Research Agreements Procedure

TARGET AUDIENCE and SETTING

All Monash Health employees who conduct research involving Monash Health patients, consumers, staff or use Monash Health facilities, equipment or resources and where the research involves an external individual, organisation or company.

PURPOSE

This procedure outlines the legal documentation of agreements for research studies that involve collaboration with an external organisation, company or individual.

DEFINITIONS

Commercially Sponsored study – A study that sponsored by a company or organisation such as a pharmaceutical or medical device company.

Investigator Initiated study – A study that is led by a Monash Health employee or an individual from an external organisation, such as another health service or research institute.

Collaborative Research Study – A study that is led by a group of individuals or organisations or companies, working in collaboration where the group has been formally recognised/created under a separate legal agreement.

PRECAUTIONS/CONTRAINDICATIONS

The following legal and commercial risks may arise if Monash Health does not enter into and comply with the terms of a formal research agreement:

- Breach of patient privacy and/or breach of confidentiality of commercially sensitive information;
- Failure to document Monash Health's contribution (financial/resources/scientific knowledge);
- loss of Intellectual Property rights;
- financial loss;
- Inability to enforce MH's legal rights and ensure compliance by 3rd party or its responsibilities; and
- reputational risk.

STANDARD REQUIREMENTS

When undertaking any clinical interaction with a patient, staff are expected to;

- Perform routine hand hygiene. Refer to the Hand Hygiene Procedure.
- Introduce themselves to the patient and carer/ family if in attendance
- Check patient identification. Refer to the Patient Identification Procedure.
- Obtain consent as per the Consent to Medical Treatment Procedure.
- Keep the patient/carer informed and involve them in decision making.
- Document interaction in the electronic medical record or health record using black pen; including date, time, signature and designation.

PROCEDURE – APPROVALS AND LEGAL REQUIREMENTS

Prior to a research study commencing at Monash Health, the study requires:

- Human Research Ethics Approval
- Site Specific Authorisation;
- Documenting the arrangement in a research agreement.

A research agreement is a legal agreement that formally documents the relationship, rights and responsibilities of each party (individual/organisation or company) involved in the research study. It is an essential step prior to the commencement of the research.

In general, all research agreements include an 'indemnity'. This may be in the form of:

a clause in a research agreement, OR

a separate indemnity agreement that operates alongside the research agreement.

An indemnity is a legal obligation by one party to reimburse or pay the other party financial compensation where it suffers financial loss relating to research study. It is commonly required in Commercially Sponsored Studies. That company or organisation agrees to indemnify (compensate) the party conducting the research study (eg Monash Health) if that party suffers financial loss due to conduct of the research study. For example: where a patient who has participated in a research study suffers physical injury (due to the drug or medical device) and brings a claim in negligence against Monash Health, then the company is to reimburse Monash Health for the loss that Monash Health incurred by resolving the patient's claim.

Monash Health has adopted a series of template agreements that are appropriate for research studies and have been approved by the Legal department at Monash Health. Where those approved templates are used in an unmodified form, the Legal department does not need to review it for each use. However, the Legal department must review a research agreement where:

- a non-standard template is used, or
- the other party to the agreement seeks to alter the wording in a template research agreement.

Allow a minimum of 2 weeks for legal review.

All agreements must be submitted to the Research Support Services Team in the first instance via research@monashhealth.org.

The correct legal name and business details for Monash Health to include in agreements are:

'Monash Health (ABN 82 142 080 338), 246 Clayton Road, Clayton, Victoria, 3168.'

If a researcher would like to request prior review of an agreement, this may be emailed to research@monashhealth.org. In the email, it must state the local Monash Health Reference number and study title. If the study has not been submitted for Human Research Ethics Review or Site Authorisation, then please state this in the email.

Human Research Ethics Review

Circumstance	Document(s) required	Review Process
Commercially sponsored drug trial	Medicines Australia HREC Review Form of Indemnity is provided with the submission to the Human Research Ethics Committee.	Standard document that does not require review by the Legal Team, unless modified. The Research Support Services Team will arrange signing by an authorised representative upon Human Research Ethics Committee Approval being granted.
Commercially sponsored device trial	Medical Technology Association of Australia HREC Review Form of Indemnity is provided with the submission to the Human Research Ethics Committee.	Standard document that does not require review by the Legal Team, unless modified. The Research Support Services Team will arrange signing by an authorised representative upon Human Research Ethics Committee Approval being granted.
Investigator led study for an external organisation that is not a public health service or University. Eg a private hospital or private practitioner	An Agreement – Ethical Review of Human Research Services is submitted with the application to the Human Research Ethics Committee.	Standard document that does not require review by the Legal Team, unless modified. The Research Support Services Team will arrange signing by an authorised representative upon Human Research Ethics Committee Approval being granted.

Site Specific Authorisation

Circumstance	Document(s) required	Review Process
Commercially sponsored drug trial through the Research Support Program with Monash University.	Agreement – Monash Tripartite – Sponsor Template & Medicine's Australia Standard Form of Indemnity To be submitted with the Application for Site Specific Authorisation.	Standard document that does not require review by the Legal Team, unless modified. The Research Support Services Team will arrange signing by an authorised representative upon Site Authorisation being granted.
Contract Research Organisation sponsored drug trial through the Research	Agreement – Monash Tripartite – CRO Local Sponsor Template & Medicine's Australia Standard Form of Indemnity	Standard document that does not require review by the Legal Team, unless modified. The Research Support Services Team will arrange signing by an authorised

