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ORIGINAL PAPER

Biobanks: Will the Idea Change Indian Life?

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Abstract Biobanks are an international phenomenon today and promise solutions to hitherto unanswered questions in biomedical research. However, though India may benefit from biobanking activities and output, the regulatory landscape for biobanks remains woefully inadequate. The Guidelines of the Indian Council of Medical Research, which prescribe the conditions for the operation of biobanks, do not adequately address the concerns that emerge in view of the socio-politico-economic backdrop peculiar to the Indian situation. The lack of awareness and understanding of the implications of bioethical issues and requirements on the part of research participants, and inadequate engagement with these issues and requirements on the part of interested personnel (including biobanking administrators, and review and regulatory bodies) could exacerbate growing concerns over effective scientific and ethical management of biobanks, especially commercial ones that have emerged. The role of the State is to be highlighted here as (a) facilitator of such research, mindful of the developmental and health-related needs of the Indian people, (b) regulator of such research, ensuring ethical and regulatory requirements are met, and (c) enabler of access to the productive outcomes of such research, keeping in mind the principles of egalitarian distribution of common resources for the good of all.

Keywords Biobank · Health · India · ICMR · Constitution

> "It is science alone that can solve the problems of … vast resources running to waste … Who indeed could afford to ignore science today? At every turn we have to seek its aid … The future belongs to science and those who make friends with science."
>
> —*Jawaharlal Nehru*, *First Prime Minister of Independent India* (Mackay 1991)

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Introduction

Time Magazine projects biobanking as one of the top ten ideas changing the world in recent times (Caulfield and Murdoch 2017). While some authors refer to these repositories as organic bank accounts and the effort behind these as bio-investments and harbingers of the "greater medical good," biobanks raise as many questions as they promise answers to. Currently, the legal miasma surrounding biobanks raises queries as to whether what are conceived as scientific and economic gains could be in consonance with the broader social and political agenda.

While biobanks are generally described as substantial collections of human biological material, practically, they also include smaller collections of tissue—pathology samples, biological fluids—for instance, blood and urine, surgically removed tissue amassed in diagnostic departments, etc. (Vaz et al. 2014). A simple definition of a biobank would be that it is a collection of samples *together with* the data associated with such samples. Thus, samples stored in bio-repositories as well as medical, genealogical, and lifestyle-related data linked with such stored biological samples, by themselves or in congruence with each other constitute a biobank.

The Ethical Guidelines for Biomedical Research on Human Participants of the Indian Council of Medical Research (2006) (ICMR Guidelines) define a biobank as a collection of resources that can be accessed to retrieve human biological material and data, thus including both physical samples and databases (Gupta 2011, p. 521). Bioinformatics associated with these samples and data has also been included within the scope of this definition. With some exceptions, biobanks in India have mainly been established and maintained for health care and research purposes within public institutions. In recent years, new commercial biobanks (for example, Apollo Hospitals 2013) have entered the fray, which requires a rethinking of the status of biobanks as conventional and relatively small-scale affairs as well as purely governmental or government-funded enterprises. Such an advancement, along with technological developments in the area of precision medicine and "big data" analytics (Jain et al. 2016), highlights the need to re-evaluate the existing modalities and instruments of biobank governance.

It is relevant to note that in India—while there is no specific legislation that seeks to regulate biobanks—the legal framework including the penumbral structure of the Constitution, together with other legal norms, governs the functioning of the existing biobanks. In the Indian context, a citizen has a fundamental right to pursue his or her scientific temper and spirit of inquiry for the advancement of the nation, while keeping in mind the fundamental ingredient of humanism. In the realm of right to health, such a balancing act becomes even more relevant, particularly in view of the fact that the Indian judicial trend seems to favor protection of the rights of vulnerable sections of society, alongside the long since reaffirmed right and duty of development and scientific progress. Against such a backdrop, it is necessary to investigate the adequacy of existing regulation of biobanks, spearheaded by the ICMR Guidelines in India. Biobanks may well be a boon to the Indian people; however, their functioning must be regulated so as to maximize benefits to the Indian populace, while taking adequate measures to ensure that they do not result in violation of rights of the same group. Though the ICMR Guidelines address concerns such as informed consent, privacy and confidentiality, fair and equitable benefit sharing as well as other established bioethical

tenets, their practical application in the Indian context is inadequate, and perhaps even inappropriate for the current politico-legal climate. This could exacerbate the already precarious position of biobank regulation in India.

