



Version	Approved by	Approval date	Effective date	Next full review
1.1	Manager, Biospecimen Services	30 April 2024	14 May 2024	May 2027
Guideline Statement				
Purpose	The purpose of this document is to provide guidelines for researcher outputs generated from biospecimens and/or data obtained via the Health Precincts Biobank.			
Scope	The Data Publication Guideline for Researchers applies to Researchers accessing biospecimens and/or data provided by the Health Precincts Biobank. For further information and/or guidance for specific projects, contact: HealthPrecinctsBiobank@unsw.edu.au			
Are Local Documents on this subject permitted?	<input type="checkbox"/> Yes, however Local Documents must be consistent with this University-wide Document.			<input type="checkbox"/> No
Guideline				

1. Introduction

1.1. The Health Precincts Biobank recognises the value of publishing research findings arising from studies using biospecimens and/or data in a format that is both ethically responsible and scientifically useful¹. An obligation of responsible data stewardship is that participant privacy must be maintained at all times ^{1,2}. Researchers should publish their results in a format that minimises the risk of research participants being identified from published deidentified data.

2. Privacy and Confidentiality

2.1. Privacy and confidentiality requirements

- 2.1.1. The Health Precincts Biobank does not release data that identifies a participant such as name, date of birth or MRN.
- 2.1.2. All data released by the Health Precincts Biobank is de-identified and coded with a unique ID.
- 2.1.3. Researchers should not attempt to re-identify participants from supplied data or other information.
- 2.1.4. Researchers must not publish the ID issued by the Health Precincts Biobank in any format, including but not limited to: manuscripts, theses and reports, poster and oral presentations, or when uploading data to publicly available genomic databases.
- 2.1.5. When publishing research results, researchers must consider the possibility that a participant could be re-identified based on limited information such as the rarity of their condition or unique genomic sequence(s). Researchers must ensure adequate steps are taken to mitigate this risk. For more information please refer to Chapter 3.1: The elements of research, Element 4: Collection, Use & Management of Data and Information of the [National Statement on Ethical Conduct in Human Research](#) and Section 3 of the NHMRC

document [Management of Data and Information in Research: A guide supporting the Australian Code for the Responsible Conduct of Research](#)

- 2.1.6. Any data breaches must be reported to the Health Precincts Biobank HealthPrecinctsBiobank@unsw.edu.au and managed according to the researcher's own institutional guidelines for managing data breaches.
- 2.1.7. The UNSW Data Breach Policy can be found [HERE](#)

3. Data Provided to Research Studies

3.1. Information on how the Health Precincts Biobank provides data

- 3.1.1. Data is provided in a deidentified format with unique IDs that only the Health Precincts Biobank can use to trace back to participants.
- 3.1.2. Age at diagnosis is provided rather than date of diagnosis.
- 3.1.3. Age at death is provided instead of date of death.
- 3.1.4. See Data Release Guideline – Health Precincts Biobank

4. Requirements for Researchers when Publishing Research Findings

4.1. When publishing results, the following requirements should be followed:

- 4.1.1. Cases must be coded with a participant ID that is unique to your project and randomly assigned so that participants within studies are not in sequential order based on their unique ID issued from Health Precincts Biobank.
- 4.1.2. Individual participant age will not be provided by the Biobank. However, should this information be known to the researcher from another source, report the participant's age range only so that an individual participant's age cannot be used as an identifier.
- 4.1.3. Do not publish participant data that could be used independently or in combination to identify a participant e.g., a combination of a rare disease diagnosis, location of treating hospital/study site, treatment type and imaging. Use a code for study sites (if applicable) or use a broad definition of location rather than identify specific locations.

5. Publishing Genomic Data Generated from Biospecimens

5.1. To mitigate the risk of participant reidentification from genomic studies, the following requirements must be considered:

- 5.1.1. The benefits of publishing genetic and genomic data generated from biospecimens must be balanced with the risk that individuals could be identified from their de-identified genomic data³.
- 5.1.2. Genomic data-sharing must be considered and addressed in the relevant approved project ethics application(s). Consider the sensitivity of the data to be published and choose an appropriate database for uploading sensitive genomic data.
- 5.1.3. When uploading data to publicly available genomic databases, consider submitting aggregated data where possible. For example: consider providing data in multiple distinct upload batches, so that it will not be possible to calculate the number of participants in a study.
- 5.1.4. For more information please refer to Chapter 3.3: Genomics Research, Element 4: Data Collection and Management of the [National Statement on Ethical Conduct in Human Research](#)

- 5.1.5. The article [Responsible, practical genomic data sharing that accelerates research | Nature Reviews Genetics](#)⁴ contains summaries of the levels of risk associated with different genomic data types and a list of repositories for publishing genomic data.
- 5.1.6. In general, “Conduct data sharing with a view towards minimising harms and maximising benefits.”⁵

6. UNSW Standards and Procedures

- 6.1. The UNSW Data Classification Standard that describes the framework for assessing data sensitivity can be found [HERE](#).
- 6.2. The UNSW Handling Research Material & Data Procedure that details requirements for data storage and retention can be found [HERE](#).
- 6.3. The UNSW Cybersecurity Standard – Data Security that details the appropriate conditions for storage and transmission of data can be found [HERE](#).

