Guidelines for the establishment of a Research Databank / Biobank

For the purposes of this document a Research Databank and Biobank (referred to in this document as "Bank") is defined as:

Databank: "A systematic collection of data, whether individually identifiable, re-identifiable or non-identifiable" (NHMRC National Statement on Ethical Conduct in Human Research)

Biobank: "…. 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 held specifically for use in health and medical research." (NHMRC Biobanks Information Paper 2010)

Researchers requesting data and/or samples be collected or retained for use in future research from any source will be either adding to an existing bank or will be establishing a Bank.

When establishing a Bank for research purposes thorough planning is necessary to ensure the bank is set up and maintained according to ethical and legislative requirements.

Researchers should refer to:

– 'National Statement on Ethical Conduct in Human Research' (National Statement) 2007 and updates

– Health Records Act (2001)

– NHMRC Biobanks Information Paper 2010

Researchers should consider the following Bank elements and provide detail accordingly within the Protocol or standalone documents as appropriate.

Document version & date	Include information in the protocol or standalone document as appropriate
1. Name of the Bank	• E.g. ABC Registry, EFG National Biobank
2. Purpose of the Bank	• The reason for set-up / proposed use; e.g. why are the samples / data being retained, might researchers (other than those on the current application) seek access to the stored samples/data in the future? • Is there a timeframe for the Bank or is it to be maintained indefinitely
3. Custodian of the Bank	• Position or person with overall responsibility for the Bank. • NB: If a specific person is nominated the protocol must include a contingency should that person no longer remain the custodian
4. Governance structure	• What is the governance structure of the Bank? i.e. Governance, Scientific, Data committees Provide a Flowchart if useful • Provide the titles/roles of members of each committee • Describe the role of each committee
5. Resourcing the Bank	• Staffing • Physical resources • Funding sources – sustainability
6. Location of the Bank	• E.g. Department, Institution. • Physical location of freezers/fridges • Server location for e-files/databases
7. Criteria for Bank 'participants'	• E.g. patients with a specific condition(s), attending a specific department, specific results / samples or specific research participants. • Researchers may also need to consider cultural sensitivities and/or religious beliefs of the participant population. Any specific requirements or considerations should be detailed within the Protocol.
8. Sample/data type(s) and where these will be obtained from and over what time period	• Type of records / samples • Will these be obtained from Interviews, medical records, clinical test results, clinical tests (left over samples), research projects etc.? • Are the samples /data already existing (retrospective) or to be obtained (prospective) or a combination of both? E.g. is data already held in an RMH clinical database registered with the OFR?

	• If samples/data will be obtained via a research study – has the PI agreed to this, ensure consents permit the sharing and conditions of consent can be upheld • Will samples /data be added indefinitely? • Will the bank include linked data? • Is there a possibility of samples /data being obtained from, or sent, interstate or overseas
9. Sample/data identifiability:	• Will the samples / data be stored as individually identifiable, re-identifiable or non-identifiable (National Statement Section 3.2) • If re-identifiable, how will this be managed: o where will the link/key be stored o who has access o what are the conditions for re-identifying samples/data
10. Required data fields	• Consider current and possible future use/analysis when establishing data fields; e.g. type of consent obtained including any restrictions on use, what contact details are required (is it possible participants may be contacted in the future e.g. for future consent / research purposes / research findings). • Is re-consent at the age of eighteen years required for participants? I.e. are participants (minors) likely to turn 18 years during the life of the Bank? If so, what contact details are required e.g. more than one source. • Changed circumstance i.e. should there be steps in place to check for possible changes e.g. change of address, checking the deaths register? • Is consent for future linkage/research to be obtained and recorded? • Could any future linkage/samples include other family members?
11. Sample and data input	• Who will input the data and samples to the databank? NB: Stating the role of person(s) instead of individual names is recommended. If a specific person is nominated the protocol must include a contingency should that person no longer be available.
12. Confidentiality/security of samples/data	• Coding (who/how). • Who will have access to the key to the code and where is this stored? • Who will have 'open' access to the bank samples /data? • What are the requirements for access to the samples /data, including for audit/research, including type of research and under what conditions e.g. following HREC approval? • What security system will be put in place to protect the information on the Bank e.g. password protected, backing up of all data and where the back-up data will be kept? • How often will back up occur and how often will recoverability testing of back up data occur? • *Security* - the Bank must be secure against unauthorized access; systems that can access the Bank should also be secure. There should be rigorous standards around passwords (e.g. number and type of characters, passwords should be changed at regular intervals). Who will issue passwords and ensure removal of access once a project is finished or a researcher moves on, etc. Criteria for databank permissions should be set according to the principle of least access. • Will access to the Bank be logged/monitored and by whom? • Will access be able to be audited? • Who (position or person) will be responsible for the maintenance and integrity of the Bank? NB: If a specific person is nominated the protocol must include a contingency should that person no longer be available. • What systems are in place to ensure integrity of tissue samples (if applicable) is maintained e.g. temperature alarms on storage units?
13. Consent process for obtaining the samples/data	• E.g. informed written consent (opt in), informed opt out consent, waiver of consent. Also is the consent Specific, Extended or Unspecified (as per the National Statement) NB: May involve one or more consent process dependent upon samples /data to be accessed.