Situating Biobanking within India's Constitutional Context and Tradition

As the nations of the world realize the significance of big data, the large-scale correlative studies and analysis, and their possible impacts on public health, there is an increasing effort discernible in governmental support and encouragement of biobanking (Fan et al. 2014). Alongside ubiquitous projects involving the decoding of the human genome increasingly being undertaken with public funding and support at a global scale, such big data bioinformatics acquires special significance (Jafarey et al. 2017). In India, scientists were successful in decoding the entire genome map of a 50-year-old male in 2009 (Patowary et al. 2012), and since then, similarly projects have been initiated.

India, as the second most populous country in the world, has a database of immense proportions and as far as bioinformatics and related research are considered, such a catalogue would be beneficial not only to the Indian population, but also the world at large. As the population in India is multi-ethnic, multi-cultural, multi-linguistic, and as the genetic composition of the present population varies across a wide range of genotypes, the significance of biobanks cannot be overlooked or disregarded. Studies substantiate the existence of such diversity; for example, the classification system of K. S. Singh's 1998 *India's Communities* (cited in Kashyap et al. 2006) documenting 4693 population groups including 2205 major communities, 589 segments, and 1900 territorial units in India indicates the remarkable variances in the genetic composition. Also, endogamy and similar customary practices resulted in matrimonial ties between members of the same family and consanguinity, contributing to several rare genetic diseases. Further, India has the capacity to not only reproduce therapeutics and other technologies developed in scientifically advanced countries, but also to develop such novel technologies in its own right, as evidenced by the more than 50 research centers pursuing various types of cutting edge biomedical research in India (Vale and Dell 2009).

The promises that biobanks are predicated on are that they would provide answers to as yet unanswered questions such as the cure for cancer and other presently incurable diseases, act as the scaffolding for identifying risk factors, enable diagnosis of diseases with greater accuracy, enable projections based on huge population health data, and the most attractive enticement of all, customize and personalize health care delivery. However, advancement of biobanking and related technologies in India must be consistent with supervening constitutional and legal norms.

International human rights instruments classify the right to health as an important socio-economic right (for instance, United Nations 1966, Article 12(2)). The World Health Organization defines health as a state of physical, mental, and spiritual well-being and not merely freedom from diseases (United Nations 1947). In India, Article 21 of the Constitution guarantees to each person within its territory the right to life and personal liberty. The Constitutional mandate of the right to life has been interpreted by

the judiciary as including the right to health—this being an indispensable element of a dignified human existence (Abichandani n.d.). In *Paschim Banga Khet Mazdoor Samiti v. State of West Bengal* (1996) 4 SCC 37, the Supreme Court of India held thus:

> In the context of Constitutional obligation to provide free legal aid to a poor accused, this court has held that state cannot avoid its constitutional obligation in that regard on account of financial constraints. The said observations would apply with equal, if not greater force, in the matter of discharge in constitutional obligation of the state to provide medical aid to preserve human life.

However, the right to health is not an absolute right, but must be balanced against other rights that are afforded under the Constitution. Where biobanking is concerned, it should also be noted that, Article 51A (h) and (j) entrusts to every citizen of India the duty to develop his or her scientific temper, humanism, and the spirit of inquiry and reform as well as exhorts him or her to strive towards excellence in all spheres of activity, individual as well as collective, so that the nation relentlessly rises to elevated levels of endeavor and progress. Further, Entries 65 and 66 of List I, Schedule VIII to the Constitution empowers the Parliament of India to enact laws *a propos*: for Union agencies and institutions to promote special studies or research, or provide scientific or technical assistance and coordinate and determine standards in institutions for higher education or research and in scientific and technical institutions. These Constitutional provisions protect the scientific endeavors and developments in India, more broadly intended for the benefit of its people. Thus, any development in biomedical research including biobanks can be protected under these provisions, but provided that the common good is advanced. Simply reading these two constitutional provisions together suggests that due consideration should be given to establishing and governing biobanks in a way that would most likely offer people with a claim to the right to health and a chance for therapy (Steinbock 1992, p. 199). From the perspective of millions in India suffering from life-threatening diseases, for which such new technologies may offer a cure, biobanks are justified health care instruments. Hence, a reading of Article 21 cannot be completed without taking into account these points of view which categorically promote and justify biobanks, to the extent the right to health (and life more generally) and personal liberty are promoted.

