New Policies for Research Governance at Melbourne

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The research governance framework project for research integrity, ethics and safety

What does the University want to say? What can or should we say?

Principles-based policy frameworks for...
  - Various aspects of responsible conduct e.g. authorship
  - Human research ethics
  - Animal welfare and ethics
  - Gene technology, biosafety and biosecurity

Key elements of each framework
  - Creation of the Melbourne standards

Consultation is open!
The research governance framework project for research integrity, ethics and safety
Research @ Melbourne strategy
University Research Strategy

- **Research @ Melbourne Strategy**
  - Two years analysis and consultation
  - Vision statement – ‘*increase excellence and impact of our research*’
  - Narrative around three Grand Challenges
  - Focus on People and Collaborations
  - Money for researchers and to enable collaboration
The Grand Challenges philosophy does not imply the abandonment of deep, discipline-based scholarship at the highest level. Rather, the philosophy assumes that all our researchers should have the opportunity to engage in a whole-of-University research endeavour, drawing on their discipline-specific research to meet a wider agenda.
Research @ Melbourne strategy

Investment, implementation and a response

**Settings**
- Enabling research
- *Currently affected by BiP*

**Collaboration**
- Embedding the Grand Challenges

**People**
- Continuing appointments
- Career development

Shortly following approval an extra $50M was provided to kickstart the strategy via recruitment
A principle of the strategy is that ‘research is conducted to the highest ethical standards with integrity and openness. This value is embedded in every aspect of our work including our choice of research partners and collaborators.’

Commitment to research excellence and impact – a response:
Research ethics and integrity makes research excellent and trustworthy. Research ethics and integrity ensures impact.
### 4 key areas of response by OREI

<table>
<thead>
<tr>
<th>(i) Clarifying expectations</th>
<th>(ii) Building cultures</th>
<th>(iii) Providing support</th>
<th>(iv) Gathering evidence</th>
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<tbody>
<tr>
<td>RGFP</td>
<td>EIDG</td>
<td>TwOREI</td>
<td>RICS</td>
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<td>training and education</td>
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<td>RIAs</td>
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- **RGFP**: RGFP
- **EIDG**: EIDG
- **TwOREI**: TwOREI
- **RICS**: RICS
- **RIAs**: RIAs
- **training and education**: TwOREI
current University Code of Conduct for Research is rule based
  - does not encourage reflection or discussion
  - does not adequately allow for recognition of disciplinary differences
principles based codes are better suited for concepts that require some consideration prior to implementation by individuals
...the why versus how
over 2013, we are reviewing the University’s Code and shifting related policies from rules to principles-based
broad consultation and engagement with the Academy
authorship framework already complete
RGFP plans

• RGFP will review the University Code of Conduct for Research and produce new policy frameworks for authorship, research data management, conflict of interest, supervision of research trainees, peer review, publication and communication, collaborations, research misconduct, human ethics, animal ethics, gene technology and biosafety...

• all will shift to a principles + responsibilities model

• fundamental to enhancing a culture of research integrity at the University
Clear expectations
Research governance

Principles-based
- Responsibility
- Education and dialogue
- Rationale, Good practice

Rules-based
- Conformity
- Punitive action
- Clearly enforceable

Principles where possible, rules where necessary.
Sources of expectations

- **Legislation**
  - Enterprise Bargaining Agreement (Federal)
  - Gene Technology Act 2000 (Federal)
  - Autonomous Sanctions Act and Regulations 2011 (Federal)
  - Prevention of the cruelty to animals Act and Regulations (State)

- **Agreements**
  - Funding agreement between funding bodies and institutions

- **Approvals and Certifications**
  - Committee approval (Animal, Human, IBC)

- **Codes, Policies, Procedures and other Frameworks**
  - Australian Code for the Responsible Conduct of Research
  - Australian code of practice for the care and use of animals for scientific purposes
  - National Statement on Ethical Conduct in Human Research
  - Institution policies

- **Unwritten expectations**
  - Research culture: small and large communities, discipline conventions, reputations matter
• Code of conduct for research – overarching, highest level

• Research integrity
  – Authorship policy framework
    • Policy > Two Procedures > Many Guidelines
  – Others include publication and communication, peer review...

