Merit and Integrity in Ethical Human Research – Institutional Responsibilities

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Merit and Integrity

- The National Statement on Ethical Conduct in Human Research (NS) defines research as that which is conducted “with or about people, or their data or tissue” (2007:8).
- Institutions which conduct human research are responsible for establishing procedures for the ethics review of research conducted under their auspices. This may include establishing a Human Research Ethics Committee (HREC) and/or an ethical review body.
- Institutions must be satisfied that research they are responsible for is:
  - Designed and conducted in accordance with the Australian Code
  - Ethically reviewed and monitored according to the NS
  - ***Conducted to meet relevant scholarly or scientific standards (emphasis added)***

Research Merit (NS:12)

- Justifiable by its potential benefit (to knowledge, improved social welfare, skill and expertise of researchers
- Designed using methods appropriate for achieving the aims
- Based on a thorough study of the literature
- Designed to ensure that respect for participants is not compromised by the aims, how it is carried out, or by the results
- Conducted or supervised by persons or teams with experience, qualifications and competence
- Conducted using facilities and resources appropriate for the research

Research Integrity (NS:12)

- Research that is conducted with integrity is carried out by researchers committed to:
  - Searching for knowledge and understanding
  - Following recognised principles of research conduct
  - Conducting research honestly
  - Disseminating and communicating results, whether favourable or unfavourable, in ways that permit scrutiny and contribute to public knowledge and understanding.

Research merit and integrity – pre-approval (practical matters)

- The principle of merit and integrity is especially important in the following situations:
  - Waiver of consent
  - Opt out approach

- Only an HREC can grant a waiver of consent – and it must be satisfied that:
  - Involvement is no more than low risk
  - The benefits of the research outweigh the risks of harm of not seeking consent
  - It is impracticable to obtain consent
  - There is no reason for thinking participants would not have consented
  - Sufficient protection of their privacy

Research merit and integrity – pre-approval (practical matters) cont…

- There is an adequate plan to protect the confidentiality of the data
- In cases where the results are significant to the welfare of participants a plan for informing them should be considered
- Commercial exploitation of derivatives of the data/tissue will not deprive participants of any financial benefit
- The waiver is not prohibited by law

Research merit and integrity – pre-approval (practical matters) cont…

- Opt out approach may be considered where the project is of such scale and significance that obtaining consent is not practical or feasible
  - Involvement carries no more than low risk
  - Public interest in the activity substantially outweighs the public interest in the protection of privacy
  - Research activity is likely to be compromised if the participation rate is not near complete
  - Reasonable attempts are made to provide all with a plain language statement
  - Time to allow potential participants to decline to participate
  - Data collection and storage complies with security standards
  - Not prohibited by law

Research merit and integrity – pre-approval (practical matters) cont…

- Qualitative methods NS:25)
  - Relationships
  - Professional skills
  - Generalisability
  - Rigour

Research merit and integrity – pre-approval (practical matters) cont…

- Biobanks
  - Description of how data will be collected, stored, used and disclosed
  - Consent
  - Collected and stored in ways that permit use in future research projects

Research merit and integrity – pre-approval (practical matters) cont…

- Clinical trials and innovations, especially Phase I and II
  - Phase I trials (health volunteers) need to be undertaken in centres equipped with appropriate monitoring and surveillance
  - Phase II trials (efficacy and safety) participants require close supervision and conducted by researchers regarded as specialists in the field

Research merit and integrity – pre-approval (practical matters) cont…

- Institutions (NS:31)
  - Establish standards to determine when innovations requires systematic investigation
  - Systematic investigations should be assessed by the HREC
- Researchers must show (NS:32)
  - Research directed to answering specific questions
  - Scientifically valid hypothesis and equipoise
  - Suitable size and profile of sample
  - Meets GCP guidelines
  - Declare COIs, financial interests and restrictions on publications

Research merit and integrity – pre-approval (practical matters) cont…

- HRECs should be satisfied (ibid) (especially)
  - Funding is sufficient
  - Facilities are appropriate
  - Researcher expertise is appropriate
  - Payment (to researchers and participants) is not coercive

