



THE UNIVERSITY OF
MELBOURNE

Key issues in research contracts

Annual Seminar for MACH Study Coordinators

St Vincent's Hospital Melbourne

21 March 2018

Madeleine Crawford (and Katherine Payne)

Legal Services, The University of Melbourne





Overview

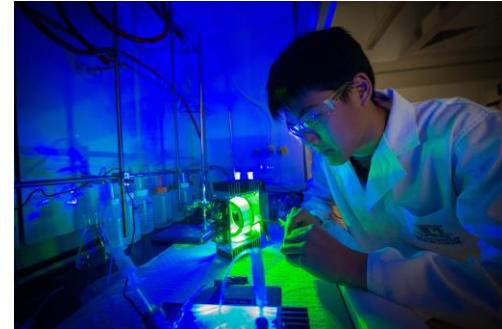
- Research contracts 101
 - ➔ Aims and types of research contracts
 - ➔ Sources of funding
- Intellectual Property
- Publications & Confidentiality
- Restraints on academic freedom



What are the aims of a research contract?



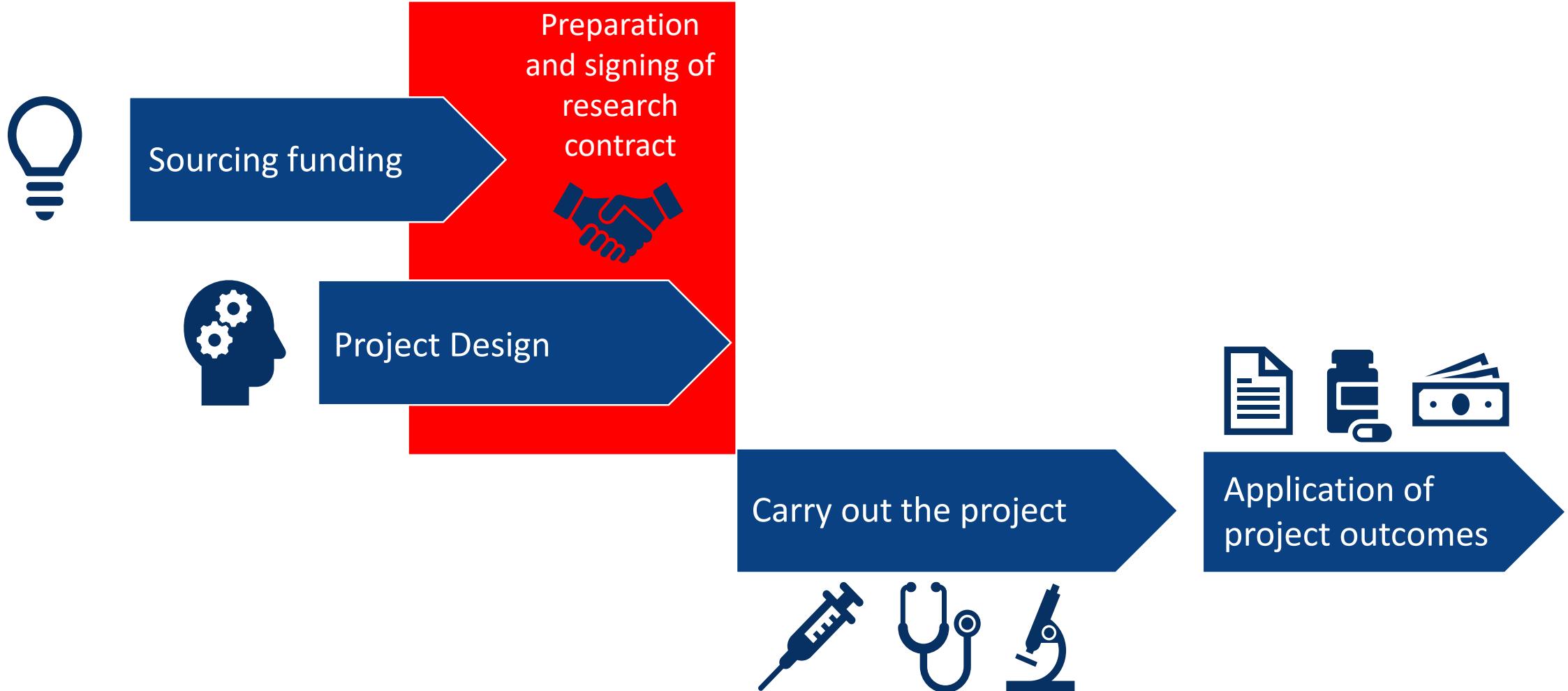
To facilitate the **research process** and **application of outcomes** by defining the parties' rights and obligations



