Human Research Ethics Application

Application Management Information
Application ID: 178147
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Version Number: HREA V1.3.1 (2018)
Application submitted to: The Sydney Children's Hospitals Network, The Sydney Children's Hospitals Network Human Research Ethics Committee

The applicant has requested that this ethics application be considered under the Low risk review pathway.

Section 1 – Core Information

Pre-application conditions

Before completing this application, acknowledge that:

1) The HREA has been designed for ethics review of human research, as defined in the National Statement.
2) Adequate resources must be available to conduct this research project.
3) All relevant institutional polices pertaining to the conduct of this research project should be considered and adhered to.
4) Research activities must not commence until ethics approval (and site authorisation, if appropriate) has been provided.
5) The HREA requires the attachment of a Project Description/Protocol.

◉ Acknowledge and Continue

PROJECT OVERVIEW

Q1.1. What is the project title (as presented in the Project Description/Protocol)?

NAVMAN TRIAL: A multi-centre, staggered entry, waitlisted randomised controlled trial in children with chronic kidney disease

Q1.2. Provide a summary of the research project in non-technical language.

This is a multicentre trial to assess the effectiveness and costs of a patient navigator program in children with chronic kidney disease.

Q1.3. Which category/ies of research best describes the project?

Clinical trial

Q1.4. In what environment/s will the research be conducted?

☑ Clinic(s)

☐ Community centre(s)

- [ ] Cultural/religious organisation(s)
- [x] Hospital(s)
- [ ] Online
- [ ] Private residence(s)
- [ ] Professional organisation(s)
- [ ] Public place(s)
- [x] Research institute(s)
- [ ] School system(s)
- [ ] University(ies)
- [ ] Workplace(s)
- [ ] Other

Q1.5. What organisation/entity has overall responsibility for this project?

The University of Sydney will be responsible for overseeing the conduct of this research.

Q1.6. Describe how this research project is currently, or will be, funded.

Currently, seed funding has been secured through the Ludwig Engel Research Fellowship for a pilot study. A NHMRC project graft application for funding in 2019 has been submitted.

Q1.7. When do you anticipate starting the research project?

- [x] As soon as ethics and any other relevant approvals have been provided.

Q1.8. What is the anticipated duration of the research project?

3 Years

PROJECT TEAM

Q1.9. Investigator/ Research team

Provide information on the investigator(s)/ researcher(s) conducting the research.

Investigator/ Researcher 1

Q1.9.1 Title

Associate Professor

Q1.9.2 First Name

Germaine

Q1.9.3 Surname/family name

Wong

Q1.9.4 Email Address

germaine.wong@health.nsw.gov.au

Q1.9.5 Is this person the contact person for this application?
◉ Yes ○ No

Q1.9.5.1 Contact Email Address

germaine.wong@health.nsw.gov.au

Q1.9.5.2 Contact Phone number

0288902696

Q1.9.5.3 Contact Mailing address

Department of Renal Medicine and Transplantation, Westmead Hospital, Westmead 2145

Q1.9.6 Is this person a student on this project?
○ Yes ◉ No

Q1.9.7 Institutional affiliation and position.

CI Wong is an academic transplant nephrologist at Westmead Hospital, in Sydney. She is also a NHMRC Career Development Fellow (Level 2) at the School of Public Health, University of Sydney.

Q1.9.8 Staff ID Optional

Q1.9.9 ORCID Identifier Optional

Q1.9.10 What is the position of this person on the research project?

Chief Investigator/Researcher

Q1.9.11 Does this person have authorisation to sign the application on behalf of all members of the research team?
◉ Yes ○ No

Q1.9.12 Describe the research activities this person will be responsible for.

CI Wong will have overall responsibility for the management of the research project. She will be responsible for developing the research proposal, overseeing the day to day progress of the project and the overall trial design. She will also be responsible for the data analysis, presentation at scientific meeting s and for peer-reviewed publications.

Q1.9.13 Describe the person's expertise relevant to the research activity.

CI Wong has conceived, developed and coordinated one of the largest longitudinal study, the Kids with CKD study (KCAD), across Australia and New Zealand. This observational study has provided the necessary multicentre study infrastructure for the NAVMAN trial, consisting of a clinical coordinating centre that regularly interacts with site investigators and coordinators dedicated to the trial objectives.

