Guidelines for sustaining DBT- Bio-Banks and Cohorts

Outline

Guidelines for sustaining DBT- Bio-Banks and Cohorts

1. Executive Summary

Bio-banks, bio-repositories and research cohorts (including demographic sites) are national assets established with considerable efforts. Recent advances in the tools and technology of molecular biology, genetics, environmental sciences, epidemiology and demography have increased the demand for well-annotated, properly-preserved biological specimens and associated epidemiological and demographic data. In response to the demand, bio-banks, cohorts and demographic sites have been established in several parts of the country within the past 10-15 years and more are in development. Most of these have been established with Government of India funds. A strong governance structure and oversight mechanism will help safeguard their scientific relevance, financial sustainability, operational efficiency and social value. Programmes are necessary to offer sustained and long term financial support to these national assets that guarantee their continued relevance along with an in-built mechanism of accountability to science and the people ofIndia.

During the recent past, the Department has supported major programs and studies on cerebral stroke biology, adult health and brain aging, dementia, stem cell technology, TB, HIV, maternal & child health, young adolescents, trajectories for healthy life, renal biology, chronic kidney diseases, cancer, auto-immune disorders and genomics of healthy people. These studies resulted in the establishment of several bio-banks, bio-repositories, clinical trial facilities, disease specific cohorts and demographic sites.

Bio-banks, bio-repositories, disease specific cohorts, clinical trial and demographic sites are to be considered as national assets and Department should bring about provision to support them on long term basis. This will help the Department to leverage the sizeable investments made so far for future R&D projects and programs to stay in the race for leadership in bio-medical science and technology activities. Towards this aim, various consultation meetings have been conducted to prepare a roadmap and national guidelines for long term sustainability of bio-banks and cohorts for future research endeavors.

Further, the Department is also proposing to facilitate and coordinate various activities related to biobanks and cohorts to harmonize the processes, protocols and archival activities of the existing facilities. Considering the immense potential of these studies and facilities for future R&D endeavors, the Department is willing to extend the support on other gap areas of national concerns with long term handholding.

Keeping a watch on the present situation, the COVID-19 pandemic is expected to continue to be the most critical international concern for years to come, from public health perspective, societal disruption and the resulting economic consequences. As the number of cases and fatalities continue to mount, bio-banks, cohorts and demographic sites will serve as the anchor for understanding various aspects of infection and outcomes of infection. Towards these efforts, the Department is also supporting COVID-19 bio-repositories.

Financial support and scientific oversight of bio-banks, cohorts and demographic sites are going to be invaluable for their sustainability and the advancement of science in India. The strategy will prepare the country to handling emergency situations like COVID 19 pandemic even in the absence of support from outside, enable meticulous description of epidemiologic, clinical, pathological and molecular basis of existing and emerging diseases and preparing the country for taking global leadership in developing diagnostic, therapeutic and other domains of bio-medical sciences in times to come.

The financial and administrative support to these units will have to be linked to 3-5 yearly detailed audit by a National Executive Committee constituted by DBT for: sustained scientific and technical contributions that primarily lead to national good; provide access to researchers from across the country to escalate scientific research; become opportunities to link with private players

and align with international initiatives, become centers of capacity and skill building for next generation of research leaders; have robust governance structure in place; and ability to demonstrate long term vision and a strategic roadmap for the sustainability of the bio-banks and cohorts. It is proposed that a minimal core support is provided to the enlisted bio-banks, cohorts and demographic sites and additional support will be contingent on to achieve pre-defined benchmarks.

2. Definitions

A **repository** is defined as a formally managed physical or virtual entity that may receive, process, store, and/or distribute specimens and/or samples and their associated data (both retrospective and prospective) as appropriate in support of current or future use. A repository may be further defined by the collection of specimens as a **bio-repository if the specimens represent, or are biological specimens** (International Society for Biological and Environmental Repositories, 2018). The terms "bio-repository"and"bio-bank"areoftenusedinterchangeablyasthedistinctionisblurred.Forthe purposes of this document, the term"bio-bank"isused for uniformity.

A **cohort** is defined as a group of people with a shared characteristic. The type of **epidemiologystudy**in which individuals are identified according to exposure, or shared characteristics and followed to determine subsequent disease risk is known as a **cohort study**. Such cohorts will also include small numbers of patients/individuals who are part of small projects but have significant scientific potential due to their uncommon nature and also need for progress towards personalized medicine. A **health and demographic surveillance system** gathers longitudinal health and demographic data for a dynamic cohort of the total population in a specified geographic area. As part of this document, cohorts refer to all of the three conditions described in this paragraph.

Table 1: Typologies of bio-banks, cohorts and demographic sites

Based on use/coverage
1. General/Population
2. Disease- specific (brain bio-bank, cancer bio-bank, atherosclerosis bio-bank)
Based on source of funding/governance
1. Public
2. Private
3. Public-Private partnerships
Based on source of samples
1. Clinical setting
2. Research studies
3. Geographic regions
4. Pharmaceutical industry
Based on time/period of collection
1. Prospective collections
2. Retrospective collections
Based on size/degree of access
1. Investigator driven
2. Institutional
3. Regional/National
4. International

(Adapted from: Vaz, M., Vaz, M., &Srinivasan, K. (2014). Ethical challenges in bio-banking: moving the agenda forward in India. Indian Journal of Medical Ethics, 11(2), 79–88. https://doi.org/10.20529/IJME.2014.022)

3. Scope

A. This document has been developed to provide guidance on sustaining existing bio-banks/repositories, and cohorts/demographic sites in India.