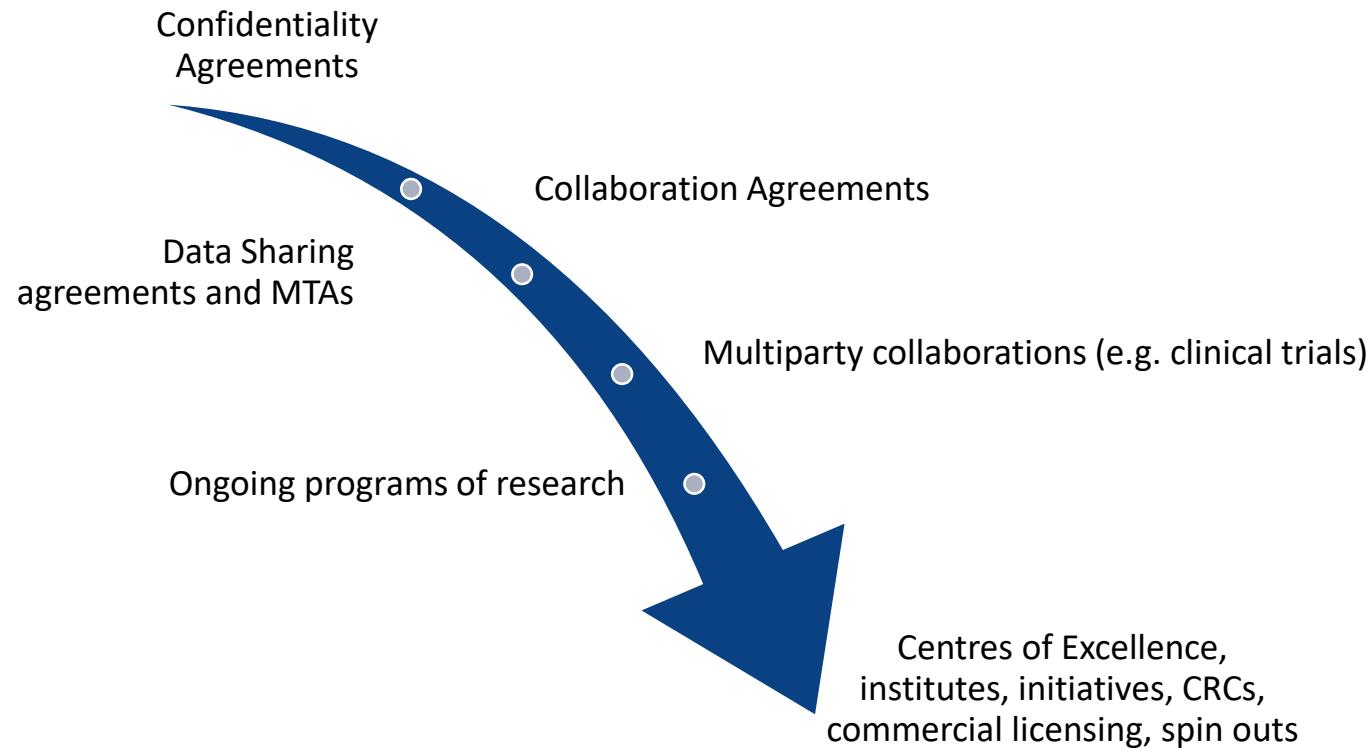
On a project-by-project basis, this involves the balancing of many different considerations:

Legal Certainty	Advancements in field of research	Access to patients
Student interests	Access to funding	Reputation
Preserving Academic Freedom of Expression	Risk profile	Ensuring freedom to continue research
		Commercial potential
	Publication rights	Intellectual Property

The Research Story

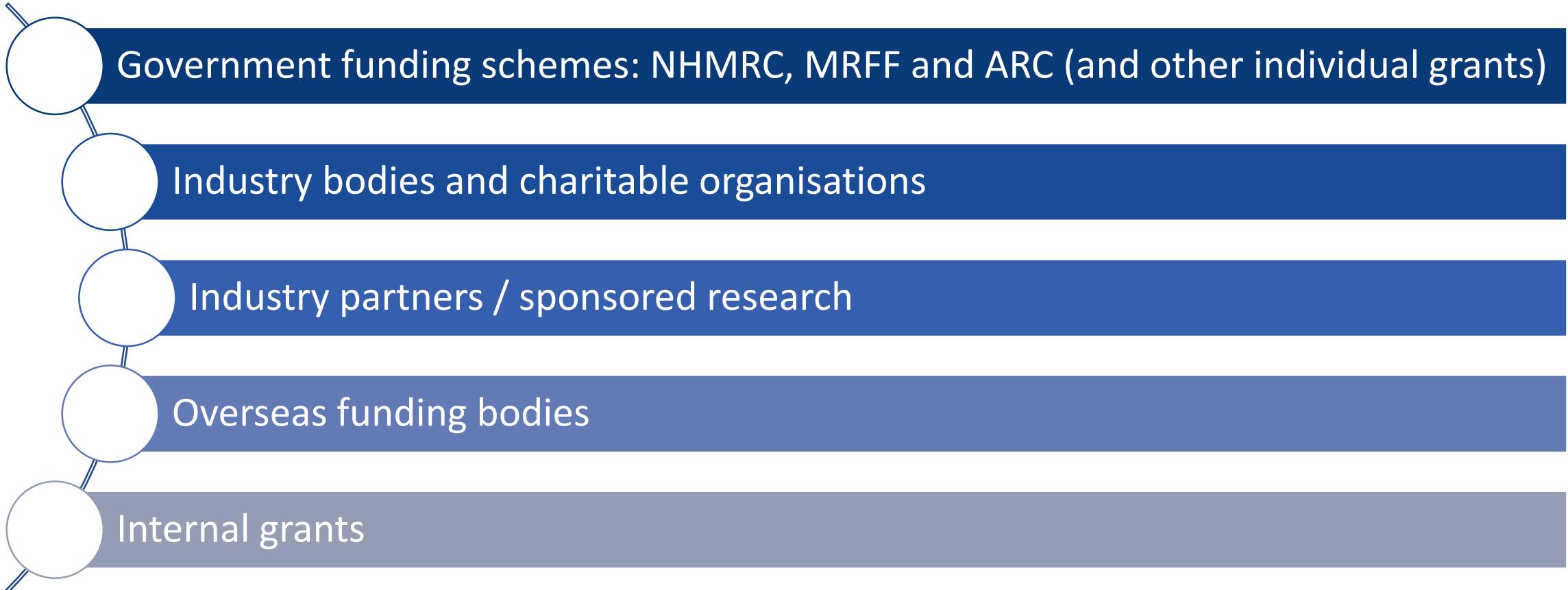


Types of research agreements



NB: Any of these agreements could be subject to external funding arrangements

Source of Funding



Source of Funding (cont.)