The exact scope of the right to health remains elusive, however. An examination of case law on the right to health as a fundamental human right enforceable against the State remains amorphous in its exact definition and content. The Constitutional stress on the health rights of the Indian citizenry is evident through Articles 38, 39(e) and (f), 42 and 47. Here, the emphasis has been on public health (*Vincent Panikurlangara v Union of India* (1987) 2 SCC 165) as well as on protection of vulnerable members of the population such as the sick, disabled, women, and children (*State of Punjab & Ors v Ram Lubhaya Bagga* (1998) 4 SCC 117; *Confederation of Ex-servicemen Associations and Ors v Union of India*, AIR 2006 SC 2945). These decisions, while iterating the significance of the right to health as an element of the right to life, specify the restrictions as per the differential capacity of the State. The Supreme Court has on numerous occasions, read these provisions in the light of Article 21 to give specific protections to people in need of immediate medical assistance (*Parmanand Katara v Union of India and Others* (1989) 4 SCC 286) and the health of workers (*CESC Ltd. v*

Subhash Chandra Bose (1992) 1 SCC 441). In *Consumer Education & Research Center v Union of India* (1995) 3 SCC 42, the Court dealt with the problem of occupational health hazards and diseases sustained by the workmen employed in the asbestos industry. It was held that the right to health and medical aid for workers during service and thereafter is a fundamental right of workers. Apart from these, this mandate has yet to be realized as a positive dictate applicable against the State in all aspects relating to health. Where many of the health care providers are private enterprises, the role of the State as an active and causative player in ensuring health of all its citizens is limited. This is especially so as no State can ensure perfect health to all its citizens, as health is a factor complex of genetic dynamics, individual's propensity to diseases and lifestyles adopted (United Nations Committee on Economic, Social and Cultural Rights 2000). Herein, the role of the State as regulator of technologies as well as therapies in the medical care sector through legislation appears to be emphasized instead, also where biobanking and related health technologies are concerned.

With time and technology advancing, it can be seen that the right to health is also evolving to new heights in India. In the landmark decision of *All India Lawyers Union (Delhi Unit)* v. *Govt. of NCT of Delhi & Ors* 163 (2009) DLT 319 (DB), a public interest litigation was filed by All India Lawyer's Union seeking directions for ensuring free medical treatment in terms of an agreement entered into between the Government of National Capital Territory of Delhi (GNCTD) and the Indraprastha Medical Corporation Ltd. (IMCL) to establish a multi-disciplinary super specialty hospital. Pursuant to the agreement, government land was given on a no-profit-no-loss basis to a private hospital. The latter was directed to provide free medical and other facilities to at least one-third of its admitted patients and 40% of patients receiving outpatient care without any discrimination. As a commitment to serve various cross-sections of people, the hospital was to offer: (a) 10% of the facilities free of cost, (b) 10% of the facilities where patients pay only for the medicines and disposables, and (c) 10% of the facilities at subsidized rates. The management of the company took the stand that there was no obligation to provide free medical service or free consumables which would include consultation, bed, diet, investigation, nursing, and medicines. Thus, the issue of free treatment to needy citizens mostly remained on paper. The High Court of Delhi held that a super-speciality hospital constructed on government land by private parties cannot deny its duty of catering to the needs of the disadvantaged and the vulnerable patients who cannot afford such specialty care. Herein, the court incorporated the duty of the State to provide superior quality of health care to the needy into the agreement that bound the private hospital. This decision certainly enlarged the scope and ambit of right to health and has tremendous significance to biobanks in India. Where such endeavors are carried out using government funds, the State can regulate its conduct as well as its commercial outcomes on the basis of the *All India Lawyers Union* decision. Also, its role as regulator and manager of medical resources will ensure the accessibility to the therapeutic outcomes of biobanking to the people of India. With reference to the General Comment of the United Nations Committee on Economic, Social and Cultural Rights (2000), the court states that the right to health in all its forms and at all levels should contain all of the following interrelated and essential elements: availability, accessibility, acceptability, and quality. Their exact application is less clear at the present time and will require regulatory guidance.

