Guidance Document for Human Research Biobanks and Associated Data

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Government of South Australia
SA Health

Disclaimer

In developing this Guidance Document for Human Research Biobanks and Associated Data, every effort has been made to ensure that the information reflects and represents best known practice.The Crown, the Minister and the Department will not be liable for any injury, damage or loss sustained by any person or biobank in relation to the operation and management of a biobank and the resources and data held by it.Biobanks are reminded that they are responsible for any decisions made and it is their own responsibility to ensure the safe, legal and ethical operation and management of the biobank and its resources and data.The information contained in this Guidance Document does not constitute technical, safety, medical, legal or ethical advice.The Department for Health and Wellbeing recommends that you seek your own advice.

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Part 1: Purpose of this document

This Guidance Document for Human Research Biobanks and Associated Data (Guidance Document) draws reference from national and international sources to provide guidance to South Australian biobanks on the:

- minimum standards required for biobanking;
- principles and best practices related to biobanking governance, business planning, funding, data management and consent; and
- management of risks.

This Guidance Document is intended for use by government and non-government organisations within South Australia including, but not limited to, private and not for profit organisations, independent researchers and multi-centre collaborations that cross state and national boundaries.

This Guidance Document is intended to apply equally to the future activities of biobanks created from existing resources as to those formed de novo. It has been written with particular focus on biobanks with multiple users and unspecified future use. However, smaller biobanks should consider the implementation of aspects of the Guidance Document to the extent that it is relevant to them.

This Guidance Document is not intended to apply to biobanks established primarily for non-research purposes such as for diagnostic, therapeutic, forensic, audit, public health surveillance, or marketing authorisation purposes.

Part 2: Introduction to biobanks

Biobanked specimens and data, and the research they enable, make a significant contribution to increasing our understanding, detection, prevention, diagnosis, treatment and cure of complex diseases[10]. A sound policy framework to support access to human biological materials (biospecimens) and personal data by researchers is critical to ensure that the public has confidence in the management of biospecimens and associated personal health information, and that participant privacy and confidentiality is maintained.

The establishment of biobanks poses a number of legal, ethical, regulatory and financial challenges. Irrespective of the size of a biobank, some risk to the community is unavoidable due to the sensitive nature of the materials and the data they contain[7]. The purpose of this Guidance Document is to guide the management of such risks. The success of biobanks also depends on the community's support and willingness to participate[7].

What is a biobank?

Biobanks are commonly large collections of human biological materials (biospecimens) linked to relevant personal and health information (which may include health records, family history, lifestyle and genetic information), and are held predominantly for use in health and medical research[7]. Sources of human biospecimens include voluntary donation, material taken for clinical purposes, and material collected post-mortem (after death)[7]. Biobanks provide a valuable resource to researchers in their efforts to advance our understanding of human health and disease.

Characteristics of a biobank

Biobanks have numerous defining characteristics[7]:

- They contain biospecimens that may be linked with phenotypic data (e.g. disease information, health linkages, and health outcomes), genetic and genomic data and/or other non-health data (e.g. ancestral records).
- They are ongoing in design and will generally involve future research projects that may be undetermined at the time of bank formation and data collection.
- They commonly provide access to samples and/or data, for ethically approved research purposes, to researchers other than the custodian/s of the biobank.
- While the banked information and biospecimens will not generally be identifiable to researchers, there is a requirement that they remain potentially re-identifiable by the custodian. This requirement ensures that it is possible to identify study participants in those limited circumstances where re-identification is necessary to fulfil legal, and/or ethical, and/or medical, and/or participant requests for banked information and biospecimens. Re-identification and recontact of participants may only occur with the prior permission of the study participant or a National Health and Medical Research Council (NHMRC) certified Human Research Ethics Committee (HREC).

- Biobanks have a focus on the public interest; they are less concerned about individual benefit for participants themselves and are more about public benefit for future generations through the translation and application of research findings.

Applicability

Biobanks vary significantly in size. Therefore there is debate as to whether it is appropriate to make a clear differentiation between large and small scale collections when formulating guidance documents, as risk rather than size is the key factor necessitating ethical consideration[7].

There are relevant differences between large and small scale biobanks. Smaller-scale collections may be limited to specific population cohorts, or specific research programs, or a specific research group. In many circumstances the custodian of the biobank will be undertaking research using materials stored in the biobank[7].

Large scale biobanks are usually created as resources for undetermined future research projects by research teams who may or may not have a direct connection with the custodian of the facility[7].

Case Study: South Australian Cancer Research Biobank

The inception of the South Australian Cancer Research Biobank (SACRB) occurred in the 1980s as a South Australian Pathology (then known as the Institute of Medical and Veterinary Science, or IMVS) Haematology Department Leukaemia Bank. During the 1990s, collecting leukemic cells became routine, and collection was extended to include myeloma cells. Consent and samples were obtained as part of the bone marrow biopsy procedure at the Royal Adelaide Hospital. Therapeutic stem cell harvesting involved collection of pilot samples in addition to samples collected for tissue banking for research. By the year 2000, a hospital consent form formalised the consent process, and the scope of the collection was extended to include those patients diagnosed with myeloproliferative and myelodysplastic disorders.

