

Managing the ethics workload in a busy University Teaching Hospital:
Implementation of a 3-tiered ethics review system based on the Griffith Model

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Introduction (1)

- HRECs face an ever-increasing workload
- HRECs continue to struggle to recruit and maintain membership levels
- Any change that can ease work-load pressures on individual committee members should be examined


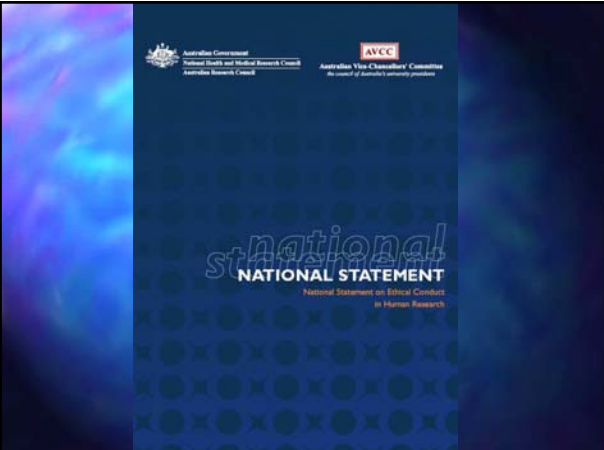


Introduction (2)

- In 2003 Griffith University introduced its Research Ethics Reform Plan
- Based around the establishment of a 3-tier review system
- Its aim was to allow low-risk research and research with easily-manageable risk to proceed through an expedited review system
- Result: reduced workload for full-committee and faster ethics review for all applications

Introduction (3)

- In 2005 Flinders Human Research Ethics Project established
- Stake-holders from University & Hospital (clinical and management) involved
- Use the Griffith model as a base
- Adapt it for the local needs of the Flinders research community and its 2 HRECs
- Establish a pilot system and evaluate its performance prior to final roll-out

Australian Government
Department of Health and Ageing
National Health and Medical Research Council
Australian Research Council

AVCC
Australian Vice-Chancellors' Committee
the Council of Australian University Presidents

national
NATIONAL STATEMENT
National Statement on Ethical Conduct
in Human Research



"These two documents herald a new era in the governance of research involving humans in Australia. At a time when commercial and other pressures on researchers may be increasing the risk of fraud and misconduct, it is crucial that the system for the oversight of research be sufficiently robust to protect participants and maintain community confidence in research."

- Prof Warwick Anderson, CEO, NHMRC.

Minimising Duplication of Ethical Review

"where prior peer review has judged that a project has merit, the question of its research merit is no longer subject to the judgement of those ethically reviewing the research."

National Statement p12 par1.2

Minimising Duplication of Ethical Review

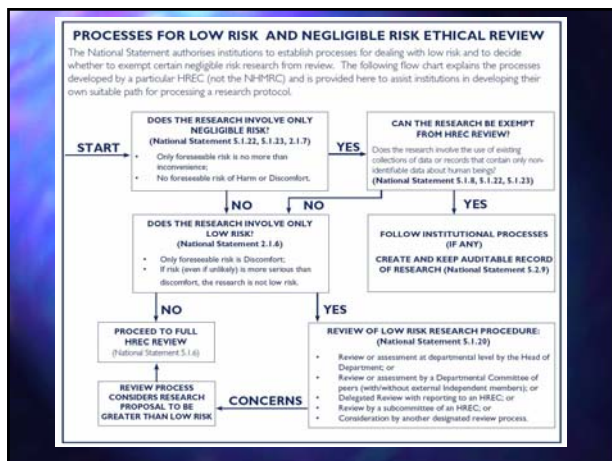
Where research has previously been approved by a properly constituted HREC elsewhere, the project can be considered by some form of expedited review

National Statement p87 ch5.3

Audit Vs Research

NHMRC has confirmed that 2003 guidelines still apply

When does Quality Assurance in Health Care require Independent Ethical Review? Canberra: NHMRC; 2003



Expedited Review Working Party Recommendation 2:

Criteria for Levels of Review
 It is recommended that these criteria have the status of a policy document endorsed by both Flinders University and Southern Adelaide Health Service. It is expected that, as legislation and guidelines under SAMSA/University policy change, that the criteria will be reviewed and amended as required.

Levels of consideration

Non-Review (N)
 Projects not requiring HREC review
 These projects may require some other level of review or registration. This must be considered at organisational level.

Expedited Review Level 1 (E1)
 This level will apply to projects which raise no significant ethical issues.