NHMRC

Commonwealth Grant Scheme (currently under review, will introduce a new a dedicated funding stream for Clinical Trials and Cohort Studies)

<https://www.nhmrc.gov.au/restructure>

ARC

National Competitive Grants Program
(Discovery and Linkage streams)
<http://www.arc.gov.au/grants>

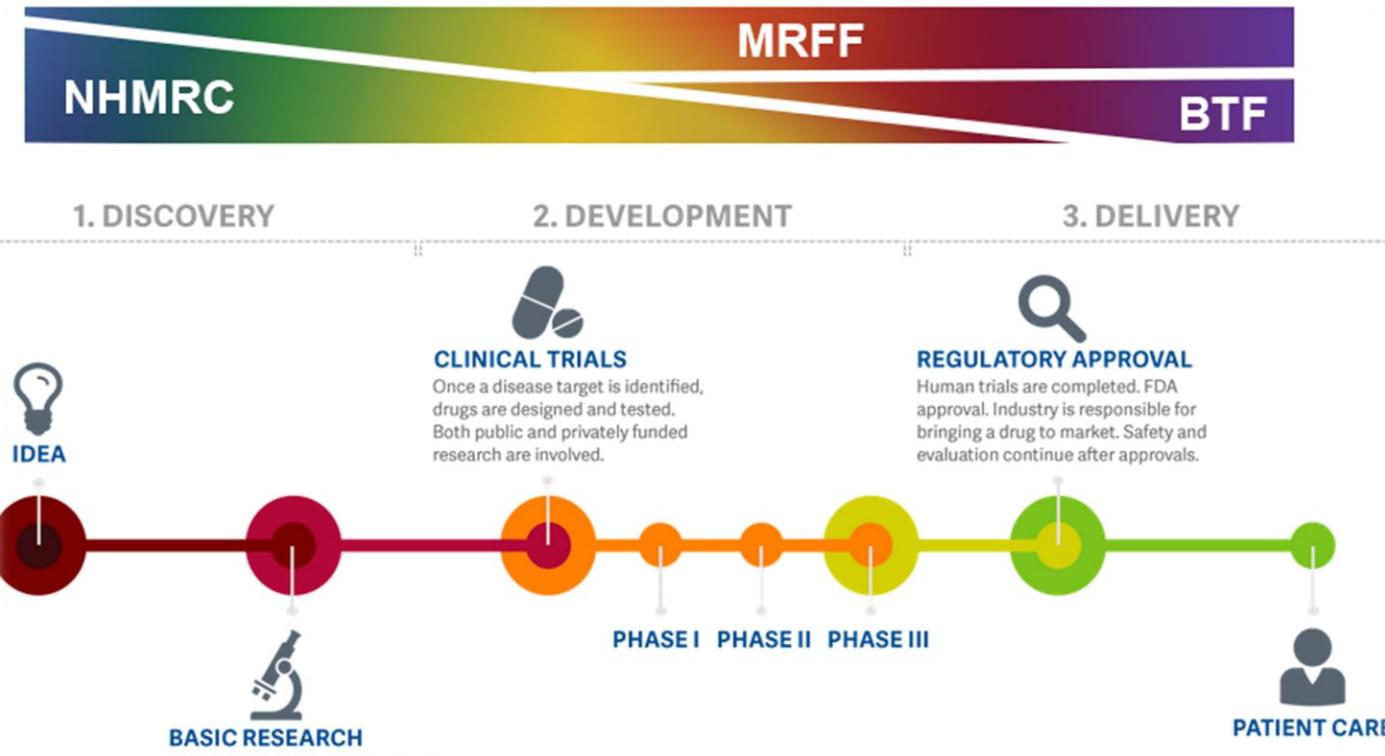
Medical Research Future Fund (MRFF)

Endowment fund – target \$20 billion 2021
www.health.gov.au/MRFF

Biomedical Translational Fund (BTF)

Equity co-investment venture capital program
\$250m Commonwealth; \$251.25m private sector

<https://www.business.gov.au/Assistance/Venture-Capital/Biomedical-Translation-Fund#key-documents>

