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Navigating bioethical frontiers: critical concerns in biobanking

Salma Darmayanti*, Nuke Ayu Febryana, Adila Zafrullah, Novian Wildan Rosyidi, Isna Maulida Hanum, Dellarious Benefit Yubaidi

Master of Biomedical Science, Faculty of Medicine, Public Health, and Nursing, Gadjah Mada University, Yogyakarta, Indonesia

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ABSTRACT

A biobank constitutes a systematically organized collection of biological specimens, accompanied by corresponding data and information. These specimens encompass a range of materials such as genetic matter (RNA, DNA, cDNA), blood, serum, plasma, urine, tissue and others. Particularly valuable in longitudinal cohort studies, biobanks facilitate the accumulation of samples over extended durations. This is made feasible by the storage facilities within biobanks, which ensure the preservation of specimen quality over time. However, the utility of biobanks across diverse domains brings to the fore a spectrum of ethical dilemmas, encompassing aspects like informed consent, confidentiality, ownership, property rights, commercialization, feedback mechanisms, and re-contact procedures. Informed consent stands as a cornerstone in a biobank operation. Studies indicate a preference for broad consent due to the forward-looking nature of biobank research and its alignment with prevailing ethical standards. Concurrently, the establishment of a tailored regulatory framework becomes imperative to uphold robust ethical oversight, while also accommodating the values of participants. Addressing concerns regarding ownership, property rights, and commercialization entails the formulation of comprehensive agreement forms detailing donor identity, sample type, intended usage, and potential commercial prospects. Furthermore, ensuring adherence to data confidentiality and individual privacy mandates equips researchers and biobank personnel with ethics training. Regular monitoring and evaluation serve to verify compliance with confidentiality regulations. In instances of noteworthy findings, the biobank can provide feedback or initiate re-contact, with protocol adjustments made in alignment with ethical principles. Consideration may also be given to re-consent procedures as deemed necessary. These protocols may be integrated into the original informed consent documentation, with oversight responsibilities vested in the ethics committee of each biobank.

ABSTRAK

Biobank adalah kumpulan sampel biologis yang disertai data terkait, tersusun secara sistematis. Sampel-sampel tersebut meliputi materi genetik (RNA, DNA, cDNA), darah, serum, plasma, urine, jaringan, dan lainnya. Keberadaan biobank penting dalam studi kohort jangka panjang, karena memungkinkan pengumpulan sampel selama bertahun-tahun dengan kualitas terjaga. Namun, keberagaman manfaat biobank menimbulkan berbagai permasalahan etika, termasuk pernyataan persetujuan, kerahasiaan, kepemilikan, komersialisasi, dan kontak kembali. Pernyataan persetujuan, khususnya persetujuan yang luas, sangat penting dalam pengelolaan biobank, sesuai dengan norma etika yang berlaku. Perumusan regulasi yang sesuai kebutuhan untuk memastikan pengawasan etika yang kuat sambil memperhatikan nilai-nilai peserta. Masalah kepemilikan dan komersialisasi dapat diatasi dengan formulir kesepakatan yang mencakup identitas donor, jenis sampel, penggunaan yang dimaksud, dan potensi komersialisasi di masa depan. Pelatihan etika bagi peneliti dan staf biobank menjadi krusial untuk melindungi kerahasiaan data dan privasi individu. Pemantauan dan evaluasi rutin diperlukan untuk memastikan kepatuhan terhadap aturan kerahasiaan. Biobank dapat memberikan umpan balik atau menghubungi kembali peserta jika diperlukan, dengan penyesuaian protokol sesuai pertimbangan etika. Kebijakan ini dapat dimasukkan dalam dokumen persetujuan informasi asli, dengan pengawasan dari komite etika biobank masing-masing.

