



Keeping Track of Human Research Projects

Dr Ted Rohr
Manager, Research Compliance

<http://www.latrobe.edu.au/research-services/>



Definitions:

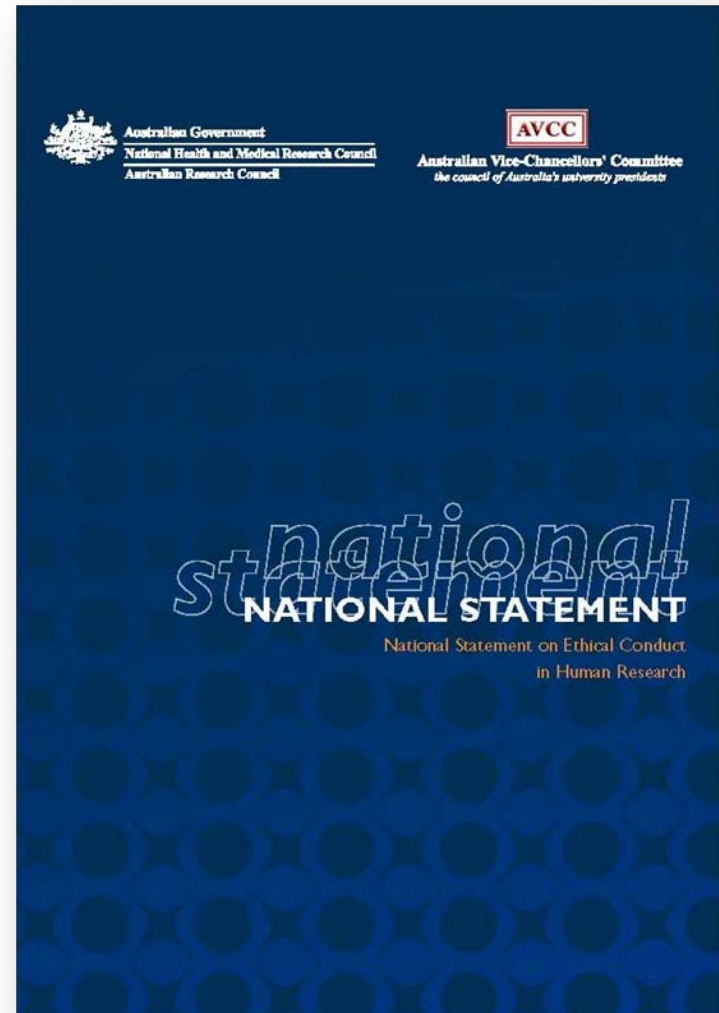
- ‘Keeping Track’ includes
 - Monitoring: routine for all projects on a regular basis
 - Auditing: randomly for set percentage + at time of suspicion
- Ethics processes only, not governance in general (finance, audit, personnel etc.)
- Overall purpose: risk management
- Embedded within the Institutional Framework





National Statement:

- ‘Monitoring’: ensuring that research conforms to the approved proposal
- ‘...all of its approved research is monitored’
- Degree and frequency determined by degree of risk to research participant



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National Statement (cont.):

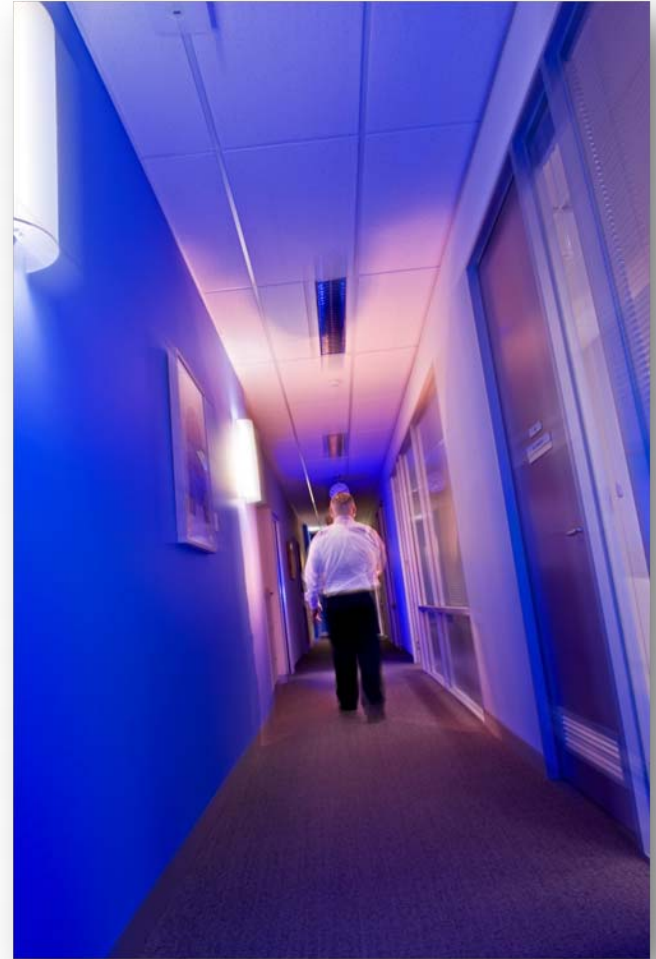
- Responsibilities for ‘Monitoring’:
 - Institutions (and research sponsors): via research governance procedures
 - HRECs: via working procedures
 - Researchers: via on-ground role