Research merit and integrity – pre-approval (practical matters) cont…

- Genetics (NS:42)
  - Researchers should develop an ethically defensible plan in cases where research may discover information of importance to participants or their families including
    - Process for finding out whether participants want relevant information
    - How to inform participants of relevant information
    - Matters relating to confidentiality in relation to informing family members (or when to override)
    - Ensuring access to counselling

Research merit and integrity – pre-approval (practical matters) cont…

- Children and young people (NS:50-51)
  - Research and methods should be appropriate for participants
  - Research design should include
    - How a child's vulnerability and capacity to consent (assent) will be assessed
    - Description of the discussions with children about the research and its effects
    - How the guidelines will be applied

Research merit and integrity – pre-approval (practical matters) cont…

- People in dependent of unequal relationships (NS:53)
  - May influence a persons' decision to participate – thus particular attention to how consent is negotiated is required
  - Invite potential participants to discuss consent with significant others or guardian
  - Research design should include steps to minimise
    - The effect of relationship on the conduct of the research
    - The detrimental effects on participants

Research merit and integrity – pre-approval (practical matters) cont…

- People highly dependent on medical care who may be unable to give consent (NS:55)
  - Research on people who are highly dependent on medical care may be approved where:
    - It is likely the research will lead to increased understanding/improvements of this population
    - Relevant jurisdictional laws are considered
    - Any risks justified by the benefits or where people can consent, the risks are acceptable to them and justified by the potential benefits

Research merit and integrity – pre-approval (practical matters) cont…

- People with a cognitive impairment, intellectual disability, mental illness (NS:58)
  - Research design must take into account factors which may affect the capacity to receive information, consent or participate
  - Determine whether people's impairment increased their susceptibility to discomfort or distress and minimise this

Research merit and integrity – pre-approval (practical matters) cont…

- Illegal activity (NS:60)
  - Research designed to expose illegal activity should be approved only where it bears on the discharge of a public responsibility or fitness to hold public office
  - Participants maybe subjected to risks because of their involvement in the research – it should be clearly established that these risks are justified by the benefit of the research

Research merit and integrity – pre-approval (practical matters) cont…

- Aboriginal and Torres Strait Islander peoples (NS:63)
  - Methods are respectful and acknowledge cultural distinctiveness
  - Evidence of community support
  - Research methods provide for mutually agreed mechanisms to recruit, inform, consent and report (to) participants

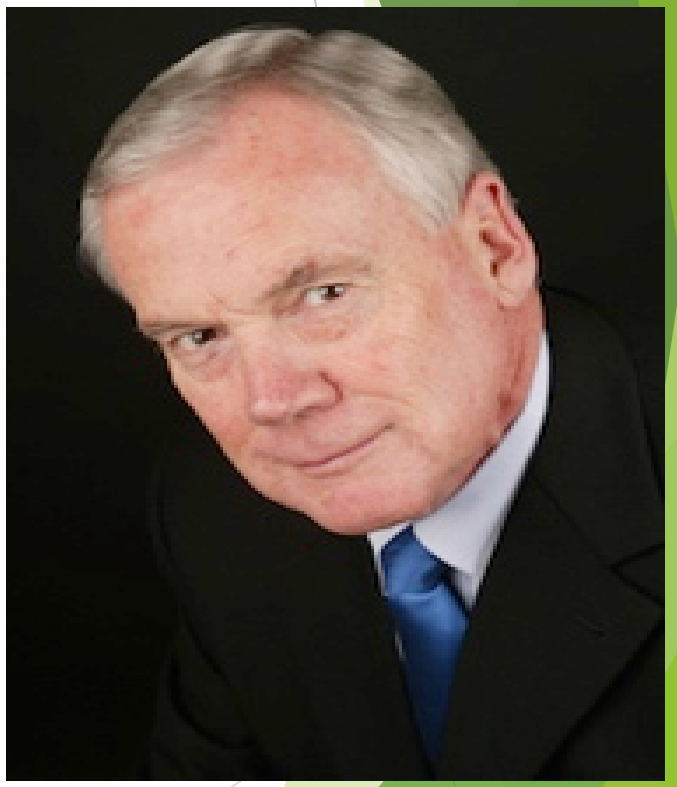
Research merit and integrity – pre-approval (practical matters) cont…

