Research Ethics & Compliance

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Legislation:

- Prevention of Cruelty to Animals Act 1986
- NHMRC Act 1992
- ARC Act 2001
- Prohibition of Human Cloning Act 2002
- Research Involving Human Embryo Act 2002
- Gene Technology Act 2000
- Quarantine Act 1908
- National Health Security Act 2007
- Privacy Act 2000
Codes of Practice

• NHMRC & ARC
  – Australian Code for the Responsible Conduct of Research
  – Australian Code of Practice for the Care and Use of Animals for Scientific Purpose
  – The National Statement on Ethical Conduct in Human Research
  – Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research

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Review Processes

• Monash University Human Research Ethics Committee

• Animal Ethics Committees (10 x local)

• Monash University Institutional Biosafety Committee
What is Human Research?

- Taking part in surveys, interviews or focus groups
- Undergoing psychological, physiological or medical testing or treatment
- Being observed by researchers
- Researchers having access to personal documents or other materials
- Collecting organs, tissues, fluids or exhaled breath
- Access to information (individually identifiable, re-identifiable or non-identifiable) as part of an existing published or unpublished source or database
Risk and Benefit

• benefits justify the risks

• level of ethical review should reflect the level of risk
Consent

• Participation is voluntary

• Consent must be informed
  – Sufficient information to understand the purpose, demands, risks and potential benefits.
Animal Ethics Review:

• All Monash scientific activities (teaching or research) using animals requires approval from a Monash AEC before work can commence.
Animal Welfare General Principles:

- Justification
- Responsibilities
- Replacement
- Reduction
- Refinement
Applications:

• Applications are made to local AEC
• Must be reviewed by full committee in “face to face” meeting.
• Application usually require amendments
• Often approved once amendments are received by secretary and reviewed by chair.
Gene Technology (GT) Act, 2000

- Introduces a national scheme for the regulation of GMOs in Australia

- Protect the health and safety of Australians and the environment

- Identify and manage the risks posed by or as a result of gene technology
Requirements of the GT Act

• Organisations undertaking dealings are “Accredited”
• Dealings are classified based on their level of risk
  – Exempt
  – Notifiable Low Risk Dealings
  – Licensed (non-intentional release & intentional release)
• Facilities for certain “Dealings” are “Certified”
Funding Bodies

- **Requirement of clearances**
  - Funds aren’t released until clearance approvals have been sited.

- **Code for the Responsible Conduct of Research**
  - “Compliance with the code is a prerequisite for the receipt of NHMRC and ARC funding”
What you need to know.

That……

- Approvals for your work are in place
- You names are added to any existing or new approvals
- Be familiar with the content of the approved application
- Be familiar with any conditions of approval…..and comply with them