)

(b) Biohazards:

14. Scope of application in terms of the following anticipated outcomes (100 words):

(a) Plan for organization and development of a full scale Bio-bank:

(b) Formulation for procedures and equipments needs:

(d) Identification of Logistical problems and their solutions:

15. Project Summary (300 words):

16. The main strength(s) which merit(s) this support should be described in less than 200 words:

PART II : TECHNICAL DETAILS OF PROJECT

17. Introduction (about the proposed Bio-bank in 1000 words):

17.1 Origin of the proposal:

17.2 (a) Rationale of the study supported by cited literature:

(b) Hypothesis:

(c) Key questions:

17.3 Current status of research and development in the subject (both International and National status):

17.4 The relevance of the proposed study:

17.5 Current area of research of the participating institution relevant to this project and Preliminary work done so far:

18. *Major Objectives of the project (in one para):

(a) Specific objective for Phase I (Pilot Study for 2 years):

(b) Specific objectives for Phase II (Scale-up Study for 4 years):

19. Specific work plan including methodology, time schedule and deliverables/proposed outcome (in a tabular form):

(a) For Phase I (Pilot Study for 2 years):

(b) For Phase II (Scale-up Study for 4 years):

20. Existing Facilities, Infrastructure and Equipment available to the team for implementing the project (this information will strengthen the merit of your proposal):

21. Specific research facilities/ infrastructure required for the project with detailed justification:

(a) Proposed Bio-bank capacity:

(b) Up-gradation of Existing Facility for implementation of the proposed Bio-bank (if provided by the parent Institute/University/Hospital/Organization):

(c) Establishment of New Facility (if not provided by the parent Institute/ University/Hospital/Organization):

22.*Brief on Proposed Bio-bank Operations:

A. Designing of Biospecimen processing and storage methods:

i. Following Plans of the operations for proposed Bio-bank in Phase I:

- a. Designing of the proposed Bio-bank:
- b. Robust methods for Testing:
- c. Robust methods for Carrying out the operations:

ii. Following plans in Phase II:

- a. Robust methods for sample receipt:
- b. Robust methods for sample processing and storage:
- c. Robust methods for sample distribution:

B. Quality Control and Assurance:

- a. Plans to test and monitor the collection method and pre-processing services at the collection site (if any) to ensure that specimens reaching the proposed Bio-bank are not compromised
- b. Plans for and tests of quality processing, storage and distribution methods
- c. Methods for rapid and accurate retrieval of samples
- d. A plan as to how samples will be tested for end-process suitability
- e. Planned systems and tests for notifying staff of an equipment failure and corrective actions;
- f. Plans as to how the bio-bank will test and ensure the continuous integrity, authenticity, and sterility for each sample type needed for the proposed Bio-bank including but not limited to barcode labeling, DNA fingerprinting, etc.

C. Bioinformatics:

- a. **The current and planned bioinformatics capacity of the bio-bank:**
- b. **Issues of both current and planned data acquisition, data management, data storage, database security and analytical capability:**
- c. **Designing of Indian Bio-bank website:**
- d. **Data Sharing and Release plan:**

D. Training of manpower:

- a. **Training in Bio-banking skills at all levels i.e., technical staff, research scientists and database developers/ managers:**
- b. **Collaboration on the development of Standard and consistent Operating Procedures:**

E. Administration:

- a. **Administrative structure:**

- b. **Management of the procedures, services, operations and engaged manpower in the proposed Bio-bank:**
- c. **Monitoring and Evaluation Plan:**

23.*Institutional and National Commitments:

24. *Fund requirements from DBT (in tabular form) for complete project duration (i.e for 6 years- including Phase I and Phase II) for each year details of different components, wherever required. Clearly state what is meant for infrastructure support or basic equipment. *The cost the concerned Institute/University/Hospital/Organization is prepared to share, should be indicated in a separate table:*

25. One Page Bio-data of each Participant (Please incorporate only that information which justifies your expertise and capability for this project):