*corresponding author: salmadarma27@gmail.com

INTRODUCTION

A biobank is a structured collection of biological specimens accompanied by associated data and information, all systematically organized within a designated system. The biological specimens typically stored in a biobank include genetic material (RNA, DNA, cDNA), blood, serum, plasma, urine, and tissue samples. The associated data generally comprises the donor's identity and name, the sample type, the physiological and pathological condition of the sample, the date of collection and donation, and the specific research purposes for which the sample is intended.[1-3] Biobanks are subsequently classified based on their scope and primary purpose. For instance, population-based biobanks collect samples from the general public to facilitate large-scale epidemiological studies, while disease-oriented biobanks focus on specific pathologies, such as cancer or diabetes, to support targeted translational research. The inherent variety in sample types, combined with the immense scale of collection, necessitates a comprehensive and well-structured approach to their overall management.[4–6]

The widespread application of biobanks in medical research demands a high standard of governance and operational integrity. Effective biobank management is key to ensuring the quality, traceability, and long-term viability of specimens and associated data over long periods. This involves strict standard operating procedures (SOPs) for sample collection, processing, storage (e.g., proper temperature monitoring in ultra-low freezers), and distribution.[7,8] To manage the massive and complex dataset, a robust supporting information technology (IT) system is essential. This system, often an integrated Laboratory Information Management System (LIMS), is necessary for tracking the sample's "chain of custody," managing donor consent status, linking clinical data, and providing researchers with searchable access to the inventory, all while maintaining strict data security and confidentiality protocols. This technological infrastructure is the backbone that transforms a mere collection of samples into a valuable research resource.[9,10]

The applications of biobanks are extensive across the medical field. They are fundamental for mapping genetic predisposition to diseases, facilitating pharmacogenomic profiling for personalized drug metabolism screening, and accelerating the development of new vaccines and biological therapeutics.[4] Furthermore, biobanks enable multiomics analysis, which is critical in cancer research for identifying comprehensive molecular signatures.[3,5,11] Due to their capacity for long-term, high-quality preservation, biobanks are particularly valuable in cohort studies that demand extended follow-up periods.

However, the wide application in various fields makes biobanks inseparable from ethical, legal, and social issues (ELSI). The long-term storage and future-use nature of biobanks inherently create several potential conflicts of interest. These conflicts often arise from the tension between public benefit (the advancement of science and medicine) and individual rights (privacy and autonomy). Specifically, issues related to property ownership and commercialization can lead to conflict when samples donated altruistically are later used to develop highly profitable products, leading to disputes over benefit-sharing. Furthermore, the practice of using broad consent can conflict with the donor's right to full autonomy and control over their genetic information, especially when research scopes change over time. Other core ethical issues include informed consent,

confidentiality, feedback to participants, and re-contact ethics.

In this review, various ethical issues are discussed in more detail, accompanied by examples that occur in society, as well as alternative solutions that are proposed to overcome various ethical problems in biobanks.

MATERIAL AND METHODS

This review employed a structured approach to identify, appraise, and synthesize scholarly literature concerning the bioethical dimensions of biobanking. An extensive search was undertaken across major scientific database including PubMed, ScienceDirect, and Google Scholar using the terms "biobank," "bioethics," "informed consent," and "data confidentiality." Publications issued between 2004 and 2025 were screened, restricting inclusion to peer-reviewed English-language articles. The retrieved studies were critically examined to elucidate dominant ethical tensions, normative frameworks, and proposed governance mechanisms underlying biobank practice. The resulting synthesis was organized narratively to articulate emergent ethical themes, interrogate conceptual ambiguities, and highlight unresolved gaps within current biobanking ethics discourse.

RESULTS

The narrative synthesis identified six principal ethical domains in contemporary biobanking discourse: informed consent, broad consent, confidentiality, ownership and commercialization, participant feedback, and re-contact ethics. The literature consistently emphasized informed consent as the foundational ethical requirement in biobank operations, with the broad consent model emerging as a pragmatic, albeit imperfect, solution to accommodate the long-term and evolving nature of biobank research. However, several studies underscored the persistent tension between research flexibility and participants' autonomy, exemplified by landmark cases such as Havasupai Tribe vs. Arizona State University, which highlighted cultural and moral breaches in consent practices.