The SACRB was formalised in 2012 to expand the haematological cancer biobank at the Royal Adelaide Hospital/SA Pathology campus to a state-wide biobank by including collections from Flinders Medical Centre, The Queen Elizabeth Hospital and the Women's and Children's Hospital. At present the SACRB is the largest haematological disease biobank in Australia, both in terms of the total number of patients and specimens, and in the number of individual diseases collected. It is a sequential bank, therefore the samples collected are a more accurate reflection of the full disease spectrum, including patients who did not receive treatment and those who did not qualify for and enrol in clinical trials. The median age of patients with specimens stored by the SACRB is reasonably close to the state population median age of 39.8 years at June 2013 (Australian Bureau of Statistics), highlighting the relevance of the collection to the general population. Perhaps of greatest value, the SACRB holdings include a large number of remission samples, enabling longitudinal studies to be conducted.

The clinically annotated SACRB collection has facilitated researchers' participation in major international studies. Further, the SACRB has provided an up-to-date and regulation-compliant ethical platform for a number of smaller collections. Its Executive Committee includes representatives from all clinical and laboratory haematological cancer research groups in South Australia, and provides a highly valuable meeting place for researchers working on different campuses across Adelaide.

The SACRB is an example of one of the many highly valuable biobanks that exist within South Australia.

Guidance Document structure

Part 3 of the Guidelines sets out Principles and best practices applicable to biobanks.

- Principles are overarching statements of concepts and ideals that should guide all biobanks.
- Best practices give effect to overarching concepts and ideals. It is not always possble for smaller biobanks to apply best practices but they should decide how they might best adhere to these recommendations within their particular circumstances.

Part 3: Principles and best practices

3.1 Structure and Governance of biobanks

Principles

A The primary objective of the biobank shall be to foster research and improve the health and wellbeing of the population[8].

B Key governance principles are transparency and accountability[8]. Governance structures shall be established to ensure that the rights and well-being of participants prevail over research interests, and the operators have in place oversight mechanisms to ensure that governance, management, operation, access to, use of, and discontinuation of the biobank comply with legal requirements and ethical principles[8].

C The custodian or initiator of a biobank should formulate the biobank governance structure to include oversight of[10]:

- operational policies, procedures and financial management considerations
- technical, legal, and ethical issues
- biobank security, access and decommissioning
- consumer engagement that includes consultation with cultural groups
- compliance with relevant legislation and guidelines.

D In accordance with the principles of transparency and accountability, this information should be freely available to the public[8].

E The governance structure of the biobank shall be subject to independent ethical review, approval and monitoring, and be administered according to the best practice principles of good corporate governance[10].

F The need to modify policies, protocols and procedures over the lifespan of the biobank will occur and the custodian should have a plan for addressing this[10].

G All biobank personnel, researchers and partners have a responsibility to ensure that activities related to the biobank are carried out according to policy, protocol and procedure, as well as legal and ethical frameworks[10].

Best practices

Structure

1. Biobanking governance structures should include mechanisms for:
    - 1.1 independent scientific, medical, legal, financial and ethical oversight, which is to be approved by an NHMRC certified HREC, to ensure that the governance, management and operation of the biobank are in accordance with policies and relevant regulatory, legislative, and ethical frameworks[8] prior to its establishment and on an ongoing basis
    - 1.2 proposed endorsement from the appropriate host institution/responsible authority, including funding endorsement
    - 1.3 defined governance arrangements with any responsible authority/host institution, including mechanisms of appointment, credentialing, reporting lines, and processes to deal with any conflict of interest. The arrangement must be consistent with the principles of transparency and accountability[8]
    - 1.4 independent auditing mechanisms to monitor collection of, access to and the use of samples and data, adherence with research ethics approvals, access approvals and the research uses agreed to by participants during the process of informed consent[10]
    - 1.5 an independent complaint procedure or review process by which participants can address concerns about breaches of policy, legislation or ethical frameworks[8].
2. Biobank oversight mechanisms should include annual reporting on compliance with relevant legislation, regulations and ethical frameworks[10].
3. Independent auditing mechanisms should be available to conduct random auditing as indicated, with funding made available for such contingencies[10] as guided by the governance committee.

4. There should be clearly identified and delineated roles and responsibilities of those persons who are involved in the biobank's activities, including those people responsible for[10]:

    4.1 ensuring compliance with biobanking requirements including legal, financial, ethical, policy, managerial and reporting requirements

    4.2 ensuring the security of specimens and data including privacy and confidentiality of participants.

Governance

5. Governance should include consideration of:

    5.1 what is to be collected and a plan for specimen and data collection that is fit for purpose[8]

    5.2 what information needs to be recorded about the source, nature and reason for collection of biospecimens[7]

    5.3 the requirements for participant consent, including circumstances where waiver of consent may be justified[7]

    5.4 how confidentiality and privacy of samples and information can be secured, and who has access to samples and information[7]

    5.5 how disposal of samples should be undertaken[7]

    5.6 what socio-cultural factors impact the above listed considerations[7]

    5.7 collaboration or amalgamation of bio-specimen and data collections to avoid unnecessary proliferation of biobanks.

Modification of policies

6. Processes around the modification of the biobank's policies, protocols and procedures should include reasonable provisions for participants to be informed of these modifications[10].

7. Where there is significant modification of the biobank's policies, protocols and procedures, the biobank custodian should ensure that approval is sought and obtained from an NHMRC certified HREC[10].

8. Where significant modification of policies, protocols and procedures may result in breaching previous consents, the biobank custodian should ensure that a new informed consent is obtained from the participant or the substitute decision maker, unless an exemption exists through a waiver of consent authorised by an NHMRC certified HREC and other internal parties[10].