- a. **Current Areas of Research**
- b. **Five best Publications in this area in last five years**
- c. **Patents/technologies developed and transferred in this area in last five years**
- d. **Give a statement of the funds above Rs. 50 lakhs for R&D already received from DBT and other S&T agencies:**
- e. **Any other information (main strength which merits this support)-One page**

(Note-All * marked fields are explained in detail in the Instruction Manual)

26.Declaration/Certification

It is certified that

- a) The same project has not been submitted to any other agency/agencies for financial support.
- b) The emoluments for the manpower proposed are those admissible to persons of corresponding status employed in the institute/university or as per the Ministry of Science & Technology guidelines
- c) Necessary provision for the scheme/project will be made in the Institute/University/State budget in anticipation of the sanction of the scheme/project.
- d) If the project involves the utilization of genetically engineered organism, it is agreed that we will ensure that an application will be submitted through our Institutional Biosafety Committee and we will declare that while conducting experiments, the Biosafety Guidelines of the Department of Biotechnology would be followed in toto.
- e) If the project involves field trials/experiments/exchange of specimens, etc. we will ensure that ethical clearances would be taken from concerned ethical Committees/Competent

authorities and the same would be conveyed to the Department of Biotechnology before implementing the project.

- f) The institute/university agrees to sign detailed MOU with DBT for management of programme when approved
- g) The institute/university agrees that the equipment, other basic facilities and such other administrative facilities as per terms and conditions of the grant will be extended to all investigator(s) throughout the duration of the project.
- h) The Institute assumes to undertake the financial and other management responsibilities of the project.
- i) We agree to accept the terms and conditions

Signature of Research Group Leaders

Signature of Programme Director

Date:

**Signature of Executive Authority
of University with seal**

Signature of Programme Investigator

Date:

**Signature of Executive Authority
of University with seal**

Annexure-II

Instruction Manual For submission of Pre-proposals under Call on Bio-Banking

Eligibility Information

1. Eligible Organizations

- a. Central/State Govt. Institutions of Higher Education
- b. Private Institutions of Higher Education
- c. Research institutes, universities, medical schools, IIT's and other engineering institutions, other recognized research laboratories in the public sector and not for-profit institutions. The Institute should have well established research facilities as well as a core faculty with expertise in the relevant area. The grants under the scheme are intended for institutions with a substantial investment in, and commitment to, the area of thematic focus.
- d. The institution must be recognized by DSIR as a Scientific and Industrial Research Organization (SIRO), if outside public sector.
- e. The institution should provide an assurance of support and space.

2. Required Registrations

Private institutions/Hospitals/ NGOs should be registered in **Darpan Portal, Niti Aayog website.**

3. Eligible Individuals-Program Director(s)/Principal Investigator(s)

- Scientists working in Universities/Academic Institutions/National Laboratories/Industries [Department of Scientific & Industrial Research (DSIR)-Recognized R&D Centre] & Non-Profit Organizations with necessary facilities and strong scientific background in the proposed area as the Program Director(s)/Principal Investigator(s) is invited to work with his/her organization to develop an application for support.
- Collaborative projects with clinicians, patient supportive groups and industry people would only be considered for funding.
- **Eligibility for Program Director/ Principal Investigator:**
 - I. He / She must be an investigator working in a regular capacity at an Indian institution dealing with Human Genetics. Several Co-PIs are accepted including from industry and hospitals.
 - b) He / She must required years of regular service still remaining at the institution where the current work is proposed till the Bio-bank is fully operational.
 - c) He / She must have a proven track record of knowledge and expertise central to the thematic focus of the proposed inherited disorder/s as evidenced by peer-review, publications, patents etc.
- **Profile of the Program Director:**

The Program Director of the proposal must be an established research scientist who will ensure that high-quality research is performed and who has the experience to effectively administer and integrate all components of the program. The Program Director must have an active research program that receives support in the scientific area of the centre and should also have the requisite administrative experience required for establishment of

bio-bank including the effort put in for mentoring and administrative oversight of the program. The Program Director should be a competent scientist in the relevant area, as evident from publications in world class refereed journals and patents held / applied in the last five years. The Program Director biodata should also include details of research projects handled, number of Ph.D. students registered, number of patents filed / granted and technologies transferred etc. The Program Director will give an undertaking to commit at least 50% of his time to the scheme, and to continue to be involved in the programme for the entire duration. Multiple PIs/Co-PIs are accepted.

