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

RESEARCH GOVERNANCE UNIT
St. Vincent's Hospital (Melbourne)
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MANAGEMENT OF RESEARCH DATA AND PRIMARY MATERIALS

Statement of Intent and Outcomes

The St Vincent's Hospital Human Research Ethics Committee is committed to fulfilling section 2.5 of the Australian Code for the Responsible Conduct of Research (2018) by ensuring a framework for the responsible management of research data and primary materials.

Definitions

Research data is defined as information obtained directly or indirectly for research purposes and information that may be used for research purposes. For example, Information obtained directly from a person in interview, questionnaire, focus groups, personal and medical histories, demographics, biographies, audiotape, audiovisual records, photographs; Clinical, social or observational information from a source other than the person whose information it is, such as from medical history notes, doctors notes, surgical notes, carer or relative; Information derived from human tissue such as blood, bone, muscle, organ and waste products, including genetic and radiological information.

Data bank and database are considered to have the same meaning. A databank is a collection of data or information, as defined above. It may be stored on paper and kept in files or stored electronically and kept on a hard drive or on disk.
A databank may be established with the intent to use the information contained within for a use other than research such as disease surveillance, trend identification and the stimulation of ideas for possible future research. It is foreseeable at some future point in time that such databanks may be useful for future research. Therefore such databanks are subject to these guidelines.

Primary material is defined as the raw material/data that is collected during a research study. This includes transcripts, audiotapes, biological materials and other materials from which analyses occur.

Disclosure 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

The collection of all research related materials and data must be appropriately stored, retained and/or destroyed.

Retaining research data is important as it may be all that remains of the research work at the end of the project. While it may not be practical to keep all primary material (including biological material, questionnaires or recordings), durable records derived from them (such as assays, test results, transcripts, and laboratory and field notes) must be retained in an accessible format.

It is the responsibility of the research team to determine which data and/or primary materials should be retained; however, such decisions must account for legislative and regulatory requirements, conditions of funding, or by convention of the applicable discipline.

The central aim is that sufficient materials and data are retained to justify the outcomes of the research and to defend them if they are challenged. The potential value of the material for further research should also be considered, particularly where the research would be difficult or impossible to repeat.

The storage of data must be appropriately secured, depending on the potential for re-identification. For example, non-identifiable data may be stored in a less secure manner than potential re-identifiable information, or identified information; the latter requiring storage in a locked storage device, in a locked/secure location. Access must also be restricted to those involved in the research. Wherever possible and appropriate, research data should be held in the researcher's department or other appropriate institutional repository, although researchers may be permitted to hold non-identified copies of the research data for their own use. If research data or primary materials are held at other locations such storage and/or use must be documented.

For all electronic records, systems must be secure. Furthermore, all staff responsible for the management of electronic records must understand and maintain their responsibilities for network security and access control.

These types of information must be included within the Application Form, to allow the HREC to consider and approve its use. If the circumstances under which the storage and/or use of research data or primary materials changes, a formal submission must be made to the HREC for review and approval.

In general, the minimum recommended period for retention of research data is 7 years from the date of publication. However, in any particular case, the period for which data should be retained should be determined by the specific type of research. For example:

- For short-term research projects that are for assessment purposes only, such as research projects completed by students, retaining research data for 12 months after the completion of the project may be sufficient
- For most clinical trials, retaining research data for 15 years or more may be necessary
- For research including gene therapy, research data must be retained permanently (e.g. patient records)
- If the research has community or heritage value, research data should also be kept permanently, preferably within a national collection.

The duration of retention and the disposal of any primary materials for each study must be included within the Participant Information and Consent Form (PICF) to ensure participants

are informed of the intended fate of research data and primary materials prior to providing informed consent.

The storage and/or disposal of primary materials must also be clearly communicated, and must adhere to legislative requirements and local policy guidelines. For example, all biological samples must be destroyed by incineration, by an appropriately accredited organisation. For all biological samples collected and/or stored at St Vincent's Hospital, this must be achieved using the hospital incineration protocol.

For all other primary materials, disposal must occur in line with legislative requirements and local policy guidelines. For example, all documents must be destroyed via shredding using the hospital confidential bins.

Researchers are obliged to keep records which confirm the time, date, method of disposal and the person responsible for the disposal.

If the results from research are challenged, all relevant data and materials must be retained until the matter is resolved. Research records that may be relevant to allegations of research misconduct must not be destroyed.

If the Principal Investigator leaves the institution, or otherwise ceases to be available, the institution must consult with the sponsor/funding body and use reasonable endeavours to nominate an adequate replacement (agreed upon by all parties). If an adequate replacement cannot be found or agreed upon, the study may be ceased, or relocation to another suitable site.

If the study is unfunded and the Principal Investigator leaves the institution, or otherwise ceases to be available, the institution must be consulted as soon as possible to nominate an adequate replacement (agreed upon by all parties). If an adequate replacement cannot be found or agreed upon, the study may be ceased, or relocation to another suitable site.

Relation to another suitable site may require additional ethical approval and the development/execution of new research agreements. This will remain the responsibility of the Investigators, without exception.

If data and/or primary materials are to be relocated outside of Australia, the Investigators must ensure that the same minimum standards pertaining to confidentiality and privacy are maintained, as per the conditions of the St Vincent's Hospital HREC ethical approval.

Reasonable measures to maintain the confidentiality and privacy of all data should occur at all times. If the research is collaborative, or sponsored, measures must be detailed in a written contract prior to the commencement of research. All parties must also be informed of relevant confidentiality agreements and restrictions on the use of research data.

Specifically, all parties involved in the research must ensure access to study related data and/or primary materials is limited to appropriate personnel. Furthermore, personnel must not use of disclose any confidential information at any time, other than where the extent of such use or disclosure is necessary for the performance of the study, or compliance with institutional/regulatory requirements.

All parties must also ensure that any personal and/or identified information arising from the study (including that specific to study participants or study personnel) is collected, stored, used and disclosed in accordance with relevant Privacy Laws.

All data and primary materials (including that held within 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.

Research data should be encouraged as a shared resource by allowing other researcher to access the data where appropriate, unless this is prevented by ethical, privacy or confidentiality matters and an appropriate data sharing agreement be in place.

Associated Procedures/Instructions
Nil

Reference Documents

- The National Statement on Ethical Conduct in Research Involving Humans in accordance with the NHMRC Act, 2007 – Updated 2018 (Cth)
- Australian Code for the Responsible Conduct of Research (2018)

Authorized by:

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