

THE VIRTUAL BIOBANK

ACCESS POLICY

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1. INTRODUCTION AND SCOPE

The Virtual Biobank is an initiative at the University of Newcastle, NSW Australia and is managed by the 3D Tissue Clearing and Lightsheet Microscopy Facility, housed at the Hunter Medical (HMRI) Institute. The Facility was established at HMRI in 2015, and funding from the National Australian Data Service (ANDS) under the High Value Collections Program is assisting to develop The Virtual Biobank. This Access Policy encompasses the online publication of 2D/3D image datasets with associated metadata from the 3D Tissue Clearing and Lightsheet Microscopy Facility and the Hunter Cancer Biobank (HCB). Datasets and metadata within The Virtual Biobank are 'open source' and available to the public at large. Access is not limited to geographical, financial, institutional or political affiliations.

2. PURPOSE OF ACCESS POLICY

The Virtual Biobank Access Policy sets out the standard practice and conditions for accessing datasets contained in The Virtual Biobank. The Access Policy will:

- 1) Provide a platform to support/facilitate a broad range of research, in an ethical manner.
- 2) Establish the principles, policies and procedures according to which access may be granted.
- 3) Enable efficient collaboration, at a national and/or international level.
- 4) Encourage fair, rapid and transparent access for research and educational purposes.

3. USE CASE

It is anticipated that most Users will be researchers in the medical space, in particular, those who work in the field relevant to the 3D image datasets available in The Virtual Biobank. Users will have the opportunity to enrich datasets within The Virtual Biobank through citation and submission of DOIs for published work that utilise The Virtual Biobank datasets and/or metadata. Participating biobanks may use to generate awareness of their collections.

4. DATA TYPE(S) AVAILABLE FOR ACCESS

Primary datasets:

- 3D and 2D images of 'cleared' and stained biobank samples

Metadata:

- Contributor
- Sample
- Experimental
- Imaging
- Data Transformation
- Clinicopathological

All data made available within The Virtual Biobank is 'open-access' (further information is available in *Data Licencing and Re-use*). All efforts are made to ensure data is not 're-identifiable'. Physical samples represented by The Virtual Biobank may be requested from the sample custodian.

5. ACCESS REQUIREMENTS AND LIMITATIONS

Access to The Virtual Biobank is established via an online Web Form located on the landing page (virtualbiobank.newcastle.edu.au). Approval is contingent on the applicant's understanding, acknowledgement and agreement to the terms and conditions stipulated within this Access Policy. Information about the applicant (including name, email address, affiliation and reason for use) is also required. This information will be used to inform The Virtual Biobank management on use case.

Access and use of The Virtual Biobank data/metadata (including derived data) for commercial purposes is expressly prohibited as per the CC-BY-NC-SA (Attribution-NonCommercial-ShareAlike) licence.

Exclusive access will not be granted to any party.

6. ACCESS TO PHYSICAL SAMPLES

To access physical samples related to datasets within The Virtual Biobank, Users must make a submission to the sample Custodian (typically, the biobank from which tissue samples were obtained) and follow standard access protocols required by the custodian. Contact information for the Custodian will be available for each dataset via The Virtual Biobank.

7. PRIVACY OF PARTICIPANTS

The Virtual Biobank is committed to maintaining the privacy of Participants *as per* the consent form of the participating biobank and these obligations are extended to Users of The Virtual Biobank. The data provided to Users have been de-identified to protect the privacy of Participants. As a minimum, Users of The Virtual Biobank must adhere to the following:

- Acknowledge the rights of Participants to their privacy
- Maintain adequate security measures to protect data (including derived data) obtained from The Virtual Biobank
- Users must not disclose, transmit or transfer any of the data to unauthorised third parties, unless the third party is an Approved User of The UON Virtual Biobank
- Users **must not** attempt to re-identify Participants under **any** circumstances
- Immediately report any identification of Participants to The UON Virtual Biobank

8. GOVERNANCE OF DATA ACCESS

Governance of data access is regulated by The Virtual Biobank Operations Committee and reviewed by The Virtual Biobank Steering Committee. Information on the composition, roles and meeting

schedules for these committees can be found in The Virtual Biobank Governance and Ethics documentation.

