



Considerations in determining if an activity such as quality assurance requires ethical review

Each question must be asked in order to determine whether or not an activity requires ethical review by a Human Research Ethics Committee (HREC). Following due consideration of **all** questions listed below:

- If **all** of your answers to each question listed below are answered in the **negative** it is likely that you are conducting an activity that **does not require ethical review**.
- If **any** of your answers to any of the questions listed below are in the **positive** it is likely you will need to **consult further with a HREC to determine if you will require ethical review by a HREC**.

Whether you are conducting an activity or research requiring ethical review, you should consult any relevant institutional policies as well as any legislative requirements for the sector.

1. Does my activity require ethical review?

- Consider the National Statement definition of research (p. 7).
- Is the activity required to undergo ethical review as defined in the National Statement (5.1.6.b)?
- Does the activity fit the description as defined in the National Statement (2.1.6 and 2.1.7) to be low or negligible risk research?
- Does the activity fit the description as defined in the National Statement (5.1.22) to be exempt from ethical review?

2. What is the reason/s for conducting the activity?

- Is the activity being conducted for reasons other than the sole purpose of assessing a service for internal purpose only?

3. To determine which category your activity falls into:

- Consider the application of the values and principles in the National Statement. The process should not be a mechanical application but should weigh up the risks and benefits and burdens to the participants (National Statement 2.1).
- Does the proposed activity require consent to be sought from potential participants? (National Statement 2.2).
- Does the activity require the participant to contribute beyond their normal involvement? (E.g. a patient to attend an extra appointment or complete a questionnaire that is not part of their routine care).

4. Does the use of the data/sample comply with Commonwealth Privacy Principles?

- National Privacy Principles (see s95A guidelines)?
- Information Privacy Principles (see s95 guidelines)?
- E-health (TBA)

5. Publication

- Will the outcomes be presented or published outside the institution?

If **all** answers are 'no'

Quality assurance activity

It is likely that the activity is for quality assurance or clinical audit purposes.

Consult institutional policies regarding the conduct of quality assurance activities as well as any legislative requirements for the sector.

If **any** answers are 'yes'

Consult with HREC for full or low/negligible risk process

Contact the HREC to determine:

- That you have identified the correct level of ethical review for your research
- The institutional processes in place for ethical review
- If you may be eligible for low/negligible risk review (http://www.nhmrc.gov.au/guidelines/ethics/human_research/pubs.htm)