Adventist HealthCare Research

Apply to be Exempt from Ethical Review

If your project meets the following criteria as stated at 5.1.17 of the National Statement (NS)¹, it may be possible to apply for an exemption from ethical review:

- The proposed project is of lower risk² and satisfies one or more of the conditions in (a) (d) below
- (a) 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:
 - (i) not to attempt to re-identify those with whom the information or data is associated;
 - (ii) 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
 - (iii) 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; and/or
- (b) 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; and/or
- (c) 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; and/or
- (d) 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.

Example:

You would like to conduct a retrospective analysis of existing patient data, pre- and post intervention, and you don't need any personal identifiers (e.g. name, DOB, MRN, etc) to conduct your analysis. There is a data custodian, who is not on the research team who will extract and de-identify the data from the existing patient database, then pass it on to you to conduct the analysis. This proposal would qualify for an exemption from ethical review.

¹ National Health and Medical Research Council, Australian Research Council and Universities Australia (2023). *National Statement on Ethical Conduct in Human Research*. Canberra: National Health and Medical Research Council. Retrieved from NHMRC.gov.au: <u>https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023#block-views-block-file-attachments-content-block-1</u>

² lower risk (research): Research in which there is no risk of harm, but in which there is a risk of discomfort and in which there may also be a foreseeable burden (low risk research) OR research in which there is no risk of harm or discomfort, but which includes a potential for minor burden or inconvenience (minimal risk research).

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PROCEDURE

- 1. If you believe your research qualifies for an exemption of ethical review, please download and complete the form *Protocol Outline Exemption from Ethical Review*³
- 2. Email your completed Protocol Outline to the Research Office at research@sah.org.au.
- 3. Upon receipt of your submission, the Research Office will conduct an internal review of the proposal.
- 4. Should the project comply with above criteria, we will recommend to the AHCL HREC Chairperson to exempt the project from ethical review.
- 5. The Research Office will issue a letter confirming your project's exemption from ethical review once the HREC Chairperson's confirmation is received. You can use this letter as proof of ethical consideration for journals and conference organisers.

³ Available on the Sydney Adventist Hospital website at: <u>https://www.sah.org.au/research-ethical-review/</u>