Information

9. The information related to the governance, management and oversight of the biobank should be publicly available in easily accessible formats (including a website), and should include:

    9.1 the purpose of the biobank, including aims and scope of research[10]

    9.2 the ethics approval obtained to establish the biobank[10]

    9.3 the relationship of the biobank to any host institution/responsible authority and funder(s) and the nature of such organisations

    9.4 the funding and financial management[10]

    9.5 the mechanism of appointment of a governance committee and representation of various interests on that committee[10].

    9.6 the mechanisms and responsibilities that are in place for governance, management, oversight, review of applications for access and use, auditing and redress, and complaint processes[10]

    9.7 the operational policies and procedures of the biobank including security and data protection measures and data access policies[10]

    9.8 governance and operational policies that address procedures for when the bio-specimen/sample is used/exhausted and associated data remains available

    9.9 significant modification of the biobank's policies, protocols and procedures[10]

    9.10 the legislative, regulatory and ethical frameworks that the biobank operates under; including how to access information related to these, and the consequences of non-adherence[10]

9.11 annual reports of the biobank's compliance with relevant domestic laws, regulations, finance and ethical guidelines[10]

9.12 the type of specimens being held, potential health and scientific benefits, and/or risks from the use of the biobank

9.13 expected duration of the biobank

9.14 where more information in relation to the biobank can be found, including contact details for a representative who will respond to questions from the public[10].

Cultural sensitivities

10. Policy on procurement, processing, storage, use and destruction of human biological material and data should take into consideration cultural, heritage and/or religious beliefs known or disclosed by participants and their associated groups[7].

11. Relevant community and cultural groups should be engaged early in setting up biobanks to ensure that policies are culturally sensitive; for example, the Aboriginal Health Council and/or other Aboriginal advisors and the Migrant Health Service and/or Migrant Resource Centre of SA.

12. Engagement with relevant community and cultural groups will also assist with the translation of information sheets and consent forms for participants from various cultural groups to ensure they are culturally and linguistically appropriate.

Liaison with donor groups

13. Given the reliance of biobanking on the voluntary support of the public, consideration should be given to engaging the public during the establishment phase of the biobank, the type and extent of which should be consistent with the nature and design of the biobank[8]. Please refer to items 17 to 21 for further considerations regarding the involvement of individuals, including minority groups, in research.

Qualifications, education and training

14. The biobank custodian should have the appropriate qualifications and training to carry out their responsibilities[10].

15. It is the responsibility of the biobank custodian to ensure personnel have the requisite professional qualifications as set by recognised standards, as well as the experience, skills, contemporary knowledge, education and training relevant to their assigned responsibilities[10].

16. It is the responsibility of technical staff to ensure that policies and procedures developed by the biobank custodian are implemented[10]. Ongoing training in appropriate areas, including in-house training, must be sufficient to ensure best practice. The custodian of the biobank or person with appropriate skills should regularly reassess the work practices of all staff to ensure procedures and protocols are maintained.

Custodianship of samples and data and benefit sharing

17. Consideration should be given to who the custodian of the biobank is, and whether any legal or ethical issues that arise in relation to ownership of samples and data[10]. Current Australian legislation on 'ownership' or 'stewardship' of samples and data is ill defined. Refer to items 22 to 26 for further considerations. Donors should be made aware of the institution's policies.

18. The custodian, whether a nominated person or a committee, should consider that donors may perceive a loss of comfort and control after the consent and collection of samples has occurred[11]. This is particularly likely for minority groups and/or when the consent has been relatively open-ended and lacking in specificity[11]. The custodian should assess compatibility of ongoing use with the original consent, and consider whether donors would be comfortable with the evolving uses of their samples and data, and whether such uses are compatible with the intent of the donation[11]. Ongoing communication with donors is likely to assist with such assessment and enable donors to retain a sense of comfort or alternatively, lead to re-examination of the evolving use of samples and data[11].

19. Benefit sharing from research may arise in the form of financial benefits, information, licensing, or transferring of technology or materials. The biobank custodian should ensure the existence of clear, detailed, publicly available policies related to these aspects of benefit sharing[10].

20. Recent Australian research indicates that many Australians would expect information specific to them and their families arising from research on donated samples to be made available to them[9].

21. As a general principle any benefits from research should be shared widely with the community[10], noting any personal information which may have led to the beneficial finding is to be de-identified. In Australia, the Prime Minister's Science, Engineering and Innovation Council Report (2006) recommended "that the principle of open equitable access to publicly funded scientific data be adopted wherever possible and that this principle be taken into consideration in the development of data for science policy and programmes"[3].

Intellectual property (IP) rights for biobanking in Australia

22. IP rights establish ownership and exclusive control of researchers' innovation. Registered IP rights such as patents, trade-marks and design rights are not granted automatically. Researchers need to apply with IP Australia and meet specific criteria under the relevant legislation.

23. In Australia, the law with regard to property in human tissue remains unsettled[13]. Arguments that could be made about the status of human tissue include the following:

    23.1 There can never be full property rights in human tissue, but there may be more limited possessory rights;

    23.2 There can be some form of property in human tissue when it has undergone transformation (or processing or treatment, to use the wording in the Australian human tissue legislation), in which case ownership may vest in the person or organisation undertaking the transformation (this could be the researcher, the researcher's employer or the biobank);

    23.3 There may be ownership of human tissue by the person providing the tissue, but claims to ownership may be abandoned when the tissue is provided to the biobank or researcher; or

    23.4 The person providing the tissue has ownership rights in it and retains some of those rights, even after the tissue has been donated to the researcher or biobank.