Expedited Review Level 2 (E2)
 This level will apply to projects where the ethical issues are easily managed, and for those where the procedures and risks are well understood and have been previously approved.

Full Review (F)
 This level will apply to applications not meeting the criteria for E1 or E2 review.

Notes on Procedures:

- At each level of review it is open to the reviewers to determine that the project requires a higher level of review and to forward it for further consideration at a higher level. This may delay the review process.
- Interim approval will allow the project to commence.

2 Expedited Review Level 1 (E1)
 Projects which raise no significant ethical issues in total.

1 Projects which raise an ethical issue or which are defined under Expedited Review Category C.
 Use of category only those of data or records involving all forms of medical imaging that involve only non-identifiable data about human beings.
 To qualify the requirement information must be available to the researcher as identified here. It is not sufficient that identifiable information have the identifier removed by the researcher, either on the day required information has an identifiable source. In however, ascertainable that information may be identified by a researcher but transfer to the researcher without identifiers.

3 Research involving non-identifiable human tissue from a tissue bank, hospital or other source in which the tissue was disposed with appropriate consent.
 This category includes tissue which is identified at the research but protected by the researcher as non-identifiable from an ethics request (as identified by all being codes and identifiers have been removed from the sample).

4a Observation of legal public behaviour that involves no interaction with those observed, provided the information obtained is recorded in such a manner that those observed cannot be identified in any way.
 Projects involving this type of record keeping will not be reviewed in this category.

4b Projects which are covered by a different consent or with only administrative involvement of a previously approved study.

Note that even where projects meet the review criteria for Expedited Review categories, it is open to the reviewers to determine that the project requires a higher level of review and to forward it for further consideration at a higher level. This may delay the review process.

1 Expedited Review Level 2 (E2)
 This level will apply to projects where the ethical issues are easily managed, and for those where the procedures and risks are well understood and have been previously approved.

1 Projects for which the ethical issues can be managed on indicated under Expedited Review Category B.
 This category applies OREC 1.

2 The project has already been approved by an Australian HREC.
 This category applies OREC 2.

Note: OREC 2 (University is HEC the primary site or host organisation for the research).

Note: OREC 3 (which are reviewed under the provisions for Expedited Review Level 2) will be reviewed by the Clinical Drug Trials Committee prior to E2 review.

The application to be reviewed of a previously approved project with minor modifications.
 This exemption applies only if:

- The modifications are of only minor ethical or scientific significance. It remains open to the ethics committee to determine that the project should be reviewed by the full committee.

All proposed research procedures have been included in a Register of Approved Procedures.

1 Modifications collected by a clinician for teaching/learning purposes including a device.
 This exemption classification applies OREC 3.

- The participants are not vulnerable.
- The information being collected does not deal with sensitive aspects of the participant's condition or behaviour, such as sexual preference, drug use, contact, use of alcohol, any use of potentially controversial health interventions, etc.
- Identifiable information is available in all aspects of the project design, implementation and analysis.

Note that even where projects meet the review criteria for Expedited Review categories, it is open to the reviewers to determine that the project requires a higher level of review and to forward it for further consideration at a higher level. This may delay the review process.

Expedited Review

- N : Executive officer
- E1 : Chair or Deputy-chair
- E2 : Chair, deputy-chair & committee member