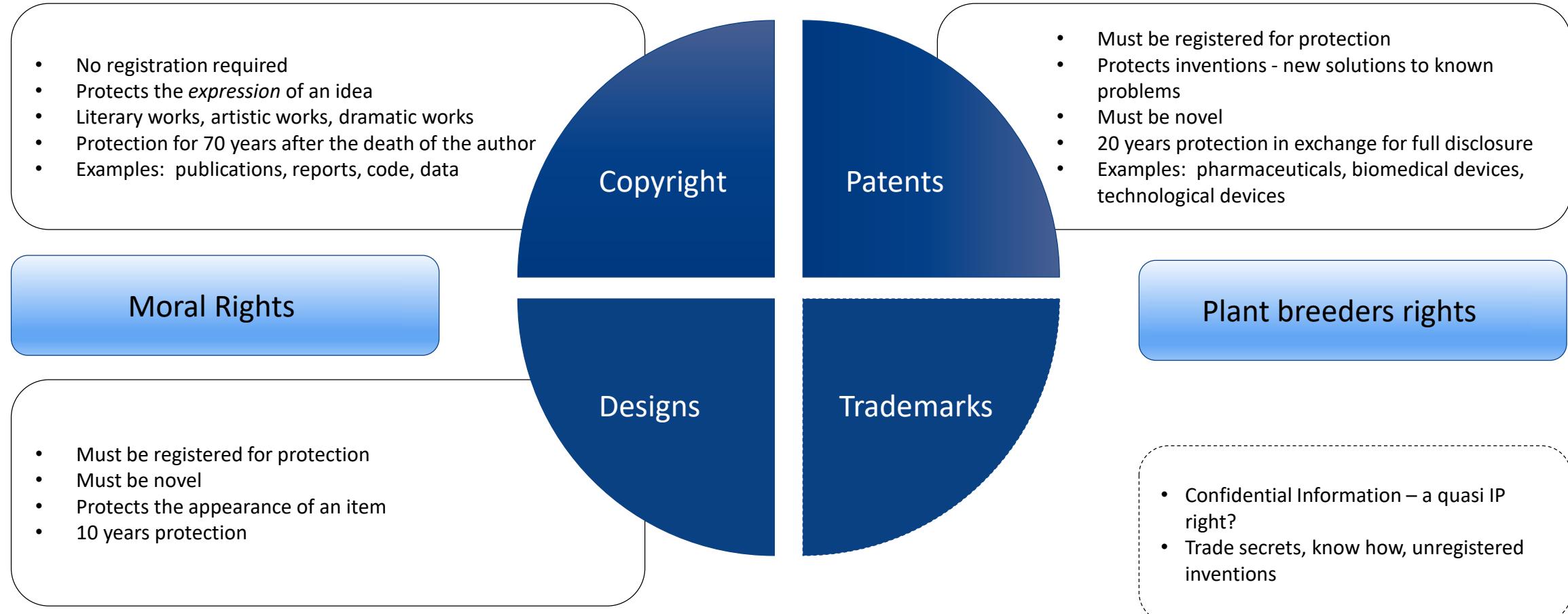




Repeat issues in research contracts



IP overview



IP issues

Background IP

- Do you own the Background IP? Is it available to be used for the project?
- Do you retain ownership of the Background IP? What is the scope of any Background IP licences?
- Are there warranties around Background IP?



Project IP

- How is the Project IP defined? Is it clear what will be captured?
- What sort of IP will come out of the project – e.g. a paper or an invention?
- Who will own the IP and who will have use rights? (almost always up for negotiation)
- Consider issues around joint ownership

IP issues: Joint ownership

Seemingly an “easy” solution and consistent with the “spirit” of collaboration... but...

- Means different things in different jurisdictions (e.g. US vs AU)
- Co-owners of copyright are not entitled to exercise their copyright, or authorise others to exercise copyright, without the consent of the other co-owners (for example, copyright in protocol, consent forms, results, databases and other study materials).
- Co-owners of patents can exploit the patent without the need to account to the other owners (for example, issue if only one owner has the capability)
- Impedes ability to use in further research without appropriate licences
- How is joint ownership determined? Equal / Agreed % / Based on contribution   
- Impedes commercialisation (e.g. by creating due diligence issues, industry partners wary of joint ownership because any use is contingent on co-owners’ consent)
- ...and many other issues (e.g. standing to enforce intellectual property rights i.e. copyright co-owner can litigate without the other co-owners)

May be appropriate in some circumstances (e.g. blue sky research building on work already in the public domain and where further publication is the only aim), but contract must be carefully drafted.