Further, the Supreme Court has in the case of *Mohammed Ahmed (Minor)* v *Union of India & Ors* W.P. (C) 7279/2013, decided on 17 April 2014, directed the State institution AII India Institutes of Medical Sciences (AIIMS) to provide treatment to a patient who was unable to afford the necessary expensive treatment. In this case, a young boy aged about 7 years was the petitioner through his father, a rickshaw puller. He suffered from a rare genetic disease called Gaucher Disease, wherein the body cannot process fat resulting in accumulation of fat around vital organs of the body. If left untreated, he would die, as did his three siblings before him. The cost of treatment, Enzyme Replacement Therapy, was estimated at approximately 6–700,000 rupees (or about USD 10,000) every month. Only one company, Sanofi sells its Gaucher's drugs in India. The Government of Delhi, the Union of India and AIIMS stated that in view of their restricted resources they were not able to fund the treatment of the petitioner as it was lifelong and his condition was chronic. The court ruled that Government of NCT of Delhi is to discharge its constitutional obligation and provide the petitioner with enzyme replacement therapy at AIIMS free of charge as and when he requires it. Herein the court reasoned that while courts cannot direct that all inhabitants of the country be given free medical treatment at State's expense, yet no Government can say that it will not treat patients with chronic and rare diseases due to financial constraint. The court states thus (at para. 80):

> Just because someone is poor, the State cannot allow him to die. In fact, Government is bound to ensure that poor and vulnerable sections of society have access to treatment for rare and chronic diseases, like Gaucher especially when the prognosis is good and there is a likelihood of the patient leading a normal life. After all, health is not a luxury and should not be the sole possession of a privileged few.

As per this decision, such intervention is part of the core, non-derogable duties of the State. The court points out thus: By virtue of Article 21 of the Constitution, the State is under a legal obligation to ensure access to life saving drugs to patients. This means that Government must at the bare minimum ensure that individuals have access to essential medicines even for rare diseases.

An analysis of this dictum presents an expansion of the hitherto restrictively interpreted right to health in India. Here, the State was held specifically liable to meet the health requirements of one of its subjects, by using money from its own coffers. The decision seems to suggest a seismic shift from the emphasis on public health to health of single individuals in India. If this decision and its impact are expansively interpreted, the State not only has a duty to ensure the regulation of biomedical research, but once proven effective, has a duty to ensure access of its people to such therapies and products. Also, this viewpoint of the court, with emphasis not only on provision of primary health care, but also on accessibility to expensive drugs for a very small percentage of the population, is of relevance to biobanks as well. Once the promise of biobanks and the hoped-for technologies are realized, the therapies and products derived from such research should become available to address previously incurable diseases and conditions. Thus, biobanks could well be conceived as a tool to determine the feasibility of health care options. This places a tremendous responsibility on the State to address issues of access,

availability and assurance of quality of such products that could become an integral part of the health care system in India.

In reality, access to health and equitable sharing of resources (whether biological or otherwise) continue to be formidable challenges in a country like India, with a literacy rate of a mere 74.04%, where 69% of its population of 1.24 billion resides in rural areas, where the ratio of patient to doctor is 1500:1 and the percentage of GDP spent on health is a mere 4%. Against such a backdrop, the effectiveness of any law will be limited due to the lack of information and awareness, as well as ignorance of the populace. The result? Biobanks exist and function in an almost untrammeled manner, and this could well compromise public good and the social value of science.