Instructions to write a Pre-proposal

All Pre-proposals will be processed through the usual procedure following the Peer-Review / Expert Committee mechanisms. The Bio-bank application must be submitted as a single application and should be clearly organized into two phases: (Phase I) and (Phase II). To clearly distinguish between the two phases, applicants should specify separate Phase I and Phase II research strategies in the Research Plan of the proposal.

In preparing the application, investigators should consider the fact that applications will be assigned a single impact/priority score for both Phase I and Phase II phases. Thus, clarity and completeness of the application with regard to specific goals and the feasibility of milestones are critical. Milestones should be sufficiently scientifically rigorous to be valid for assessing progress in the Phase II and will reflect the scientific judgment and experience of the applicant.

The following instructions must be followed while writing the proposal on Bio-bank:

Part I-General Information:

- 1. Vision for the proposed Bio-bank:** This section should describe the vision for the proposed Bio-bank in terms of research and services facilitation which will provide the long term impact on R & D in the area of Medical Genetics. The PI should discuss about the vivid strategies for the population-specific/area-specific Bio-banking services as per the need of local/regional/National requirement for the inherited disorders affected people and their family of our country.
- 2. Significance:** This section should describe why building a National bio-bank in India is important for improving Indian health. The PI should discuss the barriers to success in both phases of the project, how this study will address the problems and what new improvements in Indian genomic research, health care, therapies or technical capabilities might be expected if the bio-bank is successful.
- 3. Short-term and Long-term Goal and Strategies:** Short-term and Long-term Goal of the project should be clearly defined. For Phase I, the Strategy Section should describe in detail how the applicant will use the initial two-year feasibility period to lay the foundation for a fully functional, scaled-up bio-bank in the most useful, forward-looking way possible. For Phase II, the Research Strategy Section must include description of how the bio-bank will be further developed in Phase II based on the Phase I plan and feasibility data generated during Phase I.
- 4. Innovation:** This section of the Research Strategy should address what innovative solutions are being proposed to meet the special challenges of establishing a National bio-bank in India. Describe what novel concepts, approaches and technologies will be employed to meet the challenges of successfully establishing an Indian bio-bank capable of receiving and sending samples from other parts of the country. Importantly, the applicant should describe

how success in this project will improve the Indian bio-bank service in general and promote the field of genomics in India.

5. **Feasible Approach:** This section of the research should describe the overall strategy and methodologies that will be used to accomplish the specific aims of the project. PI should address the feasible way out to establish a successful, sustainable bio-bank in India.
6. **Sustainability:** One of the major goals of this program is to establish National bio-banks in India that will in turn, help to enable Indian scientists to excel in their research. While it may be premature to expect that applicants will be able to develop concrete plans for sustaining the bio-banking activity six years in advance (the two-year Phase I study period plus the four-year Phase II scale-up period), applicants should discuss the issue of future sustainability of the envisioned bio-bank, its capacity to sustain itself beyond the DBT funding program, and if appropriate, the ability to eventually provide bio-banking services beyond this program. The discussion of sustainability should be compatible with the letters of institutional and national commitments in providing an overview of the long-term prospects for a sustained bio-banking activity. In addition to institutional commitment, sustainability issues that should be considered, include but are not limited to, potential future income from fee for services, availability of funds from other sources, equipment replacement/modernization, continuous access to space, essential supplies, services, and stability of the positions for trained personnel.
7. **Protection measures:**
 - a. **Human subjects protection:** The application for the Phase I award should include a discussion of any issues involving human research participants that the bio-bank will need to address, and how the bio-bank will address those issues. Applicants should be sure to address all the ethical and regulatory issues associated with Human Bio-banking. Informed consent document should provide information regarding the specimen collection, storage and the purpose for which it will be used, disposal of the material, use for other research projects including from Investigators outside the parent Institution. A clear option of not willing to either provide the sample or not willing to allow storage/use of tissues/blood etc collected for diagnostic uses for research should be part of the Informed consent. Any use of the collected samples for research should get the Ethical committee's clearance, especially for Investigators not associated with the original research project under which the sample could have been collected. All the samples planned to be stored should be anonymized; at the same time patient-related clinical data should be linked without patient identifiers to the sample, to ensure proper annotation of the samples. A sample informed consent form will need to be enclosed, mandatorily. Details of the Institutional Ethical Committee including its registration with DCGI need to be provided. Work plan with regard to data/sample securing procedures and procedures for data sharing should be provided.