National Statement (cont.):

- Mechanisms for ‘Monitoring’:
 - Reports from researchers
 - Reports from independent agencies
 - Review of adverse event reports
 - Random inspections
 - Interviews with participants



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Questionnaire:

- Survey of Active Project Review Methods currently used in AUS
- Sent to ARMS Ethics and Research Integrity SIG members

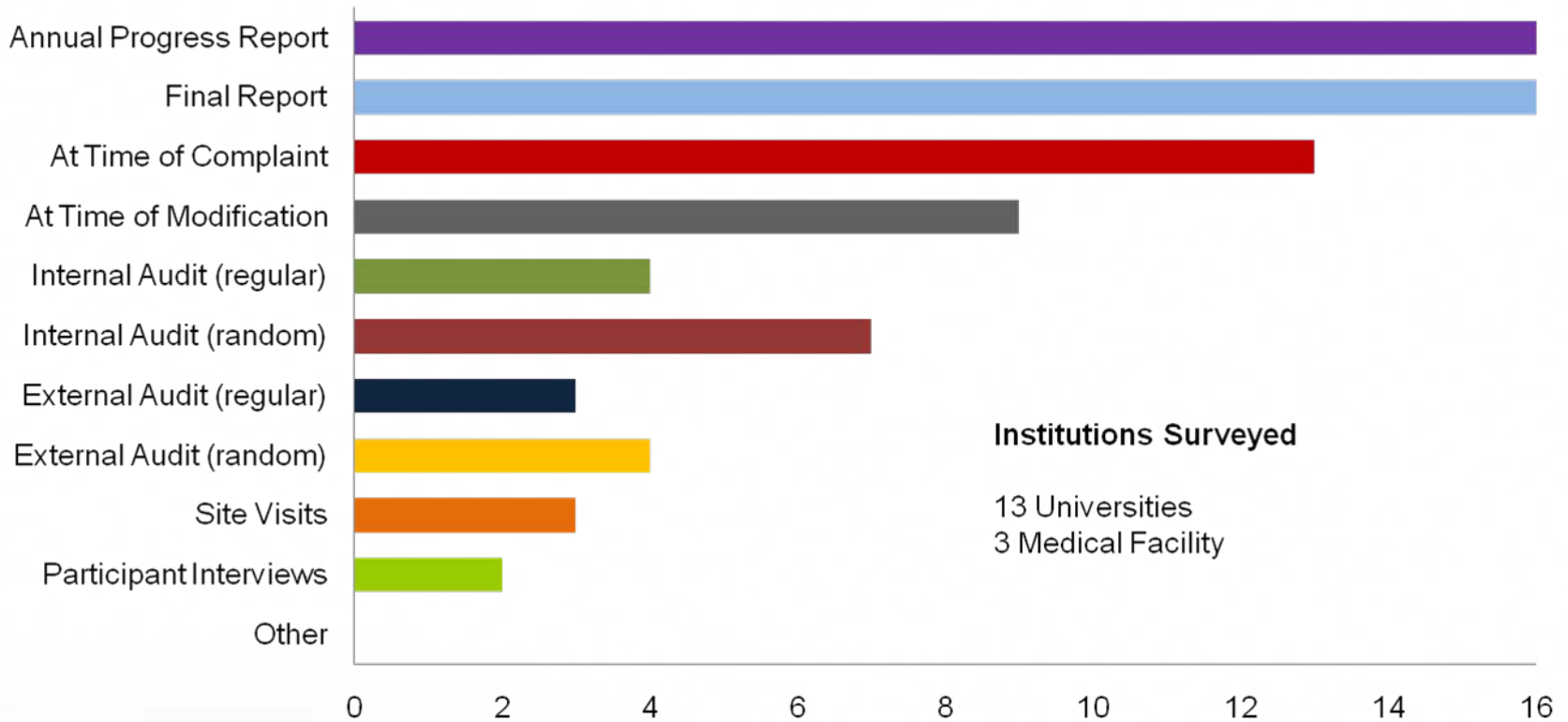
Active Project Review Methods

Review Method	In Place (yes/no)	Comments
Annual progress report		
Final report		
Internal audit (regular)		
Internal audit (random)		
External audit (regular)		
External audit (random)		
Site visits		
Participant interviews		
At time of Complaint		
At time of Modification		
Others:		



