Research risks…

• are strategic and operational
• arise from funders’ requirements, regulatory agencies, codes of practice or conduct, and internal policies and procedures (plus any other law)
• have financial, legal and reputational consequences
• research is risky
Some examples

• **strategic** – failure of marketing strategy to attract the best graduate researchers; failure to maintain national and international rankings

• **operational** – inattention to requirements for facilities for work with biological hazards

• **financial** – inappropriate use of grant funds

• **legal** – use of animals for research without approvals

• **reputational** – research misconduct

• **personal** – failure to submit progress reports
Deputy Vice-Chancellor (Research)  
Prof. Jim McCluskey

Pro Vice-Chancellor (Research Collaboration)  
Prof. Liz Sonenberg  
0.5fte

Pro Vice-Chancellor (Research Partnerships)  
Prof. Mark Hargreaves  
0.5fte

Pro Vice-Chancellor (Research)  
Prof. Lyn Yates  
0.5fte

Executive Director, Research  
Dr David Cookson

Pro Vice-Chancellor (Graduate Research)  
Prof. Dick Strugnell  
0.8fte

Office for Research Ethics and Integrity

Melbourne Research Office

Melbourne School of Graduate Research

Research Infrastructure Project Office

e-Research

VLSCI

• University research institutes  
• Research infrastructure  
• IBM

• Relationships with external partners  
• MRIs

• ERA  
• Faculty relationships and performance  
• Research integrity  
• Research ethics administration  
• Gene technology and biosafety

• Research policy and administration  
• Research marketing and communication  
• Research systems  
• Research analytics  
• Animal welfare

• Research training  
• RHD scholarship policy  
• RHD recruitment
Office for Research Ethics and Integrity

Human Research Ethics

Animal Ethics

Gene Technology, Biosafety and Biosecurity

Research Integrity

Animal Welfare

Applications and Committees

Reporting and Auditing

Policy

Education and Training

Education and Training

Policy

Oversight of Misconduct Investigations

Director
Dr Paul Taylor
What are research ethics and research integrity?
Expectations of the General Public

Rules and Regulations

Expectations of the Research Community

YOU ARE HERE
Ethics or integrity

• research ethics
  – making sure that no unreasonable harm is done to humans, animals or the environment as a result of research
  – benefit should outweigh the risks

• research integrity
  – principles that describe how research should be conducted
  – translation of the principles of personal integrity into research context
Shifting sands and changing resolution

- rules are always being updated – e.g. new GT Regs on Sept 1 2011, new Code of Practice for animals under review…
- tend towards increasing complexity rather than simplification
- audit tools more sophisticated and examining arrangement across the organisation
Closer look – Office of the Gene Technology Regulator

- governs all work with genetically modified organisms and the facilities that are used for this work
- ‘fully’ legislated (GT Act, GT Regs) and monitored by the OGTR
- at UM – approx 450 projects, 160 certified facilities
- penalties for failure to comply
  - suspension of project/certification
  - loss of accreditation (all work with GMOs stops)
  - jail time and fines (up to $1.1M per day) for the organisation and individuals
Closer look – OGTR audit tool

• 24 pages, 126 questions like this...

12. Do your polices and procedures set out management and staff roles and responsibilities in relation to GT Act compliance? Can you show us examples of this in your arrangements (per above)? Is this done some other way? If so, may we have a copy? How are changes to the personnel in the roles detected with consequential informing/instructing inducted personnel in these responsibilities? (IBC membership, partner’s personnel, contractors, persons named in licences, managers, organisational regulatory coordinators)

• well beyond the scope of the traditional role for gene tech officers and committees

• similar activity in other regulatory areas (e.g. NHMRC and ACRCR)
## Principles of research integrity

<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 dissemination</td>
<td>‘Responsible’; one data set = one publication;</td>
<td>track record; performance</td>
</tr>
<tr>
<td>Authorship</td>
<td>Must have met requirements; keep record of agreement</td>
<td>track record; recognition; performance</td>
</tr>
<tr>
<td>Peer Review</td>
<td>Participate ‘responsibly’</td>
<td>contribution to research</td>
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<tr>
<td>Conflict of Interest</td>
<td>Disclose and manage where appropriate</td>
<td>transparency and trust</td>
</tr>
<tr>
<td>Collaborations across institutions</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 and trust</td>
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These are extreme examples, but they demonstrate how the ‘basics’ of research, when ignored, can have serious consequences for all involved.
Is there a role for Internal Audit in supporting research risk management?
YES!

- there is a role for IA in supporting the management of research risks
- role same as that for supporting the management of other risks encountered in a University
  - helping to ensure whole-of-organisation awareness
  - coordinating a response across an organisation
  - provision of advice
Thanks
(and any questions?)