Support Program with Monash University	To be submitted with the Application for Site Specific Authorisation.	representative upon Site Authorisation being granted.
Commercially sponsored device trial through the Research Support Program with Monash University.	Agreement – Monash Tripartite – MTAA (Device Trial) Template & MTAA Standard Form of Indemnity To be submitted with the Application for Site Specific Authorisation.	Standard document that does not require review by the Legal Team, unless modified. The Research Support Services Team will arrange signing by an authorised representative upon Site Authorisation being granted.
Commercially sponsored Phase 4 Clinical Trial	Medicine's Australia Phase 4 Clinical Trial Agreement	Standard document that does not require review by the Legal Team, unless modified. The Research Support Services Team will arrange signing by an authorised representative upon Site Authorisation being granted.
Investigator Initiated Study with Commercial Support	Agreement – Investigator Initiated with Commercial Support to be submitted with the Application for Site Specific Authorisation.	Standard document that does not require review by the Legal Team, unless modified. The Research Support Services Team will arrange signing by an authorised representative upon Site Authorisation being granted.
Collaborative Research Study with an organisation within Monash Partners	Agreement – Monash Partners Collaborative to be submitted with the Application for Site Specific Authorisation. The Guidance for Monash Partners Collaborative Agreement Template may assist in completing the schedules.	Standard document that does not require review by the Legal Team, unless modified. The Research Support Services Team will arrange signing by an authorised representative upon Site Authorisation being granted.
Collaborative Research Study with another organisation (within Australia)	The preference is for Agreement – Monash Partners Collaborative to be submitted with the Application for Site Specific Authorisation. In some instances, the other party will insist on their agreement being submitted.	A non-standard agreement will require review by the legal team if it substantially varies from an approved template and/or if the agreement includes Monash Health providing an indemnity to another organisation. The research team emails the agreement to research@monashhealth.org and should allow a minimum of 2 weeks for review feedback.

		If the agreement is acceptable, The Research Support Services Team will arrange signing by an authorised representative(s) upon Site Authorisation being granted. If this agreement includes an indemnity clause, the agreement must be approved under the Contract Approval Process. This will add 1-2 weeks to the process. This must be factored into the timeline for the study.
Collaborative Research Study with another organisation (internationally)	The preference is for Agreement – Monash Partners Collaborative to be submitted with the Application for Site Specific Authorisation. In some instances, the other party will insist on their agreement being submitted.	A non-standard agreement will require review by the legal team if any of the following apply: • it substantially varies from an approved template; • it includes Monash Health granting an indemnity to another organisation; • the privacy and data security of health and personal information collected from Monash Health and/or its study participants is governed by laws that are NOT either: -the General Data Protection Regulation (GDPR -EU Law); or -Australian (Victorian or Commonwealth) privacy laws. • the Laws of another country (jurisdiction) applies to the agreement. The research team must email the agreement to research@monashhealth.org and should allow a minimum of 2 weeks for review feedback. The Research Support Services Team will (if necessary) arrange for legal review and then signing by an authorised

		representative(s) upon Site Authorisation being granted. The Contract Approval Process will apply if the agreement has been subject to review by the legal department.
Quality Improvement Activity involving data transfer	Agreement – Data Transfer Agreement for Monash Health providing data to be submitted with the Application for Site Specific Authorisation.	Standard document that does not require review by the Legal Team, unless modified. The Research Support Services Team will arrange signing by an authorised representative upon Site Authorisation being granted.
Research study that involves material transfer	Agreement – Material Transfer Agreement Template to be submitted with the Application for Site Specific Authorisation.	Standard document that does not require review by the Legal Team, unless modified. The Research Support Services Team will arrange signing by an authorised representative upon Site Authorisation being granted.

Other Research Agreements

Circumstance	Review Process
Company/collaborator requesting completion of a Non-Disclosure or Confidentiality Agreement	Submission to Research Support Services via research@monashhealth.org. The vast majority will be standard and will not require review by the Legal Team. The Research Support Services Team will review and arrange signing by an authorised representative In instances where the other party is requesting Indemnity from Monash Health, this must be removed, prior to submission. In instances where Monash Health is being asked to abide by laws of another country, this must be amended to state that **each party** will comply with the local laws of its respective country.
Multi Institutional Agreement (MIA) for NHMRC or MRFF grants	Submission to Research Support Services via research@monashhealth.org. The vast majority will be standard. However, MIAs generally include indemnification clauses and will require review by the Legal Team and must go through a contract approval process, which will add 1-2 weeks to the process. This must be factored into the timeline for the study. The Research Support Services Team will arrange signing by an authorised representative
Service Level Agreements	Submission to Research Support Services via research@monashhealth.org. These may require review by the Legal Team. The Research Support Services Team will arrange signing by an authorised representative

RELATED DOCUMENTATION

The templates for Research Agreements and Indemnities are located: Research Support Services Forms Library

BACKGROUND

Monash Health is a public health service, insured under the Victorian Managed Insurance Authority for the conduct of research.

In the event, the research is sponsored by a commercial entity, the agreement must include the following clauses:

- Insurance. The sponsor must obtain and maintain professional indemnity and public liability insurance, and provide Monash Health with a certificate of currency of the insurance; and
- Indemnity. The Sponsor must indemnify Monash Health for any loss or damage that Monash Health may suffer as a result of the research study.

Where the research is collaborative or investigator-initiated, Monash Health is acting as the sponsor. An agreement is still required to document each party's rights and responsibilities and obligations. This is a requirement under the Australian Code for the Responsible Conduct of Research.

KEY STANDARDS, GUIDELINES OR LEGISLATION

Australian Code for the Responsible Conduct of Research

National Statement on Ethical Conduct in Human Research

KEYWORDS

Research Agreement, Indemnity, Site Specific Authorisation, Human Research Ethics Review

Document Governance	
Supporting Policy	Human Research (Strategic)
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