Survey Results:

Active Project Review Methods





Current Developments in Australia:

- NHMRC HoMER initiative
- State support for multi-centre ethical review
- Governance and monitoring take on increasing importance





Developments in North America:

- Research governance frameworks are strategic investments for institution
- Audit processes well-defined at US universities and medical institutes
- OHRP monitors US-sponsored research overseas
- Canada: monitoring should be considered as a preventative strategy





Other Developments Overseas:

- Second World Congress on Research Integrity held in Singapore
- Increasing ties with Universities and Institutions in Africa and Asia
- ESF developed the ‘European Code of Conduct for Research Integrity’
 - Abuse of research subjects [*sic*] defined as research misconduct





Challenges in the Near Future:

- Assigning the role of monitoring
- Keeping track of modifications
- Evaluating effectiveness
- Securing the resources

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8 PARTICIPANT DETAILS

(If your project involves human participants, complete this question. If your project involves use of data banks only, proceed to Question 9, or if your project involves use of existing human tissue/fluid samples only proceed to Question 14)

(a) Number of Participants: Males: 2550 Females: 400200 Total: 425250

If a gender imbalance in the number of participants is apparent, please explain why.

Women are about twice as likely as men in the United States to be diagnosed and treated for depression. About 20-25% of women and 12% of men will experience a serious bout of depression at least one time in their lifetimes.

(b) Age Range: ~~18~~12-45

(c) Will any participants be ill or frail?

No

Yes (provide details)

Depression is a listed mental disorder which includes altered mood; it may occur daily associated with diminished interest or pleasure in most or all of the activities. Depression is considered to be a disorder. This is because it involves everything in the patient's body, mood and thoughts.

(d) Are there any criteria that will determine whether participants are included or excluded from the research?

No

Yes (provide details of all inclusion and exclusion criteria and explain why each criterion is important to the purpose of the research)

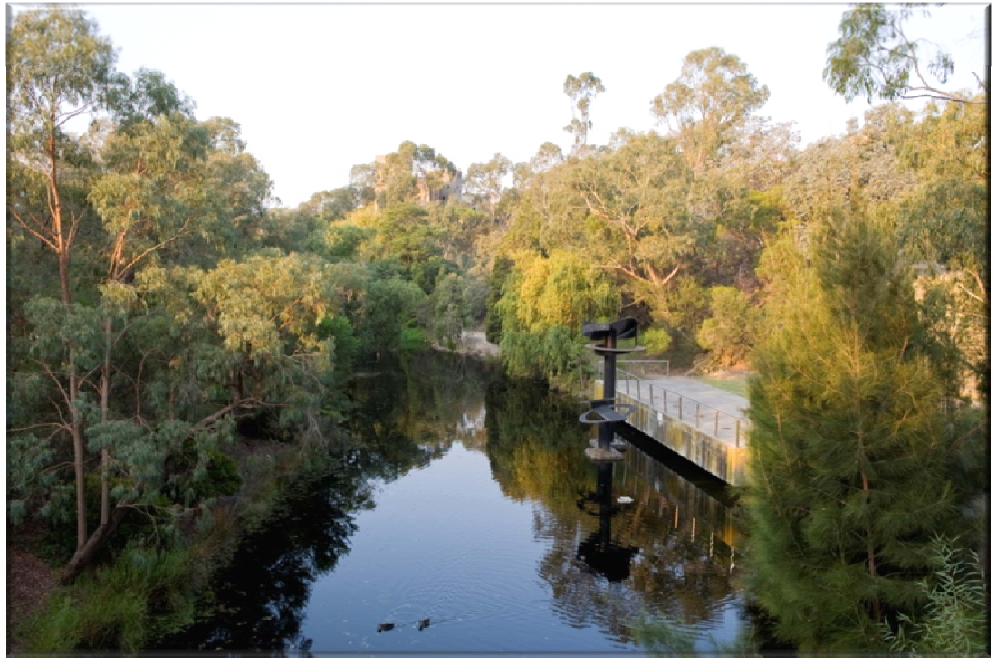
Research participants must fall within the specified age range and have no other serious health issues. As for children, depression shows up equally in both boys and girls. As children begin to grow and reach the adolescence stage however, girls tend to become more depressed than boys.

(e) Recruitment Method

Please state how names and contact details of potential participants will be



Thank You.



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