The ICMR Regulatory Framework: Reflections in the Context of Biobanks

In terms of biobanking, prevailing rules that relate to ethical concerns arising from a more traditional or conventional biomedical research setting would not adequately address newer practices and goals. Of significance is the fact that the manner of collection and storage, as well as the very reason for such collection and storage of biological samples, whether for diagnosis, clinical treatment or voluntary and altruistic donation, both for therapy and research is different today from the past. Evidently, biobanks have re-defined even biomedical waste as an important resource, capable of translation to concrete and tangible productive outputs of value.

However, it is not clear whether the present regulatory system in India has actually taken into consideration such differences. Of principal concern is the fact that biobanking has been categorized as dealing with DNA, cell line banking, and has been limited to the section on "Human Genetics and Genomics Research" in the ICMR Guidelines. Universally, biobanking today encompasses a vast multitude of materials and is hence not limited to genetic and genomic research alone. Apart from its limited scope, the ICMR Guidelines are only advisory in nature and have no regulatory force. This seems to be a serious limitation as India does not have legislation that responsibly tackles the possible bioethical and legal issues inherent to biobanking. Furthermore, the implications of bioethics in particular fields such as biobanking do not seem to be fully addressed; for instance, the ICMR Guidelines state (2006, p. 71) thus: "Research on banked human tissue samples is conducted in a laboratory; hence, it does not directly involve the individuals". Based on this premise, it goes on to state thus: "The steps involve the initial process of collecting, processing, freezing, "anonymizing," and storing tissue with its corresponding clinical information in a database." As biobanking concerns research at a later time, the ethical issues pertaining to consent requirements for the further uses of tissue and DNA samples, their control and ownership, and benefit sharing with the individual or community are not adequately addressed. The main problem with the current formulation is that it seeks to underplay the significance of "anonymizing" data. In the same breath as "anonymization," benefit sharing has also been stated as a component of the biobanking equation in India. Putting these two seemingly irreconcilable factors pertaining to biobanking together creates confusion and scope for misconstruction.

Also, the ICMR Guidelines (2006, p. 72) state that human biological samples in biobanks may include organs (heart, liver, kidney, lung, pancreas, etc.), tissues, cells (somatic and gonadal), body fluids or samples like serum, buffy coat, DNA, hair, nails, excreta, sweat, buccal scrapings, etc. Further, the sample collector is to obtain informed consent of the donor, while possible risks and benefits, conditions under which samples from the Repository shall be given out for other purposes, the duration of such storage, etc., are also to be explained. Alongside, it is provided that" what will be the costs to individual researchers in obtaining samples from the Repository" has to be clarified to such donors. Even more confusingly, it provides that:

> if any commercial use is made of the samples in the Repository, appropriate written benefit-sharing agreements, consistent with the policies stated earlier, must be jointly signed by the donor, sample collector and Repository in-charge.

Such donor may be an individual or a group and the guidelines provide for group consent in appropriate instances as well. In cases where the samples are required by bodies or individuals, the Repository is to conduct the transfer as per material transfer agreements that have to be executed. However, the format of such agreements has not been specified.

Interestingly, the ICMR Guidelines foresee that "in all reports, patents or copyrights arising out of these samples," the specific identity of the Repository must be mentioned. Thus, intellectual property rights that arise from such samples and data are accepted as legal and valid from the ICMR perspective. Yet, the scope of this remains ambiguous and indeterminate; for instance, it provides (ICMR 2006, p. 71) that:

> due intellectual property rights should be given while granting access to samples, through a contractual agreement … [and that] … for any publication resulting out of research from samples taken from repository, appropriate acknowledgement should be given to the original contributor of samples, sponsors of research, repository, donors and participants.

The main problem in the context of novel technological infrastructure such as biobanks is the uncertainties that arise from biobanking practices due to the lack of physical evidence in cases of violation or deviation from the informed consent. It is unclear if a uniform system of audit is in place to ensure that requirements under the ICMR Guidelines are met. Such consent could be vaguely and ambiguously collected at the time of sample donation, and it seems that blanket use is permitted. As far as secondary or tertiary uses of the data or even the samples are concerned, the guidelines provide that in case the data is anonymized, consent is waived and the approval of the ethics committee would suffice. Also, while it is stated that a participant to any research may withdraw at any time, such option is not extended to "anonymized data," which results in ambiguity, to say the least. While such flexibility is important to support research, it needs to be supported by robust governance. Further, the ICMR Guidelines are silent about re-seeking consent of a child whose biological material was collected (provided, with the consent of the guardian), at the time when such child attains the age of majority.

