Cabrini Research Agreements Guide

When are agreements required?

Agreements are required when there is more than 1 organisation involved in the research.

Why are written agreements needed?

Agreements are needed to:

- Minimise risk of conflict and confusion
- Clearly states what costs and payments are involved
- Protects Cabrini and you
- Facilitates compliance with our legal and regulatory obligations
- Clarifies IP ownership
- Protects our reputation

Templates

Try to use approved templates for your agreements, otherwise full legal review will be required and this will take additional time.

Find approved templated agreements:

Cabrini Intranet – Corporate Support Legal Templates (accessible by employees only)

https://monashpartners.org.au/disciplines/clinical-research-facilitation/

https://www.medicinesaustralia.com.au/policy/clinical-trials/clinical-trial-research-agreements/ (MA - Drug)

https://www.mtaa.org.au/clinical-investigation-research-agreements (MTAA - Device)

https://www.australianclinicaltrials.gov.au/resources/collaborative-research-agreement-template-projects-not-involving-clinical-trials

Sponsorship Arrangement	Type of Study	Name of Agreement	Type of Indemnity
Feasibility studies commercially sponsored	Clinical Trial or Interventional Study	CDA or NDA	Not applicable
Commercially Sponsored	Clinical Trial or interventional study	➢ Standard CTRA – MA ➢ Standard Clinical Investigation Research Agreement (CIRA) – MTAA	Standard Indemnity
Commercially Sponsored	Clinical Trial or interventional study - CRO	➢ CTRA: Contract Research Organisation (CRO) acting as the local sponsor – MA ➢ CIRA: Contract Research Organisation acting as the local sponsor - MTAA	Standard Indemnity
Collaborative Group / Investigator-initiated	Clinical Trial or interventional study - CRG	➢ CTRA - Collaborative or Cooperative Research Group (CRG) studies – MA	Responsibility of each institution
Commercially Sponsored	Clinical Trial (Phase 4)	➢ CTRA - Phase 4 Clinical Trials (Medicines) - MA	Standard Indemnity

Sponsorship Arrangement	Type of Study	Name of Agreement	Type of Indemnity
Commercially Sponsored	Clinical Trial (Post Market)	➢ CTRA – Phase 4 Clinical Trials (Medicines) CRO acting as local sponsor - MA ➢ CIRA – Post Market Clinical Trial (Medical Devices) – CRO acting as the local sponsor - MTAA	Standard Indemnity
Investigator Initiated	Clinical Trial or interventional study	➢ CTRA – Collaborative or Cooperative Research Group (CRG) studies – MA	Responsibility of each institution
Investigator Initiated	Non-interventional study	➢ Research Collaboration Agreement or Data Transfer Agreement	Not required
Investigator Initiated	Minimal to Low Risk	➢ Research Collaboration Agreement or Data Transfer Agreement	Not required
3rd party project	Clinical Trial	➢ Agreement between sponsor and 3rd party. Cabrini is not a party to the agreement unless Cabrini services are required.	Standard Indemnity

Details on Agreement

Cabrini Health Limited entity:

Cabrini Health Limited

ABN 33 370 684 005 / **ACN** 108 515 073

183 Wattletree Road, Malvern Victoria 3144

Notices: Gavin Horrigan, (03) 9508 3460, ghorrigan@cabrini.com.au

Please ensure that the ACN number is included on all agreements.

Confidential Disclosure Agreement (CDA) also referred to as Non-Disclosure Agreement (NDA)

CDA or NDA is a legal agreement between a minimum of two parties which outlines information the parties wish to share with one another for certain evaluation purposes, but wish to restrict from wider use and dissemination.

A CDA or NDA is provided by a commercial sponsor prior to supplying information on a possible project (feasibility study). Some commercial sponsors prefer Master CDA's (covering multiple projects from that sponsor) rather than project specific CDA's.

Who initiates the agreement?

It is the responsibility of the project sponsor to initiate the agreement. For commercially sponsored studies, this will generally be the local contract research organisation (CRO). For investigator-initiated studies or collaborative / cooperative research group (CRG) studies, the coordinating principal investigator (or their delegate) from the lead site will oversee initiation, drafting and signing of agreements.

Indemnifying the Sponsor / CRG

An indemnity is a contractual obligation of one party to compensate the loss incurred by another party. Clinical trial sites take out insurance or indemnity arrangements to protect themselves against liabilities that may arise as part of their clinical trial activities. This indemnity is between the sponsor and the institution that hosts the study to be conducted.

When Data or Material Transfer Agreements should be used

Data Transfer / Sharing Agreements should be used where data is being transferred to another entity or person. This might be imposed by an entity or person transferring data to Cabrini or vice versa. Multiple entities might also be involved. This type of agreement is required even if the data is de-identified. You will not need a Data Transfer Agreement if there is another agreement in place relating to the research which covers confidentiality, privacy, ownership and data security and delineates the specific purpose(s) of which the data can be used. Material Transfer Agreements are required where material, such as tissue samples or blood samples, are being transferred to another entity or person. Like Data Transfer Agreements, these might be unilateral (only one way), mutual (both parties are transferring and receiving) or multi-party. If there is data that is accompanying the transfer of material, you will need to incorporate relevant confidentiality, privacy and data security provisions. You will not need a separate Material Transfer Agreement if there is already a research agreement in place which covers this.

If you have any queries regarding agreements, please ensure that you contact the Cabrini Research Governance Office (CRGO), not legal directly.

