RESPONSIBLE EXECUTIVE	Angela Watt
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IMPLEMENTATION STRATEGY	Email update to all employees and uploaded to the Office for Research website.
EVALUATION STRATEGY	Updated policy to be evaluated by Melbourne Health Office for Research Governance management team.
STANDARD/S (National, Aged Care, Disability Services)	NSQHS Clinical Governance Standard.
VERSION SUMMARY	The Agreements, Ownership and Intellectual Property Guideline has been developed to clearly set out when a research agreement is required, the roles and responsibilities of Melbourne Health (MH) stakeholders in identifying the requirement for an agreement, review, execution and compliance with terms and condition of the agreement. These guidelines have been written in accordance with the *Australian Code for the Responsible Conduct of Research (2018)* and applicable MH Policy.

EXECUTIVE SUMMARY

1. All MH stakeholders involved in research studies must understand their role and responsibilities in respect to management and protection of MH Intellectual Property
2. MH Research Policy MH18 requires that when a research study involves more than one organisation, an agreement between the organisations be executed before the study is started.
3. Subject to any written agreements to the contrary, MH will remain the custodian of Intellectual Property created at MH.
4. All Study Protocols should identify organisational ownership of the document.
5. Agreement must be submitted to the Office for Research for review before execution.
6. Agreements must be executed according to MH delegation's manual.
7. Amendments to agreements must be approved by the Office for Research before execution.

1. ASSOCIATED MELBOURNE HEALTH POLICY

1. MH Research Policy MH18
2. Documentation and Records Management MH 05
3. Intellectual Property Policy MH 12
4. Intellectual Property Procedure MH 12.01
5. Clinical Documentation MH05.01
6. Privacy and Confidentiality of Patient Information MH03.08

2. PURPOSE AND SCOPE

To describe the use and ownership of Intellectual Property in research conducted at Melbourne Health.

Applicable to all research undertaken at Melbourne Health, including investigator-initiated research, collaborative research, and all phases of clinical trials for the investigation of medicinal products, devices and diagnostics.

Relevant to Principal Investigators (PI), Associate Investigator (AI) research coordinators, data managers and other staff involved in research duties.

3. DEFINITIONS

Intellectual Property	Means all patents, discoveries, inventions, know-how and improvements in any equipment, device, process, procedure, method, formula, code, chemical or biological substance or the like, trade marks (registered or unregistered), designs (registered or unregistered), any literary work within the meaning of the Copyright

	Act 1968 (including computer programs and adaptations thereof and any applications), any development or potential development, research or practice in the fields of surgical, medical, dental and therapeutic treatment and care, social welfare or health (including mental health) created under the auspices of MH and all associated rights.
Background Intellectual Property	Means all Intellectual Property: 1) Belonging to or under the control of a Party at the Commencement Date of the study; or 2) Developed or created by a Party after the commencement date but independently to and separately from the study agreement; and 3) Are made available for the conduct of the study, including all rights subsisting in background materials; and as set out in the Schedule of the study agreement.
Party	A party (organisation, institution, company, person) to an agreement, its successors and permitted assigns and persons for whom it is responsible.
Project Intellectual Property	All Intellectual Property developed or discovered in the course of the research, excluding the copyright for any student thesis.

4. RESPONSIBILITIES

MH, through the Office for Research, should confirm if an agreement(s) is required for a study/activity, review the agreement to confirm acceptance of the terms and conditions, and manage execution of the agreement.

The PI is responsible for ensuring that agreements are established when required.

The PI is responsible for providing all information required to support the review of an agreement.

The PI is responsible for ensuring that personnel involved in the research are informed of the terms and conditions of the executed agreement and obligations, and that MH's obligations regarding research agreements are met.

All members of research study teams are responsible for abiding by the terms and conditions of research agreements.

5. PROCEDURE/GUIDELINE/POLICY

5.1. INTRODUCTION

All MH stakeholders involved in research studies must understand their role and responsibilities in respect to management and protection of MH Intellectual Property.

5.2. AGREEMENTS

MH Research Policy MH18 requires that when a research study involves more than one organisation, an agreement between the organisations be executed before the study is started.

The Parties to an agreement are in general organisations (e.g. MH), and not individuals.

Note: an exception to this is a confidentiality agreement where a Party may be an individual.

The PI is responsible for ensuring that MH's obligations regarding research agreements are met by:

- Determining if an agreement is required for a research study.
- Ensuring draft agreements are reviewed and approved by the Office for Research prior to execution.

- Ensuring agreements are executed before starting any activities covered by the agreement.
- Ensuring that all members of the study team are informed of and abide by terms and conditions of agreements during all phases of the research study including the archiving and data access phases.
- Ensuring the Office for Research is informed of breaches of agreements in a timely manner.

Points to remember when drafting agreements:

- MH agreement templates should be used for all MH initiated research studies. Use of other agreement templates is negotiated on a case by case basis.
- Where external parties initiate a research study (i.e. MH did not write the protocol) then that Party may nominate the agreement template to be used. In this case, submit a draft of any agreements (in Word format) to the Office for Research for review.
- Draft agreements (in Word format) should be submitted to the Office for Research with research governance applications for review BEFORE execution. The review is undertaken so that MH as an organisation can ensure it understands and can comply with the terms and conditions of the agreement.
- The Office for Research manages legal and/or intellectual property review of agreements if required for specific research studies.
- The study agreement should cover all pertinent aspects of the management and conduct of the research study including:
  - Each participating organisations' role and responsibilities.
  - Funding, management.
  - Investigational products.
  - Warranties.
  - Insurance and indemnity.
  - Ownership of Project Intellectual Property and Background Intellectual Property
  - Reporting.
  - Publication.
- Negotiation of agreements is on a per research study basis.