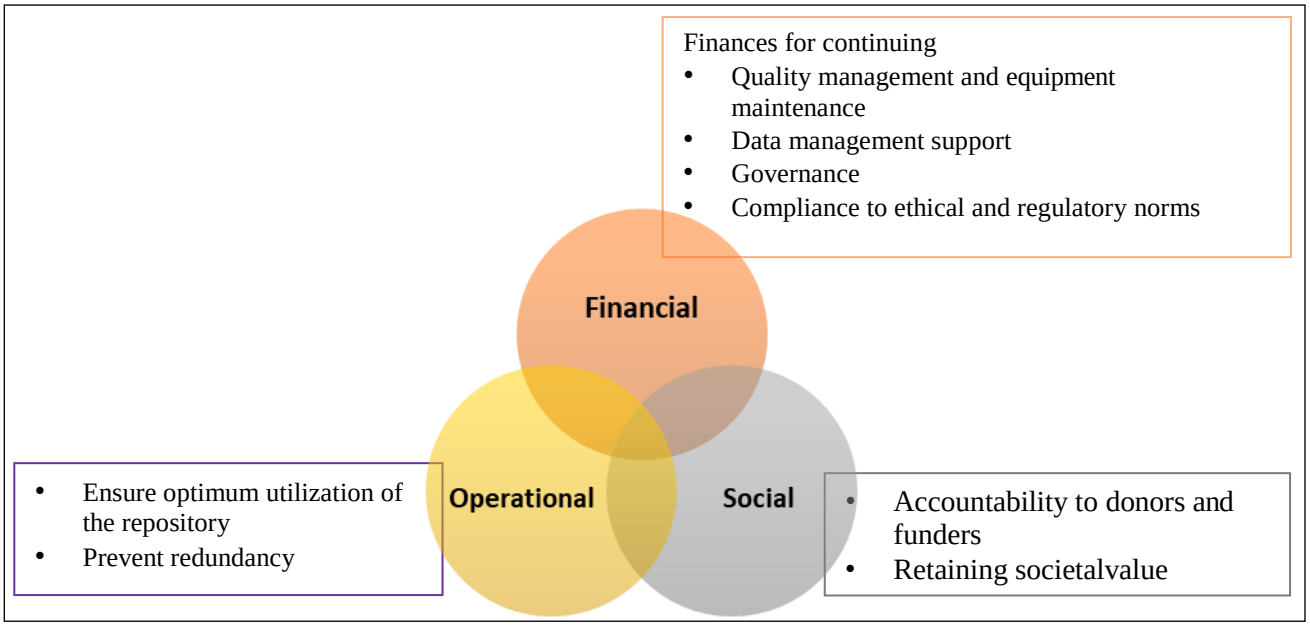
B. This document also outlines key considerations for programs intending to provide sustainability support to existing bio-banks, cohorts and demographic sites, with special reference to those established as part of Department of Biotechnology funded research projects.

C. Value and relevance based criteria might also be used to recruit private biobanks and cohorts as part of the network.

4. Dimensions of sustainability

Sustainability can be approached from there dimensions: Financial, operational and social (Figure 1). Though the discussion of sustainability is often heavy on the financial dimension, each dimension is critical and challenging. Comprehensive sustainability strategies should be devised considering the perspectives of all stakeholders (such as the public, the bio-bank, the researcher, and the funders – governmental &others).

Figure 1: Dimensions of sustainability



In Table 2, the challenges in the three dimensions and possible solutions are listed. It is worth noting that a single solution package cannot be prepared or prescribed for sustainability, due to the diverse types and uses of bio-banks, cohorts and equally diverse stakeholders. However, no repository will be awarded any support without such a sustainability program.

The next section describes the aspect of governance in detail, since good governance can ensure sustainability in all the dimensions described above.

5. Proposed governance model

It is necessary that a nationally cohesive and integrated governance model is prepared that allows the bio-banks, demographic sites and cohorts becoming truly national assets, contribute to science, and are accessible to investigators and scientists from across the country to justify support and make these accountable to public investments.

Governance policies and procedures will be developed with the full repository/cohort lifecycle in mind to ensure long term sustainability. The level of policies and procedures governing the bio-banks and cohorts should be scalable to its nature, size, and available resources. The governance, SOPs and management structure will ensure achieving international benchmarks in a transparent and auditable manner for all the activities of the bio-banks and cohorts. This will be necessary to attract both national and international funding agencies, scientists and industries. This is essential to ensure that the resource is well utilized and it is worth the effort and expense involved in maintaining it. It will also honor the spirit in which the donor provided the sample.

The policies are usually stipulated in a governance document that describes the objectives and scope of the bio-bank, the organizational structure, the scientific and economic strategy of the bio-banks and cohorts (which will be articulated in an annually updated work plan in sync with the long term strategies), and contingency plans in the event of closure. The governance document also includes policies on data protection and privacy as well as procedures governing specific operational activities of the bio-bank.

A. Governance framework

The model described in this document is adapted from the Standards developed by the International Agency for Research on Cancer (IARC). The roles of committees depicted in Figure 2 are described below:

i. Empowered/Apex National Executive or Steering Group (Constituted by DBT and based at DBT headquarters)

The Committee shall provide

a. Overall oversight to the technical, scientific and financial functioning of the bio-banks, cohorts and demographic sites across the country
b. Secretary DBT will nominate the Chair of the Apex National Executive Group.
c. The Committee will comprise science manager, basic and applied scientists, epidemiologists, scientists with previous experience in bio-banking, cohorts and demographic site management
d. Develop a score card for transparent and objective assessment of the performance of these structures. The Committee will decide about the benchmarks for making the site eligible for continued and quantum of support from the department.
e. The Committee shall undertake annual reviews.
f. The decision to continuation of the support shall be decided by a structured and detailed audit at 3-5 yearly intervals, defining strategic scientific objectives aligned with national research priorities, recommend financial support, and suggest resource generation strategies, revising and/or adopting new policies, and developing a communications strategy.
g. Site visits will be made by the National Steering Committee as per the needs and before extending the support for the next round of evaluation.
h. After the first round of detailed audit, the Committee will organize bi-annual conference to bring together site investigators, bio-medical scientists from across the country and potential international collaborators for efficient use of the resources available at the bio- banks, demographic sites and cohorts.

ii. Site specific governance

The following Committees are indicative and there can be flexibility for combination of one or more committees. However, ***ethics committee and scientific oversight committee*** are essential and to be maintained as a separate entity by every bio-bank, cohort and demographic site. The task of some of the other committees can be clubbed together as decided by the site but the site SOPs should cover all the tasks mentioned for the various committees.

a. *Ethics committee:* Provides ethical oversight, to all aspects of the bio-bank, cohort and demographic site including legal and policy issues. Responsible for the ethical conduct of the all site specific activities as per the most recent national guidelines.
b. *Scientific oversight (or advisory) committee:* Site specific guidance for developing research agenda and strategic road map, and oversee ongoing projects, consider the pertinence of new research priorities, review proposals submitted by external investigators

for use of bio-bank, cohort and demographic sites data and facilities, advice on sample and data collections, storage and procedures.

c. *Operations or management committee:* Support the scientist in the committee for the strategic decisions of the bio-bank and to provide expertise in all aspects of bio-banking operations (e.g. safety; quality and efficiency, including processing, storage, and distribution of bio-specimens and associated data).
    - *Laboratory safety and bio-security:* Oversight of which may also consider general health, safety, and security issues.
    - *Data and sample access:* Oversight of access requests, monitors related procedures, and ensure that participants' interests are protected and bio-bank protocols are followed.

d. *Public engagement committee:* Help researchers to better understand public opinion and regularly engage with public. For some larger bio-banks, cohorts and demographic sites, advisory panels of study participants meet regularly and provide feedback on new projects and review study materials, newsletters, and questionnaires. The role of this committee can also be undertaken by ethics committee.