Confidentiality was recognized as a critical issue, particularly in genetic and psychiatric research, where the potential for privacy violations and stigmatization necessitates stringent anonymization, data security, and ethical oversight mechanisms. Discussions on ownership and commercialization revealed ongoing disputes over property rights and benefit-sharing, notably illustrated by the Moore vs. Regents of the University of California case, reinforcing the need for transparent agreements outlining sample usage and potential commercial outcomes.

Ethical concerns related to participant feedback and re-contact were also prevalent, with consensus across studies stressing the importance of maintaining communication with donors, especially in longitudinal and pediatric biobanks. Approaches such as dynamic consent were frequently proposed to enhance participant engagement and autonomy. Finally, the literature addressing biobanking in Indonesia revealed unique regulatory challenges stemming from the absence of a dedicated legal framework. The integration of the 2022 Personal Data Protection Law was identified as a crucial step toward ensuring explicit consent and data governance. Recommendations included the establishment of dynamic consent systems, transparent benefit-sharing mechanisms, and the formulation of a National Biobank Standard to unify ethical and legal practices. Collectively, the findings underscore the imperative for adaptive, culturally sensitive, and legally coherent ethical frameworks

to sustain trust and integrity in global biobanking practices.

DISCUSSION

Six main ethical issues in biobanking were identified through a literature review of relevant research. These issues include:

Informed consent

Human biobank is a storage of human biological material, data, and information. In personalized therapy, biobank is one of the pillars and a vital resource for current and future research. Over the last 15 yr, along with the development of genetic technology and genome, there have been many changes related to biological material. Extensive databases containing large quantities of genotype and phenotype data have been developed. Therefore, specific ethical, legal, and social issues must be met to protect a person (data subject = person associated with such data), a donor of a biobank and his/her personal data. The most important ethical issue document is informed consent. Informed consent for the storage and use of human biological material and related data for research purposes is signed by the person who is the donor of biological materials to the biobank. A consent is given to the collection, storage, and use of specimens and is a process that provides sufficient information to the donor to enable them to make a choice as to whether to donate the specimen and data to the place of storage and to consent to future research. Informed consent is an ethical and legal requirement for research involving human participants in medical research to guarantee privacy and the possibility of commercial use of samples. Many newly established biobanks around the world have explained their approach in solving ethical, legal and social issues, and informed consent is one of the most difficult tasks.[12]

Informed consent generally in many countries in Europe is a wide-ranging agreement that is modified, depending on the biobank or its institution. Informed consent must protect donor privacy and human dignity, as well as respect social and cultural aspects. The Broad consent model offers the best level of protection for participants, although this model has some significant weaknesses related to protection against violation of participants' values and long-term protection of autonomy, if applied without qualification. Broad consent is not the perfect solution to the problem of informed consent in biobank. Even with the profound nature of the broadly modified approval process, there is still a risk that the values of participants will be accidentally violated by future research. However, the Broad consent model is better for biobank than other approval models. It is best suited to protect participants while at the same time achieving the research objectives of the biobank.[13]

Broad consent

Broad consent allows individuals to authorize the use of their samples and data in future biobank research within a predefined framework. This framework aims to ensure ethical oversight of any research utilizing participant data. Participants providing broad consent retain the right to be informed of any changes to the framework and may withdraw their consent at any time.[14] While broad consent offers researchers advantages such as time efficiency and flexibility, it has also raised concerns. Critics argue that broad consent diminishes participants control over their samples and data, violating their moral right to control information about their bodies.[15]

The threats to participant autonomy are not merely hypothetical. A landmark example can be seen in the Havasupai Tribe vs. Arizona State University (ASU)

case. Members of the Havasupai Tribe in the United States initially provided blood samples under broad consent for diabetes research.[16] However, ASU researchers later utilized these samples for highly sensitive studies, such as those concerning schizophrenia and the tribe's ancestral migration patterns (inbreeding), without obtaining renewed consent.[17] This case exemplifies how broad consent, while administratively efficient, can deeply undermine cultural integrity, collective values, and the principle of autonomy, particularly when subsequent research purposes deviate from the participants' original understanding. The dispute was resolved through a settlement requiring the return of the biological samples and financial compensation, thereby underscoring the ethical limits of employing broad consent without rigorous qualification and continuous oversight.[18]

