TAKSHASHILA INSTITUTION

Issue Brief: Biobanking policies in India

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Executive Summary

Biobanks are set to become the norm as large scale datasets appear likely to drive the future of life science and healthcare research. However, there are concerns around ethics and consent processes that need to be addressed. In India, there is no specific law to address these concerns. In their absence, vulnerable sections of the society may be left open to abuse. This paper does a literature survey of biobanking policies and concerns of consent and privacy in the context of India. This paper lays the foundation for a discussion around biobanking policies and the formation of an India-specific biobanking law.

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Introduction

Biobanks are repositories of human biological materials that are linked to personal and health information. They are a valuable resource for researchers as it allows them to expand their understanding of human health and disease[1]. Biobanks may not lead research projects by themselves, but can include institutions that support research by providing biological samples. The biological samples are usually collected through voluntary donations or post-mortem. The aims of research may not be defined at the time of collection of samples. Biospecimens can also be collected with future usage in mind.

Biobanks and data repositories will become widespread as the power of largescale data analysis becomes apparent. For example, we now understand the power of understanding the Indian genome. Consequently, both Council of Scientific and Industrial Research (CSIR) and Department of Biotechnology (DBT) have launched projects to collect and analyse DNA from thousands of Indian samples to decipher the Indian genome. Similarly, data repositories of samples with Sars-CoV-2 are being created to understand the biology of the virus and human immune response. New tools easing mass data analysis and subsequent derivation of representative datasets have led to an increased need for biobanking. Creation and access to large data sets will be important to India's ambition of becoming a research leader.

However, there are significant ethical concerns associated with biobanking because they store personal data[2] and can have ambiguous consent mechanisms. Human biological samples can also be a source of sensitive genetic formation, which can be used to glean more information than consented to. Moreover, the future-oriented nature of research associated with biobanks makes it difficult to get fully "informed" consent. Hence, biobanks need to be regulated to govern the way samples are collected, stored and used.

The ethical concerns associated with biobanking may be compounded by the local context in India. A sizeable population of India lives in poverty and the rate of illiteracy is also high[3,4]. These social factors may impact the acquisition of informed consent[5]. It is plausible that illiterate and poor people might be misled and coerced into signing informed consent. Furthermore, India does not have a law that explicitly protects personal data. It should be noted that India has a diverse population, which is often of interest to high-income countries when it comes to research, but which also increases the chances of exploitation[6].

Studies have shown that trust in a country's legal and regulatory systems and biobanking institutions is one of the primary motivtors for people to donate their samples and participate in research[7]. With more biobanks expected to be established in the future, it is important to look at whether there are enough regulations in place, in India. Currently, biobanking in India is governed by various guidelines from the Indian Council of Medical Research (ICMR). However, these guidelines are not legally binding. Thus, it is essential that India approves biobanking laws so that it will be easier to gain people's trust and thereby, further biobank research.

Existing regulations in India

India does not have any laws specifically for the governance of biobanks. Currently, biobanking is regulated through ICMR's National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017. It defines a biobank as an "organized collection of human biological materials with usually associated dataset stored for years in appropriate facilities for research and potential commercial purposes, with inbuilt policies for transparency"[8].

The guidelines lay down the degree of identifiability of the biospecimens in the context of confidentiality and privacy of donors. It recognises ethical issues of consent at multiple stages – storage, analysis, use of data linked to the sample, incidental findings, return of results, etc. It also lists out the various types of consent that may be applicable in biobanking[9].

The guidelines call for the establishment of a technical authorisation committee which will govern the collection and disbursement of specimens and data to researchers. The committee will have representation from science, ethics and external (not belonging to the organisation) members as well. They recommend biobanks to have detailed SOPs that list out the guidelines for collection, coding, anonymisation, storage, access, retrieval and sharing of biospecimens and data[10].

