NEGLIGIBLE RISK RESEARCH and CLINICAL AUDITS (including & QUALITY ACTIVITIES)

In some circumstances, attempts to clearly separate QA from research are unhelpful. Moreover, QA, evaluation and research exist on a continuum of activity, and work that begins as one form of activity can evolve into another over time. Importantly, QA and evaluation commonly involve minimal risk, burden or inconvenience to participants, and, while some level of oversight is necessary, Human Research Ethics Committee (HREC) review processes are often not the optimal pathway for review of these activities. As per the NMHRC, these types of studies can undergo ethical review via an alternate pathway, or in some cases exemption from ethical review. As such these applications will undergo organisational review at the Research Office level to be granted approval (or exemption) to commence.

What really matters is that:

- **participants in QA/evaluation are afforded appropriate protections and respect**
- **QA and/or evaluation is undertaken to generate outcomes that are used to assess and/or improve service provision**
- **those who undertake QA and/or evaluation adhere to relevant ethical principles and state, territory and Commonwealth legislation**
- **organisations provide guidance and oversight to ensure activities are conducted ethically including a pathway to address concerns.**

The NHMRC National Statement on Ethical Conduct in Human Research (2007) (chapter 2.1), defines negligible risk as "*when 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*".

The NHMRC: Ethical Considerations in Quality Assurance and Evaluation Activities (2014), state that these studies' "*primary purpose is to monitor or improve the quality of service delivered by an individual or an organisation.*" Furthermore, evaluation is a term that generally encompasses the systematic collection and analysis of information to make judgements, usually about the effectiveness, efficiency and/or appropriateness of an activity which include, but are not limited to, clinical audits, quality improvement activity or health service delivery evaluation.

This application pathway has been developed to expedite the approval of negligible risk type research or provide the oversight for quality and evaluation activity as described above.

THIS FORM CAN BE USED FOR TWO PURPOSES:

1) **To expedite the process of negligible risk type research, where an ethics approval certificate will be provided.**
2) **To provide oversight for quality and evaluation activity, where an organisational approval /exemption from ethics review certificate will be provided.**

THIS FORM IS TO BE USED IF THE INTENDED PROJECT FALLS INTO ONE OF THE FOLLOWING CATEGORIES :

A. The research involves the potential for no more than **negligible risk**, for example:
- Use of anonymous existing clinical data with no foreseeable risk; or
- Use of existing research data for which consent has been provided for the secondary use; or
- Project using surveys or basic short interviews

OR

B. The proposed access is directly related to a **quality/evaluation activity** e.g. clinical audit, training or health service delivery evaluation, where the proposed investigators:
- Have "rightful" access i.e. for clinical data as a treating clinician, head of department or junior medical staff under direct supervision from either of these persons, or for research data the Principal Investigator; AND
- Are using non-identifiable data only; OR

- For use of research data the extended consent provided by the participant covers the secondary use of the data.

THIS FORM IS <u>NOT</u> BE USED IF:

- It is activity which is greater than negligible risk e.g. vulnerable groups are involved; or
- sensitive questions are being asked, or participation which involves more than inconvenience;
- The activity potentially infringes the privacy or professional reputation of participants, or organisations;
- Identifiable data will be accessed by staff who do not have rightful clinical access and/or consent was not obtained to use this data for research;
- If there is a reasonable expectation that the project findings arising from the project may be clinically relevant to the individual participants e.g. the disclosure of genetic testing/results; or
- It is a project that will last for more than two years.
- The study is multi-site

NOTE: In each of the above cases a standard research submission for research ethics approval is required.

PLEASE NOTE:

- This form is for use in Victoria only. If data from other organizations will also be used as part of the project, i.e. multi-site, **consider** if this is the most appropriate form to be used. If other sites are conducting the same project, this from will need to be submitted to each participating site
- This application facilitates an expedited review and acknowledgment process. Once approved, a formal letter of approval (for Negligible Risk research) or exemption (for Quality Assurance & Clinical Audits) will be issued to the Principal Investigator.
- Projects submitted via this pathway cannot be amended once approved; amendments must be submitted as a new application.

IMPORTANT: Please contact your Research Office for guidance if you are unsure whether this application process best suits your proposed study.