- b. **Biohazards:** Applicants should provide the valid justification whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

8. Scope of application:

- a. **Plan for organization and development of a full scale Bio-bank:**
- b. **Formulation for procedures and equipments needs:**
- c. **Identification of Logistical problems and their solutions:**

Part II-Technical Details:

9. Major Objectives:

The purpose of this Call is to solicit combined applications for the Phase I pilot study and the Phase II scale-up bio-banks.

- A. Phase I Study:** The objectives of initial two-year Phase I study are to develop a plan that will lay the foundation for establishing a bio-bank to serve initially the case-specific research and to demonstrate the applicant's ability to accomplish the activities that will be necessary for providing a full-scale Bio-bank facility in the Phase II.

The grant application for Phase I should include a description of the following:

- a. The vision for the full-scale bio-bank, in terms of the services that will be provided and the infrastructure and capabilities that will be necessary to provide them, that the applicant will be working toward during Phase I
 - b. How the applicant plans to utilize and improve the existing infrastructure at the institution, in terms of facilities, equipment, software, personnel and scientific networking as well as institutional and National commitment to the bio-bank
 - c. How the expertise for development of sample receipt, handling, storage and distribution to the investigators within the country will be accomplished
 - d. The problems and obstacles that are anticipated in order to meet the challenge of serving as a bio-bank to multiple investigators from multiple institutions
 - e. How the applicant will create or take advantage of forward-looking solutions to solve those problems and overcome those obstacles
 - f. The plan during the Phase I period to test or demonstrate the validity of the proposed approaches, e.g., receipt and distribution of samples within India, and
 - g. The training in bio-banking management and sciences to meet the needs of the full-scale National Bio-bank and subsequently enhance the expertise of Indian scientists in the field of genomics and/or laboratory sciences
- B. Phase II Scale-up:** For Phase II, the grant application should address
- a. How the implementation of the bio-bank will build on the plan and data generated during Phase I and
 - b. How the services of the bio-bank may eventually be expanded (for self-Sustainability)

10. Bio-bank operations:

- A. Biospecimen processing and storage methods:** The application should describe all of the operational aspects of a proposed Bio-bank and how the plans for designing, testing and carrying out the operations will become routine in Phase II. It should describe, which (if any) of those Bio-bank operations are already in place at the institution. This section should begin with a description of the overall flow of samples into and out from the Bio-bank. Additional details should be provided for:
- a. Robust methods for sample receipt
 - b. Robust methods for sample processing and storage
 - c. Robust methods for sample distribution.

In each case, the applicant should discuss how the methods of choice will be determined, any innovations planned and how the methods or new approaches will be tested (including any plans to test certain methods during the two-year Phase I period). The processing and storage methods must be consistent with the end use expected for the sample, for example DNA sequencing or genotyping. Methods may include, but are not limited to, separation of blood lymphocytes for making cell lines as needed, extraction of DNA from isolated blood cells or other tissue, aliquoting, cryopreservation, dry storage, etc. The applicant should describe how specimens will be aliquotted and/or formatted prior to storage or shipment. In addition, the applicant should comment on how the collection methods and pre-processing services at the collection site, if any, will be monitored to ensure that specimens reaching the proposed Bio-bank are not compromised.