B. Access to and sharing of samples and data:

This is an essential objective of establishing these national assets and will be an important criterion for continuation of the financial support to the sites. Each bio-bank, cohort and demographic site should have a data and sample sharing policy as part of its governance framework. Sharing of resources is crucial to ensure those bio-banks and cohort infrastructures are used optimally for advancement of science in the country at all times. This policy should detail:

i. Publication of a catalogue of types of samples and data available
ii. A national website to be established to give details of the available bio-bank, demographic sites and cohorts: and available data
iii. In case of bio-banks/cohorts established as part of a research study, a period of moratorium may be considered after which the resources will be made available to other researchers on request.
iv. Procedure for applying for access todata/samples
v. Procedure for reviewing accessrequests
vi. Procedure for transferring samples/data once request isapproved
vii. Procedure for monitoring use ofsamples/data
viii. Procedure of providing access to international investigators aligned with national and international guidelines
ix. Proper mechanism for Material Transfer Agreement (MTA) to enable broader sharing and use of biological materials by biotechnology practitioners working within the practical realities of technology transfer.

The above framework will be determined by the various committees constituted as part of the governance mechanism described in the previous section. A template for policy on data sharing and access and associated documents is given in Annexure 1.

6. Guiding principles for programs intending to provide sustainability support

A. Eligibility: Which bio-banks/cohorts may be considered for long term support?

i. Essential criteria:

a) Uniqueness of the bio-specimens with clinical, demographic and sample attributes that are managed with highest quality standards
b) Data Custodianship is with recognized R&D organization in India (Scientific and Industrial Research Organization-SIRO recognition)
c) Site resources are used for research purposes that primarily lead to national good
d) Commercialization for larger societal benefit; particularly to the Indian scientists and commercial entities and with prior permission from the site specific ethics and scientific committees.
    - Use of samples for development of diagnostics, therapeutics, vaccine candidates as part of the business model
e) Ability to bring international collaboration for advancement of science and commercial purposes (the target can be global but not overlooking requirements and interest of India and Indian population)
f) Functional robust and transparent governance structure in place
g) Ability to demonstrate long term vision and a strategic roadmap for the sustainability of the bio-banks and cohorts.
    - Business model for sustainability: Every bio-bank and cohort will have to demonstrate existence of a professionally developed business model for generation of resources with the overall aim of cost recovery and sustaining the entity financially and infrastructure wise.
    - This will include tiered fee-for-service approach for Indian scientific and academic organization, commercial entities and international collaborative activities
    - Assemble and set up national and international networks/collaborations of academics who can exploit the resources of the biobanks and the cohorts for attracting research grants
    - Ability to attract the entrepreneurs (both national and international) for undertaking translational work and commercialization of the material available at the biobank
h) Ability of the bio-banks and cohorts to attract RFPs from different Indian and international funding agencies
    - Request for Proposals (RFPs) for specific research questions- This approach may be useful for agencies like DBT, CSIR, ICMR, DST which have detailed information available regarding existing bio-banks/ cohorts and therefore can solicit expert opinion in a transparent manner to decide research questions that could be relevant for the national science and commercial requirements. These will refer to specific biobank/cohorts. National scientists in collaboration with international scientists will also be able to apply. The samples and the data from the bio-banks/cohorts will be made available as per the business model of the respective institution. Authorship will be only for the investigators and the respective bio-bank/cohort will be recognized and acknowledged.
    - RFPs with open research questions- The interested candidates submit proposals detailing research questions that can be answered using existing bio-banks/cohorts. The investigators can obtain funding from any source which is to be communicated and acceptable to the Scientific Advisory

Committee/Management Committee of the bio-bank/cohort. The site will undergo 3-5 yearly audit by the National Executive Committee and scored to determine the eligibility for the financial support by thedepartment

i) Desirable criteria: Accreditation through a recognized international/national accreditation programme (e.g., College of American Pathologists Bio-repository Accreditation Program or an Indian program) and Certification (ISO 20387:2018 Biotechnology- Bio-banking- General requirements for bio-banking) could be highly desirable criteria at least in the beginning.

B. Mode of identifying eligible institutions/bio-banks/cohorts for providing core and recurring financial and technical support

a) Based on previous track record: The bio-banks/cohorts/demographic sites which have performed well during the main research study which had led to their inception may be offered continuing support beyond the lifetime of that study provided these structures have a sustainable strategic plan for long term survival and are ready to share specimens and data for higher scientific advancement.

(1) Government agencies should take initiative to establish certain designated centralized state-of-the-art bio-banks/cohorts and organization of existing smaller collections under this centralized infrastructure. This should also include cohorts and samples of uncommon conditions with limited sample size for their scientific value and progress towards development of personalized medicine

(2) Private biobanks, cohorts and demographic sites established with broad scientific and commercial objectives and with robust governance mentioned in the document

b) Competitive Request for Proposals (RFPs): Interested sites submit a case for support and will be selected based on the scientific, academic and societal relevance of data housed in their bio-banks/cohorts and potential for supporting emerging national needs from time to-time.

(1) The selection process should include vigorous technical review and assessment of administrative and infrastructural capabilities by the site specific ethics and scientific committees and endorsed National Executive Committee. Site visits may be planned for this purpose.

C. Apportionment of funds

a) Core funding: DBT shall provide core support for management and basic maintenance of the biobanks, cohorts and demographic sites selected for financial and technical support. The core support shall vary according to the nature and size of the biobanks, cohorts and demographic sites.