	• Any restriction on the use of samples /data (as per the consent **or** HREC approval) is to be recorded. • How and where will consent forms (for the bank) be kept? • How, where and for how long samples/data will be kept. • The conditions and purposed for which samples/data may be share with external parties. • Process of reporting incidental findings back to participants • What is the process for participants to change or withdraw consent? How will this be documented? • Information to participants should include any limitations on when consent can be withdrawn? i.e., for identifiable samples/data can be destroyed but samples/data that have had used or where identifying information/links have been removed will not be able to be withdrawn.
14. Process for returning incidental findings	• Ethically Defensible Plan or equivalent describes process and responsibilities for researchers, biobanks and clinicians to confirm, assess, and potentially return any findings that are discovered in the course of research (as per Chapter 3 of the National Statement) • Process to ensure that only findings that meet each of the following criteria will be returned: o Significant: The finding indicates a life threatening health condition. o Clinically actionable: There are specific established therapeutic interventions or other available actions. o Confirmed: The finding has been checked and confirmed as accurate and/or valid, as far as reasonably possible in a research context.
15. Communication with participants	• What is the process for communication with participants for example: o Will there be a website o Will there be on-going direct contact (with consent) –emails, newsletters
16. Criteria for accessing samples/data	• What are the criteria for applying to access the Bank? • Access to samples/data must be in accordance with ethical and governance approvals, consents, privacy legislation, NHMRC guidelines, Bank policy and any other applicable requirements.
17. Process for applying to access Biobank samples/data	• What is the process for researchers to apply to access samples/data? o What samples/data will be available? o What is the application process o Who at the Bank will review the application? o Will there be fees to recover processing costs? o Who will pay for shipping of samples? • How will data be shared (consider security of transfer process)?
18. Complaints	• What is the procedure for managing complaints
19. Modifications to Bank Protocol	• What (and by whom) is the required process (prior to submitting to the HREC for approval) if a change of purpose/data fields/type of samples etc is to be considered? For example, is the custodian the only person/position that recommends/implements changes or are required changes to be decided by committee/fellow researchers?
20. Destruction of Samples/data	• Under what circumstances e.g. participant request, condition of consent (timeframe) or discontinuation of Bank? • How will this be managed and by whom? • Are there any cultural or religious requirements regarding the destruction of samples e.g. tissue samples?

Additional References:

- NSW Health Statewide Biobank Consent Toolkit https://biobank.health.nsw.gov.au/researchers/nsw-health-consent-toolkit/

Acknowledgements:

- Adapted from RCH Databank/biobank guidelines (Research Ethics & Governance (Jan 2014))