UNIVERSITY of TASMANIA

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REGULATION OF INNOVATIVE HEALTH TECHNOLOGIES – AN INTERACTIVE MAP PROJECT

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THE PROJECT

- *Reforming the Regulatory Environment for Innovative Health Technologies*
- Australian Research Council Discovery grant DP180101262, 2018-2023 $628,576
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‘INNOVATIVE’ HEALTH TECHNOLOGIES

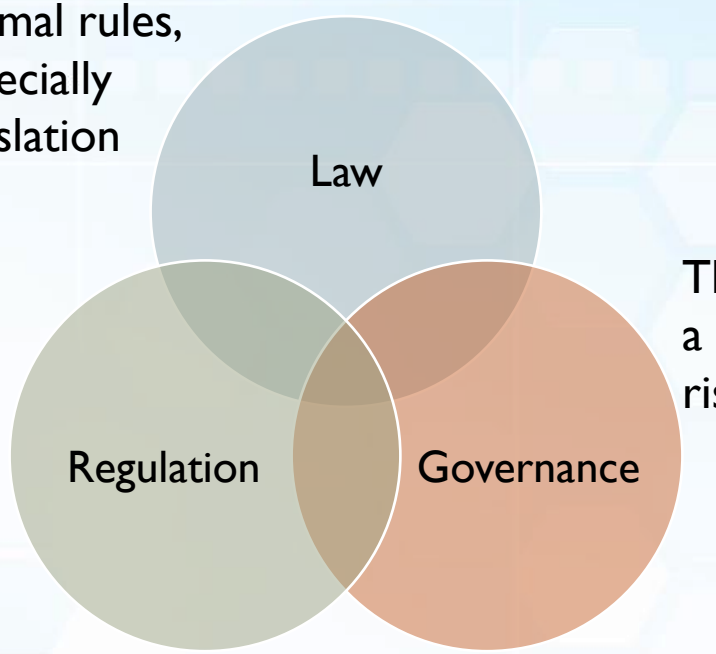
- Health technology: ‘the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives’ (WHO, 2007)
- ‘Innovative’ health technologies may be:
  - radically new, opening up new possibilities rather than simply being a variation/improvement
  - at an early, emergent or investigational stage of their life cycle, so their full range of applications may not yet be understood
- What are the implication for law, regulation, governance?

THE PACING PROBLEM

- 'Law, marching with medicine but in the rear and limping a little; (Windeyer J, Mount Isa Mines, 1970)
- Most new technologies are in fact governed by existing law, regulation and governance … at least to some extent
- What is so different about *innovative* health technologies? Is new regulation needed?

WHAT RULES APPLY?

Formal rules, especially legislation



The processes used to oversee a given activity, and to manage risk

The organised attempt to manage risks or behaviour in order to achieve a publicly stated set of objectives

PURPOSE OF REGULATION

- Regulation should intersect with research into, and development and use of innovative health technologies in ways that ensure:
  - the ethical conduct of researchers, manufacturers and health professionals developing the health technology
  - the safety of patients who use them and research participants who assist in their development
  - the appropriate use of resources both to fund research and development and to pay for technologies in healthcare
  - the appropriate use of incentives to encourage innovation where we need it most
  - appropriate recognition of the broader public interest

PROJECT AIMS AND METHODS

- Identify gaps and areas of congestion
- Investigate how health technology and regulation intersect and interact