Investigator/ Researcher 2

Q1.9.1 Title

Doctor

Q1.9.2 First Name

Hugh

Q1.9.3 Surname/family name

McCartney

Q1.9.4 Email Address

hugh.mccartney@health.nsw.gov.au

Q1.9.5 Is this person the contact person for this application?
◯ Yes ◉ No

Q1.9.6 Is this person a student on this project?
◯ Yes ◉ No

Q1.9.7 Institutional affiliation and position.

Hugh McCarthy is an academic nephrologist and an Early Career Research Fellow at the Children 's Hospitals at Westmead and Randwick encompassing the Sydney Children's Hospital Network (SCHN). He is head of Renal Genomics within SCHN and is a conjoint clinical lecturer at University of Sydney and senior lecturer at University of New South Wales.

Q1.9.8 Staff ID Optional

Q1.9.9 ORCID Identifier Optional

Q1.9.10 What is the position of this person on the research project?

Principal Investigator

Q1.9.11 Does this person have authorisation to sign the application on behalf of all members of the research team?
◯ Yes ◉ No

Q1.9.12 Describe the research activities this person will be responsible for.

PI McCarthy will assist with site specific issues at The Children's Hospital at Westmead and Sydney Children's Hospital Randwick. He will assist with recruitment, and provide intellectual input into the study.

Q1.9.13 Describe the person's expertise relevant to the research activity.

PI McCarthy is a paediatric nephrologist and an Early Career Research Fellow at the University of Sydney. He is also head of renal genomics within the Sydney Children's Hospital Network and chair of the registry subcommittee for the national renal genomics flagship (KIDGEN) of the Australian Genomics Health Alliance (AGHA). For the proposed project, Hugh will identify potential eligible patients, provide supervision to the navigator and oversee the study project across the Sydney Children's Hospital Network. Hugh currently is a committee member on the Sydney Children's Hospital Network Research Committee and the Randwick PaediatricResearch Committee.

Investigator/ Researcher 3

Q1.9.1 Title

Doctor

Q1.9.2 First Name

Fiona

Q1.9.3 Surname/family name

Mackie

Q1.9.4 Email Address

fiona.mackie@health.nsw.gov.au

Q1.9.5 Is this person the contact person for this application?
◯ Yes ◉ No

Q1.9.6 Is this person a student on this project?
◯ Yes ◉ No

Q1.9.7 Institutional affiliation and position.

Dr Mackie is a Staff Specialist in Paediatric Nephrology at Sydney Children's Hospital, Randwick and is a Senior Lecturer for The School of Women's and Children's Health at UNSW.

Q1.9.8 Staff ID Optional

Q1.9.9 ORCID Identifier Optional

Q1.9.10 What is the position of this person on the research project?

Principal Investigator

Q1.9.11 Does this person have authorisation to sign the application on behalf of all members of the research team?
◯ Yes ◉ No

Q1.9.12 Describe the research activities this person will be responsible for.

Dr Mackie will oversee the NAVMAN trial at Sydney Children's Hospital, Randwick and assist with any site specific issues. She will contribute to the overall design of the trial, patient recruitment and provide intellectual input into the study.

Q1.9.13 Describe the person's expertise relevant to the research activity.

Dr Mackie is a PI on one of the largest longitudinal study, the Kids with CKD study (KCAD), across Australia and New Zealand. This observational study has provided the necessary multicentre study infrastructure for the NAVMAN trial.

Investigator/ Researcher 4

Q1.9.1 Title

Associate Professor

Q1.9.2 First Name

Amanda

Q1.9.3 Surname/family name

Walker

Q1.9.4 Email Address

amanda.walker@rch.org.au

Q1.9.5 Is this person the contact person for this application?
◯ Yes ◉ No

Q1.9.6 Is this person a student on this project?
◯ Yes ◉ No

Q1.9.7 Institutional affiliation and position.

A/Prof Amanda Walker is the director of the department of Nephrology at Royal Children's Hospital in Melbourne. Her Qualifications include BMedSc, MBBS, FRACP.

Q1.9.8 Staff ID Optional

Q1.9.9 ORCID Identifier Optional

Q1.9.10 What is the position of this person on the research project?

Principal Investigator

Q1.9.11 Does this person have authorisation to sign the application on behalf of all members of the research team?

○ Yes ◉ No

Q1.9.12 Describe the research activities this person will be responsible for.