General guidance for identifying which agreement to use:

- **MH only research studies** – a collaboration agreement is not required. However, a services agreement may be required where a third party is engaged to undertake any fee for service aspect of the research study. Service agreements must stipulate that ownership of Intellectual Property remains with MH.
- **Collaborative research studies** – before the research study is started, ownership of the Project Intellectual Property must be defined and documented in a collaborative research agreement. Where MH owns the protocol, the collaborative research agreement template (MACH) should be used.
- **Clinical Trials** – use the following standard templates unless otherwise agreed by the Office for Research on a per study basis:

  - Medicines Australia (MA) for drug trials.
  - Medical Technology Association of Australia (MTAA) for devices.

- **MH only studies that become collaborative via the addition of a site –** Ownership of Project Intellectual Property and Background Intellectual Property must be defined and documented in an agreement. Agreement negotiations must consider factors such as (i) protocol development and ownership (ii) ownership and definition of existing MH Background Intellectual Property (iii) amount of information already collected, (iv) extent of contribution of the new party to the research study, (v) ownership of the Intellectual Property from the collaborative component of the Project (vi) if payments are involved (i.e. is it a collaboration or a fee for service), prior to signing of the agreement and transfer of any study Intellectual Property between the collaborators.
- **Adding new collaborating parties to existing multi-site collaborative studies** - Agreements to add new collaborating parties must be negotiated/reviewed with consideration of existing agreement/s and efforts made to ensure consistency across terms and conditions of all agreements including Intellectual Property ownership.
- **Commercially sponsored clinical trials** – An appropriate Medicines Australia clinical trials research agreement.
- **Service agreements -** A service agreement is required when a third party is engaged to conduct a research study activity for a fee. Service agreements must stipulate that ownership of the Project Intellectual Property remains with MH.
- **Research studies involving students** – An agreement with the student's educational institution is required (including, where required, embargo on thesis publication to protect commercially sensitive information). Researchers must be aware that for studies that produce a student thesis, the student owns the copyright of the thesis. This is irrespective of any other terms and conditions regarding copyright in an agreement between the collaborating institutions.

Contact the Office for Research or refer the website for advice or further information including; confirmation that the study requires an agreement, agreement temples and content.

Execution of agreements

By signing an agreement (execution) MH and our study teams are bound to the terms and conditions of the agreement.

Note, some of the terms and conditions of the agreement, survival clauses, do not expire and must be met even after expiry or termination of an agreement

Execution (signing) of research agreements by MH must be in accordance with the MH delegation log.

PIs must ensure that:

- Agreements are submitted to the MH Office for Research to manage MH execution of the agreement.
- Execution of research agreements by other Parties is the responsibility of the other Parties to agreements to identify the appropriate delegate to sign the agreement.
- The Parties to the agreement must agree on the method of documenting execution of the agreements i.e. if the agreement is to be executed by wet ink signature, and /or on the basis of an exchange of facsimile or scanned copies of the Agreement. A pdf cut and paste insert of a signature on an agreement is not an acceptable method of execution of the agreement.

Amendments to agreements

Agreements, including any associated schedules and annexures, may be amended from time to time.

Requests to amend the term and conditions of an agreement must be submitted to the MH Office for Research using the standard amendment process for review.

Once the amendment has been approved by MH and the updated terms and conditions have been accepted by the other Parties to the agreement, the Office for Research will manage MH execution of the agreement.

5.3. OWNERSHIP AND INTELLECTUAL PROPERTY

Ownership of Intellectual Property created at MH and by MH employees is outlined in MH12 Intellectual Property Policy and MH12.01 Intellectual Property Procedure.

Subject to any written agreements to the contrary, MH will remain the custodian of all MH Background Intellectual Property and Project Intellectual Property created at MH.

It is important that you can demonstrate that you have sought advice on and addressed all matters related to ownership of Intellectual Property that apply to the study/resources. Involve the Office for Research in Intellectual Property discussions and negotiations, if required, and submit agreements with research governance applications for review BEFORE execution.

Contact the Office for Research for Intellectual Property advice specific to a research study.

With respect to the ownership of Data and information used in or generated by research involving Aboriginal and Torres Strait Islander peoples and communities, MH and its researchers may hold data or information. However, its Indigenous owners (if any) should be consulted prior to making any decisions about the access to or reuse of this data or information.

5.3.1 Identify ownership of the protocol

When developing protocols, always include a statement of ownership and confidentiality on the front page:

- Where only MH employees wrote the protocol then the confidentiality statement must be: "*This document is confidential and the property of Melbourne Health. No part of it may be transmitted, reproduced, published, or used without prior written authorization from the institution*."
- Where employees from other organisations co-write the protocol then each authoring organisation should be listed in the confidentiality statement.
- For clinical research studies, the recommended protocol template is located at https://www.thermh.org.au/research/researchers/ethics and contains the above Confidentiality statement.

5.3.2 Define ownership of existing data

Define ownership of existing data that will be used in the study in accordance with MH12 Intellectual Property Policy and MH12.01 Intellectual Property Procedure in the study:

- Data Management Plan (OFR SOP): and
- Source Data Identification Log (OFR GCP SOP7).

6. REFERENCES

1. Note for guidance on Good Clinical Practice (CPMP/ICH/135/96) annotated with TGA comments DSEB, July 2000
2. VMIA CTN Guidelines (2006)
3. MACH template research agreement for collaborative studies https://www.machaustralia.org/research-collaboration-agreement

7. REVISION AND APPROVAL HISTORY

Date	Version	Author* and contributors
2 September 2019	1	Sarah Rickard, Manager Research Governance and Audit