



THE UNIVERSITY OF
MELBOURNE

Legal Services Contracts & Agreements

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Legal Services - MDHS

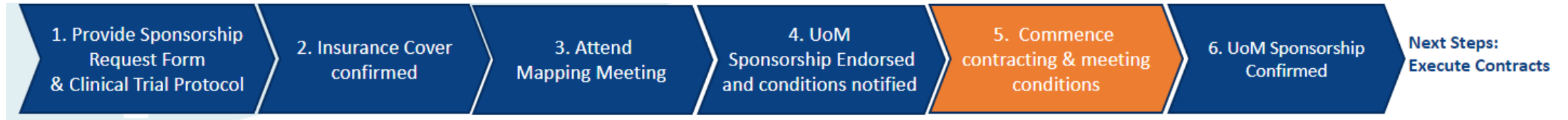




About Clinical Trial Contracting

- Legal services assists CI's/trial managers with their contract drafting for UoM sponsored clinical trials.
- When you submit a Sponsorship Request Form via Infonetica, Legal services are looped into the correspondence and documentation. You do not need to contact them separately.

Clinical Trial Sponsorship Request Process



Summary of UoM Sponsored Clinical Trials

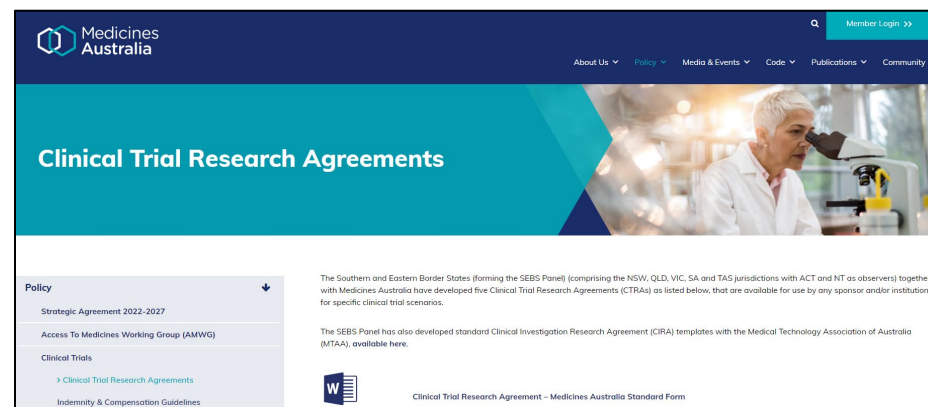
No. of Clinical Trials (Nov 18 – Feb 22)	93
No. of CTs with LEX ID and assigned to lawyer in legal services	71
Average no. CTs per year (2019-2021)	22
CTs with Site Agreements Type of Site Agreements	43.7%; Av. 10 CTRAs per clinical trial MA CTRA 71%
CTs with Service Agreements	37%; Av. 2 Serve Agreements per clinical trial
CTs with Collaboration Agreements	27%
CTs with International Agreements	10%

Site Agreements

To expedite the contracting process UoM use a suite of standard template agreements.

Site Agreements

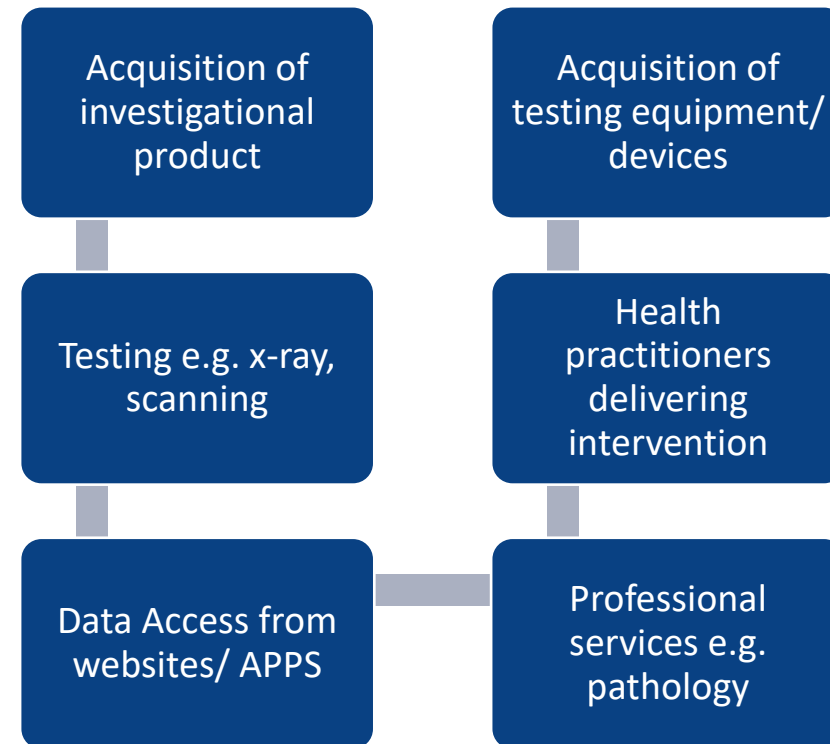
- For studies undertaken in Australian hospitals we use the Medicines Australia CTRA. This also includes template clauses related to funding terms, such as NHMRC or MRFF.
- For studies that are undertaken in medical clinics we use a simple letter agreement.
- Legal services will send you the templates that are relevant - after the mapping meeting.
- If your study is recruiting participants at a hospital but you do not require use of facilities, equipment or staff you may not require a site agreement. Legal services will determine this at the mapping meeting.



Service Agreements

Service Agreements

- Legal services have developed templates when you require services from external parties, including drug manufacturers, testing laboratories, data collection platforms etc.
- For studies that require professional services from health practitioners such as physiotherapists, you will need a simple letter agreement.
- During the mapping meeting we will identify what service agreements you require and send you the relevant templates.





Collaboration and International Agreements

Collaboration Agreements

- When you collaborate with partners on non-commercial research you will need a collaboration agreement. E.g. Melbourne Academic Centre for Health (MACH) partners.
- The collaboration agreements are in standard form and includes key information about conduct, IP, confidentiality, publication, insurance etc.

International Agreements

- If you plan to enrol participants overseas, you need to identify an appropriate partner to become the 'overseas' sponsor or equivalent.
- Often the overseas sponsor will manage the implementation of the protocol at relevant sites.
- You need to bring as much information as possible along to the mapping meeting for the legal team to determine the most appropriate agreements. Often, these are not templated but need to be developed based on the involvement of the overseas partner.



How to prepare for mapping meeting

- Name and roles of sites (e.g. recruitment, participation etc).
- Spend per site.
- Name and roles of collaborators.
- Name of your department head for signing agreements.
- Name of service providers, are there any contracts already in place.
- Does the university already have a licence to use the service e.g. Qualtrics.
- Details of international collaborators.
- Details of any other contracts related to the clinical trial.
- Consider conflicts of interests where you or others have a joint appointment with a study site.



Non-UoM Sponsored Clinical Trials

- If your study is being sponsored by another organisation such as a hospital. They may require UoM to enter into agreements.
- To access legal services, you need to lodge a request through Themis.