THE VIRTUAL BIOBANK

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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 the HMRI in 2015, and funding from the National Australian National Data Service (ANDS) under the High Value Collections Program is assisting to develop the Virtual Biobank. This document outlines the governance structure and ethics considerations for the ANDS funded component of the Virtual Biobank project running from 1/6/16 to 30/5/17. This project 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).

PURPOSE, AIMS AND PRINCIPLES

The purpose of Virtual Biobank is to provide open access to 3D image datasets and associated metadata of physical biobank samples along with corresponding experimental and clinicopathological metadata. For the first time, the Virtual Biobank will enable valuable, human tissue samples to be freely and easily accessed, viewed, shared and analysed by researchers around the globe.

Our aims are to:

- Build and contribute to the capacity for virtual biobanking in Australia
- Facilitate increased access to tissue samples by publishing a rich, open dataset of 3D tissue sample images generated by the 3D Tissue Clearing and Lightsheet Microscopy Facility and participating biobanks (in this case, the HCB).
- Provide medical researchers with access to the next generation of tissue bank data
- Enhance opportunities for access and re-use of tissue data

The principles by which the Virtual Biobank is to be governed and managed are:

- The Virtual Biobank will be governed and managed with integrity, transparency, accountability and respect for human rights and freedoms.
- The Virtual Biobank will engage independent members of relevant and diverse publics and communities in decisions about its establishment, governance and use.
- The governance structure will ensure the rights and well-being of the participants and the common good prevail over the research interests of the initiators and users of the biobank.
- It will be anticipated that the need to modify the policies, protocols and procedures over the lifespan of the Virtual Biobank will arise, and therefore requires that a process is in place for undertaking these modifications.

GOVERNANCE AND MANAGEMENT

The governance and management of The Virtual Biobank is facilitated via two Committees encompassing a membership of researchers, scientists and clinicians representing stakeholders and peers. These are the Steering Committee and the Operations Committee. These committees advise and inform the Management/Contributors Group whom furnish The Virtual Biobank with datasets and metadata for ongoing access by Users.

STEERING COMMITTEE

The Steering Committee provides advice and guidance on overall strategic direction including policy, ethics confirmations, strategic planning, capacity building, review of new use cases, development of service agreements and growth and sustainability of the Virtual Biobank. Bi-annual meetings will be held to ensure policy updates and strategic direction is adapted in a timely manner. Members of the Steering Committee include stakeholders and peer representatives:

Marie Gleeson: Faculty of Health and Medicine, UON
Bob Callister: Faculty of Health and Medicine, UON
Alan Brichta: Faculty of Health and Medicine, UON
Susan Goode: Hunter Cancer Research Alliance
Jamie Flynn: 3D Tissue Clearing and Lightsheet Microscopy Facility, UON
William Palmer: 3D Tissue Clearing and Lightsheet Microscopy Facility, UON
Antony Martin: 3D Tissue Clearing and Lightsheet Microscopy Facility, UON

OPERATIONS COMMITTEE

The Operations Committee provides oversight and management of operational procedures including the day-to-day operations of the Virtual Biobank infrastructure, storage, security, sample de-identification, and data quality/relevance. Communication within this committee will be carried out on a need-only basis as operational issues arise. Members of the Operations Committee include:

Craig Gedye: Oncologist and cancer researcher, UON/HMRI
Aaron Scott: Research Solutions Architect, UON IT
Rick Thorne: Manager at Hunter Cancer Biobank
Jamie Flynn: 3D Tissue Clearing and Lightsheet Microscopy Facility, UON
William Palmer: 3D Tissue Clearing and Lightsheet Microscopy Facility, UON
Antony Martin: 3D Tissue Clearing and Lightsheet Microscopy Facility, UON

MANAGEMENT/CONTRIBUTORS GROUP

Management/Contributors Group is the central team responsible for collating and implementing input from the Steering and Operations Committees and the release of datasets and associated metadata to users of the Virtual Biobank. Members of the Management/Contributors Group include:

