ST VINCENT'S HOSPITAL MELBOURNE
A FACILITY OF ST VINCENT'S HEALTH AUSTRALIA

RESEARCH GOVERNANCE UNIT
St. Vincent's Hospital (Melbourne)
Caritas Christi Hospice
St. George's Health Service
Prague House
Cambridge House
DePaul House

DATABANKS

Statement of Intent and Outcomes

The St Vincent's Hospital Human Research Ethics Committee is committed to fulfilling Section 3.2 of The National Statement on Ethical Conduct in Human Research (2007, updated 2018) by ensuring the appropriate method of review is applied to all research involving databanks, including the collection and use of individually identifiable data, re-identifiable data and non-identifiable data.

Definitions

Databank is defined as the collection and storage of information, including data, tissue or other information. A database is considered to be a databank.

Identifiable data is defined as where the identity of a specific individual can reasonably be ascertained. Examples of identifiers include the individual's name, image, date of birth or address;

Re-identifiable data is defined as data from which identifiers have been removed and replaced by a code, but it remains possible to re-identify a specific individual by, for example, using the code or linking different data sets

Non-identifiable data, which have never been labelled with individual identifiers or from which identifiers have been permanently removed, and by means of which no specific individual can be identified. A subset of non-identifiable data are those that can be linked with other data so it can be known that they are about the same data subject, although the person's identity remains unknown.

***All efforts should be made to avoid the term 'de-identified data', as its meaning is unclear. While it is sometimes used to refer to a record that cannot be linked to an individual ('non-identifiable'), it is also used to refer to a record in which identifying information has been removed but the means still exist to re-identify the individual. When the term 'de-identified data' is used, researchers and those reviewing research need to establish precisely which of these possible meanings is intended*

Disclosure of data is defined as allowing persons other than those who have access to the data for the purpose of the approved research study for which it was collected, access to the data. Those who would be expected to have access to the data would include, the Principal Investigator, Co-investigators, Study Co-ordinators and associated administrative staff for the particular study for which the data was collected.

Procedure

To ensure the appropriate assessment of research proposals involving the use of data banks, the St Vincent's Hospital Human Research Ethics Committee must be familiar with, and apply the principles of The National Statement on Ethical Conduct in Human Research (2007, updated 2018), and in particular Section 3.2, to the ethical review of research.

The HREC must ensure that these guidelines are considered when determining the appropriate use of databanks, specific to the type of information collected (identifiable data, re-identifiable data and/or non-identifiable data), the protection of patient confidentiality and privacy, the conditions of storage and access, and the future use / disposal of such data. All decisions, including the ethical issues identified with each case must be documented within the minutes.

Researchers should recognise that data stored in an identifiable form cannot be used in research that is exempt from ethical review. Access to identifiable data must be restricted to research personnel.

Any restrictions on the use of participant's data should be recorded and kept with the collected data so that it is always accessible to researchers who want to access those data for research.

Researchers and custodians of the databank should be clearly stated in the written application/protocol, and must observe the conditions of participant consent regarding stored data, and should take every precaution to prevent the data becoming available for uses to which participants did not consent.

When collecting data for the purposes of databanking, researchers should provide clear and comprehensive information about the form in which the data will be stored, the purpose/s for which the data will be used and/or disclosed, whether there is potential for the data to be used commercially and/or for commercial gain, whether there is intent to outsource the data, and whether specific, extended or unspecified consent for future research is being sought.

Consent may be classified as:

1. Specific and limited to the project under consideration
2. Extended and given for the use of data and tissue for future use. This must be closely related to the original project and/or the general area of the initial research.
3. Unspecified for the use of information for unrestricted future research.

Where unspecified consent is sought, the Patient Information and Consent Form must detail the terms and wide-ranging implications associated with participation, as comprehensively as possible (including examples where possible). This must also be accompanied by a statement which informs participants that the complete scope of potential use is unknown, but that all subsequent, unrelated work involving such information will be reviewed and approved by an appropriate constituted HREC prior to use.

If the databank has potential commercial interests, this should be justified.

All data and databanks that exist within St Vincent's Hospital (Melbourne) are considered to be owned by St Vincent's Hospital. In projects that are conducted across institutions, an

agreement should be developed at the beginning of the project covering the ownership of data and databanks. As a general rule, data retained at the end of a project are the property of St Vincent's Hospital. However ownership of the research data may be negotiated with another institution. It is also noted that ownership of data may also be influenced by the funding arrangements for the project.

If the databank is part of a sponsored multicentre trial, or a collaborative research group study, a written contract must be in place between the appropriate parties, prior to the commencement of the study which details ownership, financial management, intellectual property, confidentiality and copyright issues, managing research findings, commercialisation and the sharing of commercial returns, authorship and publication, consultancy and secondments, responsibility for ethics, safety and regulatory clearances, and ongoing reporting to appropriate agencies. Where possible, this should be in the form of a standard contract of either Medicines Australia or the Victorian Managed Insurance Authority.

Associated Procedures/Instructions

Procedure 2.2 – Obtaining and Honouring Consent
Procedure 2.3 – Qualifying or waiving conditions for consent
Procedure 5.8 – Collaborative Research Groups

Reference Documents

- The National Statement on Ethical Conduct in Research Involving Humans in accordance with the NHMRC Act, 2007 (Cth) – Updated 2018
- Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders (2018)
- Australian Code for the Responsible Conduct of Research (2018)

Authorized by:

Dr Megan Robertson
Director of Research

Author: Dr Tam Nguyen, Deputy Director of Research	
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