- B. Quality Control and Assurance:** Quality control and assurance procedures will be critical for a Bio-bank to provide high quality services and to ensure the continuous integrity, authenticity and sterility for each sample. Therefore, a critical part of the Phase I study process is to propose and test a robust quality control and assurance plan.

- C. Bioinformatics:** An essential part of the Bio-bank plan will be the plans for software and database support for the proposed Bio-bank.

- i. **The current and planned bioinformatics capacity of the Bio-bank** should be clearly described, both at the level of the overall program and at the level of each functioning component of the Bio-bank.
- ii. **Issues of data acquisition, data management, data storage, database security and analytical capability, both current and planned** should be addressed. The choice of sample management database should be described and justified. The bioinformatics tools that will be used for each of these functions and the applicant's experience and plans to receive more training for the repository staff with these tools, if needed, should be described in the application. Additionally, current or planned backup systems for recovery in case of electrical failure should be discussed.
- iii. **Designing of Indian Bio-bank website:** In phase II, DBT anticipates there will be a need for a common **Indian Bio-bank website** to provide information about the Indian Bio-banks and to present a single catalog of available resources for users. While it is difficult to make specific plans for interacting with other Bio-banks without knowledge of what those Bio-banks are, the application should include ideas about the issues that

will be faced in establishing a common Indian Bio-bank website and the applicant's willingness to participate in its development. The applicant should describe his/her preference for a website design; a common design will be agreed by the Phase II awardees if the Phase II funds are awarded. Individual Bio-banks may also maintain their own individual websites if desired, but will not be required to do so once the existence of a common website has been established.

- iv. **Data Sharing and Release plan:** A plan for data and resource sharing and release is expected for all applications and an applicant must have submitted an acceptable Data and Resource Sharing and Release plan before it can be funded. Thus, in addition to a well thought-out plan for distributing the resources received at the Bio-bank, the application is expected to include a plan for widely sharing the data that accompany those resources. After all Bio-bank awards have been made, the Bio-bank Consortium should be developed.

D. Training of manpower: A key objective of the Indian Bio-bank program is to help support the ability of the next generation of Indian researchers to take advantage of genomic approaches to health research. Therefore, the application must include in both Phases I and II a component for training in biospecimen handling and processing and other Bio-banking skills. The training elements can include:

- a. Training in Bio-banking skills at all levels i.e., technical staff, research scientists, and database developers/ managers; and provision of opportunities for career and leadership development for Bio-banking personnel.
- b. Collaboration the development of Standard and consistent Operating Procedures: The Phase I component of the application, must discuss the applicant's willingness to participate in such a collaborative system and how the applicant will approach the objective of establishing such interactivity and harmonization such as collaborating on the development of Standard Operating Procedures for the proposed Bio-bank in Phase II.

E. Administration:

- a. **Administrative structure:** The application for the Phase I study award must discuss the management plan for Phase I and how it will be scale up for Phase II, the administrative and management issues that the full-scale Bio-bank will face and the proposed plan must include a strong management plan for Phase II.
 - b. **Management of the procedures, services, operations and engaged manpower in the proposed Bio-bank** must be discussed in the application.
 - c. **Monitoring and Evaluation Plan:** Applications for the Phase I study award should include a discussion of how the funds and supported activities will be monitored and evaluated, specifically for the Phase I and more generally for the scaled-up Phase II Bio-bank. The application should include a well-defined set of milestones for both the phases.
- 11. Institutional and National Commitments:** Applications should include letters from the appropriate institutional official (University or Medical School President, Dean or Director, or the head research administrator or equivalent from the institution) stating its

commitment to the proposed project and its sustainability. The institution should also indicate its commitment to overcoming any administrative obstacles to the implementation of the proposed Phase I study activities and the Phase II activities. Appropriate institutional commitment to the program includes the provision of adequate staff, facilities, and resources that can contribute to the planned program.

12. **Budget:** Please note that a 6 year budget is required for the entire application; this is made up of the Phase I (2 years) and Phase II (4 years) budgets.