    23.5 These options are discussed in the Australian Law Reform Commission/National Health and Medical Research Council's Australian Health Ethic Committee Report[13]. The Report concludes by recommending that full property rights in untransformed human tissue should not be recognised, essentially rejecting the options described at 23.3 and 23.4. It would seem, however, that the option described at 23.2 is not precluded in Australian law.

24. Each biobank should obtain its own legal advice in relation to IP issues.

Intellectual Property Policy incorporating the Monetary Rewards Framework for SA Health

25. Intellectual Property (IP) management is vital and should be considered part of the biobank's strategy for both the bank and the data associated with the biobank.

26. The identification, protection and commercialisation of IP can be complex; early expert advice on IP issues is recommended. These may include consultations with legal, financial and technical advisers, patent attorneys, commercial consultants and specialised public sector agencies with relevant expertise. This advice is particularly important when negotiating and developing appropriate contractual arrangements, and prior to undertaking legal commitments.

Additional considerations

27. There appears to be little current support in Australia or internationally for generic biobank legislation or generic genetic legislation[7]. Those responsible for governance of a biobank need to be aware of and comply with any legislative changes, and also be aware that there may be future requirements for licensing or registration for large biobanks.

3.2. Funding and business planning

Principles

A The biobank shall have a clearly articulated current and future purpose, and proposal for operation[10].

B The biobank custodian shall ensure a business plan is developed[10].

C The biobank custodian shall ensure operational policies and procedures are developed[10].

D When establishing a biobank, consideration shall be given to maximising design flexibility and optimising opportunities for future collaboration and cooperation, particularly in relation to database compatibility and interfaces[10].

E When establishing a biobank, the custodian shall carry out consultation with stakeholders, including participants and potentially the general public, including cultural groups[10].

F The biobank custodian should ensure that information regarding the existence, purpose(s), rationale for, and operation of, the biobank is publicly available and easily accessible[10].

Best Practices

Establishment of a biobank

1. Establishment of a biobank de novo for research purposes necessitates careful planning to ensure that the biobank follows best practice principles from inception, and meets an area of need[10]. The key considerations are related to a defined purpose or business plan including governance, funding and other financial considerations, data and specimen management, and consent.

2. When considering establishing a biobank, the initiators and/or the principal data custodians of the intended biobanks should:

   2.1 define the objectives that take into consideration the current and future purpose, operational, social and financial requirements of the biobank[10]

   2.2 consider the possibility of contributing to and accessing existing, established biobanks if the material meets the intended research needs. The option of a centralised biobank may help promote collaboration amongst researchers, plus reduce costs associated with establishing and operating biobanks

   2.3 develop a business plan that includes operational policies and procedures including[10]:

   - background
   - objectives
   - methodology
   - operational policies and procedures
   - feasibility
   - financial management issues
   - ethical issues.

   2.4 obtain project endorsement with the appropriate host institution / responsible authority, including funding endorsement

   2.5 develop a formal agreement between the funding body/bodies and the institution/s involved.

3. The biobanking custodian should be responsible for documentation development and endorsements through the project implementation. This includes:

   3.1 elements of the project plan

   3.2 consideration of conducting a pilot project

   3.3 ethics review and approval

   3.4 recruitment

   3.5 collection of samples and data

   3.6 quality assurance activities.

4. The biobanking custodian shall ensure information related to the existence, purpose, rationale, operation and governance of the biobank is publicly available[10].

5. A business strategy should be developed to consider project withdrawal in the event that funding is terminated or its nature is changed[10].

Biobanks created from existing resources

6. Biobanks will be created from existing resources, or will combine old and new resources. Whilst past practices may not be fully compliant with contemporary best practice, best practice is such that this Guidance Document is as relevant to the future activities of biobanks created from existing resources as to those formed de novo[7].

7. The initiators or custodians should ensure the existence of criteria for sampling and participant selection to ensure that the data contained within the biobank is representative of the targeted population and is appropriate for a clearly defined purpose[10].

Funding and other financial considerations

8. The financial details to be captured within the biobank business plan should consist of:
   - 8.1 a financial model intended to be adopted over the biobank lifespan[10]
   - 8.2 explicit and transparent information about the nature and source of funding that details income, expenditure, assets, and liability information[10]
   - 8.3 income information would include, but is not limited to grants and service fees associated with operational costs, donations, and/or revenue from commercial opportunities
   - 8.4 expenditure information would include, but is not limited to, payroll information, consumables, storage and infrastructure, promotion costs, audit fees, transport costs, and contractors/consultants
   - 8.5 assets information would include such items as equipment or buildings, or even trademarks or patents
   - 8.6 liability considerations would include, but are not limited to an obligation to pay for something, outstanding legal or estimated costs for the decommissioning of a biobank.
9. The following document may assist with populating the relevant information to include in a business plan (Finance template page 16). Other considerations include:
   - 9.1 information related to the financial and research feasibility of the biobank that addresses assumptions, or risks identified in the establishment of the biobank[10]
   - 9.2 proposed staffing and resource requirements to effectively maintain the operational capacity of the biobank over its lifespan. This should be included within the costings[10]
   - 9.3 considerations for the ongoing financial and public support of samples and data[10]
   - 9.4 an annual cost benefit analysis review to confirm that the collections being obtained and retained still meet the objectives of the current and future purpose, operational, social and financial requirements of the biobank (costs versus outcomes). This will identify areas for operational change that may improve investments without diluting the purpose/objective[10]
   - 9.5 a business strategy in the event that funding is terminated or its nature has changed[10].
10. Where any private or foreign investment or commercial or international collaborations are foreseen by the biobank custodian, this should be clearly communicated to participants, and domestic law and regulation[10] compliance observed.
11. In most circumstances it would be appropriate to explain to participants that personal benefit is unlikely.
12. The biobanking custodian must ensure that staffing and resources are sufficient for the maintenance and preservation of data and specimens, audit and quality control activities, and for the management of requests for access to data and samples[10].