• Research ethics
  – Human research ethics policy framework
  – Animal welfare and ethics policy framework

• Research safety
  – Gene technology, biosafety and biosecurity policy framework
Research integrity – the responsible conduct of research
• What are the hallmarks of research that can be trusted and has been conducted responsibly?

• There are international, regional, national and institutional codes of conduct that attempt to capture these principles.

• There are two that are worth looking at a little more closely
  – The Singapore Statement (singaporestatement.org)
Singapore Statement

- Developed at the 2\textsuperscript{nd} World Conference on Research Integrity.
- Aims to capture the principles (4) and responsibilities (14) that are common to all research, irrespective of jurisdiction or geography.
- Four principles:
  - \textbf{Honesty} in all aspects of research.
  - \textbf{Accountability} in the conduct of research.
  - \textbf{Professional courtesy and fairness} in working with others.
  - \textbf{Good stewardship of research} on behalf of others.
Australian Code for the Responsible Conduct of Research

- Released in 2007.
- Developed by the NHMRC, ARC and Universities Australia.
- Compliance with requirements is a condition of receiving funding from NHMRC and ARC.
- Two Parts
  - Part A provides general advice to institutions and researchers about the responsible conduct of research.
  - Part B provides a framework for handling allegations of research misconduct.
<table>
<thead>
<tr>
<th>Principle</th>
<th>Practice</th>
<th>Why?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data and records</td>
<td>Maintained, retrievable, safe, owned</td>
<td>Gold, reuse and sharing, insurance</td>
</tr>
<tr>
<td>Supervision of research trainees</td>
<td>Induct, provide appropriate environment</td>
<td>The future of research, vulnerable</td>
</tr>
<tr>
<td>Publication and communication</td>
<td>Be accurate, honest</td>
<td>Trust, credit</td>
</tr>
<tr>
<td>Authorship</td>
<td>Must meet requirements, record agreement</td>
<td>Credit, accountability</td>
</tr>
<tr>
<td>Peer Review</td>
<td>Fair, impartial, confidential, participate</td>
<td>Contribution to research, trust</td>
</tr>
<tr>
<td>Conflicts of interest</td>
<td>Disclose and manage, transparency</td>
<td>Trust</td>
</tr>
<tr>
<td>Collaborations</td>
<td>Have agreements in place</td>
<td>Prevent disputes, clarify responsibilities</td>
</tr>
<tr>
<td>Research misconduct</td>
<td>Have processes in place and respond to allegations</td>
<td>Transparency, trust</td>
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Authorship: An important beginning for research integrity policies
Authorship is a complex ecosystem
• Authorship
  – New principles-based policy go.unimelb.edu.au/2asn
  – Honesty, fairness, consistency, transparency and generosity within requirements
  – Significant intellectual or scholarly contribution and accountability
  – Talk early and often
  – Agree on authorship
  – Describe contributions
Other frameworks in development

• Conflict of interest in research

• Peer review
  – Fair, rigorous and impartial review of merit and integrity that generates trust.

• Publication and communication
  – Honesty and accuracy. Openness after considering restrictions. Open access.

• Research misconduct
  – Procedural fairness, public trust, being a good employer/institution.
Research ethics – similarities and differences
Research ethics – similarities and differences
Research ethics governance

• Externally influenced by regulators and funding bodies

• Focus on compliance – funders asked for ethics approval numbers before money would be released (a sure way to direct attention!)

• “It is University policy that ethics approvals are required...’ but we couldn’t find the policy

• Opportunity to refocus attention on the benefits of doing ethical and quality research through the framing of the policies
General structures

- Principles
- Responsibilities
- Mechanisms for review – committee structures
- Standards
- Authorities
1.1 The University is committed to the ethical conduct of human research.

1.2 The University considers that in order to be considered ethical, human research must meet the following principles:

- respect for the rights, interests and welfare of the participants in human research;
- beneficence through minimising risk of harm or burden to research participants and enhancing potential benefits of research;
- justice in the distribution of benefits and burdens of research; and
- research merit and integrity.
• 1.1 The University is committed to the ethical conduct of research or teaching activity that involves the use of animals. The University will only use animals in research and teaching activity where there is need for their use, and the research activity or teaching activity has merit, integrity and justifiable benefit.