- Every site has to have an administrator who maintains continuity of activities, prepares the background documents for National Apex Advisory Committee, and the other committees falling under the governance structure of the specific site. Another important task of the administrator is to coordinate the functioning of the scientific and ethics committee of the site.
- Sites chosen for financial support will submit their requirements for: human resources, sample handling and equipment costs and some utility expenditure. A sample template to guide preparation of budget outlay is shown in Table 3.

b) Technical support: Department will organize consultations and visits by national and international experts for bringing state-of-art knowledge and experience for constant upgradation of the management of biobanks and cohorts, data management, analytics and bio-informatics

D. Accountability metrics for monitoring and evaluation of performance

Metrics that are relevant to all stakeholders and appropriate for different types of bio-banks and cohorts will be developed so that funders and institutions can debate and assess the need and appropriate scale of funding allocation. These will include quantitative and qualitative metrics. Few examples for quantitative and qualitative metrics but not restricted to are:

i. Governance of the sites (assessed through site visits and quantitative data)

ii. No of RFPs from funding agencies for use of the samples and data from the sites

iii. Number of data access requests

iv. Number of actual users of bio-banks, cohorts and demographic sites (new and repeat users)

v. Number of samples that passed quality check for integrity during regular review process

vi. Number of successful research discoveries

vii. Number of publications from bio-bank samples and data based research

viii. Number of patents generated based on the research and commercialization of the products and innovations

ix. Population retention statistics for cohorts

x. Perception of the funders, scientist and commercial collaborators of the bio-banks, demographic sites and cohorts about their performance, value-addition and ease of interacting with their investigators/officer in-charges (Qualitative metrics could be derived through periodic user surveys and interviews with stakeholders to gain in-depth insights into operational issues)

E. "Market the resource"- Increase visibility

A well-managed and archived bio-bank or regularly followed cohort population serve no scientific purposes, if these remain unused. Such sites are neither scientifically nor socially sustainable and do no justice to the research participants who have consented to use their samples for scientific advancements. The proposed national initiative will also undertake following activities for sustainability:

i. Creation of a public directory of existing bio-banks, cohorts and demographic sites including website

ii. Opportunities to promote and facilitate utilization by the larger research community and not restricted to a single investigator group, through a well-defined data access and sharing policies.

iii. Organize seminars and workshops for researchers, academics, entrepreneurs, start-ups and funders to promote the opportunities the biobank and cohorts offer for scientific advancement

iv. Advocacy with national and international funding agencies for bringing out RFAs for specific research questions and open calls for encouraging the research community and optimal utilization of the resources created.

v. There must be a complementary cross-talk between govt. supported and private bio-banks emerging in the country and it must be a continuous effort.

7. Conclusions

Bio-banks, cohorts and demographic sites are national assets- a source of valuable material and data necessary for furthering scientific research and innovation in the country. India is in the initial stages of developing these assets and a systematic effort to sustain these assets is critical.

Guidelines for sustaining DBT- Bio-Banks and Cohorts

Sustained financial support and scientific oversight of bio-banks, cohorts and demographic sites till 2050 is going to be invaluable for the advancement of science in India. The strategy will prepare the country to handling emergency situations like COVID 19 pandemic even in the absence of support from outside, enable meticulous description of epidemiologic, clinical, pathological and molecular basis of existing and emerging diseases and preparing the country for taking global leadership in developing diagnostic, therapeutic and other domains of bio-medical sciences in times to come. The core support will be linked to score card based assessment on transparent and objective criteria and decided by an empowered National Executive Committee constituted by DBT. The underlying principle of supporting will be based on the principles of long term and futuristic scientific, academic and societal benefits accrued through these units. Such a programme will guarantee their continued relevance along with an inbuilt mechanism of accountability to science and the people ofIndia.

8. References

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Guidelines for sustaining bio-banks and cohorts

Table 2: Dimensions of sustainability

Challenges	Possible solutions	Remarks
Financial dimension		
1) Finances required for continuing • Well annotated sample/datastorage • Quality management andequipment maintenance • Data managementsupport • Governance • Compliance to ethical andregulatory norms 2) Major expenses include: Manpower (~40%), Sample handling (~25%) and Equipment costs (~ 20%); others& utility costs (15%)	1) Prepare a sound strategic framework- work plan/ long termroadmap 2) Sources: • Governmentfunding • Institutionalfunding • Research grants (national &international) • Cost recovery models (user fees, servicecharges) • Commercialisation of material, research resultsor derivedproducts • Philanthropicorganizations	• A combination of sources may berequired • Government funding is dependent on politicalwill, allocation for health R&Dsector • Primarily support will come from governmentalsectors • Recovery models may not be very important this time. Unlikely that bio-bank financial sustainability can be totally achieved only with this policy, also varies basedin the type of samplesavailable • Commercialisation activities need to be strictly monitored and profits should be channeled back to bio- bank maintenance in public funded banks, associated with lower rates of consent and public trust. Ethical guidelines also suggest that some of the profits should be route back to communities from samples havebeencollected.
Operational dimension		
1) Ensure optimum utilization ofthe repository 2) Prevent redundancy or wastage dueto non-use 3) Governmental support be contingentto firm current or future use forR&D	• Create centralised and specializedrepositories • Advertise to increasevisibility • Promote and facilitate utilization ofsamples/data • Funding agency(ies) come up with RFAsthat encourage the use of theserepositories • Invest on capacity building so that personnel are well updated on recent advances and best practices • Plan right from the design stage- Foresee, bio-repositories stay relevant and cater tofutureresearch needs	• Needs strong governance and accountability atdifferent levels • Onus will be on national agencies to identify andcreate central repositories and make information on them available on publicplatforms

