|  |
| --- |
| **NSLHD HUMAN RESEARCH ETHICS COMMITTEE (HREC)**  **APPLICATION FOR THE REQUEST OF A WAIVER OF CONSENT** |

In order to waive the requirement of consent for the use of personal information, or personal health information, for a secondary purpose (i.e. medical research) the NSLHD HREC must be satisfied that the conditions for a waiver of consent are met as per:

Sections 2.3.9 and 2.3.10 of the [National Statement on Ethical Conduct in Human Research, 2007 (updated 2019)](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018)and;

Section 4 of the Statutory Guidelines on Research contained in the [Health Records and Information Privacy act 2002 (NSW)](https://www.ipc.nsw.gov.au/sites/default/files/file_manager/privacy_statutory_guidelines_research.pdf).

Please provide the following information to assist the HREC in determining the suitability to grant a waiver of consent for the proposed research.

|  |  |
| --- | --- |
| **The organisation(s) proposing to collect, use and/or disclose personal and/or health information for this project.** |  |
| **The data variables sought from the organisation(s) or to be used by the organisation(s) and approved by the HREC.** |  |
| **The number of patient medical records involved** |  |
| **How the use and disclosure of personal health information in this project is reasonably necessary for research in the public interest.** |  |
| **Provide confirmation that reasonable steps will be taken to de-identify the information, or if the purpose of the research cannot be served by using or disclosing de-identified information.** |  |
| **Requested Date Range** |  |
| **Justification for a waiver of consent as per 2.3.10 National Statement. Please respond to each in a point-wise manor.** |  |
| *a) involvement in the research carries no more than low risk (see paragraphs 2.1.6 and 2.1.7, page 18) to participants.* |  |
| *b) the benefits from the research justify any risks of harm associated with not seeking consent.* |  |
| *c) it is impracticable to obtain consent (for example, due to the quantity, age or accessibility of records).\** |  |
| *d) there is no known or likely reason for thinking that participants would not have consented if they had been asked.* |  |
| *e) there is sufficient protection of their privacy.* |  |
| *f) there is an adequate plan to protect the confidentiality of data* |  |
| *g) in case the results have significance for the participants’ welfare there is, where practicable, a plan for making information arising from the research available to them (for example, via a disease-specific website or regional news media)* |  |
| *h) the possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled.* |  |
| *i) the waiver is not prohibited by State, federal, or international law.* |  |

* **Other factors an HREC may consider when assessing if it is impracticable to seek consent in the circumstances (As per IPC Statutory Guidelines on Research):**

The proportion of individuals who are likely to have moved or died since the health information

was originally collected;

· The risk of introducing potential bias into the research, thereby affecting the generalisability and

validity of the results;

· The risk of creating additional threats to privacy by having to link information in order to locate and

contact individuals to seek their consent;

· The risk of inflicting psychological, social or other harm by contacting individuals with particular

conditions in certain circumstances;