- People in other countries (NS:65)
  - Must comply with the NS
  - Local cultural values must be acknowledged in the design and conduct of research
  - Consultation with local peoples
  - Researchers should inform HRECs whether there are ethics approval processes in the country in which they plan to conduct research and how these processes function
  - If no ethics approval processes the HREC should consider local circumstances and not impose unrealistic requirements (providing participants are accorded no less respect and protection than the NS requires)
  - Researchers must be experienced (to ensure respect), or have adequate supervision
  - Explain the experience of local researchers who are involved – and they must accord proper respect to participants

Research merit and integrity – post-approval (practical matters) cont…

- Changing personnel (relevant expertise)
- Monitoring and audits
- New applications every 5 years as evidence changes
- Regular updates to participant groups
- Adverse events, SUSARs (suspected, unexpected, serious adverse reactions

Research team



What researchers say…The Project 2013-2016 (DP103104760)

- Understand the intentions and perceptions of national funding agencies;
- Explore disciplinary differences in resistance to and compliance with institutional ethics review procedures;;
- Understand researchers‘ subjective experiences of ethics review over time
- Investigate whether the ways researchers experienced the historical transition period has affected their attitudes towards ethics committees and research ethics;
- Determine whether compliance with or resistance to institutional ethics review correlates with demographic data;
- Examine how personal and institutional histories of ethics review have impacted on how we mentor students in research ethics

Demographics and overview

- Surveys: 1415 from all 39 Australian Universities;
- Just under 80% of respondents have as their highest qualification a PhD;
- About 75% undertake research in Australia;
- According to 61% of respondents research ethics training/education is not required by their University.
- Nearly 30% report that their institution does not make training available to researchers.

Overview

- 84% always get ethics approval for human research,

- ‘Its important’
- ‘Its ethical’
- ‘It is an institutional requirement’
- ‘So I can get published’
- ‘To cover my back’
- ‘Because I have to’
- ‘I follow rules’