In South Africa, the use of broad consent in biobank research is governed by various laws and guidelines. These regulations have evolved over time. The Bill of Rights Act, Section 12(2)(c), mandates informed consent for medical or scientific research. Other regulations governing informed consent include the National Health Act and its regulations. Additionally, the DoH ethical guidelines, the SA National MTA template, and the Protection of Personal Information Act (POPIA) all have provisions regarding consent related to the use of broad consent for biobank research in the country.

Debate surrounds the use of broad consent for biobank research under POPIA. The Act requires the collection of personal information to have a purpose that is "specific, clearly defined, and lawful." Experts hold differing views on whether POPIA permits broad consent. Staunton et al argue that POPIA allows broad consent, but Thaldar & Townsend contend that POPIA does not.[19,20] Several issues with POPIA related to biobank research exist, including POPIA seemingly only allows consent for specific purposes; POPIA has exceptions for research that permit further processing of personal information. However, it is unclear whether this encompasses broad consent; and varying interpretations of POPIA lead to confusion in the research sector. Maseme advocate for South Africa's regulatory framework to allow the use of broad consent for biobank research. The authors argue that broad consent is necessary due to the future-oriented nature of biobank research and that current ethical guidelines permit it. They recommend developing a specific regulatory framework for biobank research that ensures stringent ethical oversight and balances flexibility with participant protection.[15]

Broad consent presents both advantages and challenges for biobank research in South Africa. While it facilitates efficient and flexible research, it raises concerns about participant autonomy and data privacy. Navigating the legal and ethical landscape surrounding broad consent requires a nuanced approach that balances research interests with participant rights. A tailored regulatory framework for biobank research, incorporating clear guidelines for broad consent, is crucial to fostering responsible and ethically sound research practices in this domain.

Confidentiality

Suicide is a significant public health issue worldwide, with wide-reaching and serious impacts on individuals, families, and society as a whole. Genetic research related to suicide has become a major focus in efforts to understand the genetic factors underlying the risk of suicide. Biobanks and population databases serve as valuable sources of data for identifying unique genetic markers associated with suicide risk. One of the main challenges that arise in genetic suicide research is

the issue of confidentiality concerning the data stored in biobanks. Using the genetic data of individuals who have died by suicide for research purposes raises ethical questions about how to maintain the confidentiality of their personal information. It is crucial to ensure that the data used for research remains anonymous and protected from unauthorized access to safeguard the privacy and security of sensitive information related to the mental health and genetics of individuals who have died by suicide. Confidentiality in biobank data is an important ethical issue in genetic suicide research. Protecting the genetic and health information of individuals who have died by suicide must be prioritized to prevent data misuse, privacy violations, and potential stigmatization of the families and relatives left behind. Efforts to ensure data confidentiality in the context of genetic suicide research should be based on strong ethical principles, including compliance with applicable privacy regulations and the implementation of strict data security measures to protect sensitive information related to the mental health and genetics of individuals who have died by suicide.[21]

The issue of confidentiality in biobank data, particularly in the context of genetic suicide research, can be addressed through several methods. One approach is the use of identification codes, where the genetic data of individuals who have died by suicide are identified using unique or identification codes that are not linked to their personal information. This helps maintain data confidentiality and prevents direct identification of individuals. Biobank administrators must also implement stringent data security protocols to protect sensitive information related to the mental health and genetics of individuals who have died by suicide. These security measures may include data encryption, restricted access, and audit trails to monitor data usage.[22] Another step to address confidentiality issues in biobank data for genetic suicide research is to implement broad consent. Obtaining broad consent from individuals or their close family members at the time of autopsy for the use of genetic data in secondary research can be a solution to uphold the principle of autonomy and maintain data confidentiality. This consent should include information about data usage, security procedures, and protected privacy rights. Providing ethics training for researchers and biobank staff on the importance of maintaining data confidentiality and respecting the privacy of individuals involved in genetic suicide research is also crucial. Awareness of confidentiality issues can help prevent ethical breaches and data misuse. Lastly, it is important to conduct regular monitoring and evaluation. Regular monitoring and evaluation of compliance with data confidentiality policies in biobanks and the effectiveness of the implemented security measures can help identify potential risks and improve existing data security systems. By implementing these steps, it is hoped that the issue of data confidentiality in biobank genetic suicide research can be effectively addressed, ensuring the privacy and security of sensitive individual information while supporting research progress in understanding the genetic factors associated with suicide.[21]