3.3. Data and specimen management

Principles

A Biobanking databases shall be developed using a standardised approach for the collection, storage and analysis of samples and data, to maximise the potential for cross-biobank data exchange and sharing[10].

B The biobank shall be established, managed, governed and operated in a manner that protects the privacy and confidentiality of the participants who have contributed biospecimens and their data, and which prevents the inappropriate and unauthorised access to these materials[8].

C The biobank must have mechanisms for re-identification in order to:

- meet future diagnostic requests
- fulfil requests for no further use or destruction of samples
- fulfil requests for the disposal of samples in accordance with cultural sensitivities
- enable adverse findings from research to be traced back to the participant such that the participant can be advised in an ethical and appropriate manner, and
- allow for those limited circumstances where re-identification is necessary and ethically justified to allow maximum research value[9].

Best practices

Protection of samples and data

1. The biobank custodian should:
   - 1.1 develop and implement procedures to ensure that privacy, confidentiality, integrity and availability of human biological materials and data meet legal requirements during all phases of operation
   - 1.2 make adequate information available to participants about how their materials and data will be protected[8]
   - 1.3 implement a combination of mechanisms and robust infrastructure to preserve the privacy and confidentiality of all materials and participant data including: secure storage of samples and data, consent forms, data encryption, coding, separation of information that can readily identify the individual, and/or the use of an independent third party responsible for ensuring identified information is separated from other data[7]
   - 1.4 ensure that there are clear, detailed, publicly available policies and protocols guiding the disposal of samples and data in the event of a participant withdrawing consent[7].

Release of biobank samples and data

2. The biobank custodian should develop clear, detailed, publicly available policies, protocols and procedures governing the release of all samples and associated data[10].
3. The biobank custodian should ensure that:
   - 3.1 the end user has undertaken any relevant research ethics and governance approval requirements, as applicable, to permit access to the samples for the specific research project
   - 3.2 the transfer, access and use of samples and data are consistent with the purposes for which consent was provided by participants; respect the participants' privacy; preserve the confidentiality of the samples and data; adhere to any relevant laws and conditions of research ethics and/or research governance approval; and ensure good safety and laboratory practices[10]
   - 3.3 sample and data transfer is authorised only to end users who have adequate standards relating to participant privacy, confidentiality and security of the samples and data, safety and laboratory practices, and in accordance with relevant law and regulations[10]
   - 3.4 a material transfer agreement, or equivalent, is developed where specimens are transferred for a specific project[10]
   - 3.5 a confidentiality agreement is used with each end user to protect data supplied[10]
   - 3.6 participants are informed in plain language applicable to the participant on whether or not their samples and data, in whole or in part, will be made available to third parties, family members or law enforcement agencies, and the conditions under which this may occur[10]. Access to translation services must also be available if, and/or when needed. The consequences of such information should be discussed with the participant. Where samples are to be sent overseas, the custodian must check if legal and/or ethical issues are compliant with Australian standards and consent standards
   - 3.7 appropriate data release practices are established to minimise the risk of potential re-identification of participants. This might include a range of strategies, for example, providing age groups rather than age
   - 3.8 in authorising the release of materials (genetic data or otherwise), the custodian considers the context in which the recipient will use the information with respect to potential re-identification. Consideration should be given to a range of practical physical and technological access and audit controls[10], such as database software, hardware, international cloud hosting of data, database, licensing, and legal implications
   - 3.9 information relating to, and outcomes of, projects utilising samples held by the biobank should be publicly available[10]
   - 3.10 the access and fee policies of the biobank are published, and while they may be stratified, they should be non-discriminatory, transparent and not inhibit research[10]
   - 3.11 requirements pertaining to the return or destruction of samples and data provided to end users at the completion of their research should be clearly outlined[10]
   - 3.12 processes exist to ensure that any information of significance to the health of individual participants that comes from research can be traced back to the participant, and retrospective follow up can occur in a clinically and ethically appropriate manner.

Demise of the biobank

4. The biobank custodian should ensure that:
   - 4.1 a plan is available describing a course of action for when the biobank no longer meets its scientific need, as well as for an unforeseen demise, such as a discontinuation of funding[10]
   - 4.2 where possible, and within the limitations of consent, the specimens should be made available to another biobank[10]
   - 4.3 the disposal of samples and data should be consistent with consent, cultural sensitivities and the biobanks privacy principles[10]
   - 4.4 the plan should reference clear, detailed and publicly available policies and protocols guiding the disposal of samples and data in the event of discontinuation of the biobank[10].

Emergency preparedness

5. The biobank custodian should ensure that:
   - 5.1 the biobank has a documented disaster response and business continuity plan for responding to a wide range of emergency situations, as well as the prominent display of emergency contact numbers[5]
   - 5.2 the disaster response plan is tested at least annually to ensure staff have the requisite training, and it meets an anticipated need[5]
   - 5.3 depending on the nature of the collection, key individuals are rostered "on call" at all times to respond to an emergency at the biobank[5]
   - 5.4 power providers are advised to prioritise power restoration to the biobank in the event of an emergency[5]
   - 5.5 security and environmental monitoring system notifications associated with the biobank should be routinely monitored and verified[5].