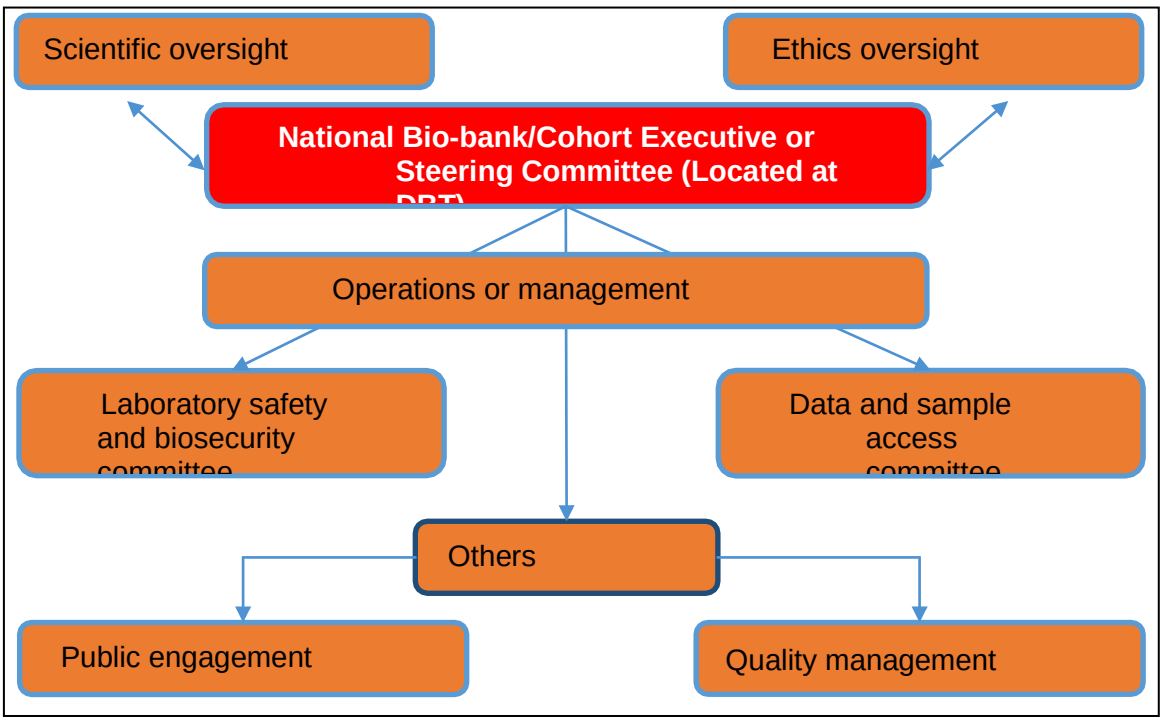
Guidelines for sustaining bio-banks and cohorts

Social dimension		
1) Accountability to donors andfunders 2) Retaining societalvalue	• Active solicitation of public input into operation of bio-banks (e.g., deliberative forums, public workshops)	• Important in public fundedinitiatives • Oftenneglected • Needs strong and transparentgovernance
	• Develop sustainability metrics for monitoringand use foradvocacy • Demonstrate commitment to globallyaccepted standards ofpractice • Compliance with ethical andadministrative regulations • Accreditation and certificationprograms	• These repositories to have governance structure like structures/institutions that proactively monitor the utility and strive for sustainability leastgovernmental funding and support is taken forgranted

Guidelines for sustaining bio-banks

Figure 2: Sample governance model for bio-banks/Cohorts

(Red Box is national committee located in DBT and rest of the boxes are site specific)



(Adapted with permission from: Mendy M, Caboux E, Lawlor RT, Wright J, Wild CP. Common Minimum Technical Standards and Protocols for Biobanks Dedicated To Cancer Research Standards and Protocols. In IARC Technical Publication No. 44)

Guidelines for sustaining bio-banks

Table 3: Sample template for budget preparation (ANNUAL)

Categories	Sub categories (indicative)	Year 1				
		Description	Number	Person time	Cost/Unit time	**Total cost**
Manpower	Personnel costs					
	Personnel typology (Site Administrator)					
	Personnel typology (e.g.,Lab Technician, field staff, clinical support staff)Quality manager)					
	Personnel typology (e.g., datamanager/bio-informatics)					
	Training costs					
Travel	Follow up of cohort&demographic population					
Equipment	Storage equipment	Description	Number	Cost per unit		
	Storage equipment type (e.g., deep freezers)					
	Data Storage (e.g., server hiring….)					
	Laboratory equipment					
	Laboratory equipment type					
	Laboratory equipment type…					
	Laboratory consumables	Description	Number	Cost per unit		
	Laboratory consumables type					
	Utility expenses					

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Equipment	Office equipment	Description	Number	Cost per unit	
	Contingencies and Office supplies (i.e. Stationary)				
	Space related utilities (e.g., rentals, electricity etc.)				
	IT equipment	Description	Number	Cost per unit	
	IT equipment type (e.g. Computers)				
	Software upgradation, replacement…				
	Maintenance	Description	Units	Cost per unit	
	Maintenance type (e.g. Laboratory, website, media platforms)				
Research		Description	Cost		
	Research project 1*				
	Research project 2*				
	Fund raising cost (i.e. fund scanning,consortiumBuilding, network building)				
Networking		Description	Cost		
	Network participation (i.e. travel costs)				
	Network participation(i.e.Communicationplatforms)				
	Public engagement (meetings)				
Marketing		Description	Cost		
	Marketing strategy (i.e. Website,)				
	Marketing strategy (i.e.Publications)				
	Marketing strategy (i.e., socialmedia….)				

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Quality		Description	Cost	
	Quality (i.e. Accreditationprograms)			
	Quality (External evaluations)			
Safety		Description	Cost	
	Safety (i.e. Security systems)			
	Safety (i.e. Biomedical waste management)			
	Safety…			
Service costs		Description	Cost	
	Service cost (i.e., Electricity)			
	Service cost (Overheads/ Contingencies)			
Total cost (FINANCIAL NEED)				

*Detailed budget for individual biobank, cohort, demographic site should be prepared separately

Guidelines for sustaining bio-banks

Policy on access to data and biological samples maintained in _____ cohort/bio-bank/demographic surveillance site

Introduction

(Provide a description of the Repository, including type of data/biological samples stored within. Describe the governance mechanism)

This biobank/cohort/demographic site (referred to as the Repository) was established with support from the Department of Biotechnology in_____ *(Mention year).* It is committed to ensuring that the data and/or biological samples maintained by it is available to the larger scientific fraternity for societal and national good.

This document establishes the principles and procedures according to which sharing of data and biological samples stored at the Repository will be enabled.

Definitions

Biological samples: Could include primary sample directly collected from the participant and/or its derivatives. *(Define the samples as per the Repository)*

Data: Data covers raw data, processed data (in aggregated or disaggregated manner). Electronic repository of processes and protocols describing the processes followed for the data/sample collection, processing and storage are also part of the data.