In all instances you should check with your institute’s research office.

IP issues (cont.)

Remember:

- IP is created in most of our activities
- It can be a powerful tool but also a powerful weapon (i.e. both an enabler and a disabler)
- It must be clearly dealt with in any research contract
- Consider what IP may be generated on a project-by-project basis and negotiate/draft accordingly
- IP ownership and access to a share in the benefits from commercialising the IP are not inextricably linked (i.e. can have a right to share in benefits without owning IP)



Publications and Confidentiality

Researchers need to be able to publish *promptly, independently and objectively*

Essentials to look for:

- Can the other party only object to a publication to protect IP or confidential information (and is there an appropriate time limit?)
- Deemed consent to publication
- No editorial input from sponsor
- Does one party need to be able to publish first?

Example Publications clause (CTRA, clause 11)

PUBLICATIONS

- 11.1 The Institution, Principal Investigator and other investigators (each a Discloser) involved in the Study have the **right to Publish the methods, results of, and conclusions from, the Study, subject to this clause and in accordance with copyright law.**
- 11.2 If the Study is a Multi-centre Study, then the Institution agrees that **no Publication of the Study results may be made until Publication of the results of the Multi-centre Study or 2 years after Study Completion, whichever is the sooner.**
- 11.3 The Institution must ensure that the Discloser gives a copy of any proposed Publication drafted by them and/or other Personnel involved in the conduct of the Study to the Sponsor **at least 40 days** before forwarding it to any person that is not bound by the confidentiality obligations set out in clause 9.
- 11.4 The Sponsor may, within that 40-day period do any one or more of the following:
- (1) provide comments on the **proposed Publication to the Institution, in which case the Institution must consider such comments but will not be bound to follow them;**
 - (2) request delay of Publication for **no more than 120 days** to allow the Sponsor to file patent applications or take other measures to preserve or secure its Intellectual Property, in which case the Institution must abide by that request; or
 - (3) request that the Discloser remove specified Confidential Information (other than the results of the Study) from the Publication, in which case the Institution must **remove such specified Confidential Information as is reasonably required to protect the Intellectual Property of the Sponsor.**
- 11.5 If the Institution has not received any comments from the Sponsor on the proposed Publication within 40 days of giving a copy to the Sponsor under clause 11.3, **the Discloser may proceed to make the Publication.**
- 11.6 Where the Sponsor intends to Publish the method, results or conclusions from the Study, any person **named as an author on that Publication will be given a reasonable opportunity to review the Publication.**



Restraints on academic freedom

Examples:

- Very broad conflict of interest clauses
- Restrictions on dealing with sponsor's competitors
- Restrictions on publication rights (e.g. "object for scientific reasons")
- Granting pipeline rights to improvements of Project IP or granting broad options
- Restrictions on the ability to funding from other sources
- Giving exclusive rights to IP without carving out a right back to conduct research
- Non-disparagement (e.g. restriction on remarks that may damage the reputation or goodwill of the funder/partner)
- Waiver of moral rights

