Does the Activity require Ethical Review? What Level of Ethical Review?

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| **Checklist for Quality Assurance/Audit** | | | **Yes** | | **No** |
| 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. | | | | | |
| 1 | Does the proposed activity pose any **risks/burden** for patients beyond those of their routine care? |  | |  | |
| 2 | 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? |  | |  | |
| 3 | Does the proposed activity risk breaching the confidentiality of any individual’s personal information beyond that experienced in the provision of routine care? |  | |  | |
| 4 | Does the proposed activity seek to gather information about the patient beyond that collected in routine clinical care? |  | |  | |
| 5 | Does the proposed activity involve any clinically significant departure from the routine clinical care provided to the patients? |  | |  | |
| 6 | Does the proposed activity involve randomisation or the use of a control group or a placebo? |  | |  | |
| 7 | Does the proposed activity compare cohorts or vulnerable groups? |  | |  | |
| 8 | Does the proposed activity potentially infringe the rights, privacy or professional reputation of carers, healthcare providers or institutions? |  | |  | |
| 9 | Does the proposed activity test non-standard (innovative) protocols or equipment? |  | |  | |
| 10 | 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? |  | |  | |
| **If “No” to all of the above, the 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 for the purpose of publication.** You are able to obtain a letter from the Office of Research and Ethics confirming this for publication purposes. | | | | | |

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| **Checklist for Case Study Reports/Series** | | | **Yes** | | **No** |
| Reference: ***BMJ Publishing Group Limited Guidelines*** | | | | | |
| 1 | Is the report regarding an individual patient(s)? |  | |  | |
| 2 | Have you obtained consent from the participant or next of kin (deceased patient’s) |  | |  | |
| If **“Yes”** to both questions then this project meets the criteria as a case report. If required for publication purposes you are able to obtain a letter from the Office of Research and Ethics confirming so. Please note that consent is required to publish case reports the Eastern Health HREC **will not** grant waiver of consent for case reports. | | | | | |

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| **Checklist for HREC Review** | | | **Yes** | | **No** |
| Reference: ***NHMRC 2007 (Updated 2018) – National Statement on Ethical Conduct in Human Research***  Negligible or Low Risk Research reviewed by HREC Sub-Committee | | | | | |
| 1 | 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).* |  | |  | |
| 2 | Does the research include interventions and therapies, including clinical and non-clinical trials and innovations? |  | |  | |
| 3 | Does the research include human genetics or human stem cells? |  | |  | |
| 4 | Does the research activity target women who are pregnant and the human fetus? |  | |  | |
| 5 | Does the research activity target children and young people? |  | |  | |
| 6 | Does the research activity target people in dependent or unequal relationships? |  | |  | |
| 7 | Does the research activity target people highly dependent on medical care who may be unable to give consent? |  | |  | |
| 8 | Does the research activity target people with a cognitive impairment, an intellectual disability, or a mental illness? |  | |  | |
| 9 | Does the research activity target people who may be involved in illegal activities? |  | |  | |
| 10 | Does the research activity target Aboriginal and Torres Strait Islander Peoples? |  | |  | |
| If **“Yes”** to one or more questions 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. | | | | | |