3.4. Consent

Principles

A The biobank custodian shall ensure voluntary and informed consent is obtained from each participant or substitute decision maker, or by an approved ethics committee[10].

B Participant recruitment shall be carried out in a non-coercive and equitable manner[10].

C Communication strategies shall take into consideration the differing needs of participants[10].

D Biobank participants shall have the right to withdraw[10].

E The biobank custodian shall ensure clear, detailed, publicly available policies and protocols are in place regarding recruitment, participation and the process of informed consent[10].

F Biobanking participants shall not be paid for their participation[10].

Best practices

General

1. For human biospecimens and data collected for research purposes, including biobanks, there should be ethical review and approval by an NHMRC certified HREC of the proposed procedures for obtaining information and consent, and for the collection, processing, storage and distribution or disposal of information and biospecimens[6].
2. Specific consent may be obtained for a research project where the details of the project are specifically outlined; extended consent may be obtained for research which is related to the initial research project; unspecified consent may be obtained for future research which is currently undefined, in which case general information about possible future research uses should be provided[6].
3. Where possible, participants should be provided with options for graduated consent to allow for varying levels of involvement in biobanking[10].
4. The physical impact (such as discomfort) and psychological burden of collecting biospecimens (especially from children) shall be minimised.
5. There shall be a clear rationale for seeking the participation of children in a biobank[6].
6. Inclusion of children in research shall not be contrary to their best interests.

Recruitment

7. Recruitment of participants should be undertaken in a manner that is respectful of the individual's right to freedom of choice and equity, and avoids any form of coercion[8]. Those undertaking consent should be aware of and prevent potential power imbalances.
8. Recruitment processes need to be responsive to the participant populations contributing to the biobank.
9. In general potential participants should initially be approached with information about the biobank by a clinician involved in their care. Subsequent consent should be through a representative of the biobank who is trained in dealing with sensitive issues[10].
10. Biobanks shall only obtain and store biological samples and data from minors if the research questions cannot be answered by the study of adults.

Who can provide consent?

11. The consent of donor(s), or substitute decision maker where ethically and/or legally appropriate, should be obtained and recorded when collecting human biospecimens and data for the purpose of research[6].
12. For consent to be valid, those providing it should have capacity, which is the voluntary choice made by an individual provided with sufficient information, who has adequate understanding of the proposed research and the implications, potential risks and benefits for those participating in it[6].
13. Where a potential participant lacks capacity, consent may be provided by another appropriate decision maker or statutory body with legal authority. In such cases consent should not be contrary to the potential participant's best interests[6].
14. Consent should be reviewed where capacity for consent changes because of maturity or clinical change[6].
15. For biospecimens that were initially collected for clinical purposes but are now being requested for research use, a waiver of consent must be requested from an NHMRC certified HREC in those cases where it is not feasible to obtain consent from the donor or substitute decision maker.

What information is required for consent?

16. Consent must be a voluntary choice based upon sufficient information and adequate understanding of the proposed research and the implications, potential risks and benefits for those participating in it[6].
17. Consent materials should be written in a clear, concise and simple manner to enable informed consent to be obtained[8]. The information provided should be age and culturally appropriate.
18. Different formats and modes can be utilised when providing information to participants during the informed consent process[10].
19. Before potential participants consent to donation of their biospecimens and associated data, they should be given sufficient information about:
    - 19.1 the nature of the biospecimens and data to be collected, including data expected to be derived from analysis of the biospecimens or obtained as a result of data linkage with other sources
    - 19.2 the research for which biospecimens are to be used[6]
    - 19.3 the nature of consent including whether it is specific, extended or unspecified[6]
    - 19.4 procedures and safeguards used to protect confidentiality and privacy, and to protect the security of biospecimens and associated data. Information should be given about the planned duration of storage of biospecimens and how they will be stored, used, transferred, and disposed of, including any processes to be adopted to respect personal or cultural sensitivities[6].
    - 19.5 The extent to which biospecimens and associated data will be identifiable, and how privacy and confidentiality will be protected, including;
        - 19.5.1 access to biospecimens and data for clinical purposes by the participant or relatives of a deceased participant, and for other non-research and commercial purposes, or by third parties, and the circumstances where this may occur
        - 19.5.2 whether the biobank is legally obliged to provide human biological material and data, in whole or in part, to third parties (families of deceased individuals, law enforcement agencies, employers, insurance providers) for non-research purposes, and the circumstances where this will arise[8]
        - 19.5.3 whether biospecimens and associated data may be distributed to other researchers[6]
        - 19.5.4 whether biospecimens and associated data may be distributed outside Australia[6]
        - 19.5.5 whether or not research using the biospecimens and associated data could provide information (including incidental findings) that may be important to the health of the participant, their blood relatives or the community[6]

19.5.6 if information of the kind referred to in 19.5.5 is likely to be revealed, whether or not the participant, their blood relatives or the community have a choice to receive this information, and how this will be managed[6]

19.5.7 if a participant chooses not to receive information that may be important for their health or the health of their blood relatives or the community how the potential interests of at-risk relatives will be addressed

19.5.8 whether information from, or about family members, in addition to that provided by participants, may be sought and how the information would be obtained and managed

19.5.9 if appropriate, whether other family members will be invited to participate in the biobank and how they will be approached