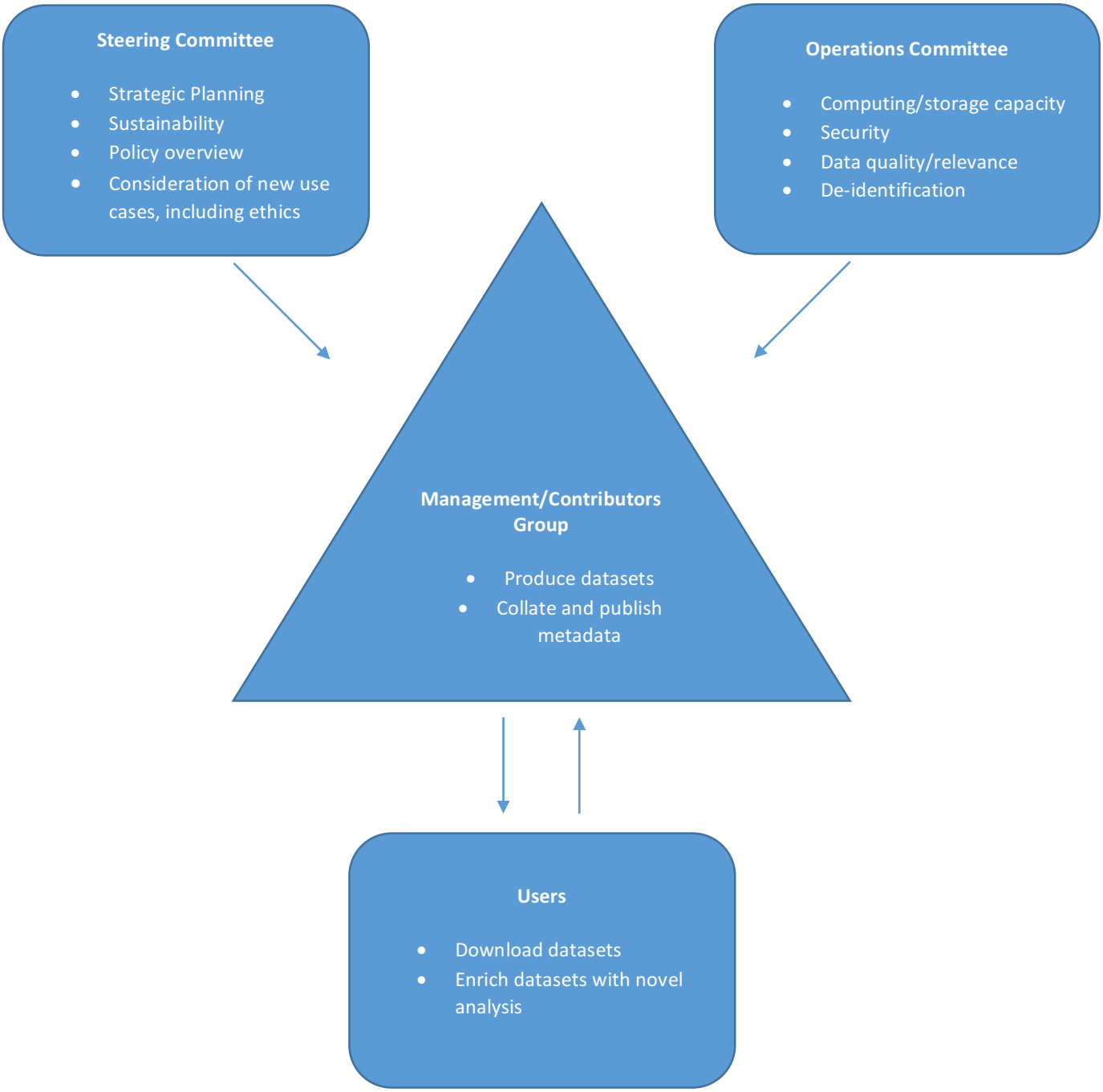
Jamie Flynn: 3D Tissue Clearing and Lightsheet Microscopy Facility, UON
William Palmer: 3D Tissue Clearing and Lightsheet Microscopy Facility, UON
Antony Martin: 3D Tissue Clearing and Lightsheet Microscopy Facility, UON

USERS

Datasets and metadata within The Virtual Biobank will be available to the general public, the only pre-requisite being an internet connection. 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. Access is not limited to geographical, financial, institutional or political affiliations. Users also have the opportunity to enrich datasets within the Virtual Biobank by

submitting DOIs for published work that has utilised The Virtual Biobank datasets and/or metadata. Users will be required to complete an online form to provide information on use cases.

GOVERNANCE FLOW CHART



ETHICS, CONSENT AND CONFIDENTIALITY

Ethics has been granted for the Virtual Biobank project to upload de-identified data and images for display to the public (HREC#: H-2016-0373). This approval is contingent on prior consent, ethics and de-identification of samples has been granted/obtained from sample custodians, in this case, the Hunter Cancer Biobank.

The Hunter Cancer Biobank has adopted a 'broad consent' system which provides freedom to perform future scientific research without the requirement to obtain consent for individual projects. Future datasets need to meet national ethics standards.

An important step to ensure participant identity is further separated from data available from The Virtual Biobank is the creation of a separate 'sample key' to replace potential identifiers such as sample/slide numbers with an arbitrary code for publication. The sample key will be kept on file with the dataset contributor.

DOCUMENT HISTORY

The *Governance and Ethics* document was last updated on 8/2/2018.