Ethical principles and NEAF – common issues

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Submitting an HREC application
HREC applications

• All applications to a QH, NSW or Victorian Health HREC must be made on the online NEAF:
  https://ethicsform.org/au/SignIn.aspx

• Online NEAF asks exactly the same questions as NHMRC NEAF
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National Statement Guidance on NEAF Online Form

(a) whether, in the country in which they intend to do research, there are ethics approval processes that are relevant to that research, and whether any such processes are mandatory or voluntary in relation to the proposed research, and

(b) how such processes function, the values and principles on which they rely, and whether they require reporting of the Australian review body’s approval.

4.8.5 Where there are no ethics approval processes in an overseas country, this National Statement may provide the only applicable process for ethical approval. In this case, the Australian ethical review body should take account of the available resources and means to conduct the research and avoid imposing unrealistic requirements, providing always that research participants are accorded no less respect and protection than this National Statement requires.

4.8.6 Some funding or national requirements will direct researchers and review bodies to conform to the ethics guidelines of local institutions or to recognized international guidelines or instruments. Research conducted under those guidelines or instruments should be approved only if participants will be accorded no less respect and protection than this National Statement requires.

4.8.7 Researchers should have enough experience or access to expertise to enable them to engage with participants in ways that accord them due respect and protection.

4.8.8 When research is to be conducted overseas by a researcher who is subject to academic supervision, researchers should inform the Australian ethical review body of how that supervision is to be effected so that due respect and protection will be accorded to participants.
Responsibilities of Researchers

National Statement 5.2.5 states researchers should demonstrate research has:

- Merit
- Reflects principle of justice
- Reflects principle of beneficence
- Reflects principle of respect
Research merit and integrity

• Justifiable
• Designed using appropriate measures
• Based on previous literature
• Conducted or supervised with persons with experience and expertise
• Appropriate resources and facilities
• Search for knowledge and understanding
• Dissemination of results
Research merit and integrity –
common HREC questions

• Sample size errors
• Detailed description of analysis to be used
  – ?appropriate
• Qualitative studies often do not have a
description of methodology
• Limits on dissemination of results
• Literature search
Justice

- Selection of research participants including recruitment
- No unfair burden on participants
- Fair distribution of benefits
- No exploitation of participants
- Fair access of the benefits
Justice – common HREC questions

- Rationale for the selection of participants
- Access to continued treatment
- Registration on publicly accessible clinical trials registry
- Vulnerability for some patient groups to be ‘over researched’
- Understanding of the Queensland Civil and Administrative Tribunal processes.
Beneficence

- Benefit justifies the risk of harm or discomfort
- Clear explanation of the risks
- Minimisation of the risks
- Clear consideration of actual risks
Beneficence – common HREC questions

• Need to address physiological risks as well as physical
• Access to independent counsellors
• Addresses needs of the community
• Consent process
• Monitoring process
Respect

- Due regard for participants welfare, beliefs, customs, cultural needs
- Privacy, confidentiality and cultural sensitivities of participants
- Ability to make own decisions
- Protection of those unable to make own decisions
Respect – common HREC questions

- Recruitment process is fair
- Assessing capacity to consent – including children
- Adequate time for consideration
- Explanation of funding arrangements to participants
- Withdrawal process for participant
- Aboriginal & Torres Strait Islander consultation
Common frustrations of a HREC

- References in the NEAF to the protocol only instead of documenting the response to the question
- Typographical and grammatical errors – shows lack of respect to participants
- Use of acronyms and scientific terminology in PICF
- Language of PICF is at ‘too ‘high’ a level – use ‘Display readability statistics’ on Word documents
HREC requirements and the National Statement

• Section 5.2.22 (c) Where a proposal is rejected, communication of the rejection must be in writing… and should include reasons linked to the National Statement.

• Section 5.2.26 A review body should record decisions about approval, amendment or rejection of proposals in writing.. With reasons for those decisions, linking those reasons to the National Statement.
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