19.5.10 the right to withdraw consent (refer to Withdrawal, page 14) for the continued use of biospecimens and associated data in research, and any limitations that may be relevant to withdrawal of consent; for example, as a consequence of the removal of identifiers, or the prior distribution and/or use of biospecimens[6]

19.5.11 any relevant financial or personal interest that those engaged in collection, processing, storage and distribution and use of their biospecimens may have[6]

19.5.12 any potential for commercial application of any outcomes of the research involving biospecimens, how this will be managed and to whom the benefits, if any, will be distributed[6]. In most circumstances it would be appropriate to explain to participants that personal benefit is unlikely

19.5.13 ethics and governance arrangements and mechanisms that are in place for the oversight of research[7]

19.5.14 circumstances in which recontact may occur and the advisability of participants notifying the biobank of changes to contact details[7]

19.5.15 any potential for disclosure of information to participants and/or relatives, in which case participants should be warned that they and/or their relatives may be required to disclose the information to third parties e.g. insurers

19.5.16 communication procedures with participants, including how participants can communicate with the biobank, the approving NHMRC certified HREC and the entity responsible for governance of the biobank, the complaints procedure, and whether participants will receive regular communications from the biobank (for example individual or aggregate results)[7]

19.5.17 processes that will be followed in the event of death or incapacity of a participant[7]

19.5.18 proposed arrangements in the event of the discontinuation of the biobank[7].

Use of biospecimens and data

20. For the duration of the biobank's existence, the research use of biospecimens and data should be consistent with the original informed consent. Where this is not possible either a new informed consent should be obtained, or a waiver of consent sought, except where ethical guidelines, domestic law and national and international norms prohibit a waiver of consent option. Special attention is necessary when biobanks are established from existing collections, or where unspecified consent has been obtained[10].

Waiver

21. A waiver of consent may only be granted by an NHMRC certified HREC for research using personal information in medical research, or personal health information or biospecimens, if it is satisfied that[6]:

21.1 involvement in the research carries no more than low risk

21.2 the research benefits are greater than any risk of harm associated with not seeking consent

21.3 impracticality is a barrier to obtaining consent (for example quantity of participants)

21.4 there is no known or likely reason for objection

21.5 there is sufficient protection of the participant's privacy

21.6 processes are in place to protect the confidentiality of data

21.7 the results have the potential to impact the participants' welfare, there is a plan for that information to be disseminated e.g. via the media

21.8 the waiver is not prohibited by state, federal or international law.

Recontacting participants

22. Biobanking custodians should ensure there are sound policy frameworks to guide recontact with participants[8].
23. Participants should be provided with the opportunity to communicate with representatives of the biobank[10].
24. Where recontact with participants is available, the biobank custodian should ensure that traceability of the samples and data is possible[10].
25. The release of non-validated results (aggregated or individual) from research using the biobank to participants is not recommended[10].
26. If individual research results are to be provided to a participant, they should be provided by an appropriately trained and experienced health professional, who in some circumstances will need to be a qualified genetic counsellor.
27. The individual may need to also be provided with information on relevant support groups available to them.

Withdrawal

28. The biobank must ensure that participants are aware of their right to withdraw, without justification, penalty or disadvantage, the requirements for exercising that right, and the implications of and any limits to exercising that right[8].
29. The biobank custodian should ensure that traceability of the samples and data is possible to enable participant withdrawal[10].
30. Different levels of withdrawal may apply including:
    - 30.1 No further contact: No further contact is made with the participant but previously obtained biospecimens and data are permitted to be retained and used, and further data can be obtained from health records[7].
    - 30.2 No further access: No further contact with the participant or access to health records is permitted but previously obtained biospecimens and data can be continued to be stored and used[7].
    - 30.3 No further use: No further contact would be made with the participant, and data and biospecimens would no longer be available for research[7]. It would be necessary to detroy biospecimens, with archiving of data for audit purposes only.

Religious and cultural considerations

31. The cultural and religious beliefs of the participant should be considered as part of the information provided to participants[10].
32. Consideration should be given to the need for certain cultures to make decisions regarding participation at a community or group level, in addition to at an individual level, and biobanking consent policies and procedures should be supportive of these practices[10].

Public information

33. The biobank custodian should ensure that clear, detailed and publicly available policies, protocols and procedures regarding recruitment, participation, and the process of informed consent exist[10].
34. Communication strategies should take into account the different needs of participants and include clear and simple language, and different formats and modes for providing information[10].
35. Wherever possible, the operators of the biobank should disclose to participants any exceptional conditions where researchers will have access to human biological materials that are not coded or anonymised[8].

Reimbursement

36. Reimbursement for any costs incurred by the participant should not be of an amount that may constitute improper inducement to participate in research[8].
37. Biobanking participants should not be paid to provide specimens and data for research[15].

Part 4: Glossary

The following definitions are provided for ease of reference. Some of these definitions are drawn from commonly used international documents and do not represent an effort to agree on the interpretation of these definitions or develop new ones.

