



GUIDELINE: RESEARCH AND ETHICS APPROVAL

Issued by the ACPS Research Committee.

1. PURPOSE AND SCOPE

To provide guidance to ACPS members on the ethical requirements for undertaking quality assurance activities.

To provide guidance to ACPS members on the requirements for ethical approval for publication of audit and clinical research.

2. BACKGROUND

Members of the ACPS are involved in several different types of analytic evaluation of the work that they undertake. Most commonly this involves clinical audit or clinical research.

When undertaking such activities a systematic approach should be utilised which aims to ensure that the work falls within the established guidelines for human research.

3. BODY OF GUIDELINE

Before beginning clinical research trials or audit activities ACPS members must set out the parameters of the proposed work in a one page document and should register the work with the ACPS research committee. When undertaking such activities a systematic approach should be utilised which aims to ensure that the work falls within the established guidelines for human research. The National Statement on Ethical Conduct in Human Research (2007) can be found at: <http://www.nhmrc.gov.au/guidelines/publications/e72>

The proposal should include:

- Project outline
- Consent protocols; for all research and audit activities appropriate consent must be sought from the participant cohort.
- Rationale for the need or otherwise of ethics approval for the work. See section below on research taxonomy.
- Trials registrar, all clinical research (trials) undertaken by ACPS members should be registered on the Australian New Zealand Clinical Trials Registry. <http://www.anzctr.org.au/default.aspx>. Trial registration should be undertaken after ACPS research committee approval.

Research Taxonomy

The National Research Ethics Service of the NHS has developed a consensus paper which provides guidance on the taxonomy of research activities. <http://www.nres.nhs.uk/>

The consensus paper is attached to this policy as Appendix 1.

The ACPS Research Committee has reviewed this taxonomy and adopted it for use by members of the ACPS.

Activities which fall under the definition of clinical audit do not require formal ethics approval and in preparing clinical audit for publication reference to the NHS consensus statement is recommended. Activities which fall under the definition of clinical research do require formal ethics approval. In this circumstance ethics approval must be sought from facilities where the intervention is taking place Eg hospital or day surgery centre. Ethics approval may also be sought from an independent university ethic committees where the researchers have an affiliation.

All ACPS members should be aware that presentation of research and or audit which cannot demonstrate compliance with an ethics policy will generally not be accepted by scientific conferences and peer review journals

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