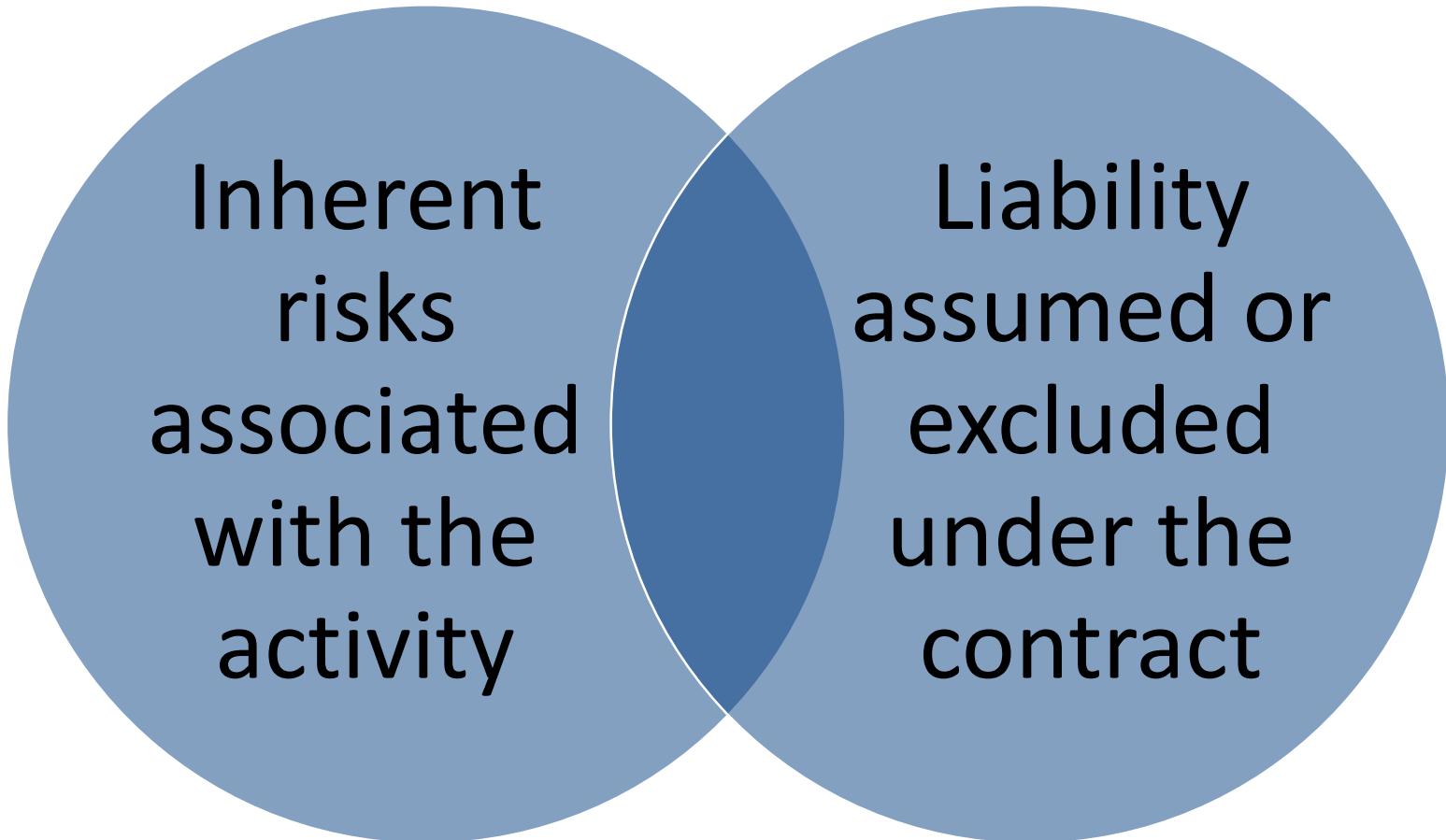


Students

- Students might own their own IP
- It is essential to protect a PhD student's rights in their thesis and their ability to have their thesis examined and published by placing a copy in the library (it could be put on restricted access for a time if it contains confidential information)
- If the project is terminated, the student still needs to be able to complete their assessments – will they require ongoing access to background IP or project IP?



Risk assessment





Ambiguity is the enemy...