9. DATA LICENCING AND RE-USE

The Virtual Biobank datasets are publically accessible with the data shared under the AUSGOAL licence framework and the CC-BY-NC-SA (Attribution-NonCommercial-ShareAlike) Creative Commons licence.



This license requires Users to appropriately attribute/cite The Virtual Biobank and specific dataset, prohibits commercial use of the datasets in any way. It allows Users to create and release modified versions (derived data) as long as it is released under the same license.

10. DURATION OF ACCESS AND TERMINATION

Once approved, Users are provided with an unlimited access period, given that Users comply with all terms and conditions of this Access Policy. The Virtual Biobank has the right to terminate a User's access upon material breach of any term of this Access Policy. The Users may terminate their access at any time with immediate effect by providing written notice to The Virtual Biobank of the termination. Upon termination, the Users agree to destroy all copies of Data except as required by publication practices or applicable law.

11. LIMITS ON LIABILITY

The Virtual Biobank will not be liable for damages related to the provision of data to Users. This includes but is not limited to damages in relation to inaccuracies, lack of comprehensiveness, or use of the data, or any delay or break in data supply by The Virtual Biobank

12. INTELLECTUAL PROPERTY

Users must not make IP claims on data derived directly from The Virtual Biobank. However, the importance of downstream inventions made with the data is recognised; patents on such inventions are permitted. In doing so, the Users agree to implement licensing policies that will not obstruct further research. Results and data which arise from Users will be bound by the CC-BY-NC-SA (Attribution-NonCommercial-ShareAlike) Creative Commons licence. This licence allows Users to create and release modified versions (derived data) as long as it is released under the same license.

13. RESULTS, PUBLICATION AND CITATION

Where UON Virtual Biobank datasets have been re-used or referenced for an Approved Research Project, Users will send reports, articles, enriched data, etc.. to The Virtual Biobank (virtualbiobank@newcastle.edu.au). The Users must endeavour to publish results in an academic

journal or in an and/or make their findings publically available via Open Access. Users agree to supply The Virtual Biobank with a copy, web address, DOI and citation of any publication. Users agree to the publication of DOIs resulting from Data derived from The Virtual Biobank on any publication (web or hardcopy) associated with The Virtual Biobank. Users agree to acknowledge and cite The Virtual Biobank in any publication or presentation on work derived in whole or in part from the Data. Citations should include the relevant handle and/or DOI for The Virtual Biobank dataset and are to be cited with the following format: 3D Tissue Clearing and Lightsheet Microscopy Facility (Year, Month and Date viewed). The Virtual Biobank, Repository name, Dataset name, Datafile name. Retrived from virtualbiobank.newcastle.edu.au

14. INDIVIDUAL RESEARCH RESULTS AND INCIDENTAL FINDINGS

Individual research results and incidental findings will typically not be returned to Participants. In the case of highly significant research results or incidental findings with potentially life threatening consequences, the matter should be referred to the sample custodian from which the physical tissue sample was sourced.

15. LINKAGE

Participants may not have consented to linkage of biobank data with administrative health data. These matters should be referred to the sample custodian from which the physical tissue sample was sourced.

16. REPORTING A BREACH

If the Users become aware that the terms of this Access Policy have been breached, they will promptly notify The Virtual Biobank of such breach. The Users will provide The Virtual Biobank in a timely manner any material information relating to the breach, including the date and nature of the event, remedial measures taken, and plans to avoid further or future breach. In the case of a breach please contact: virtualbiobank@newcastle.edu.au

17. GLOSSARY

ANDS: Australian National Data Service

Applicant: Individual/entity applying for access to the The UON Virtual Biobank

Approved User: User that has satisfied all requirements for access to The UON Virtual Biobank

Access Agreement: Agreement outlining appropriate use and access of data

AusGOAL: Australian Governments Open Access Licencing Framework

Data: The data made available to Users through The UON Virtual Biobank

HMRI: Hunter Medical Research Institute

Metadata: The metadata made available to Users through The UON Virtual Biobank

Open Access Data: Unrestricted data, available for the use and viewing of the public at large

Participant: Tissue sample donors.

Re-identification: Any process that re-establishes the relationship between data and the data subject/Participant.

UON: University of Newcastle, Australia

User: Individual/entity that has approval and is actively using The UON Virtual Biobank

18. DOCUMENT HISTORY

The *Access Policy* was last updated on 8/2/2018.