In addition to the National Ethical Guidelines, other guidelines address certain aspects of biobanking. The ICMR-DBT National Guidelines for Stem Cell Research, 2017 regulate clinical research involving human stem cells and their derivatives. They lay out the monitoring mechanisms and regulatory pathways for clinical research and product development[11]. ICMR's National Guidelines for Gene Therapy Product Development and Clinical Trials lay out the guidelines for monitoring and regulating clinical trials pertaining to gene therapy and development of gene therapy products[12].

Indian Society of Assisted Reproduction (ISAR) developed the current guidelines in 2019-2020 that are in place to provide clinical recommendations to improve the quality of healthcare within the Indian field of human reproduction and embryology. It took up the initiative to establish guidelines for the safe and ethical use of Assisted Reproductive Technology (ART) in India.

ICMR first developed the National Guidelines for Accreditation, Supervision and Regulation to regulate the ART clinics in 2005. This was transformed into Surrogacy (Regulation) Bill in 2016 and ART (Regulation) Bill in 2017. Both these bills await passing by the Parliament [13].

The aforementioned guidelines, however, are not legally binding. Since no legal status is accorded to them, the chances of violations being reported are low. Similarly, since the Surrogacy and ART bills have not been passed yet, there is no legal tenet to enforce their provisions.

In 2006-07, the Anthropological Survey of India drafted a bill to create a National Repository for Human Genetic Materials and frame rules for governing the repository. The National Repository was envisioned to collect, share and exchange human genetic materials. However, the bill was never passed.[14]

Biobanks play an important role in organ and tissue transplantation. Although the Transplantation of Human Organs and Tissues Act, 2014 addresses the preservation of human organs and tissues, it does not go into the details of what standards should be applied. It only states that they should be preserved according to the current acceptable scientific methods. [15] This ambiguity allows for malpractice as "acceptable scientific methods" can be interpreted in different ways. However, the Act does lay out the standards for registration of organ and tissue banks (only in the context of organ and tissue donation).[16]

Biobanking includes storage of samples and data; consequently, laws are needed to govern both. The Personal Data Protection Bill introduced in the Lok Sabha in 2019, seeks to legally provide for the protection of personal data. It categorises certain data as sensitive personal data which includes health and genetic data as well. However, it has not been passed yet.[17]

While the PDP Bill offers data protection of personal data, the Ministry of Health and Family Welfare approved a more specific Health Data Management Policy in December

2020. The policy sets out minimum standards of health data privacy protection. However, the policy will not be as effective in the absence of general data protection law.

Biobanking regulations across the world

European Union

There is no single law that governs biobanking across the European Union – there are different regulations that apply to different aspects of biobanking. The General Data Protection Regulations (GDPR) are concerned with the data privacy and security. It imposes obligations on all organisations that collect, and store data related to people in the EU.[18]

Clinical trials are regulated through Clinical Trial Regulation, adopted in 2014.[19] The regulation sets standards for safety of participants and aims for increased transparency in the way the trials are conducted. The Convention on Human Rights and Biomedicine is a legally binding treaty that places human rights before the interests of science and lays down a series of principles and prohibitions related to bioethics, consent, right to privacy and organ transplantation.[20]

The countries within the EU also have their own laws relating to biobanking. For instance, Finland has the Medical Research Act that came into force in 2000. The Act regulates clinical trials by setting rigorous criteria for informed consent and empowers Ethics Committees to approve studies.[21] To improve the regulation of biobanks, Finland enacted the Biobank Act, 2013. It provides for the establishment of biobanks, collection, storage and processing of samples, rights of participants and data protection.[22] Finland also has the Act on the Medical Use of Human Organs, Tissues and Cells which lays down provisions for the removal, storage and use of human organs and tissues for therapeutic purposes.[23]

United Kingdom

The UK does not have any specific law for biobanking. It has fragmented legislation that applies to different aspects of biobanking. The Human Tissue Act, 2004 regulates the removal, storage, use and disposal of human tissue through the regulatory body, Human Tissue Authority. It lists out the different purposes for which consent is required such as

research in connection with disorders, transplantation, anatomical examination.[24] The UK implements the GDPR through its Data Protection Act, 2018 which lists out the principles for data protection. It controls how personal information is utilised by the government, organisations and businesses.[25]

United States

The US does not have any specific framework for regulating biobanks. Various provisions for biobanking can be found across different legislations. The Department of Health and Human Services has laid out the Common Rule which governs NIH-funded research. The FDA has its own rules for any research that is funded by them. These rules apply to research involving human subjects and thereby to biobanking.