The ICMR Guidelines provide that the information sheet must inform the participants of their ability to exercise their choice of preventing use of their biological sample, the degree of confidentiality of records to be maintained by the researcher and the consequences of any possible breach of confidentiality by the latter (Chaturvedi et al. 2016). While the ICMR Guidelines speak about the right of the donor to seek destruction of the sample, the data associated with it may still remain at large, as is evident from experiences on biobanking across the globe (Dickenson 2004). So also, on account of the procedure where the data is anonymized for preserving confidentiality, the donors also lose the right to exercise their option of destruction of the data, and even the sample, as it is not possible to exercise such right at a later point of time. To consider a related development, the DNA Profiling Bill (Law Commission of India 2017) tried to correlate the concepts of DNA profiling with the inherent rights of a human being, by stipulating conditions regarding the qualification of the personnel and institutions as well as standards of processes associated with collection, storage, usage, retention and deletion of data regarding DNA and guarantees towards protection of rights of the individual from whom such data is collected. This Bill—which did not come to fruition—is ambiguous regarding the scope of usage, in terms of who can access the information, how long the samples may be retained, etc. The amended version in 2012 also failed to address many of these concerns adequately.

A welcome change may be effected once the proposed Biomedical Research Human Subjects Promotion and Regulation Bill 2013 becomes a reality. This particular effort was put forth in the aftermath of the death of minor tribal girls during post-marketing surveillance of an anti-cervix cancer HPV vaccine, conducted under the aegis of ICMR (Dhar 2013). Its serves a valuable lesson—the trend of dealing with problems as and when they arise may not be the right approach for Indian regulatory framework of biobanking—a proactive approach seems to be the need of the hour.

Institutional Ethics Committees as Review Bodies

The ICMR Ethical Guidelines (2006, p. 8) stipulate that Institutional Ethics Committees (IECs) have the responsibility to ensure the ethical compliance of research conducted within their respective institutions, after the same has been certified as feasible by the Scientific Review Committee. However, the flexibility envisaged by the guidelines endorses instances where the IEC itself acts as the SRC. This in itself creates confusion and uncertainty regarding the process and the quality of review of research proposals.

The composition of an IEC under the ICMR Guidelines includes legal experts, philosophers, or ethicists and lay persons, who, ideally, are to be trained so that decision-making in the review process is smooth, consistent and effective. However, the competence of IEC members is not really ascertained. Also, the fact that clinicians from various institutes as well as people from basic medical sciences are members, as required by the guidelines, often result in an exchange from the IEC of one institution to another, thereby creating confusing standards of conflicts of interests. To compound the dilemma, there is a lack of a central mechanism for reporting or supervision of the activities of these committees.

Further, an IEC may not be involved in clinical trials per se—though the ICMR Guidelines mention these as forming the regulatory framework of clinical trials. In practice, they are seen to be limited to bioavailability and bioequivalence studies, while Institutional Review Boards (IRBs), bodies envisaged under Schedule Y, Drugs and Cosmetics Act 1940, deal with other matters relating to clinical trials (Ghooi 2014). This dichotomy may impact regulation of products related to biobanks, particularly as the concept of commercial IRBs are on the rise, thus leading to concerns of conflicts of interests as well as a lack of objectivity in the decision-making process.

Conclusion

India's economic reforms are very recent, its movements towards a more free market economy, induced by the demands of globalization and liberalization, beginning as late as 1991 (Ahluwalia 2002). Since its Sixth Five-Year Plan, India, has been increasingly investing in biotechnology as the answer to meet agricultural as well as other health needs of its population (Seuba and Correa 2010). In September 2007, the Government of India approved the National Biotech Policy that focuses on overcoming lacunae in the domain and enhances synergies across sectors (Ministry of Environment and Forests 2009).

