national echo database australia

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Summary of Patient Consent Process
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Following is a guide to the informed consent process for patients whose data will be included in NEDA. Please refer to site specific agreements as appropriate.

The NEDA study protocol version 5.2 is the version of the study protocol referred to in this document. Section 8.3 discusses the consent process for retrospective data in the study.

There are two arms of NEDA: A retrospective and a prospective arm.

Retrospective arm:

For the retrospective arm, the entire database is scraped from a backup copy. Because of the nature of this type of data collection, patient consent is not possible and we have been granted a consent waiver by the Human Research Ethics Committees from the University of Notre Dame Australia (**UNDA**) and the Royal Prince Alfred Hospital, Sydney as the National Ethics Application Form (**NEAF**) principal applicant hospital. Each of the participating NEAF sites around Australia are covered by this approval. We also have approval for this consent waiver by the Australian institute of Health and Welfare (**AIHW**) for data linkage with the National Deaths Index (NDI). Individual hospitals or echo labs not covered by either the UNDA HREC or NEAF HREC have had (or will have) individual HREC applications for consent waiver for retrospective data.

Our eligibility for consent waiver for retrospective data is based on the following:

The NEDA study is a Low Risk Study to participants, with our justification based on guidelines contained in Chapter 2.3 of the NH&MRC National Statement on Ethical Conduct of Human Research:

a) We are collecting data which is already part of a standard echo examination and performed for clinical indications. We are not requesting any additional information outside of standard clinical practice.

b) Consenting individual participants would be impractical given the volume of individuals involved.

c) There are no suitable alternatives involving fuller disclosure by which the aims of the research can be achieved.

d) The benefits of the research justify any risks of harm associated with not seeking consent.

e) There is no known or likely reason a participant would refuse to be involved if consented

f) Individual patient data collected as part of this study will not be returned to the treating clinicians or patients in any form, and no changes to management of patients will result from the data.

g) There are sufficient protections in place to ensure privacy and confidentiality of data

Prospective arm:

The prospective arm of NEDA starts after the retrospective data has been collected. This involves each echo lab involved in NEDA employing a verbal consent process, which has been approved as part of the same HREC applications as described above. The verbal informed consent script is documented separately and is subject to approval at each site, without the requirement for formal written informed consent. The intention of the script is an opt-out process, whereby patients requesting not to have their data included in NEDA inform the relevant staff member of their wishes, after which NEDA investigators are informed and the patient's data is removed permanently from NEDA. The verbal script is simple, brief, and should not significantly affect the work flow for the participating echo lab.