Biobanks subjected to the Common Rule are reviewed by the Institutional Review Board which checks if there are enough provisions for data privacy and security and for informed consent.[26] For data privacy, the US enacted the Privacy Act in 1974 which "governs the collection, maintenance, use, and dissemination of information of individuals maintained in systems of records by federal agencies". [27] The Health Insurance Portability and Accountability Act has provisions to protect the privacy and confidentiality of individually identifiable health information.

China

China also does not have any law or framework specifically pertaining to biobanks. In 1998, China formulated the Interim Measures for Administration of Human Genetic Resources. They outlined the guidelines for the collection, preservation and utilisation of human genetic samples and the provision of such samples to its overseas partners.[28] However, they were weakly implemented and were not able to keep up with the latest developments in genetic research.[29]

After realising the shortcomings of the Interim Measures, the government of China enforced the Regulations on Administration of Human Genetic Resources in 2019. The Ministry of Science and Technology is tasked with approving human genetic research collaborations between foreign and Chinese partners. The new regulations set out requirements for making the information on human genetic resources available to the public or other countries. Significant penalties have been introduced in the case of violation of regulations.[30]

Brazil

Brazil's new regulation for the use of human biological materials for research was enacted by the National Health Council of Brazil. The National Guidelines for Biorepositories and Biobanks were published by the Ministry of Health in 2011. The regulation outlines the guidelines for obtaining broad consent; specific consent limited to the purpose of the study, and ensures anonymity for the donor in any form of disclosure of information derived from the use of his/her/their biological sample. It also provides an opportunity to the donor to withdraw their consent at any time without prejudice or further explanation. They also have established guidelines for ethical analysis of research projects involving human samples.

While not all the countries mentioned above have laws specifically for biobanking, it should be noted that they have some strongly implemented laws pertaining to data protection, use of biosamples and clinical trials.

Ethics of biobanking

There are fundamental ethical issues associated with biobanking, arising out of unawareness, sensitive nature of the data, unknown consequences and socio-economic inequities.[31] Informed consent, in the context of biobanking, can be a tricky concept. The samples that are collected in a biobank may not be used then and there. There is a high chance that they may be preserved and used some time in the future, for studies that are not planned at the time of the collection. Thus, the future-oriented nature of biobanks makes it difficult for the donors to be fully informed.[32]

To add to this, many people are unaware of what biobanking entails. This might make it difficult for people to distinguish between research, diagnostics and treatment, leading to misconceptions.[33] Qualitative studies have shown that people donate their samples to biobanks with expectations that they will be provided medical treatment or a free health check-up.[34] When they do not receive any treatment or a health check-up they might feel cheated and not volunteer for any more studies. Clear communication strategies, which leave no room for misunderstandings, are the key to resolving misconceptions.

Socio-economic conditions of a country/community play a significant role when it comes to ethics in biobanking. Low- and middle-income countries are characterised by genetic diversity, making them excellent representative repositories of samples for studies. However, these countries may not have proper legal frameworks in place. This allows for high-income countries to exploit these countries.

Although ICMR has formulated the Guidelines for Exchange of Human Biological Material for Biomedical Research Purposes, the adherence to it remains questionable. With regard to mechanisms for implementing guidelines, the wording leaves room for confusion and non-compliance. For instance, the guidelines state that "agencies and departments such as ICMR, CSIR, ICAR, DBT and DST could make use of these guidelines".[35] This does not guarantee compliance even by the mentioned agencies. There have been cases of biosamples being transported abroad without proper approvals.[36]