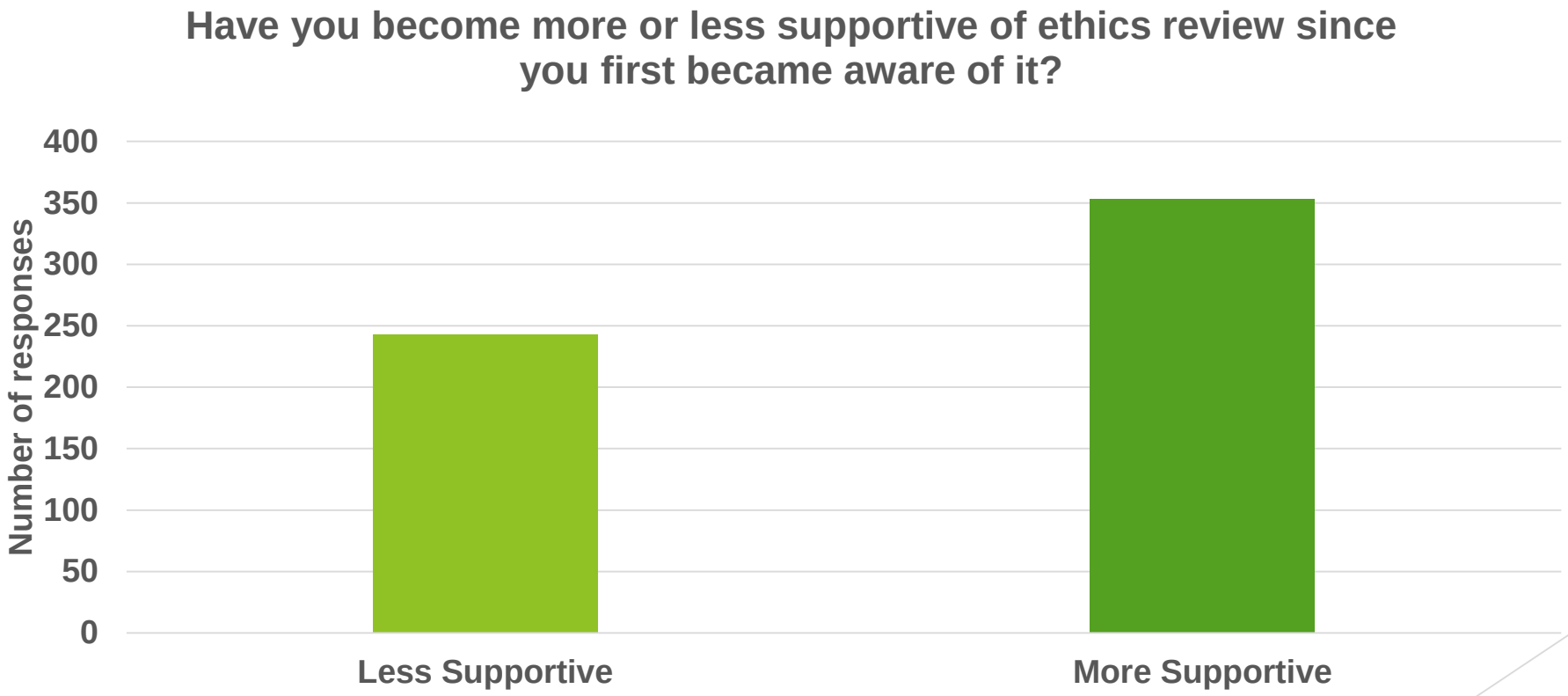
Overview

- Of the remaining 16%

- 8% usually get ethics approval for human research
- 3.5% sometimes
- 2.5% seldom
- 2.8% never get ethics approval for their human research.

- ‘To cumbersome a process’
- ‘To bureaucratic’
- ‘Time constraints’
- ‘I think they (HRECs) are an unnecessary intrusion and seek
- to avoid them as much as possible’

Support for Ethics review



Reasons why more supportive

- Review adds to the quality of research methodology as well and forces researchers to get the finer details right prior to starting (Medicine).
- Any query is very quickly and efficiently followed up with very clear recommendations (Medicine).
- The introduction of low risk committees has streamlined the review process resulting in better, more timely outcomes (Psychology).
- I submit at least 10 applications a year. I've found the process very supportive in clarifying some of the difficulties in research design… they were a bit more *relaxed about the ethical requirements than I was* (emphasis added) (Medicine).
- I am generally positive towards ethics committees, having been a member (Psychology).
- I have been a member of several ethics committees – this has made me appreciate process more (Allied Health)

Reasons why less supportive

- Research Ethics has become a bureaucratic requirement rather an issue of discussing substantive values within disciplines.
- I do get concerned with the increasing bureaucatisation of ethics and I agree that the instrumentalisation of the process largely works off positivist research assumptions which don't fit with non-positivist disciplinary approaches.
- As an anthropologist, HREC processes can be frustrating. There is rarely much understanding of the inductive nature of anthropological research, or of the fact that our methodological rigour relies on immersion and relationships.
- Ethics committee bias towards narrow research methodology means that other research projects following qualitative methodologies are often delayed due to inappropriate questions being asked … (Nursing)
- Ethics Review Committee… has no idea about qualitative research or educational studies

Less supportive (still)

- In one of my classes in qualitative research, student researchers were held up significantly in their projects because the topic of 'home and feelings of 'home' was seen as a potentially traumatic topic. I think in general the difficulties of getting through ethics committees means that students in particular will choose topics that easily get through ethics committees.

- I haven't bothered applying or doing human research in the last five years because the ethics committee's approach is so notorious (within my institution) and detrimental to my sort of research. There is no point applying for funding todo such research if the Ethics Committee will then refuse permission.