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**Research Level of Risk Checklist**

**This form is to help you ascertain whether your proposed activity will require Ethical Review and what Level of Ethical Review. This will help provide guidance on the pathway it must take.**

**This is a guide only, you are welcome to contact our office at any time for further advice**

**This form does not need to be submitted with the application.**

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| **Checklist for Quality Assurance/Audit** |  | | |
| Reference: ***NHMRC 2014 – Ethical Considerations in Quality Assurance and Evaluation Activities***  Eastern Health requires Quality Assurance/Audit activities to be registered with the Office of Research and Ethics via Ethical Review Manager (ERM) | | | |
| **Q1.** Does the proposed activity pose any **risks/burden** for patients beyond those of their routine care? | | Choose an item. | |
| **Q2.** 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? | | Choose an item. | |
| **Q3.** Does the proposed activity risk breaching the confidentiality of any individual’s personal information beyond that experienced in the provision of routine care? | | Choose an item. | |
| **Q4**. Does the proposed activity seek to gather information about the patient beyond that collected in routine clinical care? | | Choose an item. | |
| **Q5.** Does the proposed activity involve any clinically significant departure from the routine clinical care provided to the patients? | | Choose an item. | |
| **Q6.** Does the proposed activity involve randomisation or the use of a control group or a placebo? | | Choose an item. | |
| **Q7.** Does the proposed activity compare cohorts or vulnerable groups? | | Choose an item. | |
| **Q8**. Does the proposed activity potentially infringe the rights, privacy or professional reputation of carers, healthcare providers or institutions? | | Choose an item. | |
| **Q9.** Does the proposed activity test non-standard (innovative) protocols or equipment? | | Choose an item. | |
| **Q10.** Does the proposed activity involve contacting patients that is not part of routine care by any means, including but not limited to, telephone, mail or email, and therefore the patient would be unaware that such contact will be made? Will the contact be made by individuals who would not normally make such routine contact? | | Choose an item. | |
| If **“Yes”** to any question it appears the proposed activity does not qualify as a Quality Assurance or Audit Activity.  If **“No”** to all of the above questions, activity will require [Quality Assurance or Audit Activity registration](http://www.easternhealth.org.au/research-ethics/research-ethics/quick-links-to-forms-and-templates) only. This DOES NOT constitute Ethical approval. Letter of registration is provided. | | | |
| **Checklist for HREC Review** | | |  | |
| **Q1.** Is the risk more than simple discomfort? If Yes = **NOT Low Risk**  *Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk (2.1.6 National Statement).* | | | Choose an item. | |
| **Q2.** Does the research include interventions and therapies, including clinical and non-clinical trials and innovations? | | | Choose an item. | |
| **Q3**. Does the research include human genetics or human stem cells? | | | Choose an item. | |
| **Q4**. Does the research activity target women who are pregnant and the human fetus? | | | Choose an item. | |
| **Q5.** Does the research activity target children and young people? | | | Choose an item. | |
| **Q6.** Does the research activity target people in dependent or unequal relationships? | | | Choose an item. | |
| **Q7**. Does the research activity target people highly dependent on medical care who may be unable to give consent? | | | Choose an item. | |
| **Q8.** Does the research activity target people with a cognitive impairment, an intellectual disability, or a mental illness? | | | Choose an item. | |
| **Q9.** Does the research activity target people who may be involved in illegal activities? | | | Choose an item. | |
| **Q10.** Does the research activity target Aboriginal and Torres Strait Islander Peoples? | | | Choose an item. | |
| If **“Yes”** to one or more questions above the research is **NOT Low Risk and** [**a HREC application**](https://ethicsform.org/au/SignIn.aspx) **is required**.  If you have current approval from an external NHMRC certified HREC, you may apply for research governance authorisation. | | | | |

**Both Low and Negligible Risk, and Greater than Low Risk (HREC Review) applications are to be submitted via**

**Ethical Review Manager (ERM). Links/Information can be found on our website.**

[**https://www.easternhealth.org.au/research-ethics/guidance**](https://www.easternhealth.org.au/research-ethics/guidance)

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| **Checklist for Case Study Reports/Series** |  |
| **Q1**. Is the report regarding an individual patient(s)? | Choose an item. |
| **Q2.** Have you obtained consent from the participant or next of kin (deceased patient’s) | Choose an item. |
| If **“Yes”** to both questions then this project meets the criteria as a case report.  If required for publication purposes you may obtain a letter from the Office of Research and Ethics confirming so. Please note that consent is required to publish case reports as Eastern Health HREC **will not** grant waiver of consent for case reports. | |

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