Access to samples and data: Guiding principles

1. Custodianship of data and samples:

    a) For repositories that are maintained by the same institution that has originally collected the data/samples, the institution shall remain custodian.

    b) In case of central repositories that house data/samples from different contributors/ projects, the institution which has collected the data primarily shall retain custodianship during the course of the project. The institution maintaining the repository shall become the custodian after the completion of the project.

2. Applications for access the Repository's data or samples will be required to follow the procedure described below.

3. The confidentiality, anonymity and consent of participants must be protected and respected at all times.

4. The Repository shall put in place mechanisms to ensure that access requests are processed and executed in a timely and responsible manner taking into account the need to ensure data validity and sample integrity.

5. *For repositories which have originated from a research project:* Toenableadequatetimeforthecurrentinvestigatorstoacquireandanalyze data,therewillbeamoratoriumforaninitialperiod (------ years) duringwhichtimerawdataandsamples willbeavailableonlytotheresearchers associated with the parent study.After this period of moratorium, the Repository will be open to other researchers.

6. The Repository shall apply well-documented and clearly defined criteria for evaluating requests for access. The Repository reserves the right to refuse any request, but will ensure that appropriate justification for decisions made is provided to the Requesting Institution.

7. The Repository may charge the Requesting institution fees to cover the cost of sample retrieval, pre-analytical processing, and shipment.

8. The biological samples and data shall be used only for the purposes approved by the Repository as per the scope of the proposed research.

9. Those provided access to data and samples should provide proof of optimal utilization of samples through demonstration of public health interventions, or products, scientific discovery and/or publication of results based on data or samples obtained through this mechanism.

Procedure for accessing data/samples maintained by the Repository

1. Sample request: *Detailed description should be made available on the Repository's website.*

   a) The interested researchers should submit the Access request form (Annexure 1a) with cover letter to the Repository in-charge *(mention email ID)*

   b) The Repository will assign a unique number to the application for future reference and forward the application/s to Data and Sample Access Committee (DSAC) with a complete report on the availability of the requested samples and associated data

2. Review by Data and Sample Access Committee (DSAC):

   a) The DSAC will review the proposal, with inputs from domain experts if required.

   b) Timelines for review:

      - For routine research proposals: _____ *(enter timeline)*

      - For research related to public health emergencies- Expedited review will be carried out within a week of receipt of request form.

   c) Elements of review include (but are not limited to)

      - Scientific merit

      - Ethical considerations

      - Overlapping between proposed study and studies already approved

      - Sample volume requested and its impact on future scientific value of the collection (especially for rare samples)

      - Applicants' qualification and experience

      (*The Repository may combine a scientific and ethical review by structuring the DSAC to include ethical and legal experts. Alternatively, a separate EC may be constituted.)*

   d) The decision of the DSAC shall be communicated to the Requesting Institution

      - Regular review: Within a week of completion of review

- Expedited review: Within a day of completion of review

e) Once approved by the DSAC, the Requesting Institution shall share any pending approvals from their end to the Repository in order to execute the sharing agreement.

3. Agreements

The Repository shall execute an agreement with the Receiving Institute prior to data/sample transfer to document the obligations and responsibilities of parties involved. This agreement may constitute a stand-alone Data Transfer Agreement (DTA) or the necessary terms may be included in an MTDA (Material and Data Transfer Agreement). The agreement should be in place before the transfer occurs. A template for the agreement is provided in Annexure 1b.
Content of such agreements shall include:

a) Description of the data/materials to be shared

- Purpose for which the data will be used
- Protection of data against unauthorized access
- Protection of donor privacy and confidentiality and re-identification (where de-identified specimens are provided)
- Custodianship, access, and control of transferred data
- Whether redistribution or forwarding of the data to others is permitted and under what circumstances
- Disposition of data (destruction) upon research completion or agreement termination

b) Requirements for maintaining privacy and confidentiality.

c) Intellectual property rights.

d) Publication/authorship rights and required acknowledgement of the repository providing access.

e) Providing reports to the Repository about use and results

f) Other factors that may govern the transfer (e.g., indemnification, insurance, contractual requirements).

4. Upon receipt of the signed MTA/DTA/MTDA and payment of relevant sample access charges, the Repository will proceed with the sharing of data or shipment of the biological samples for the project. The transport/ shipping of the biological samples as per guidelines.

Monitoring and follow-up

1. Receiving Institute should acknowledge receipt of samples/data and report immediately if there are any problems with the samples/data.

2. Onward sharing of data/residual samples is not permitted; interested investigators will have to submit fresh applications to the Repository.

3. In order for the Repository to monitor use of shared resources, the Requesting Institute will be required to submit a Project Progress Report (Annexure 1c) on a _____ basis *(mention frequency)* after data or samples have been sent.

4. Overall accountability of reporting to funding bodies for research projects shall be the responsibility of Receiving Institute.

Acknowledgement in publications

Full acknowledgement of the sources of data must be included in any publications that arise from access to and use of the Repository's resources. Where applicable, the acknowledgements must refer to the original sample source centre as well as the source of funding. Specific authorship rules may apply in some instances; these will be agreed upon on a case-by-case basis.

Intellectual Property

1. The Receiving Institute shall be entitled to any inventions to the extent that these result from their own independent use of the data/samples. It shall grant the Repository a worldwide non-exclusive royalty-free irrevocable research licence with respect to any such inventions.

2. To the extent that the Repository and the Receiving Institute have each contributed to an invention with respect to the data/samples, they shall jointly own any rights to such an invention.

3. Considering that the Repository is being supported by public funds, the Repository and the Receiving Institute shall both ensure that the IP rights do not place any restrictions on the use of the any product or invention for public good.

Data security measures

1. All systems and resources shall have appropriate safeguards to preserve confidentiality, integrity and availability of data and samples the repository. These include physical, administrative, and technical controls such as secure storage facilities, key/password management procedures, firewalls, virus scanners, audit logging and non-repudiation mechanisms. Safeguards (e.g. appropriate encryption) shall be designed to protect data in transit.

2. Data sharing will ensure physical safety and security of the involved devices and computer servers; data security measures such as password protection; differential and role-based access to data elements for members of the research team; use of data encryption when data is transferred from one location/device to another.

3. The Repository shall also enforce basic security measures on data users—e.g. by making the award of data conditional on the data being kept on a password protected server.