Ownership, property, and commercialization

One of the important issues in biobanks are ownership, property and commercialization. “Commercialization” encompasses various activities. It might involve the commercial use of biobank resources, such as data or human biological samples, or the commercialization of research outcomes and products developed from those resources. Additionally, it can refer to

publicly funded biobanks collaborating with or obtaining funding from private, profit-driven entities, including biotech companies, pharmaceutical firms, or the medical device industry.[23] Biobanking for genomic research in all countries has raised similar ethical issues. Regarding the point above, the first issue is the tension that arises between the property rights of individual sample owners and the rights of biobanking institutional owners towards research progress.[24] Meanwhile, the second issue concerns the difficulty of reconciling interests between the non-commercial use of human body parts and the increasing role of commercial biobanks.[25]

Issues relating to property and commercialization can be exemplified in the UK Biobank. The UK Biobank's ethical governance framework provides a clear statement (and is repeated three times) stating that participants have no ownership rights to samples donated to the biobank. This statement is based on the understanding of "res nullius", that body parts once separated do not belong to anyone.[26] This understanding is correct, although it has caused a lot of public debate because of concerns that donated samples will be commercialized without providing royalties to the sample owner. The issues of ownership and commercialization have deep legal precedents. The most significant and seminal case is Moore vs. Regents of the University of California. John Moore, a leukemia patient, sued his physician and the university after discovering that his donated spleen cells had been used to develop a highly profitable cell line (the *Mo cell line*) for commercial purposes without his knowledge or any arrangement for benefit-sharing.[27] Although the court ultimately ruled that Moore did not retain property rights over his cells once they had been removed from his body, the case underscored the necessity of full disclosure regarding the potential commercial value of donated biological materials.[28]

There are solutions offered to overcome these issues of ownership, property and commercialization in biobanking, for example creating an agreement document that contains in detail the name of the donor, type of sample, purpose of using the sample, as well as a statement that in the future there is potential for commercialization. The agreement document must be known and signed by both parties: the individual donating the sample and the institution managing the biobank. The agreement document should be officially legalized. The second solution is to hold regular meetings held by the biobank management institution. The purpose of this meeting is to disseminate information and provide updated information regarding the activities and use of biobank samples to sample donors. In the end, the best way is needed to balance various interests, so that biobanks can be used as optimally as possible for research purposes, and the rights of sample owners and researchers are not neglected.

Feedback to participant

According to Tindana, one of the ethical issues discussed is the need for feedback from research participants regarding research progress and the type of research conducted on their samples and data. Research participants have an expectation to receive information about the use of their samples, the results of tests performed, and the implications for their health. A lack of feedback from previous research has caused some members of the community to be reluctant to participate in genomics research. This shows the importance of providing feedback to research participants and the need for researchers to take this seriously in the research process.[29]

According to research conducted by Amoakoh-Coleman *et al.*,[22] in Africa, there are several ethical issues associated with providing feedback to participants