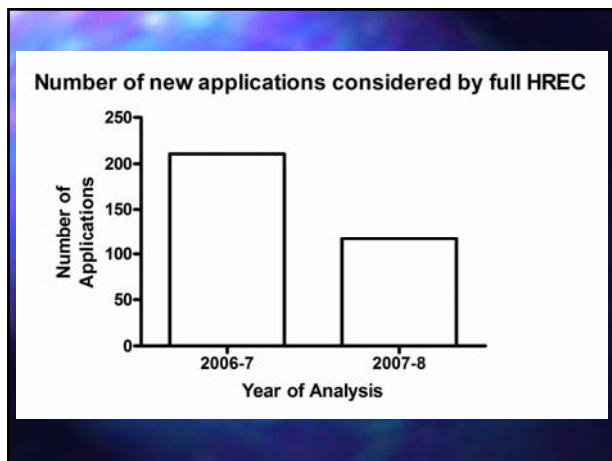
Problems

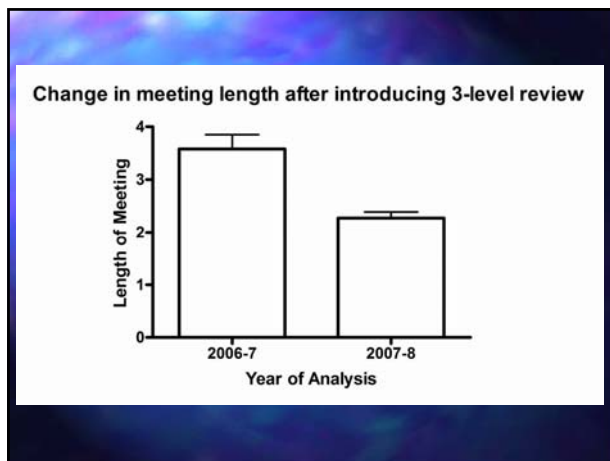
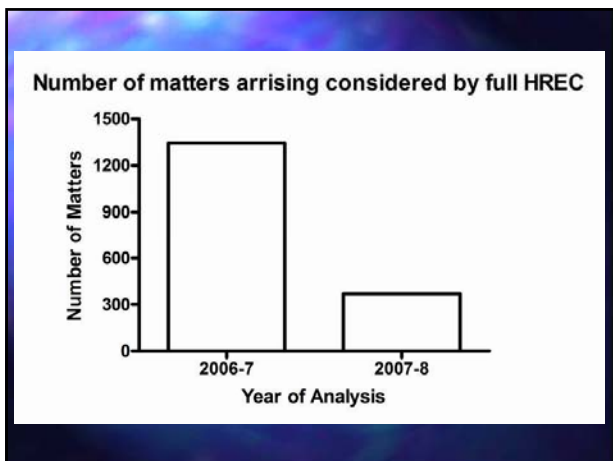
- Clinical Drug Trials!
- CDTC resistant to accept conclusions of previous HREC review



Solutions

- Ethics "report card" revealing all correspondence between local trial site coordinators and HRECs
- National database of all clinical drug trials containing HREC status and final PIS / consent forms





On-line Research Ethics Manuals

Human Research Ethics Manual

The Flinders University / Southern Adelaide Health Service Research Ethics Manual is being adapted with permission from the Griffith University Research Ethics Manual.

We acknowledge the excellent work of Dr Gary Allen and his colleagues at Griffith, which underpins this part of the project.

The Manual is a web-based series of booklets based on ethics processes, research practices or areas of common ethical concern. The intention is to make the relevant information for a particular researcher and project easy to locate and understand. We have retained the Griffith numbering for now, though that means that some numbers are not being utilized, since this allows us to maintain links and internal references.

The full list of possible topics, Booklets in red are currently available for review. Others will be provided as they progress through the review process.

Flinders University and Southern Adelaide Health Service Research Ethics Manual Booklets

- 1 Introduction to research ethics at Flinders University (SAHS) (June 2007)
- 2 Making an application for ethical clearance (February 2007)
- 3 Standard conditions of ethical clearance and the responsibilities of researchers (July 2007)
- 4 Conflict of interest (July 2007)
- 5 Flinders SAHS monitoring procedures (July 2007)
- 6 Modifying an existing ethical clearance (July 2007)
- 7 Complaints, investigations and review (October 2006)
- 8 Ethical clearance and multi-site research (April 2007)
- 9 Risks and benefits in human research (8 November 2006)
- 10 Informing and assent (December 2006)
- 11 Flinders Register of Approved Procedures (November 2006)
- 12 Introduction to human research ethics: Determining whether your work needs ethical clearance
- 13 Sources of advice on human research ethics matters (January 2007)
- 14 Research reporting approval: agreement of other bodies or organisations (January 2007)
- 15 Clinical research and device ethical approvals

Further Ethics Reform

- Encourage research teams and hospital departments to submit dedicated ethics applications for databases and tissue-banks
- Ensure appropriate consent is obtained for all data & tissue collected

Further Ethics Reform

- Standardise patient information sheets on genetic and pharmacogenetic research to facilitate ethics review

Further Ethics Reform

- Work with Government of SA to establish a Research Ethics Forum to facilitate review of multi-site research
- Amalgamate HRECs from Southern Regional Health Service

Conclusions

- Introduction of a planned expedited review system can dramatically reduce full HREC workload
- The Griffith model can be easily adapted to local circumstances
- Ethics management and governance is an essential part of the managerial structure in a teaching hospital
- Proactive behaviour by HRECs can lead to positive research benefits for the academic community