Benefit sharing

Benefit sharing with the participants will be according to the National Ethical GuidelinesforBiomedicalandHealthResearchInvolvingHumanParticipants,I CMR,2017. The guidance of the Ethics Oversight Committee and the National Steering Committee will be sought on a case to case basis.

Guidelines for sustaining bio-banks

Annexure 1a

Access request form for data and/or bio-samples of the repository

1.	Applicant details	
2.	Name of Principal Investigator (PI)	
3.	Institution/Organisation	
4.	In case of multi-centric study, provide list of participating institutes	
5.	Title of the project	
6.	Objectives of the project	
7.	Estimated timeframe of the project	
8.	Brief description of the proposal highlighting the Background, Rationale, Hypothesis, Methodology and Outcome. (upto 1000 words)	
9.	Source of funding for the project	
10.	Total budget for project	
11.	Budget for cohort and biobank	
12.	Ethical approval (If approved attach copy of the approval letters from the respective EC)	Approved Applied for Not applied
13.	Status of other regulatory approvals (Institutional Bio Safety Committee/ Review Committee of Genetic Manipulation)- If approved, attach copy of approval letters)	Approved Applied for Not applied Not applicable
14.	Nature of specimens requested	
15.	Total number of samples requested	
16.	Quantity of samples requested per specimen	
17.	Intellectual property status	
18.	Describe the different types of IP anticipated from the current proposal	
19.	Details on any relevant patent information or background IP issues	

List of attachments:

1. CV of the investigators.

2. Scanned copies of the Ethics and Biosafety Approvals.

Signature of Principal Investigator

Name of Principal Investigator

Date

For use by the Repository:

1.	Request ID	
2.	Is the requested data/samples available in the Repository	
3.	Volume of sample remaining if request is approved	
4.	Any other comments:	

Signature of Repository in-charge

Name of Repository in-charge

Date

Guidelines for sustaining bio-banks

Annexure 1b

Material/ Data Transfer Agreement

This template is based on the IARC MDTA template. The text presents generic template language (italic means that text must be adapted).

Agreement Number: [……]

REPOSITORY INFORMATION	
Name:	
Mailing Address:	
Primary Contact:	
Legal Notices:	Email to

RECEIVING INSITUTE/ORGANISATION INFORMATION	
Name:	
Mailing Address:	
Primary Contact:	
Legal Notices:	Email to

STUDY INFORMATION	
Name:	Please enter study name or title
Description:	Please enter study description

AGREEMENT INFORMATION	
"Start Date":	Date of last signature below.
"End Date":	
This Agreement includes and incorporates by this reference:	• List any attachments that are included

Subject to the terms and conditions of this Agreement, the _____ (*name of Repository*) hereby agrees to provide, and the _____ (*name of Receiving Institute*) hereby agrees to accept, the Materials and Data specified below for such Purposes of Use and subject to such Restrictions on Use as specified below. Each party to this Agreement may be referred to individually as a "Party" and together as the "Parties."

NOW, THEREFORE, the Parties agree as follows:

1. Definitions:

1.1. **"Materials":** [……] [insert precise description of Materials], held by _____(Repository), and made available to the Receiving Institute as per details attached in Attachment 1a

1.2. **"Data":** [……] [insert precise description of Data], held by _____(Repository), and made available to the Receiving Institute as per details attached in Attachment 1b

1.3. **"Purposes of Use":** The Materials/Data are provided for the following purposes, as more fully described in Attachment 2 (the "Research Project"):[……..] *[insert a brief description of the purposes for which the Materials/ Data may be used]*

2. Term of Agreement:

This Agreement shall remain in full force and effect as from the date of its signature by both parties for a duration of [……].

3. Terms of use

3.1. The Repository confirms that for the purposes of this agreement, it is entitled to supply the Data/and or Materials to the Receiving Institute and that consent covering the intended use has been obtained from the relevant donors/data subjects.

3.2. The Materials and Data are supplied by the Repository to the Receiving Institute solely for the Purposes of Use set out herein.

3.3. The Materials and Data shall not be used for any purposes other than for and within the Purposes of Use, as specifically described in Annexure 2, without the prior written agreement of Repository.

3.4. The Materials/Data shall be used only for the duration of this agreement.

3.5. The Receiving Institute shall not transfer the Materials and Data outside India without the prior written agreement of Repository and applicable regulatory clearances as per the prevailing national guidelines and legislations

3.6. The Receiving Institute shall allow only parties who have a need to know for the Purposes of Use and who are bound by similar obligations of confidentiality and Restrictions on Use as contained in this Agreement to have access to the Materials and Data.

3.7. The Receiving Institute shall require any party handling and/or using the Materials and Data to comply with all relevant laws, rules and regulations applicable to the use of such Materials and Data.

3.8. The Receiving Institute shall a Project Progress Report (as per Attachment 4) on a __ *[insert frequency]* monthly basis after Materials/Data have been shared to update the Repository. The report shall include results arising from specific analyses (including biological sample analysis, derived variables, etc.) carried out using the data and/or samples shared by the Repository.

4. Confidentiality

4.1. Before providing Data to the Receiving Institute, the Repository will remove the following direct identifiers of the data principal/data subject or of relatives, employers, or household members of the participants who have contributed their data:

names; postal address information (other than town or city and state/province/region); telephone numbers; fax numbers; e-mail addresses; government-issued identity numbers (e.g., U.S. social security numbers or other national identification numbers, driver's license

numbers, and passport numbers); medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; vehicle identifiers & serial numbers, including license plate numbers; device identifiers & serial numbers; Web Universal Resource Locators (URLs); Internet Protocol (IP) address numbers; biometric identifiers, including finger and voice prints; and full face photographic images and any comparable images.

(provide description of data anonymisation technique here).

4.2. If the Receiving Institute inadvertently receives information that identifies individual research participants, the Receiving Institute will take all reasonable and appropriate steps to protect the privacy and confidentiality of such information. This may require immediate destruction of the information on request of the Repository.

4.3. The Receiving Institute agrees to make no intentional attempt to re-identify research participants through linkage of data or otherwise.

4.4. The Receiving Institute will immediately report any identification of research participants to the Repository.

4.5. The Receiving Institute agrees not to give access to Data, in whole or part, or any identifiable data derived from the data, to any third party. The Recipient shall limit access to and processing of the data to those employees or other authorized representatives of Receiving Institute who need to process such data in order to conduct their work in connection with the project and are obligated to maintain the confidentiality of the Data and any information to be derived thereof or disclosed to them.