Master Services Agreement

Cabrini may enter into Master Services Agreements with external entities when research is to be conducted using Cabrini services. Once a Master Services Agreement has been entered into, only Work Orders detailing the fees and department authorisation are required from each Cabrini service supporting the research. CRGO then organises for the Work Orders to be signed.

Identifying the CRG or Sponsor

A clinical study sponsor refers to an individual, company, institution or organisation that takes responsibility for the initiation, management, and/or financing of a clinical study or trial. The sponsor does not actually conduct the investigation unless the sponsor is a sponsor-investigator. The sponsor carries the medico-legal risk for the conduct of the study.

A CRG is an academic and/or non-commercial collaborative research group responsible for sponsoring, initiating, managing, developing and coordinating a study between multiple entities.

When is legal review required?

All agreements must be sent to CRGO for review prior to being executed. CRGO will determine whether legal review is required and will liaise with legal directly. No research team should contact Cabrini legal directly. Cabrini legal need not be involved if pre-approved templates are used however if special conditions are included in the agreement, then this may require legal review to ascertain Cabrini's risk and liability. Using non-templated agreements automatically requires legal review.

Intellectual property

Intellectual Property (IP) means any statutory or other proprietary rights in relation to registered and unregistered trademarks, patents, circuit layouts, software, designs, copyrights, know-how and all other intellectual property rights as defined in article 2 of the Convention Establishing the World Intellectual Property Organisation of July 1967.

Ensure a research agreement defines not only that IP ownership is shared but also the terms for using the shared IP (licencing of IP).

Responsibilities of a VMO

All VMO's need to have an agreement in place to formalise their contribution to the research and the IP ownership split between themselves (i.e. their home institution, not their individual person) and the collaborating institutions.

Funding Contribution – milestone payments, cost centres and project codes

For any agreements which include milestone payments, cost centres, project codes or payments for Cabrini services, please ensure that they are clearly stated in the agreement and that all related departments are aware of the costs and charges involved. For Investigator-Initiated studies, please reference cost centre cc9490 in agreements.

Cabrini Specific Clauses

1. **Privacy**
   Agreement Type: Clinical Trials - Medicines Australia CTRA Schedule 7

   Clause 10.3 'The Sponsor is required to comply with the Relevant Privacy Laws, including the Privacy Act 1988 (Cth). If the Sponsor transfers data or Personal Information to an Affiliate or third party whether in Australia or overseas, it must impose the privacy obligations in this Agreement on the relevant Affiliate or third party. The Sponsor remains liable for any failures by the Affiliate or third party to comply with the privacy obligations in this Agreement relating to Personal Information.'

2. **NCTGF**
   Agreement Type: Clinical Trials - Medicines Australia CTRA Schedule 7

   'The Sponsor [amend as needed] agrees to comply with all reasonable directions and policies by Cabrini in relation to research quality and governance, including supporting Cabrini to meet or exceed the requirements of the National Clinical Trials Governance Framework (NCTGF). To the extent that the NCTGF applies to the Sponsor [amend as needed], the Sponsor [amend as needed] warrants that it complies with its obligations.

3. **Assisted Reproductive Technologies - Studies involving the collection, transfer and use of male or female reproductive tissue**
   Agreement Type: Monash Partners RCA – Schedule 3 *'Clause 4.4 is added:*
   "The User will comply with the Catholic Health Code of Ethics in relation to the Material, including ensuring that the Material is not used for technological interventions such as in vitro fertilisation (IVF), intra-cytoplasmic sperm injection (ICSI) or artificial insemination by donor (AID)."

How long does preparing an agreement take?

An agreement should be prepared as soon as possible to clearly define roles and responsibilities of the research entities as well as any costs or payments that are involved.

Signing / agreement execution can be completed within a few days if a template with no special conditions is used. Legal review of an agreement with wording changes can take two or more weeks.

Order of Execution

Once CRGO and legal have endorsed the agreement to go for signature, it is then returned to the sponsor/CRG for their signature. If a sponsor is involved, they may send the agreement via DocuSign or Adobe Sign to the Principal Investigator and Institution delegated signatories but they must include researchgovernance@cabrini.com.au within the signature path.

Who can sign?

The Cabrini delegated signatories are: Professor Gary Richardson OAM, Group Director, Cabrini Research and Gavin Horrigan, Director of Research Operations, Cabrini Research.

If required, CRGO will forward an agreement to signatories via Cabrini's DocuSign account.

All fully signed agreements must be forwarded to researchgovernance@cabrini.com.au for inclusion into Open Windows (Cabrini's contracts repository).

What signing platforms are accepted?

Cabrini accepts DocuSign or AdobeSign. When initiating e-signatures, ensure researchgovernance@cabrini.com.au is part of the signatory path

IMPORTANT CONTRACT QUESTIONS FOR RESEARCHERS TO CONSIDER IN ADVANCE

- How long is the project likely to take?
- How will IP ownership and licences be assigned?
- How are the project outputs (IP, data, materials) going to be used in the future? (e.g. further research, publication). Does the agreement cover this?
- What are the publication rights for each party and investigator?
- What are the financial considerations? i.e. costs for HREC/governance review and other services required to support or deliver the project, overall budget, funding source, payment terms, invoicing, cost centres
- What are the reporting obligations?
- What are the contributions and deliverables of each party?
- What are the terms of termination for each party?