Continuing from the concern above, there are some specific issues about biobanking in India that require attention. First and foremost, biobanking in India is still in its early years. There is no regulatory authority and there is no requirement of registration.[37] Around 30% of India's population is illiterate, which translates to 313 million people in absolute numbers.[38] There is a possibility that researchers may take advantage of the illiterate population, making them sign "informed" consent forms for their studies.[39]

The social inequity in India has continued to grow. According to a World Economic Forum report, around 220 million Indians live on an expenditure level of mere INR 32/per day.[40] Poverty can be a major reason for people to give their consent for incentive-based research without totally understanding the implications of biobanking. For example, a poor community in Chhattisgarh was told that they would be given free medicines and medical check-up for sickle cell disease, if they donated their blood. This was done without any consent forms being signed.[41]

A recent example of unethical practices is the issue of Covaxin vaccination trials in India. The consent form was mandated as Covaxin got the emergency use approval based on the results of phase 2 trials; the results of phase 3 were still awaited. However, there were reports of unethical practices at the clinical trial site in Bhopal and gross violation of laws and guidelines.[42] These practices included compensation for taking the vaccine, without any direct communication that the vaccine was still under trial, about its potential side-effects or follow up guidance for adverse events.

Similar instances of exploitation have been seen elsewhere in the world – for example, the case of the Havasupai tribe in the US. In 1989, the people of Havasupai Indian tribe community approached the Arizona State University, to understand why the incidence of diabetes was increasing among them.[43] These people lived in poverty and had not even completed high school. They were made to sign a broad consent and what resulted was indiscriminate use of their blood samples by other researchers for purposes that were not linked to diabetes. The researchers published studies about how the genetic makeup of the tribe was associated with alcoholism, schizophrenia etc.[44]

Further, biobanks hold a repository of genetic information which can be linked to the donors' family/community members. This could lead to ethnic or racial discrimination. People fear that their genetic information can result in stigmatisation by employers, insurance companies, the police or the judiciary system.[45]

One of the major privacy concerns of people in biobanking is massive collection, distribution and utilisation of people's personal data[46]. It is important to note that technologies evolve: the context under which the sample was collected and the current capabilities of research differ. Therefore, there is a requirement for consent mechanisms to also evolve [47].

Anonymisation also cannot be achieved easily as genetic data and medical information can be traced back to the individual. It is, therefore, better if the public attributes towards informed consent and privacy are fluid and contextual. Given that the main purpose of biobanking is to make biomaterials and data accessible to researchers, it should also ensure that the researchers can access the data without compromising the privacy of the subjects. Thus, it is absolutely essential that ethical safeguards are in place when it comes to the usage of biospecimens.

Consent models in biobanking

The concept of informed consent in biobanking is more complex than in regular research, due to the future oriented nature of biobank research. There are a few models of consent that are used in biobanking, depending upon the requirement of the research.

a. Broad consent - As the name suggests, it is a blanket consent that is given at the time of enrolment in the biobank for collection, storage and use of the sample. The consent is given against a background of assurances about the scope of the usage of the sample[48]. The researcher does not need to go back to the donor for re-consent when he/she starts with any research (National Ethics Guidelines, 2017).

   However, it should be kept in mind that broad consent can never be fully informed since the aims of scientific studies are not defined at the time. People generally give broad consent based on the trust they have for the researcher, after they are convinced that their samples will not be used for any unethical purposes. For example, new reproductive technologies have led to the development of different processes of genetic enhancement. Gene editing, particularly that using germ line cells, results in permanent changes that can be passed down to generations. Given

its cross-generational implications, germ line gene therapy raises key questions about informed consent and ethical use of this emerging technology[49]. From a biobanking perspective, this also raises a further question: is a broad consent sufficient to cover research on such controversial and emerging technologies?

b. Study-specific consent – In this case, consent is obtained for a specific research study. Participants need to be contacted every time their sample is going to be used for a new purpose. This may limit the utility of biobanks and add to the administrative burden.[50] A middle ground between broad consent and study-specific consent can be achieved by the inclusion of options such as "Do you wish to be informed about the specific research being conducted?"[51]

c. Dynamic consent - It involves constant engagement with the participants over time in response to changing circumstances under which the samples will be used. The way it differs from study-specific consent is that it uses information technology platforms.[52] This allows the participants to remain updated about the activities of the biobank in the context of their samples and to modify their consent preferences. In terms of administrative burden, dynamic consent is less cumbersome than study-specific consent.

