Ethical review & approval of data linkage research projects

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National Statement on Ethical Conduct in Human Research

Four essential criteria for ethical acceptability any human research project:

- Research merit and (researcher) integrity
- Beneficence
- Justice
- Respect for people
Research merit

Research that has merit

• is justifiable by potential benefit
• uses appropriate methods to achieve aims
• is based on current knowledge in literature
• respect for participants not compromised by aims, methods or results
• conducted/supervised by those with appropriate experience, qualifications & competence,
• uses appropriate facilities & resources
Researcher integrity

Researchers with integrity have commitment to
• searching for knowledge and understanding;
• following recognized principles of research conduct;
• conducting research honestly; and
• disseminating/communicating results, to permit public scrutiny & add to public knowledge/understanding
Justice

• Within scope & objectives of research, selection, exclusion, inclusion of categories of research participants is fair, and accurately described.
  • Process of recruiting participants is fair;
  • No unfair burden of participation in research on groups;
  • Fair distribution of benefits of participation in research;
  • No exploitation of participants;
  • Fair access to the benefits of research
  • Outcomes accessible to participants in timely & clear manner
Beneficence

• Likely benefit, to participants or community, must justify risks of harm/discomfort to participants.

• Researchers responsible
  - to design research to minimize risks of harm & discomfort;
  - to clarify potential benefits & risks; and
  - for welfare of participants in research context.

• Where no likely benefits to participants, risk to participants lower than where likely benefits.
Respect for people

• Due regard for the welfare, beliefs, perceptions, customs & cultural heritage, individual & collective of participants
• Respect for privacy, confidentiality & cultural sensitivities of participants & their communities.
• Due scope to capacity of participants to make own decisions.
• Where participants unable to make own decisions/have diminished capacity, respect involves empowering & providing protection.
Data linkage and consent

• Some projects involve individual consent to access data, e.g. MBS, PBS, that is then linked to other data collected from participants

• In other projects, access to data for linkage is sought without consent

• National Statement permits approval of use for linkage without consent

• But also provides criteria for an HREC to approve a waiver of the requirement for consent
National Statement & linkage without consent

Where research involves linkage of data sets, approval may be given to the use of identifiable data to ensure that the linkage is accurate, even if consent has not been given for the use of identifiable data in research. Once linkage has been completed, identifiers should be removed from the data to be used in the research unless consent has been given for its identifiable use.

(Paragraph 3.2.4, p.30)
National Statement criteria for waiver of consent

HREC must be satisfied that:

(a) Involvement carries no more than low risk to participants;

(b) the benefits from the research justify any risks of harm associated with not seeking consent;

(c) it is impracticable to obtain consent (for example, due to the quantity, age or accessibility of records);

(d) there is no known or likely reason for thinking that participants would not have consented if they had been asked;
Criteria for approval for waiver of consent

(e) there is sufficient protection of their privacy;

(f) there is an adequate plan to protect the confidentiality of data;
   (data linkage protocols relevant to (e) and (f))

(g) if results have significance for the participants’ welfare there is, where practicable, a plan for making that information available;

(h) the possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled;

(i) the waiver is not prohibited by State, federal, or international law.
When is waiver not prohibited by law?

When use or disclosure can be by

- exercise of powers in empowering statute
- authorised by privacy legislation following HREC review & approval using:
  - for Commonwealth agency data for medical research: criteria in Part 3 of guidelines under s95 of Privacy Act
  - for State authority health information: criteria in statutory guidelines in NSW, Queensland & Victoria*
  - for private sector health information: criteria in part D of guidelines under s95A*

* These guideline are substantially the same
Effect of HREC review and approval

• Where an HREC reviews a data linkage project and is satisfied, on consideration of applicable criteria that

  The public interest in the research (substantially outweighs s95A) (outweighs to a substantial degree: s95)
  the public interest in the protection of privacy

• That decision is a necessary – but not a sufficient – condition for the use or disclosure by a data custodian of the data the researcher seeks
Conclusion

• There are clear criteria for HRECs to use in reviewing research projects that involve data linkage
• These criteria provide ensure a robust and reliable ethical review
• The criteria can also provide the basis assessing the consistency of ethical review