• 1.2 The University is committed to minimising the impact on the welfare of animals used in research and teaching whose lives and wellbeing are dependent on us as a result of our pursuit of knowledge and learning.
1.3 In the use of animals in research and teaching, the University is committed to the principles of:

- Replacing the use of animals with alternatives wherever possible;
- Reducing the number of animals used without jeopardising the statistical validity of research results or teaching objectives and without placing an excessive cumulative burden on individual animals;
- Refining research and teaching practice and facilities in order to minimise adverse impact on animals.

1.4 The University is committed to continuously improving the standards it sets for the welfare and use of animals in research or teaching activity.

1.5 The University is committed to educating researchers and teachers with respect to advancements in animal welfare, care and use standards.
• **Principle**
  
  – The University seeks to protect the health and safety of people, animals and the environment by identifying and managing risks posed by work with RBMs.
<table>
<thead>
<tr>
<th>Human</th>
<th>Animal</th>
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<tbody>
<tr>
<td>Chairperson</td>
<td>Chairperson</td>
</tr>
<tr>
<td>Two lay people</td>
<td>Lay person</td>
</tr>
<tr>
<td>Professional carer of people (e.g. nurse)</td>
<td>Veterinary scientist</td>
</tr>
<tr>
<td>Pastoral care (e.g. minister)</td>
<td>Animal welfare advocate</td>
</tr>
<tr>
<td>Lawyer</td>
<td>Researcher</td>
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</table>
• At a high level, the aim of these policies and more importantly these decision making processes is to ensure that the potential benefits of the research outweigh the risks to participants, animals, the environment and researchers themselves.

• This is true for
  – Studies of children in classrooms
  – Behavioral studies of koalas in their natural habitat
  – Work with Salmonella to understand how it causes disease
• Generating principles based policy is the right way to go

• Creates a gap in the provision of practical advice on how to *translate* principles into practice

• Gap also in a shared understanding of what good or best practice is...clear expectations?

• Robust way of capturing and describing what is best practice

• Consideration of ethical conundrums in research practice occurs at various levels and places.

• A systematic and fair way of considering and communicating best practice

• Take the place of guidelines in the MPF
The Melbourne Standards will...

- Provide a robust and open mechanism for capturing and describing what is best practice
- Allow a mechanism for sharing of current approaches (happens in isolation in some instances)
- Be flexible to allow for required variations in best practice, which is contextual (it will be different in each research group)
- Be a best practice ‘best practice management’ tool that requires participation from the research community, rather than imposing requirements without justification or consultation
Making a standard

• Need for a standard identified (by anyone)
• Proposal sent to relevant committee
• Draft developed – evidence based, normative and informative...
• Four week consultation period
• Approval by relevant committee
• Publication with implementation advice (i.e., when it should be a requirement)
• Review/removal as required
Melbourne Standard for Vegemite Toast

- Normative
  - White bread, butter, 3-4 grams of vegemite
  - Toast until dark brown
  - Spread to the edges with teaspoon of butter then evenly distribute vegemite
  - Ingest
Melbourne Standard for Vegemite Toast

• Informative
  – Gluten-free bread, nuttelex are appropriate substitutes
  – Marmite and other yeast-based spreads are not acceptable*
  – Toast may not be required to be dark brown if the preference would result in a failure to be eaten
  – More than 5 grams of vegemite is likely to result in harm and special consideration will be required from the committee

*This statement is provided for edutainment purposes only. The University does not endorse one yeast concentrate over another
Overall aim

- To ensure that the justification for ethics and regulatory approvals is clearly stated and understood by researchers
- This should help with engagement with the systems, focusing all parts of each system on the things that matter, and providing clear expectations
- The Melbourne Standards are key to improving many aspects of ethics and integrity. They will take some work but will provide a very useful mechanism for helping to raise the bar on both research practice, committee review of applications, and clarity about expectations.
Consultation will open soon. Stay tuned for further details. Make comments.
Thanks (and questions)