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| --- | --- | --- |
| Quality assurance, audit & negligible risk research | YES | NO |
| Does the proposed project involve MORE than negligible risk?  “*Negligible risk research describes research in which there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience*.” (National Statement, 2018). |  |  |
| Does the proposed project involve physical, psychological, financial, social, and information/privacy risks? |  |  |
| Is the proposed activity to be conducted by a person who does NOT normally have access to the patient’s records for clinical care or a directly related secondary purpose? |  |  |
| Does the proposed activity risk breaching the confidentiality of any individual’s personal information beyond that experienced in the provision of routine care? |  |  |
| Does the proposed activity seek to gather information about the patient beyond that collected in routine clinical care? |  |  |
| Does the proposed activity involve any clinically significant departure from the routine clinical care provided to the patients? |  |  |
| Does the proposed activity involve randomisation or the use of a control group or a placebo? |  |  |
| Does the proposed activity pose any risks/burden for patients beyond those of their routine care? |  |  |
| Does the proposed activity potentially infringe the rights, privacy or professional reputation of carers, healthcare providers or institutions? |  |  |
| Does the proposed activity test non-standard (innovative) protocols or equipment? |  |  |
| If you answered ‘No’ to all of the above, you are eligible to submit a QA or negligible risk application.  If you answered ‘Yes’ to one or more of the above questions, please proceed to the table on the next page. | | |

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| Low and Greater than Low Risk research | YES | NO |
| Is the risk to participants more serious than discomfort? (e.g. physical, psychological, economic, emotional or legal harm) |  |  |
| Does the research include interventions and therapies, including clinical and non-clinical trials and innovations? |  |  |
| Does the research include human genetics or human stem cells? |  |  |
| Does the research activity target women who are pregnant and the human foetus? |  |  |
| Does the research activity target Children and young people? |  |  |
| Does the research activity target People in dependent or unequal relationships? |  |  |
| Does the research activity target People highly dependent on medical care who may be unable to give consent? |  |  |
| Does the research activity target People with a cognitive impairment, an intellectual disability, or a mental illness? |  |  |
| Does the research activity target People who may be involved in illegal activities? |  |  |
| Does the research activity target Aboriginal and Torres Strait Islander Peoples? |  |  |
| If you answered ‘No’ to all of the above, your research is classified as Low Risk.  If you answered ‘Yes’ to one or more of the above questions, your research requires a Greater than Low Risk application. | | |