4.6. The Receiving Institute will retain the data in a secure network system at such standard as would be reasonably expected for the storage of valuable and proprietary for sensitive/confidential data.

4.7. The information shared may incorporate confidential information pertaining to the Repository. If any Confidential Information will be transferred, then that Confidential Information is subject to the following:

4.7.1. For the purposes of this Agreement, Confidential Information includes any information relating to the Data that the Repository marks as confidential, except for information that:

- has been published or otherwise publicly available at the time of sharing; or
- was in the possession of or was readily available to Receiving Institute without being subject to a confidentiality obligation from another source prior to the disclosure; or
- has become publicly known, by publication or otherwise, not due to any unauthorized act of Receiving Institute; or
- Receiving Institute can demonstrate it developed independently, or acquired without reference to, or reliance upon, the Confidential Information; or is required to be disclosed by law, regulation, or court order; or Receiving Institute is expressly authorized by the Repository to disclose.

4.7.2. The Receiving Institute shall during the Term of this Agreement and for a period of ____ *[insert number of years]* years following its termination treat such Information as confidential and only not disclose them to a third party. The Receiving Institute shall be deemed to have fulfilled its obligations if it exercises at least the same degree of care in maintaining confidentiality as it would in protecting its own confidential information.

5. Costs and payment terms

The cost of sample retrieval, processing, packaging and shipment may be charged by the Repository to the Receiving Institute

6. Rights

6.1. Except for the rights explicitly granted hereunder, nothing contained in this Agreement shall be construed as conveying any rights under any patents or other intellectual property which either party may have or may hereafter obtain.

6.2. The Repository shall retain custodianship of the Materials and Data and shall have the unrestricted right to use, assign or distribute the Materials and Data to any third parties for any other purposes. The Receiving Institute acknowledges and agrees that nothing contained in this Agreement shall be deemed to grant to the Receiving Institute any intellectual property rights in any of the Materials or Information provided hereunder.

7. Publications

7.1. The results obtained through use of the Materials/Data within the Purposes of Use may be published by the Receiving Institute. The Receiving Institute agrees to acknowledge the Repository in any publication or presentation on work derived in whole or in part from the Materials/Data and to supply the Repository with a copy or web address of any publication.

[Specify the actual text of acknowledgement and format for citation, if required]

7.2. Upon completion of the Research Project, the Receiving Institute will send to the Repository a copy of _____*[specify: reports, enriched data, etc.]*.

8. Warranties and Liabilities

8.1. The Repository makes no warranty of the fitness of the Materials for any particular purpose or any other warranty, either express or implied. However, to the best of the Repository's knowledge, the use of the Materials and/or Data within the Purposes of Use shall not infringe on the proprietary rights of any third party.

8.2. The Receiving Institute agrees that, except as may explicitly be provided in this Agreement, the Repository has no control over the use that is made of the Materials or the Data by the Receiving Institute in accordance with the terms of this Agreement. Consequently, the Receiving Institute agrees that the Repository shall not be liable for such use.

9. Amendment, Extension and Termination

9.1. Any amendment to this Agreement, including extension of the Term of Agreement, shall be valid only by written amendment executed by the duly authorized officers of both parties.

9.2. Notwithstanding the conditions set forth in this Agreement in particular the Purposes of Use, Restrictions on Use and Confidentiality obligations, either party may terminate this Agreement with ___ days prior written notice to the other party.

9.3. When the Research Project is completed or this Agreement is terminated, whichever comes first, any unused Materials will either be destroyed in compliance with all applicable statutes and regulations or will be returned to the Repository by the Receiving Institute.

10. Publicity

No Party shall, without the prior written consent of the applicable Party, use in advertising or other publicity materials, the name, trademark, logo, symbol, or other image of such Party. No Party shall issue or disseminate any press release or statement, nor initiate any communication of information regarding this Agreement, written or oral, to the communications media without the prior written consent of the other Parties.

11. Force Majeure

No Party will be liable to another Party for delay or failure to perform its obligations under this Agreement due to causes beyond its reasonable control, provided such Party provides prompt notice and remedies such delay or failure as soon as is reasonably possible.

12. Assignment

No Party may assign or transfer (including by operation of law or court order), any of its rights or obligations under this Agreement without the other Parties' prior written approval. This Agreement will bind and benefit any permitted successors and assignees.

13. Governing Law And Dispute Resolution

This Agreement will be governed by the laws of India. Any dispute, controversy, or claim between the Parties arising from or in connection with this Agreement, including any question regarding its existence, validity, or termination, which cannot be settled amicably, will be submitted to the courts in _____, India.

14. Entire Agreement And Amendments

This Agreement constitutes the entire agreement of the Parties, and supersedes all prior and contemporaneous communications, concerning its subject matter. This Agreement may not be modified or amended, and no right or obligation waived, without the specific written consent of authorized representatives of each Party.

By signing below, each Party acknowledges that it has carefully read and fully understood this Agreement, and each agrees to be bound by its terms.

Signed for and on behalf of Repository: **Signed for and on behalf of Receiving Institute:**

Repository in-charge Principal Investigator

Name:	Name:
Title:	Title:
Designated administrative official	Designated administrative official
Name:	Name:
Title:	Title:
Date:	Date:

- Attachment 1a – Details of Samples requested
- Attachment 1b – Details of Data requested
- Attachment 2 - Research Project [Provide description of project/work to be performed using the Materials/Data]
- Attachment 3 – Format for submitting progress reports

Guidelines for sustaining bio-banks

Annexure 1c

Project Progress Report Format

1.	Project reference number	
2.	Name of Principal Investigator (PI)	
3.	Institution/Organisation	
4.	In case of multi-centric study, provide list of participating institutes	
5.	Title of the project	
6.	Status of project	Ongoing/ Completed
7.	Project progress (Short description of objective wise progress, key results obtained)	
8.	Planned Publications, Submitted publications, Accepted publications and conference presentations (provide citation, conference details as applicable)	
9.	Biological samples use status till date	
10.	Number of samples used	
11.	Quantity of samples used	
12.	Types of experiments	
13.	In case of completed projects	
14.	Samples remaining at end of project	Yes/ No
15.	Samples returned to the Repository	Yes/ No

Signature of Principal Investigator

Name of Principal Investigator

Date