

Data Publication Guideline for Researchers - Health Precincts Biobank

Version	Approved by		Approval date	Effective date	Next full review	
1.0	Manager, Biospecimen Services: Anusha Hettiaratchi		28 April 2023	12 May 2023	May 2023	
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: <u>HealthPrecinctsBiobank@unsw.edu.au</u>				
Are Local Documents on this subject permitted?		☐ Yes, however Local Documents must be consistent with this University-wide Document.				
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. A caveat of responsible data stewardship is that participant privacy should 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 that should be followed

- 2.1.1. The Health Precincts Biobank does not release data that identifies a participant such as name, date of birth and 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.
- 2.1.4. Researchers should not publish the ID issued by the Health Precincts Biobank in, including but not limited to; journals, manuscripts, theses and reports, present in posters and oral presentations or upload to publicly available genomic databases.
- 2.1.5. When publishing research results, researchers should consider the possibility that a participant could be re-identified based on limited information such as the rarity of their condition. Researchers should ensure adequate steps are taken to mitigate this risk. For more information please refer to Chapter 3 of the <u>National Statement on Ethical Conduct</u> in <u>Human Research</u> and Section 3 of the NHMRC document<u>Management of Data and</u>

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 <u>HealthPrecinctsBiobank@unsw.edu.au</u> 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 Health Precincts Biobank can use to track 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. Conditions for Researchers when Publishing Research Findings

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

- 4.1.1. Cases should 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. Report participant age only in age ranges so that individual participant age cannot be used as an identifier.
- 4.1.3. Do not publish participant data items 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, the following requirements should be considered:

- 5.1.1. The benefits of publishing genetic and genomic data generated from biospecimens should be balanced with the risk that individuals could potentially be identified from their de-identified genomic data³.
- 5.1.2. Genomic data-sharing should be considered and addressed in relevant approved project ethics applications. 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. The UNSW Data Classification Standard that describes the framework for assessing data sensitivity can be found <u>HERE</u>.
- 5.1.5. The UNSW Handling Research Material & Data Procedure that details requirements for data storage and retention can be found <u>HERE</u>.
- 5.1.6. The UNSW Cybersecurity Standard Data Security that details the appropriate conditions for storage and transmission of data can be found <u>HERE</u>.

- 5.1.7. The article <u>Responsible, practical genomic data sharing that accelerates research |</u> <u>Nature Reviews Genetics</u>⁴ contains summaries of the levels of risk associated with different genomic data types and a list repositories for publishing genomic data.
- 5.1.8. "Conduct data sharing with a view towards minimizing harms and maximizing benefits."⁵

Accountabilities			
Responsible Officer	Dr Carl Power, Head, Preclinical Imaging and Biospecimen Research Facilities Program Lead – Health Research Platforms		
Contact Officer	Dr Anusha Hettiaratchi, Manager, Biospecimen Services		
Supporting Information			
Legislative Compliance	This Guideline supports the University's compliance with the following legislation: <u>NHMRC National Statement on Ethical Conduct</u> <u>The Australian Privacy Act 1988</u>		
Parent Document (Policy and Procedure)	Nil		
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 Standard – Data Security UNSW Research Data & Materials Handling Policy UNSW Handling Research Material & Data Procedure Biospecimen Services Terms and Conditions Biospecimen Services Material Transfer Agreement Health Precincts Biobank Internal User Agreement 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		

		Additional Resources on Genomic Data Sharing:					
		OECD Guidelines on human biobanks and genetic research databases @OECD 2009 www.oecd.org/publishing/corrigenda					
		NIH Policy Data Mana	for Data Management a gement and Sharing	and Sharing <u>NOT-OD</u>	-21-013: Final NIH Policy for		
		NIH Genon <u>Guideline</u>	nic Data Sharing Guide	line <u>NOT-OD-14-124:</u>	NIH Genomic Data Sharing		
		Safe Harbour Standard HIPAA Privacy Rule <u>Methods for De-identification of PHI</u> <u>HHS.gov</u>					
		Framework for Responsible Sharing of Genomic and Health-Related Data (ga4gh.org)					
		References:					
Related Docu	Related Documents		cience Guideline Office emental Information to t ting Privacy When Sha equest for Public Comr ine for Data Management Research Participant	(2022) Request for P he NIH Guideline for I ring Human Research <u>nents on DRAFT Sup</u> ent and Sharing: Prote <u>Data</u>	ublic Comments on DRAFT Data Management and Sharing: n Participant Data <u>NOT-OD-22-</u> <u>plemental Information to the NIH</u> <u>ecting Privacy When Sharing</u>		
		2. Interna Best P <u>Practic</u>	ational Society for Biolog ractices: Recommenda <u>ses For Repositories - I</u>	gical and Environmen tions for Repositories <u>SBER</u>	tal Repositories (ISBER) (2018) , Fourth Edition <u>ISBER Best</u>		
		3. Bonon opport 10.103 PMC7 sharing	ni L, Huang Y, Ohno-Ma unities for genomic data 8/s41588-020-0651-0. 761157. <u>Privacy challer</u> g (nature.com)	achado L. (2020). Priv a sharing. Nat Genet. Epub 2020 Jun 29. P nges and research op	vacy challenges and research 2020 Jul;52(7):646-654. doi: MID: 32601475; PMCID: portunities for genomic data		
		4. Byrd, data sl https:// sharing	I.B., Greene, A.C., Pras naring that accelerates (doi.org/10.1038/s4157) g that accelerates resea	sad, D.V. <i>et al.</i> (2020) research. <i>Nat Rev Ge</i> <u>5-020-0257-5</u> <u>Respor</u> arch Nature Reviews	Responsible, practical genomic enet 21 , 615–629. <u>asible, practical genomic data</u> <u>a Genetics</u>		
		5. Knopp related <u>http://v</u>	ers, B.M. (2014) Frame I data. <i>HUGO J</i> 8, 3. htt www.thehugojournal.com	work for responsible ps://doi.org/10.1186/s m/content/8/1/3	sharing of genomic and health- s11568-014-0003-1		
Superseded Documents Nil		Nil					
File Number [For Gover		nance Use]					
Definitions and Acronyms							
ID		ldentifier					
MRN Med		Medical Re	Vedical Record Number				
Aggregated Data Multiple analyse		Multiple da analyses	data points/items that are compiled into a summary for reporting and/or s				
Sequential Order Following t		he same numeric order as the unique ID issued by the biobank					
Genomic Data Genomic gene pro This guid		Genomic d gene produ This guidel	data can be defined as "those that include the potential to profile the genes or ducts for most of an organism's genes or a collection of organisms' genes." ^{7} eline is referring to genomic data that has been generated from biospecimens.				
Deidentified Data Deidentified by a code;		d data has had all the data that identifies a participant removed and replaced it is not possible to re-identify a specific individual					
Revision H	istory						
Version A	Approved by		Approval date	Effective date	Sections modified		

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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		