Quality Assurance versus Research Project Exemption Guidelines

These guidelines provide information on the difference between a quality assurance (QA) / audit project and a research project.

Instructions:
The Office for Research advises that any projects that are classified as Quality Assurance (QA)/Quality Improvement (QI), audit, service design or negligible risk projects may not require ethical review by the Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC).

Please complete the evaluation form, providing the details of your project and email to Health.SALHNoofficeforresearch@sa.gov.au. The form will be assessed by the Ethics Officer within 2 weeks of receipt.

The Ethics Officer will notify you whether your project meets the National Statement Chapter 5.1.22 requirements for exemption for ethics review, or if an ethics application is required.

QA, QI, Audit, service design, negligible risk projects vs Research

An activity1 whose primary purpose is to monitor or improve the quality of service delivered by an individual or an organisation is a QA, QI, audit, service design, negligible risk activity, and as a rule, this does not require ethics approval.

Research is ‘negligible risk’ where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience. Where the risk, even if unlikely, is more than inconvenience, the research is not negligible risk. National Statement Chapter 2.1.7 /5.1.22.

Examples of QA/QI activities include the following:

- Evaluation to see if the service/department meets current protocol / Evidence Based Practice guidelines
- Evaluation of a service /department, to see what, if any improvements can be made i.e. what improvements can be made to the service to target pain relief to be more effective in a particular condition?
- Providing patients with a short survey while they are waiting for their doctor, to see if they are satisfied with wait times and ease of making an appointment.

By comparison research2 is defined as the original investigation undertaken to gain knowledge, understanding and insight and excludes routine testing and routine analysis of materials, components and processes.

Examples of research activities include the following:

- Collection of tissue samples beyond standard care
- Using data that has been collected routinely, to answer a question i.e. Why do patients with a particular condition get relief from using a certain treatment
- Any safety, efficacy and toxicity trials of a drug

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1 NHMRC Ethical Considerations in Quality Assurance and Evaluation Activities March 2014
• Setting up a database or registry
• Any clinical investigations outside of standard care
• Testing of non-standard (innovative) protocols or equipment and devices
• Studies that examine the experiences and or feelings of a particular group of people / patients
• Comparison of an intervention group versus a control group

Publication

Papers that are generated from QA/Audits can be submitted for publication without the need for ethics approval with most journals. The Office for Research recommends checking the publication policy of the chosen journal but where Quality Assurance and Audits are involved most require simply a statement to the effect that:

“ethics review was not sought because the study met criteria for exemption from such review according to an institutional policy (e.g. because the work was deemed an improvement activity and not human subjects research)”

If a project meets the requirements of QA and/or Audits for the purpose of this policy will be deemed to not require ethics approval and you may cite this policy in your submission as a relevant exemption.

If however a project extends beyond QA or Audit and therefore requires ethics approval, please refer to the Office for Research submission guidelines, available at the website listed below.

For more information

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If you do not speak English, request an interpreter from SA Health and the department will make every effort to provide you with an interpreter in your language.

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