The following definitions apply and should help you to determine the level of risk of your intended activity.

**Negligible Risk Research (NRR)**

The [NHMRC National Statement on Ethical Conduct in Human Research (2007 updated 2018)](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018) (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*”. For example:

* Use of existing de-identified clinical data with no foreseeable risk to the participants;
* Use of existing research data for which consent has been provided for the secondary use; or
* Project using surveys or basic short interviews

**Quality Assurance (QA), Clinical Audit and Evaluation Activity**

The [NHMRC: Ethical Considerations in Quality Assurance and Evaluation Activities (2014),](https://www.nhmrc.gov.au/about-us/resources/ethical-considerations-quality-assurance-and-evaluation-activities) state that the primary purpose of these studies’ “*is to monitor or improve the quality of service delivered by an individual or an organisation.” Audits form part of standard hospital monitoring processes and are not research.* 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 for example:

* clinical audits;
* quality improvement activity; or
* health service delivery evaluation

Irrespective of whether an activity is called research or QA or evaluation, those conducting the activity must consider whether the people involved (e.g. participants, staff or the community) will be exposed to any risk, burden, inconvenience or possible breach of their privacy.

An activity where the primary purpose is to monitor or improve the quality of service delivered by an individual or an organisation is a QA activity. Terms such as ‘peer review’, ‘quality assurance’, ‘quality improvement’, ‘quality activities’, ‘quality studies’ and ‘audit’ are often used interchangeably. We use the term ‘quality assurance’ to include all of these terms.

**Is my intended project actually a QA or NRR project?**

Investigators are advised to check that the intended project does **NOT** include any activities that would increase the risk profile of the project and accordingly escalate it to a higher level of ethical review. The checklist below has been provided to assist researchers to choose the correct submission pathway for their Project.

|  |  |  |
| --- | --- | --- |
| **LEVEL OF RISK CHECKLIST** | **Yes** | **No** |
| Is it an activity which is greater than negligible risk e.g. Vulnerable groups are involved? |  |  |
| Are sensitive questions being asked? |  |  |
| Does participation involve more than inconvenience? |  |  |
| Does the activity potentially infringe the privacy or professional reputation of participants, or organisations? |  |  |
| Will identifiable data be accessed by staff who do not have rightful clinical access and/or consent was not obtained to use this data for research? |  |  |
| Is there 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? |  |  |
| Is it a project that will last for more than two years? |  |  |
| Is it a multi-site study? |  |  |

**If you answer YES to any of the questions above the intended project is NOT APPLICABLE for submission via the QA/NRR submission pathway.**

In each of these cases, a standard research submission for research ethics approval is required. See more information [here](http://www.wh.org.au/EducationandResearch/Research/Research%20Ethics/Pages/Determine-Review-Pathway.aspx) to determine the review pathway suitable for your project.

**If you answered NO to all of the questions above the intended project IS APPLICABLE for submission via the QA/NRR submission pathway.**