Health and Disability Ethics Committees
Ministry of Health
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Wednesday, 7 March 2018

Rachael Walker
Private Bag 1201,
Hawke's Bay Mail Centre,
Napier 4142

Dear Rachael

Study title:	Remote Patient Monitoring to support uptake and sustainability of peritoneal dialysis

Thank you for emailing HDEC a completed scope of review form on 05 March 2018. The Secretariat has assessed the information provided in your form and supporting documents against the Standard Operating Procedures.

Your study will not require submission to HDEC, as on the basis of the information you have submitted, it does not appear to be within the scope of HDEC review. This scope is described in section three of the Standard Operating Procedures for Health and Disability Ethics Committees.

This study will explore patient and clinician perceptions of remote patient monitoring to support choosing and sustaining peritoneal dialysis as a treatment modality. Participants will be recruited by the participating unit and a clinician from that unit will invite patients to participate in the study. The Primary Investigator will not access any health information about potential participants prior to obtaining informed consent. This study will involve interviews with clinicians who provide peritoneal dialysis care and patients who have experienced peritoneal dialysis and their caregivers in three dialysis centres in New Zealand. This is a minimal risk observational study that involves fully informed and consenting participants who are not vulnerable, are not having treatment withheld, tissue accessed, or health information accessed without consent. Minimal risk observational studies do not require HDEC review.

An observational study requires HDEC review only if the study involves more than minimal risk (that is, potential participants could reasonably be expected to regard the probability and magnitude of possible harms resulting from their participation in the study to be greater than those encountered in those aspects of their everyday life that relate to the study).

For the avoidance of doubt, an observational study always involves more than minimal risk if it involves one or more of the following:

- one or more participants who will not have given informed consent to participate, or
- one or more participants who are vulnerable (that is, who have restricted capability to make independent decisions about their participation in the study), or
- standard treatment being withheld from one or more participants, or
- the storage, preservation or use of human tissue without consent, or
- the disclosure of health information without authorisation.

If you consider that our advice on your project being out of scope is in incorrect please contact us as soon as possible giving reasons for this.

This letter does not constitute ethical approval or endorsement for the activity described in your application, but may be used as evidence that HDEC review is not required for it.

Please note, your locality may have additional ethical review policies, please check with your locality. If your study involves a DHB, you must contact the DHB's research office before you begin. If your study involves a university or polytechnic, you must contact its institutional ethics committee before you begin.

Please don't hesitate to contact us for further information.

Yours sincerely,

Carla Denneny
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