regarding genomic data. In some regions of Africa, there is limited access to health services and resources to provide adequate feedback to participants. This can lead to inequalities in providing information to participants. In addition, culture and social values in various communities in Africa can influence the way feedback is received and understood by participants, and the privacy and confidentiality of genomic data are also widely misused by irresponsible parties. To overcome this problem, it is necessary to involve participants in the decision-making process regarding genomic data feedback. Participants should have a say in how information is presented and how they want to receive feedback. Apart from that, there are also parties who are able to provide education and training to participants about genomic data, its implications, and how to manage the information provided. This can help participants make informed decisions. It is also necessary to pay attention to the development of clear policies and guidelines regarding genomic data feedback, including privacy, confidentiality, and fairness in the distribution of benefits. These policies must take into account the cultural and social context in Africa.[22] According to Tindana, several solutions to ethical issues related to feedback to research participants have been proposed, including the importance of involving research participants in the communication process throughout the research, including providing regular feedback about research findings to participants; Use of Dynamic Consent: Dynamic consent models have been proposed as a way to allow participants to provide consent for new research projects over a specified period of time. Although this model has limitations and technological challenges, the concept of a dynamic platform for continuous communication between participants and researchers about the research conducted and the use of samples has the potential to increase trust in research and researchers. Research supports the possibility of combining technology-based approaches with traditional communication methods such as community meetings to facilitate feedback of research results to participants and the community.[29]

Ethics of re-contact

Re-contact participants is becoming increasingly important in biobank management, but there is still little literature discussing the right approach to it. As with participation and agreement, it is important to maintain a balance between providing adequate information to participants without imposing additional responsibility on them. Re-contacts should be seen as limited resources, and should be limited by mechanisms that allow this to remain possible in the long term.[26] Re-contacting in this case relates to the existence of findings or requests for renewed or additional consent. Storage on a biobank tends to have a long time being a special concern. In practice, biobank has a different approach to re-contacts and re-consent.[30]

According to Goisauf *et al.*,[31] problems related to re-contact and re-consent are related to what and how research findings should be returned to participants. Unlike secondary researchers, biobank has a unique relationship with participants that raises an ethical obligation to maintain such beliefs. Participants directly entrust Biobank with its authority in the collection, storage, and distribution of their data as well as the further freedom of authority required to obtain the data (for example carrying out testing and data accuracy). Biobank may also have access to some of the participant's health and demographic data and be able to follow participants regularly for

longitudinal studies or re-contact for further participation. Nevertheless, the obligation of the biobank is not included in the disclosure of individual research findings to participants. This obligation is more about caution in conducting relationships with participants, whose goal is to advance health research in the public interest. However, biobank may also be able to offer to accept responsibility for certain health interests of participants. For example, the Iceland biopharmaceutical company deCODE collected genomic and biomedical data from almost two-thirds of the adult population in Iceland that gave feedback to individual research results.[32]

The main challenge in returning findings or feedback to participants is lack of legal framework, professional guidance, and other resources. However, the study showed that participants tended to want to receive feedback about the research that involved them (69.1%) and the statement was placed on the informed consent. While views on re-consent differ significantly between countries that implement the General Data Protection Regulation (GDPR) and not. Re-consent is considered necessary by respondents from the GDPR state if the data is to be used for research in different fields. To date, the question of whether and how biobank participants were re-contacted and given their consent to re-entry is still debated among researchers.[31] On pediatric biobank, strong arguments support the view that participants need to be re-contacted after being mature and focus on giving them a chance to choose their continuity. According to Giesbertz *et al.*,[30] there are at least four designs that can be considered: Policy I (re-contact is not initiated by the biobank, but children can retrieve samples and/or their data); Policy II (contracts the child after reaching adulthood and is given the opportunity to withdraw. If the child does not retrieve itself, samples or data, then it can still be used in accordance with the permission of the parent previously obtained); Policy III (re-contact and re-consent. If a child cannot be found or does not respond, the sample and the data can continue to be used according to the consent of the parents previously acquired); Policy IV (re-contact and re-consent. If children could not be located or did not respond then samples and data would be destroyed).[30] At the UK Biobank, requests for re-contact must be made in accordance with the procedure submitted to the Research Ethics Committee (REC) of the UK biobank and will be evaluated by the subcommittee of access to the British biobanks. Therefore the policy selection is returned to each biobank, keeping in mind the ethical aspects.

