All improvement, innovation, and research activities conducted within ISLHD are required to screen for ethical risks prior to commencement of the project.

This form is designed to assist in screening for and identifying when a proposed 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*. The checklist below is written in the style dictated by the guideline. For more information on how to interpret the questions below refer to [GL2007\_020](https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/GL2007_020.pdf).

Steps in screening for ethical risks and seeking further review where required include:

1. **Complete Part A**: **Ethics Screening Checklist**. Answer truthfully and if unsure, select “True”. If no TRUE responses were identified by the checklist, then register your project via the [Improvement and Innovation Portal](http://islhnweb.lan.sesahs.nsw.gov.au/Improvement_and_Innovation/Register.asp) and upload the completed checklist. No further review is required.   
   If any TRUE responses were identified by the checklist, then further review is required. Proceed to Part B.
2. **Complete Part B:** **Project and Ethics Summary**. Complete all the required fields, which outline a summary of your project, including specific information that clarifies the processes for managing the ethical risk(s) identified. Part A and Part B must then be forwarded to the ISLHD Research Office for review via [ISLHD-Research@health.nsw.gov.au](mailto:ISLHD-Research@health.nsw.gov.au).
3. **Part C:** **Review and advice from the ISLHD Research Office.** The ISLHD Research Office will assess applications to determine if review is required by the ISLHD Low and Negligible Risk Research Review Committee. If review is required, the ISLHD Research Office will advise you to prepare an application for submission to the ‘LNR Committee’.   
   For assistance with your ISLHD LNR Application please contact [ISLHD-Research@health.nsw.gov.au](mailto:ISLHD-Research@health.nsw.gov.au).

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| **Part A:** Ethics Screening Checklist | | | |
| **Project Title:** | |  | |
| **Name of Project Lead(s):** | |  | |
| **Contact Email:** | |  | |
| **Phone No:** | |  | |
| **Ward/Department and Site/Service:** | |  | |
| **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. | | 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.  [ISLHD New Intervention Assessment Process Procedure](http://islhnweb/Policies_Procedures_Guidelines/Clinical/Governance/documents/ISLHD-CLIN-PD-88-NewInterventionAssessmentProcess.pdf) | | 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 provide further information to determine if review by the ISLHD Low and Negligible Risk Research Review Committee is required.  In this case, complete PART B and forward **both** PART A and PART B to the ISLHD Research Office via [ISLHD-Research@health.nsw.gov.au](mailto:ISLHD-Research@health.nsw.gov.au).  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. | | | |

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| **Register your project and this ethics screening via the ISLHD** [**Improvement and Innovation Portal**](http://islhnweb.lan.sesahs.nsw.gov.au/Improvement_and_Innovation/Register.asp)**, to assist with District reporting requirements.** | |
| Project registration has been completed. | **Yes  No** |
| **CONFLICT OF INTEREST DECLARATION** | |
| Under the [*Australian Code for the Responsible Conduct of Research*](https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018#download)(the Code), a conflict of interest exists in a situation where an independent observer might reasonably conclude that the professional actions of a person are or may be unduly influenced by other interests.  By signing below, the Project Lead agrees that conflicts of interest are being managed in accordance with the Code. | |
| Name | Signature |

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

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| **Part B:** Project and Ethics Summary | | |
| **Has patient/consumer data collection commenced for this project?** | | |
| **Yes  No** | | Click here to enter text. |
| **Project Description**  **(Provide a detailed description of the project including: aims/objectives, background, study design/methods)** | | |
|  | | |
| **List the Ethical Risks Identified in Part A, with a brief summary of what will be collected and what the plan is to minimise ethical risks, including any related documents e.g. patient survey tool, will data be de-identified** | | |
| <Include Question number where TRUE was recorded> | <Include the question where TRUE was recorded.>  Click here to enter text. | |
| *Brief Summary: <*e.g. list the ethical risks and strategies to minimize these risks.>  Click here to enter text. | | |
| Risk No. | Click here to enter text. | |
| *Brief Summary:*  Click here to enter text. | | |
| **Risk No.** | Click here to enter text. | |
| *Brief Summary:*  Click here to enter text. | | |

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

**Part C** is to be completed by the ISLHD Research Office and returned to the applicant listed on Part A.

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| **Part C:** Review and advice from the ISLHD Research Office | |
| **Have any ethical risks been identified by the ISLHD Research Office?** | |
| **Yes  No** |  |
| **Document Recommendations and Response below.** | |
| This project complies with NSW Office for Health and Medical Research Guideline 2007\_020 and is able to commence as an activity with no further ethical review required. Please register this project as outlined in the instructions at the top of this document.  This project complies with and is defined as low/negligible risk research according to the National Statement on Ethical Conduct in Human Research 2007 (Updated 2018), making it eligible for review by the ISLHD Low and Negligible Risk Research Review Committee. | |
| Ethical risks have been identified which require further advice from a Human Research Ethics Committee (HREC). See link below for additional information.  <https://www.uow.edu.au/research-and-innovation/researcher-support/ethics/human-ethics/> | |
| **Comments**  Click here to enter text. | |
| **ISLHD Research Office:** Click here to enter text.  **Date:** Click here to enter text. | |