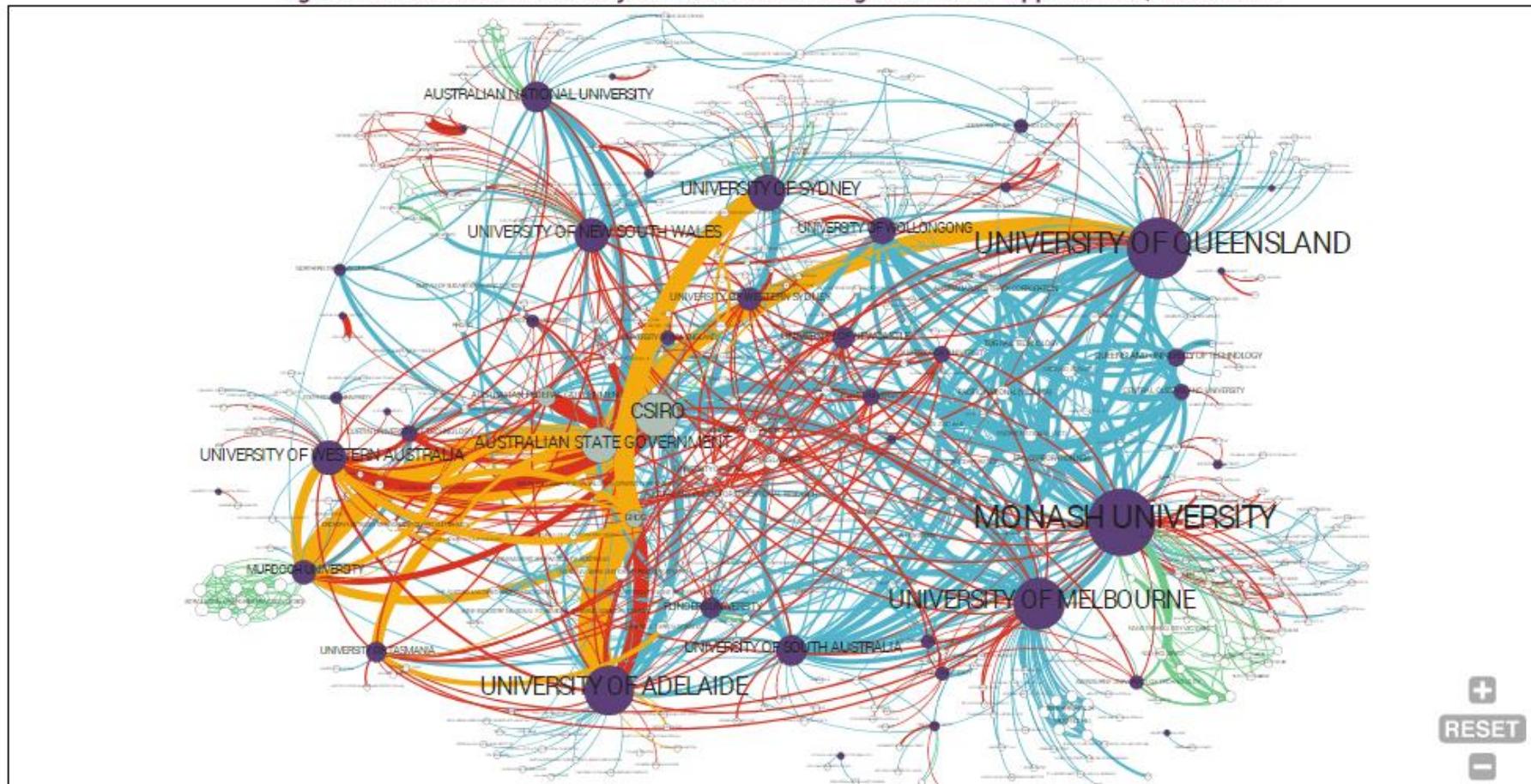
...Clarity is your friend.

Our interconnected world

In 2015, 18,076 research contracts were concluded by CSIRO, PFRA, Universities, and Medical Research Institutes.

- National Survey of Research Commercialisation, Department of Industry, Innovation and Science (<https://industry.gov.au/innovation/NSRC/Pages/default.aspx>)

Figure 13: Australian University Collaboration through co-filed IP applications, 2000-2015



From the *Australian Intellectual Property Report* 2017



THE UNIVERSITY OF
MELBOURNE

Thank you