Article 27 of the Additional Protocol to the Convention on Human Rights and Biomedicine, addressing Biomedical Research, imposes a duty of care in nations that have accepted this Council of Europe treaty, stating: ""If research gives rise to information of relevance to the current or future health or quality of life of research participants, this information must be offered to them. That shall be done within a framework of health care or counselling. In communication of such information, due care must be taken in order to protect confidentiality and to respect any wish of a participant not to receive such information". The term "offered" should be established before the start of the study, taking into account the possible desire of the participants only to know under certain conditions. In some cases, the right to information may not be restricted by domestic law or such conventions.[31] It is important to understand that an ethical review is necessary to ensure that research carried out under general consent meets its purpose. Because each participant can't judge each recent study whether it matches their values. Therefore, the biobank needs to establish qualifying conditions for the study for

this additional ethical review, taking into account the characteristics and population of the Biobank. In this way, the review will ensure that the values of the participants are considered without making excessive re-contact.[13]

Implications and policy recommendations for biobanking in Indonesia

While the ethical issues surrounding biobanks are global, their practical implementation in Indonesia presents unique regulatory challenges. Indonesia lacks a dedicated, comprehensive law governing human biobanking, leading to fragmented ethical governance. Current ethical practice largely relies on the guidelines of institutional Research Ethics Committees (KEPK) and the newly enforced Law No. 27 of 2022 on Personal Data Protection (PDP Law) (SIP Law Firm, 2023). The PDP Law is crucial as it mandates explicit consent for the collection of sensitive specific personal data, such as genetic and biometric information, inherently limiting the scope of unqualified broad consent. The Indonesian government, through initiatives like the Biomedical and Genome Science Initiative (BGSi), is actively working towards drafting national biobank regulations (Ministry of Health, Republic of Indonesia, 2023). To effectively navigate the aforementioned ethical gaps and strengthen public trust, three principal policy recommendations are essential for the future management of biobanks in Indonesia. First, it is recommended to mandate Dynamic Consent (DC) models to enhance participant autonomy. The transition from static broad consent, which carries significant risks of autonomy violation exemplified by the Havasupai case to DC, facilitated through secure digital platforms, enables continuous, granular participant control over their samples and data utilization, thereby satisfying the explicit consent requirements stipulated by the national PDP Law.[14] Second, the national regulatory framework must establish a transparent, tiered Benefit-Sharing policy. Drawing lessons from the commercialization conflicts raised by the Moore vs. Regents case, this policy must explicitly confirm the participant's non-proprietary status post-donation while detailing enforceable mechanisms for returning benefits derived from commercial products. These benefits should strategically prioritize non-financial returns, such as affordable access to developed therapeutics, capacity building for local researchers, and investment in community health infrastructure, thereby ensuring fairness and sustainability.[33] Finally, the most critical step involves expediting the National Biobank Standard (SNB) Regulation. A high-level government regulation is necessary to establish a unified legal instrument that bridges the current regulatory gap between the Health Law and the PDP Law. This SNB must specify mandatory national standards for ethical review, data security protocols (including robust anonymization techniques), quality management, and transparent access rules, ensuring that all Indonesian biobanks meet global standards while firmly upholding local ethical and legal principles.[35,36]

CONCLUSION

The application of biobanking raises a number of ethical concerns, including informed consent, confidentiality, ownership, property, commercialization, feedback, and re-contact. Informed consent is crucial for biobanks. According to various studies, broad consent is the most acceptable option because biobank research is future-oriented and current ethical norms allow this. This should be accompanied by the development of a specific regulatory framework to ensure robust

ethical oversight while maintaining flexibility and respecting participants values. To manage issues of ownership, property, and commercialization is to create an agreement form that includes the donor's identity, type of sample, intended usage, and potential for future commercialization. It is also necessary to provide ethics training to researchers and biobank staff in order to protect data confidentiality and respect individual privacy, as well as to undertake frequent monitoring and evaluation to verify that confidentiality regulations are followed. If any findings are discovered, the biobank can provide feedback or re-contact. However, each biobank must alter this protocol while maintaining ethical considerations. Additionally, re-consent may be considered if necessary. These policies can be included in the original informed consent document, and their execution can be overseen by each biobank's ethics committee.

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