India, as a technically proficient developing country, is incentivising innovation in those sectors of proficiency; yet the concerns of public health in susceptible quarters pull back its efforts at elevating its status to a developed one (Picker 2004). India possesses the assets of a rich human capital base, supported by a knowledge platform which is a pre-requisite for establishing the necessary infrastructure for advances in biotechnology. About 0.5 million postgraduates and 6607 PhDs in Biosciences and Engineering are produced yearly by India (All India Survey on Higher Education 2016) India also possesses essential and core competency in bioprocess engineering, gene manipulation of microbes and animal cells, recombinant DNA technology of plants and animals and has well-developed base industries relating to pharmaceuticals and related sectors (Department of Biotechnology, Ministry of Science and Technology 2001). Other significant factors include facilities and regulatory infrastructure relating to clinical trials in India (Vepachedu and Rumore 2004) as well as scope for bilateral cooperation and interactions from technologically superior countries.

Concurrently, the possibilities of exploitation of the weaker and susceptible populations must not be ignored or overlooked. Approximately half of the female population in India remains illiterate. This is the fraction of the Indian population most significant for some facets of biomedical research. Also, caste prejudice is entrenched in the very culture of India (Sengupta 2006); "a modern state but an ancient civilization" (Cohen 2001, p. 20). As practices across the globe evidence, the poor and marginalized often are the targets of research and commercialization involving the human body. With the perception that when participants consent, as per concept, that this means that they must agree to the demands of doctors and researchers, and practices where incentives such as vaccines and other incentives become part of the process of study and sample/data collection, consent cannot be said to be an informed one (Vaz et al. 2015). Such instances are very clearly prevalent, especially in cases where the risk of commercialization is high, such as organ transplantation, surrogacy, as well as use of innovative

(but not clearly safe or effective) technologies (Goodwin 2009). Another relevant aspect of biobanks is their possible involvement in and contribution to the ever-widening frontiers of genetic and genomic research, where the repercussions of non-compliance with universally evolved tenets of privacy and confidentiality may well prove disastrous, particularly in view of studies that have highlighted the lacunae that subsist in the Indian research sector, including the lack of ethical awareness of researchers, participants and even of IRB members and the governmental regulatory personnel (Patra and Sleeboom-Faulkner 2009). For India, as a society where social disparities far outweigh the capacity of the legal and regulatory frameworks to protect the marginalized, it is crucial that biobanks are not abused as tools to further the exploitation of vulnerable populations.

India, both in its role as a developing country with the potential and manpower to emerge as a world leader in biobanking, as well as the largest future beneficiary of the outcomes of such research in the future (Shankar and Uday 2011) due in part to its teeming population, must adopt a position that best reflects its protective stance towards its people. The Constitution of India is an efficient mechanism of balancing public and private interests that may conflict at times. Into this matrix, when one introduces the concept of biobanking, the Constitution must act as a facilitator that seeks to protect the much-valued individual rights recognized by the Constitution and the overriding public interest in a Welfare State through the strategy of social engineering (Abichandani 2003).

Herein, the duties of the State of India as pertaining to right to health become significant in the context of biobanks, namely:

1. Respecting the right to health—The State must desist from taking actions that inhibit or interfere with the ability of its people to enjoy this right;
2. Protecting the right to health—The State must protect its people from having their rights infringed by third parties, such as health care providers, private industry, pharmaceutical companies, researchers or sellers.
3. Fulfilling the right to health—The State is required to take positive action to implement the right to health by adopting policies which allocate public resources to correct deficiencies in health facilities, goods, and services.

India must ensure that any research practice, including biobanking, does not exploit women, children, the ailing, and other susceptible members of the society. At the same time, if the research yields feasible, safe, and effective therapies or therapeutics, the State has a duty to ensure equitable access for all its citizens. In order to fulfill such objectives, it is imperative that a targeted and comprehensive governance framework must be instituted which accommodates the particular requirements of regulating research, as well as the interests of researchers, and most importantly, the welfare of the ultimate beneficiaries of the research outcomes and products—the people of India.

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