Protocol Outline to apply for an Exemption from Ethical Review

|  |  |
| --- | --- |
| **Project Title:** |  |
| **Site/s / Location/s:** |  |
| **Primary Investigator** |  |
| Name: |
| Address: |  |
| Phone: |  |
| Email: |  |
| **Co-Investigators:** |  |
| **Planned Start Date:** |  |
| **Target Completion:** |  |

BACKGROUND

*Include information based on literature review, existing knowledge and investigators’ experiences.*

[…]

POTENTIAL SIGNIFICANCE

*What is the significance of this project? How will the results contribute to improving medical care? List and explain all benefits that may result from your project.*

[…]

DESCRIBE THE PROJECT DESIGN

*The methodology section is the most important part of the protocol. It should include detailed information on the procedures to be used, measurements to be taken, observations to be made, data to be analysed, locations and people involved etc.*

*Include details about the data and database you will extract your data from. Please also explain the process of de-identification, demonstrating you are meeting below requirements.*

[…]

JUSTIFICATION FOR EXEMPTION FROM ETHICAL REVIEW

*Please address the following requirements for an exemption and how you meet them. Note, only one of the clauses (a) – (d) need to be met.*

5.1.17 Research that may be eligible for exemption from ethics review includes research that carries a lower risk to participants or the community **and** satisfies one or more of the conditions in (a)–(d), below:

1. the research involves the use of collections of information or data from which all personal identifiers have been removed prior to being received by the researchers and where researchers explicitly agree:
2. not to attempt to re-identify those with whom the information or data is associated;
3. to take all reasonable steps to prevent re-identification of the information or data for unauthorised purposes or access to the information or data by those who are not authorised; and
4. that any sharing of any research data during or after the project will not create any additional risks of re-identification of the information or data;
5. the research is restricted to surveys and observation of public behaviour using information that was or will be collected and recorded without personal identifiers and is highly unlikely to cause distress to anyone associated with the information or the outcomes of the research;
6. the research is conducted as part of an educational training program in which the research activity is for training purposes only and where any outcomes or documentation are for program use only;
7. the research uses only information that is publicly available through a mechanism set out by legislation or regulation and that is protected by law, such as mandatory reporting information, information obtained from registries of births and deaths, coronial investigations or reports of the Australian Bureau of Statistics.

National Statement on Ethical Conduct in Human Research (2023)

REFERENCES

*List all sources you have used to put this proposal together.*

[…]