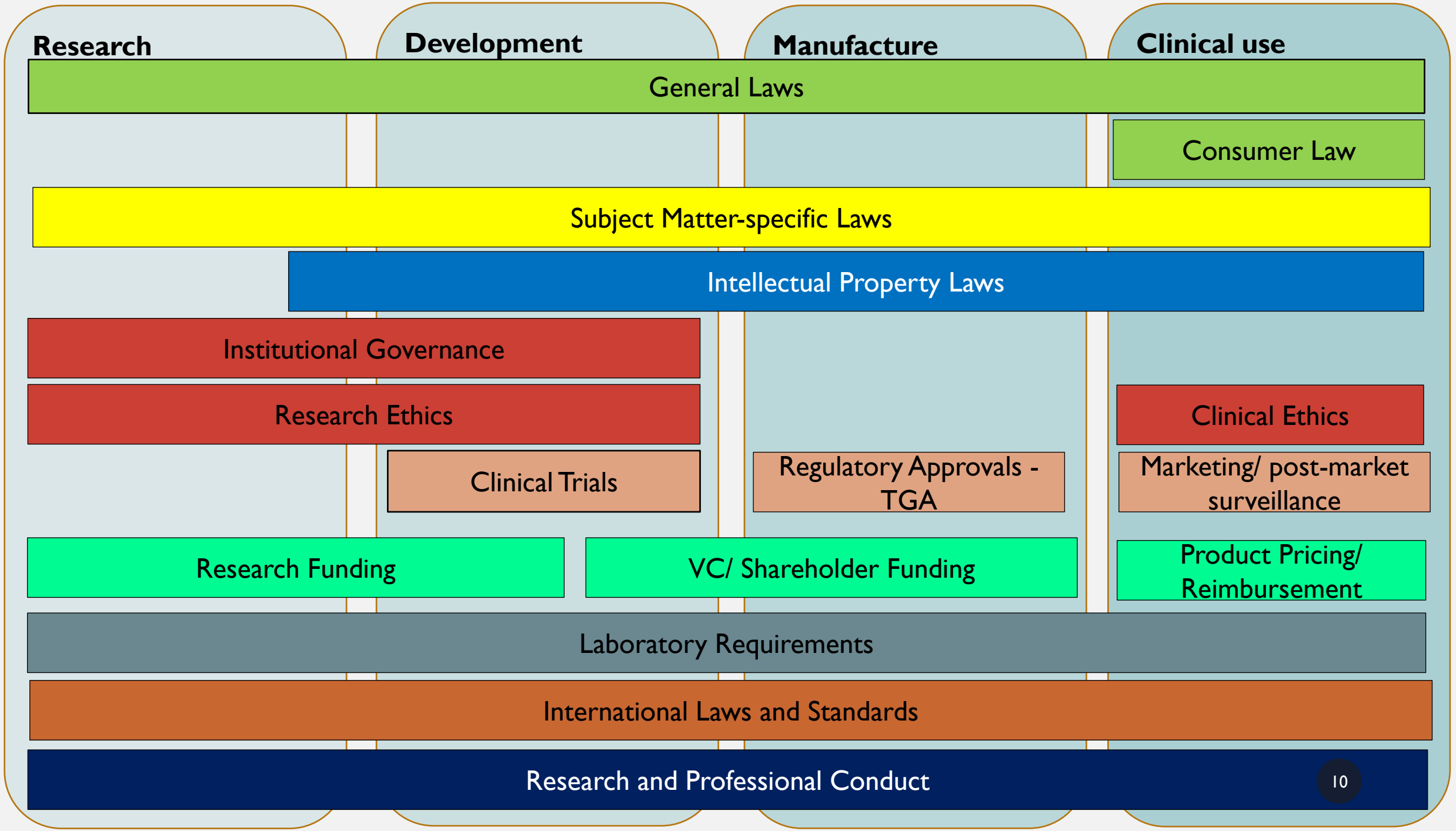
- Explore the technologies and the relevant regulatory encounters
  - Interviews with those involved in relevant areas of research
  - Desktop research
  - Mapping the regulatory environment
  - Analysis of the need for regulatory reform

MAPPING THE REGULATORY ENVIRONMENT

- Aim:
  - Mapping the different regulatory encounters in the development of innovative health technologies
  - Focusing on the four phases of research, development, manufacture and clinical use
- Case study approach:
  - 3D bioprinting, eg AxceldaPen
  - Genome editing, eg Casgevy
  - Diagnostic biomarkers, eg ProCan (proteomics of cancer)
  - Stem cells, eg iBlastoids

THE MAP – INNOVATIVE HEALTH TECHNOLOGIES - REGULATORY ENCOUNTERS FROM CONCEPT TO CLINIC

- Provides an overview of the different regulatory encounters likely to be faced by researchers, universities and research institutes, private sector organisations, hospitals and clinics, patients and research participants, and others involved in the innovative health technologies sector.
- Ranges from securing initial funding for a research project all the way through to protecting consumers from misleading advertising and defective products.


Research
Development
Manufacture
Clinical use
General Laws
Consumer Law
Subject Matter-specific Laws
Intellectual Property Laws
Institutional Governance
Research Ethics
Clinical Ethics
Clinical Trials
Regulatory Approvals - TGA
Marketing/ post-market surveillance
Research Funding
VC/ Shareholder Funding
Product Pricing/ Reimbursement
Laboratory Requirements
International Laws and Standards
Research and Professional Conduct

EXPLORE BY TECHNOLOGY

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THIS ARTICLE RELATES TO

Overview of Intellectual Property Laws

There are a number of distinct forms of intellectual property, each of which provides the owner of the subject matter to which the intellectual property attaches with certain rights to decide what can and cannot be done with that subject matter.

The generally accepted justification for the existence of intellectual property is to encourage creativity and innovation. As with other forms of property, an owner of an item of intellectual property has a set of legally enforceable rights, including the right to use and enjoy that item of property and the right to exclude others from using and enjoying it, in the absence of any agreement or other legal obligation to the contrary. In this way, owners of intellectual property rights can exercise significant levels of regulatory control over particular areas of technology, in that they can decide who can enter these areas and what they can do.

Intellectual property laws do generally include some restrictions on the exercise of intellectual property rights. These restrictions may either be imposed ex ante (before grant), by limiting the rights that are granted, or ex post (after grant) by limiting what can be done in the exercise of those rights. Other regulatory instruments may impose further restrictions. One example is that funding bodies often contractually require open access to research data. Another example is that drugs can only be made available to the public if they have satisfied the stringent regulatory

THIS ARTICLE RELATES TO

RESEARCH

Regulation of the Creation and Use of Human Embryos

Historical Context

The birth of Dolly the sheep in 1996 led to extensive debates about the future possibility of human reproductive cloning. In parallel with developments in cloning technology, embryonic stem cell technology (ESC technology) was advancing at a rapid pace. Though not uncontroversial because of the concerns it raised about the destruction of human embryos, ESC technology was recognised as offering significant potential therapeutic benefits. Four years after the birth of Dolly, the Australian Health Ministers came together and agreed to develop a national regulatory framework.

