This form is designed to assist in screening for and identifying when a proposed quality improvement activity has ethical risks associated with it. The checklist below is based upon the NSW Office for Health and Medical Research guideline [*GL2007\_020: Quality Improvement & Ethical Review: A Practice Guide for NSW*.](https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=GL2007_020) Any health professional wishing to undertake a Quality Assurance Activity must review this guideline and complete the checklist below.

In accordance with GL2007\_020, if responses to all of the statements in the checklist are “**false**”, then no ethical risks have been identified with this project and review by an ethics review committee is not required. You are not required to complete Part B of this form or submit to the Research Office. Even if submission is not required, please see [this fact-sheet](https://www.ipc.nsw.gov.au/fact-sheet-de-identification-personal-information) regarding de-identification of personal information.

If the response to any of the statements in the checklist is “**true**”, or may be “**true**”, you will need to provide further information in this form and submit for review by the Research Office or the SESLHD Low and Negligible Risk Research Review Committee. This should be done by following these steps:

1. Complete this form
2. Email form to SESLHD Research Office SESLHD-RSO@health.nsw.gov.au, with the subject line ‘QA/QI project submission’.

What happens then?

Your submission will be reviewed by the Low/Negligible Risk (LNR) Ethics Committee. This Committee meets fortnightly, please see the Research Office [website](https://www.seslhd.health.nsw.gov.au/services-clinics/directory/research-home/ethics/committee-details-meeting-dates) for meeting dates and submission deadlines. After your submission is reviewed, you will receive feedback from the Office via email. This feedback will either advise that your project did not raise any ethical risks requiring approval by an ethical review committee in accordance with NSW Health policy, or inform you that the project must be submitted for review and approval by an ethical review committee via the REGIS platform.

|  |
| --- |
| **Part A:** Ethical Risks Checklist |
| **Project Title:** |  |
| **Name of Project Lead(s):**  |  |
| **Contact Email:**  |  |
| **Phone No:** |  |
| **Ward/Department and Site/Service conducting activity:** **\*Please note that activities happening across multiple institutions are not eligible as a QA/QI submission. Please contact** **SESLHD-RSO@health.nsw.gov.au** **if unsure.** |  |
| **Declaration:** | I confirm that this project has been approved by my line manager / Head of Department. Choose an item.I have reviewed [the fact-sheet](https://www.ipc.nsw.gov.au/fact-sheet-de-identification-personal-information) regarding de-identification of personal information. Choose an item. |
| **Date:**  |  |
| **Section 1 : ISSUES THAT MAY REQUIRE CONSENT** | **TRUE/FALSE** |
|  | The project involves direct contact with patients, consumers, or members of the public. | Choose an item. |
|  | The project poses additional risks or burdens to the patient beyond their routine care. | Choose an item. |
|  | The data to be collected is of a sensitive nature or application.[GL2007\_020 extract: *“Examples of sensitive data include a diagnosis of HIV/AIDS or sexually transmitted disease, mental illness, sexual assault, domestic violence, drug and alcohol use, genetic testing or results, IVF or artificial insemination, or where a child is considered to be at risk…*”] | Choose an item. |
|  | The purpose of the activity is not ‘directly related’ to the patient’s disease, illness or its management.[GL2007\_020 extract: *“Secondary use of health information (eg for research) that is not directly related to the primary purpose for which it was collected (i.e. to provide clinical care to the patient) must be approved by an HREC…*”] | Choose an item. |
|  | The data will be used or available in such a way that may identify individuals.[Further note: project leads must also consider the risk of ‘re-identification’] | Choose an item. |
|  |
| **Section 2 : PRIVACY AND CONFIDENTIALITY** | **TRUE/FALSE** |
|  | There is no process for de-identification of data.*[Information regarding de-identification of personal data can be found* [*here*](https://www.ipc.nsw.gov.au/fact-sheet-de-identification-personal-information)*, Information and Privacy Commission, NSW]* | Choose an item. |
|  | Access to personal information will extend beyond those who are members of the clinical care team, or to others who normally do not have access to the patient’s record, or to other data sets.[GL2007\_020 extract: *“The ‘clinical care team’ refers to the group of health professionals involved in provision of clinical care…*”] | Choose an item. |
|  | The project involves rare conditions or a small community. | Choose an item. |
|  | Data will be selected or identified by:* Aboriginal or Torres Strait Islander status; or
* Ethnic, religious or minority group.

[Further note: other vulnerable or minority groups may include children, people highly dependent on medical care who may be unable to give consent, women who are pregnant and the human foetus, people with a cognitive impairment, an intellectual disability, or mental illness, people who may be involved in illegal activities or people in other countries] | Choose an item. |
|  | Data will be collected beyond that which is normally collected in routine care. | Choose an item. |
|  |  |
| **Section 3 : OTHER IMPLICATIONS** | **TRUE/FALSE** |
|  | The project uses ‘new’ interventions, protocols or equipment. | Choose an item. |
|  | The project will involve allocation of patients to groups to enable comparisons. | Choose an item. |
|  | The project will involve genetic tests/testing. | Choose an item. |
|  | The project may potentially infringe the rights, privacy or professional reputation of carers, health professionals or institutions. | Choose an item. |
|  | The project involves use of placebo. | Choose an item. |
|  | The project is likely to generate data/findings that may lead to publication. | Choose an item. |
|  |  |  |
| If the response to any of the above statements is “**true**”, or may be “**true**”, you will need to complete Part B of this form and submit the form for review by the Research Office or the SESLHD Low and Negligible Risk Research Review Committee (please follow steps at the top of Page 1).In accordance with GL2007\_020, if responses to all of the above statements in the checklist are “**false**”, then no ethical risks have been identified with this project and an ethics review is not required. You are not required to complete Part B of this form or submit to the Research Office. |

**Part B** is to be completed by applicants whose projects have been screened using the above checklist and have returned “**true**” responses.

|  |
| --- |
| **Part B:** Project Summary |
| **Project Description** |
| *Provide a detailed description of the project including: aims/objectives, purpose, background, study design/methods. Please ensure it is clear how the project is designed to improve the performance or quality of a service delivered by an organisation as judged by accepted standards, or to ensure the program/service conforms to expected norms.****Background******Primary Aim******Secondary Aims******Method*** *(data/patients to be accessed, no. of patients/records, data sources, list of data variables, method of extraction and by whom, method of de-identification and by whom).****Review/Analysis of data*** ***Data storage******Planned use of data*** |
| **For any ethical risks identified in Part A, please list the risk and provide a brief summary of what will be collected and what the plan is to minimise ethical risks, e.g. data will be de-identified and a description of how this will be done.** |
| Risk identified | *Enter risk* |
| *Brief Summary and strategy to minimise risk* |
| Risk identified | *Enter risk* |
| *Brief Summary and strategy to minimise risk*  |
| Risk identified | *Enter risk* |
| *Brief Summary and strategy to minimise risk*  |

If there are more than three identified risks, please document in a word document and attach.

Please email form to SESLHD Research Office SESLHD-RSO@health.nsw.gov.au, with the subject line ‘QA/QI project submission’.