d. Tiered consent - Participants are given a list of research categories for which the samples may be used. The participants give their consent to whichever categories they may find appropriate. This gives participants control over the scope of the usage of their samples, to some extent. This is considered to be the best practice in biobanking, as it reduces the administrative burden while also giving participants some sort of control.[53]

Benefit sharing with donors

There is no clear consensus on whether direct benefits should be shared with the sample donors. A lot of ethical connotations are associated with it. ICMR's National Ethical Guidelines 2017 leave the decision of direct benefit sharing to the researchers and biobanks. However, it mentions that informed consent forms should clarify if any benefits would be shared or not.[54] 'Ownership' is also a concept that is closely connected with benefit sharing. In a study conducted by Dr. Vaz, participants saw ownership as a 'grey area'. They considered 'patients' as the true owners and storage facility/biorepository as the 'custodian'. [55]

A majority of social sciences experts are of the view that direct benefits (such as financial, medical treatment) should not be shared with the donors as it could water down the concepts of altruism, common good and trust. Benefits may be shared indirectly by introducing new technologies in the market at cheaper prices or by sharing results with the participants, which may encourage further research. However, there is another side to this argument which questions the appropriateness of expecting altruism from poor people, whose health needs are so high.[56]

More than 60 years ago, Johns Hopkins researchers took cells from a cancer patient named Henrietta Lacks without her consent. Her cells fuelled medical breakthroughs and her cells were used in more than 74,000 studies for six decades[57]. The doctors at Johns Hopkins had taken samples of her cancerous cells while diagnosing and treating the disease. They had given the cells to a researcher without her consent. These cells went on to have extraordinary capacity to survive and reproduce. The researcher then shared it with other scientists and these cells became a workhorse for biological research.

The work done using HeLa cell line has been involved in major discoveries in the fields of cancer biology, immunology, pathology, etc. Despite all the benefits that the field of biotechnology derived from the work with her cells, none of these accrued to her family. Researchers carried on studies without taking her family's consent for generations even as they made her name public. They also made her medical records public and published her genome online which was removed following an outcry. This situation has changed only recently and has led to better awareness about benefit-sharing with donors.

Data confidentiality

To protect data confidentiality, different degrees of identification of samples have been designed.

a. Completely anonymised – When samples are completely anonymised, there is no link between the sample and its donor. Identifiers relating the sample to its donor are completely removed. The flip side to this is obstruction to the right to withdraw from research. With the sample being completely anonymised, the donor loses ownership and thereby the right to withdraw their sample.[58]

b. Identifiable – A direct link between the sample and the participant's identity exists.

c. Coded – There is no direct identifier present in the sample. However, the identifying information is coded and can be deciphered using a code key.

Public consultation in governance of biobanks

One of the key stakeholders of biobanks is the general public, a subset of which acts as donors for biobanks. It is imperative to involve them in the governance of biobanks, as it leads to building of trust, better transparency and accountability, and strengthening of ethical practices.

In a country like India which has a diverse population including minority ethnic and tribal communities, public consultation in governance of biobanks becomes very important. Biobanks in New Zealand involved the Maori tribe to develop a culturally informed model for biobanking projects involving the Maori[59]. Similarly, the US consulted with different communities to understand and gauge their awareness about biobanks, their expectations from it, and their views on inclusion of children and pregnant women. It was found that when researchers closely interacted with the community, it was easier to gain their trust with regard to data privacy protection[60]. Warrier et al. argue that engagement with the public helps in the negotiation of ethical concerns and acceptable limits of biobanking and genetic research.

Many studies have found that the trust of the public depends a lot on who runs the biobank. These have shown that people are reluctant to trust a biobank if it is funded by a private organisation. There is a fear that commercial funding of biobanks may lead to unethical usage of their samples, such as racial identification that may eventually lead to discrimination[61]. Hence, involvement of the public becomes even more important, especially in the case of privately funded biobanks.