Accountabilities	
Responsible Officer	Manager, Biospecimen Services
Contact Officer	Biorepository Technical Officer, Biospecimen Services
Supporting Information	
Legislative Compliance	This Guideline supports the University’s compliance with the following legislation: NHMRC National Statement on Ethical Conduct The Australian Privacy Act 1988
Parent Document (Policy and Procedure)	Biospecimen Services Guideline – Material Access and Release – Health Precincts Biobank, Version 1, 12/05/2023 Data Release Guideline - Health Precincts Biobank, Version 1, 12/05/2023 Biospecimen Services Material Transfer Agreement Health Precincts Biobank Internal User Agreement
Supporting Documents	Management of Data and Information in Research: A guide supporting the Australian Code for the Responsible Conduct of Research (nhmrc.gov.au) UNSW Privacy Policy UNSW Data Breach Policy UNSW Data Governance Policy UNSW Data Classification Standard UNSW Cyber Security Policy UNSW Cyber Security Standard – Data Security – Internal UNSW Document UNSW Research Data & Materials Handling Policy UNSW Handling Research Material & Data Procedure Biospecimen Services Terms and Conditions

Related Documents	<p>Additional Resources on Genomic Data Sharing:</p> <p>OECD Guidelines on human biobanks and genetic research databases ©OECD 2009 https://www.oecd.org/health/biotech/44054609.pdf</p> <p>NIH Policy for Data Management and Sharing NOT-OD-21-013: Final NIH Policy for Data Management and Sharing</p> <p>NIH Genomic Data Sharing Guideline NOT-OD-14-124: NIH Genomic Data Sharing Guideline</p> <p>Safe Harbour Standard HIPAA Privacy Rule Methods for De-identification of PHI HHS.gov</p> <p>Framework for Responsible Sharing of Genomic and Health-Related Data (ga4gh.org)</p> <p>References:</p> <ol style="list-style-type: none"> 1. NIH Science Guideline Office (2022) Request for Public Comments on DRAFT Supplemental Information to the NIH Guideline for Data Management and Sharing: Protecting Privacy When Sharing Human Research Participant Data NOT-OD-22-131: Request for Public Comments on DRAFT Supplemental Information to the NIH Guideline for Data Management and Sharing: Protecting Privacy When Sharing Human Research Participant Data 2. International Society for Biological and Environmental Repositories (ISBER) (2023) Best Practices: Recommendations for Repositories, Fifth Edition ISBER Best Practices For Repositories - ISBER 3. Bonomi L, Huang Y, Ohno-Machado L. (2020). Privacy challenges and research opportunities for genomic data sharing. <i>Nat Genet.</i> 2020 Jul;52(7):646-654. doi: 10.1038/s41588-020-0651-0. Epub 2020 Jun 29. PMID: 32601475; PMCID: PMC7761157. Privacy challenges and research opportunities for genomic data sharing (nature.com) 4. Byrd, J.B., Greene, A.C., Prasad, D.V. <i>et al.</i> (2020) Responsible, practical genomic data sharing that accelerates research. <i>Nat Rev Genet</i> 21, 615–629. https://doi.org/10.1038/s41576-020-0257-5 Responsible, practical genomic data sharing that accelerates research Nature Reviews Genetics 5. Knoppers, B.M. (2014) Framework for responsible sharing of genomic and health-related data. <i>HUGO J</i> 8, 3. https://doi.org/10.1186/s11568-014-0003-1 http://www.thehugojournal.com/content/8/1/3 			
	Superseded Documents	Nil		
File Number	[For Governance Use]			
Definitions and Acronyms				
ID	Identifier			
MRN	Medical Record Number			
Aggregated Data	Multiple data points/items that are compiled into a summary for reporting and/or analyses			
Sequential Order	Following the same numeric order as the unique ID issued by the biobank			
Genomic Data	Genomic data can be defined as “those that include the potential to profile the genes or gene products for most of an organism’s genes or a collection of organisms’ genes.” ² This guideline is referring to genomic data that has been generated from biospecimens.			
Deidentified Data	Deidentified data has had all the data that identifies a participant removed and replaced by a code; it should not be possible to re-identify a specific individual			
Revision History				
Version	Approved by	Approval date	Effective date	Sections modified

1.0	Manager, Biospecimen Services	28/04/2023	12/05/2023	Original Document
1.1	Manager, Biospecimen Services	30/04/2024	14/05/2027	Section 2: Privacy & Confidentiality and Section 5: Publishing Genomic Data Generated from Biospecimens. Section 6 added.

Further Information	
This section is not published on the final PDF document. It is for website purposes only	
Keywords for search engine	Nil
FAQs and answers	Health Precincts Biobank FAQs for Researchers can be found HERE