The *Prohibition of Human Cloning Act 2002* (Cth) and *Research involving Human Embryos Act 2002* (Cth)

By early 2002, the *Research Involving Embryos and Prohibition of Human Cloning Bill* was introduced into federal Parliament, with agreement that the States and Territories would enact mirror legislation to ensure national uniformity. Later in the year, the Bill was split into the *Research involving Human Embryos Bill* (the *Embryo Research Bill*) and the *Prohibition of*

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Low Risk Dealings. Most research undertaken in universities and research institutes would fall within the category of notifiable low risk dealings.

Genome Editing

A technical review of the *Gene Technology Regulations 2001*, which underpin the GTAct, was undertaken in 2017-2018 to determine how genome editing fitted into the gene technology scheme. The purpose of the review was to open up for public consultation a set of four options for regulating organisms created using genome editing and other new technologies. The review focused particularly on two genome editing techniques, oligo-directed mutagenesis (ODM) and site-directed nuclease (SDN) techniques. ODM makes small changes to the genome using a single strand of synthetically produced DNA. SDN techniques include familiar genome editing tools such as zinc finger nucleases, TALENS and CRISPR-Cas9. The central feature is a site specific cleavage using a nuclease and triggered repair of the cleaved site.

SDN techniques can be further subdivided into three categories based on whether any foreign DNA is introduced with the CRISPR construct, and the nature of the method of repair. SDN-1 is said to involve non-homologous end joining (NHEJ) whereas SDN-2 is said to involve homologous recombination (HR). SDN-3 can involve either NHEJ or HR.[19] For SDN-1, no foreign DNA is inserted and the site-directed breaks in the DNA molecule are triggered to repair naturally. The mutations that occur are short deletions or insertions (indels) of a small number of bases resulting from error-prone gene repair mechanisms of the cell. For SDN-2, a template is used to guide the repair, with a small number of foreign nucleotides being introduced. This technique is much more precise than SDN-1. SDN-3 also uses a template but involves the insertion of larger numbers of nucleotides, for example, whole genes.

The options presented in the review of the Regulations ranged from making no changes, through to regulating certain specifically identified technologies, to regulating technologies based on the process used and finally, to excluding certain technologies based on outcome (for example, where

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Application to Emerging Medical Technologies

The four technologies identified in this project as paradigm innovative health technologies all raise particular issues for the therapeutic goods regulatory regime.

Bioprinting

Bioprinting refers to the used of 3-dimensional printing techniques to create either personalised medical devices or complex biomaterial (such as skin tissue, bone matrices, or blood vessels).

Personalised Medical Devices

While technically outside the scope of 'bioprinting', 3D printers can create personalised medical devices described as 'patient-matched medical device[s]' in the dictionary in the *Therapeutic Goods (Medical Devices) Regulations 2002* (TG(MD)Regs). Such devices are required to be approved by the Therapeutic Goods Administration (TGA) and included in The Australian Register of Therapeutic Goods (ARTG) unless less than five devices are supplied per year. In that case, there is no need to include the device on the Register but all requirements for medical devices must be met.

It should be noted that the TG(MD)Regs also identify a 'custom-made medical device' which is distinct from a patient-matched one. A custom-made medical device must meet specific criteria for the device to be exempt from inclusion in the ARTG (but must still meet various therapeutic goods requirements, such as those applying to manufacturers).

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CLINICAL USE

National Association of Testing Authorities

The National Association of Testing Authorities (NATA) is recognised by the Commonwealth government as the sole national accreditation body for establishing competent laboratory practice. NATA accreditation provides an assurance of the competence, impartiality and integrity of facilities.

NATA is an independent, not-for-profit private company, owned by its members – over 2800 laboratories and facilities.

NATA receives a large majority of its funding (in 2024 approximately 85% of its total revenue) from fees paid by facilities it accredits. It also receives funding from the Australian Government for approved purposes deemed to be in the national interest. The Australian Government is formally represented on its Council and holds positions on its Board.

The Australian State and Territory governments are significant users of NATA accredited laboratories. These governments mandate the use of NATA accredited laboratories undertaking certain tests and calibrations, such as pathology services, and parentage testing in the judicial process, through a range of legislation and regulation.

OUR WORK ON WHETHER REGULATORY REFORM NEEDED

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- Nielsen et al, 'The Australian "Valley of Death"? Australian Research and Patenting Practices in Bioprinting and Genome Editing' in Estelle Derclaye (ed), Research Handbook on Empirical Studies in IP Law (Edward Elgar; 2023), Chapter 3, pp47-73
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REFLECTIONS ON THE MAPPING EXERCISE

- What learnings are there from the mapping exercise?
- What is the best dissemination strategy?
- How do we measure impact and utility?