Commercial uses of biobanking

Biobanking is no longer used only for research purposes; they are now established for commercial purposes as well. It is important to understand the commercial utility of biobanks and how it can contribute to better health of populations. It is also important to realise that there can be a flip side to commercial use, as it can lead to exploitation of vulnerable populations.

a. **Pharmaceutical industry** – This industry is dependent on the research to understand the efficacy of drugs so that it can produce them on a commercial scale. The samples from biobanks can be used in "clinical trials for pharmacogenomic studies to measure the effectiveness of new drug candidates or observe potential side effects".[62] Biobanks can provide access to a pool of genetically diverse samples, which can help scientists and researchers better understand the disease profile or vulnerability of that specific population. This can lead to development of more effective treatments, medicines and vaccines.[63]

b. **Health industry** – With the emergence of new technologies, it has become possible to do a lot more with a small amount of biological material. Biotechnology allows the biospecimens to be analysed in greater detail and the ability to handle large datasets. Having access to samples from biobanks can assist the biotech industry in the discovery of therapeutic biomarkers.[64]

   Biobanks have been associated with the development of personalised medicine. Investigation of human biological samples can provide "insights into molecular mechanisms underlying individual diseases, particularly in cancer".[65] For example, biobanks can facilitate translating research into better healthcare, because biomarkers in personalised medicine cannot be developed without access to biospecimens.

What should biobanking laws cover?

As is evident from the issues associated with biobanking, India needs to have a law that regulates all aspects of it. Registration of biobanks under the government and operationalisation under a legal framework will ensure that the biobanking guidelines become legally binding.

Given that the aims of research are not defined at the time of sample collection, ethical issues can crop up. Ethics committees (ECs) should be set up, specifically for biobanks because consent models here differ from the ones used in regular research.

Different types of consent models may need to be used, depending on the kind of research that may be undertaken in the future. Furthermore, India comes with its own set of socio-economic problems. These need to be taken into consideration when Ethics Committees review any proposals. The ECs should be composed of well-trained people coming from backgrounds such as medicine, social sciences, life sciences. They should have community representatives as well.

Studies have shown that people are able to trust biobanks more if a country has proper rules and regulations in place.[66] Thus, it is necessary to constantly engage with the community/public even before a biobank is established. Inclusion of the community's opinion in governance of biobanks will help in maintaining the ethical compliance.

Biobanking laws should regulate the way samples are collected, stored and used. Standard operating procedures (SOPs) for the same should be in place. Regular audits of biobanks must be conducted, to check if their systems are up-to-date and well-functioning. Having SOPs will help with audits.

As mentioned before, the transfer of biosamples in India is not regulated and they are often transported to other countries without any proper approvals. Biobanking laws should clearly state the requirements for transfer of biosamples: for example, should the samples be used only for research purposes, or can they be used for commercial purposes as well? The legislative framework also needs to consider what the technical requirements would be for transportation of samples overseas. Provisions for penalties in case of violation of laws should be made clear.

Data privacy and confidentiality should be ensured. Biobanks house a lot of genetic data that might reveal sensitive information such as gender, ethnicity, race. Procedures for data encryption, coding and re-identifying samples should be implemented.[67] Biobanks should give out adequate information on how the data of the participants will be used. Protocols for data management in the event of sample disposal or consent withdrawal should also be in place.

All biobanks should ensure that they have made their policies available in public, on aspects such as informed consent, recruitment of participants, benefit sharing, source of funding, data protection. This will ensure transparency and accountability and help in gaining the trust of the public.

Conclusion

Biobanking is going to underline the future of healthcare and research in India. It is evident that laws are needed to regulate the gathering and utilisation of such large data sets of biological samples and health data. Biobanking raises questions beyond technical procedures, and impinges on ethics, data privacy and mechanisms of consent. Given this context, it is critical that there is a wider conversation in India about biobanking and a proper law be created to regulate its use.

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