Associated data	Personal, clinical, biochemical, genetic and phenotypic information about a recipient[8].
Biobank	An organised collection of human biological material (biospecimens) and any related information stored for one or more purposes[10].
Confidentiality	Protection against disclosure to an outside person of information revealed in a professional relationship, e.g. doctor – patient[2].
Custodian	An entity responsible for managing the biobank, including control over sample/information release, use, access and destruction. Custodianship does not necessarily equate to ownership over the biobank contents.
Governance	The processes and structures that an organisation uses to set its objectives/goals, appoint the management whose responsibility it is to achieve these goals and to oversee management in its pursuit of these goals. Governance mechanisms are needed to put in place internal controls and risk management systems. Management is accountable to the governance bodies that in turn usually/should be accountable to those who have appointed them[8].
Human Biological Material	Biological material collected from an individual at the time of inclusion in the biobank (e.g. blood, urine or tissue samples) or derived from material collected (e.g. DNA extracted)[10]
Human Research Ethics Committee (HREC)	A local authority that evaluates research projects involving humans, including genetic research. The primary function of an HREC is to protect the welfare and rights of human participants in research[10].
Identifying information	Information that may lead to the identification of the participant from whom the biological material, data and associated information are obtained[8].
Informed consent	A process by which information concerning the intended research is provided to the participant or the participant's substitute decision maker with an opportunity for them to ask questions, after which specific approval is documented[8].
Management	Comprises directing and controlling a group of one or more people for the purpose of coordinating and harmonising that group towards accomplishing a goal. Management often encompasses the deployment of human resources, as well as financial, technological and natural resources. Management is responsible for achieving the objectives/goals set for the organisation[8].
Material Transfer Agreement	A binding legal agreement between the provider of research materials and the recipient of the materials and data, that sets forth conditions of transfer and use[12].
Non-identifiable	Information from which the holder of the information cannot reasonably ascertain the identity of a specific individual. This includes information that has never been labelled with individual identifiers or from which they have been permanently removed[10].
Oversight	Based on the notion that there is usually a difference between setting policy and objectives for an entity and overseeing or monitoring how these are being executed or put into operation[8].
Participant	Individual from whom biological materials, data and information are obtained[8].
Private-Public Partnership	A cooperative venture between the public and private sectors, built on the expertise of each partner and involves the allocation of resources risks and rewards[8].
Sample	A single unit containing material derived from one specimen[8].
Specimen	A specific collection of tissue, blood or urine taken from a single individual at a specific time[10].
Substitute Decision-Maker	Substitute decision-maker (SDM) is a general term for a person that is either appointed or identified to make health care decisions on behalf of a person whose decision-making capability is impaired. Depending on the situation an SDM may be either chosen by the person informally, formally appointed by the person under the legal framework that exists in the relevant State or Territory where they live, or assigned to the person or appointed to the person by the court. It is important to remember that if the person is competent, then the SDM does not have a role[1]. Please refer to the South Australian Government's Planning ahead webpage https://www.sa.gov.au/topics/citizens-and-your-rights/planning-ahead that states that the Guardianship Board can appoint an administrator to make financial and legal decisions for a person with a mental incapacity.
Third Party	Any person excluding the biobank participant and people involved in managing and operating the biobank[10].
Traceability	The ability to locate a sample during any step of its donation, collection, processing, testing, storage and disposition[4].
Virtual biobank	A controlled virtual database of samples stored at different locations.

Bio-banking Finance **Example** template

Example of a potential finance template to work out Bio-Banking Costs

	FIN YEAR $	DATA SOURCE
Salaries & Wages		
Manager		Cost Centre Report, Detailed Salary Report
Staff		Cost Centre Report, Detailed Salary Report
Medical Director		Cost Centre Report, Detailed Salary Report
Quality Control Manager		Cost Centre Report, Detailed Salary Report
General Ledger Allocated S & W		
Superannuation (9.5%)		
Long Service Leave (3%)		
Workers Compensation (0.45%)		
Skills and Retention Leave (0.3%)		
Leave Loading (0.76%)		
Total Salaries & Wages		
Direct Goods & Services		
Storage		cost centre report
Surgical Gloves		cost centre report
Medical Photography		cost centre report
Surgical Instruments		cost centre report
Surgical Instrument Sets		One set required each year not reflected in cost centre report
Med/ Surg Other		cost centre report
Syringes		cost centre report
Plastics		cost centre report
Other		cost centre report
Domestic Supplies		cost centre report
Paper Goods		cost centre report
Houskeeping		cost centre report
Minor Equipment Dental & Biomedic		cost centre report
Minor Equipment Computing Equipment		cost centre report
Minor Plant & Equipment Other		cost centre report
Repairs & Maintenance Plant & Equip		cost centre report
Repairs & Maintenance Other		cost centre report
Interstate Conferences		cost centre report
Parking		cost centre report
Taxi Hire		cost centre report
Freight		cost centre report
Other Postal		cost centre report
Printing Costs		cost centre report
Stationery		cost centre report
Fixed Telephone Costs		cost centre report
Mobile Phones		cost centre report
Other Telephone		cost centre report
Internal Recharge Telephone		cost centre report
Interstate Accomodation		cost centre report
Other Travel		cost centre report
Other Patient		cost centre report
Catering		cost centre report
Petty Cash		cost centre report
Leasing Costs		cost centre report
Total Goods & Services		
Pathology Costs Incurred by SA Pathology		
Pathology Charges (No of Donors @ $13.40)		SA Pathology to obtain unit test price
Total Direct Costs		
Overhead Alloctions		
Nursing S & W		Finance systems
Medical S & W		Finance systems
Maintenance S & W		Finance systems
Admin S & W		Finance systems
Paramedical S & W		Finance systems
Scientific & Tech S & W		Finance systems
Oncosts		Finance systems
Depreciation		Finance systems
Total Overhead Allocations		
Other Cost adjustments not included in above		
Cleaning		Estimate
Total Other Cost Adjustments		
TOTAL COST		

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