PI Walker will oversee the NAVMAN trial at The Royal Children's Hospital Melbourne and assist with any site specific issues. She will contribute to the overall design of the trial, patient recruitment and provide intellectual input into the study.

Q1.9.13 Describe the person's expertise relevant to the research activity.

A/Prof Walker is a PI on one of the largest longitudinal study, the Kids with CKD study (KCAD), across Australia and New Zealand. This observational study has provided the necessary multicentre study infrastructure for the NAVMAN trial.

Investigator/ Researcher 5

Q1.9.1 Title

Associate Professor

Q1.9.2 First Name

Steve

Q1.9.3 Surname/family name

McTaggart

Q1.9.4 Email Address

steven.mctaggart@health.qld.gov.au

Q1.9.5 Is this person the contact person for this application?

○ Yes ◉ No

Q1.9.6 Is this person a student on this project?

○ Yes ◉ No

Q1.9.7 Institutional affiliation and position.

A/Prof Steve McTaggart is a paediatric nephrologist at Lady Cilentio Children's Hospital, Brisbane.

Q1.9.8 Staff ID Optional

Q1.9.9 ORCID Identifier Optional

Q1.9.10 What is the position of this person on the research project?

Principal Investigator

Q1.9.11 Does this person have authorisation to sign the application on behalf of all members of the research team?

○ Yes ◉ No

Q1.9.12 Describe the research activities this person will be responsible for.

PI McTaggart will oversee the NAVMAN trial at Lady Cilento Children's Hospital Brisbane and assist with any site specific issues. He will contribute to the overall design of the trial, patient recruitment and provide intellectual input into the study.

Q1.9.13 Describe the person's expertise relevant to the research activity.

Dr Steven McTaggart holds qualifications MBBS, FRACP, PhD, Grad Dip Epi Biostats. Dr McTaggart has extensive experience in design, conduct and participation in clinical trials in adult and paediatric renal medicine. He is a PI on one of the largest longitudinal study, the Kids with CKD study (KCAD), across Australia and New Zealand. This observational study has provided the necessary multicentre study infrastructure for the NAVMAN trial.

DISCLOSURE OF INTERESTS

Q1.10. Do any members of the research team (including persons not listed in this application), have any financial or non-financial interests related to this research?

○ Yes ◉ No

RESTRICTIONS

Q1.11. Are there any restrictions or limits on publication of data or dissemination of research outcomes of this project?

○ Yes ◉ No

EVALUATIONS

Q1.12. Has the scientific or academic merit of the research project been evaluated?

○ Yes ◉ No

Q1.13. Has this research project had prior ethics review?

○ Yes ◉ No

Q1.14. Will any further or additional specialised review of this application be sought?

○ Yes ◉ No

LOCATION

Q1.15. Will this research project be conducted at multiple sites?

◉ Yes ○ No

Q1.16. Will separate institutional approvals or authorisations be required prior to commencing research at each site?

◉ Yes ○ No

Section 2 - Research Details and Participants

METHODS

Q1.17. From the list below, select all the research methods that will be used in the research project.

- [ ] Action research
- [ ] Biospecimen analysis research
- [ ] Data linkage research
- [ ] Ethnographic research
- [ ] Epidemiological research
- [x] Interventional/ Clinical Trial research
- [ ] Observational research
- [ ] Survey/Interview/Focus Group research
- [ ] Textual analysis research
- [ ] None of the above

PARTICIPANTS

Q1.18. Indicate with whom or with what the research will be conducted.

- (•) Human beings (via active participation), including their associated biospecimens and/or data
- ( ) Human biospecimens only
- ( ) Data associated with human beings only (i.e. as the primary object of research)

Q1.19. Will your research involve participation of any of the following?

- [ ] Women who are pregnant and the human fetus
- [x] Children and young people
- [ ] People highly dependent on medical care who may be unable to give consent
- [ ] People with a cognitive impairment, intellectual disability or mental illness
- [ ] People in dependent or unequal relationships
- [ ] People who may be involved in illegal activities
- [ ] People in other countries
- [ ] Aboriginal and Torres Strait Islander peoples

Method Specific Questions

ACTION RESEARCH

BIOSPECIMEN ANALYSIS RESEARCH

DATA LINKAGE RESEARCH

ETHNOGRAPHIC RESEARCH

EPIDEMIOLOGICAL RESEARCH

INTERVENTIONAL/CLINICAL TRIALS RESEARCH

M6.1. Briefly describe the intervention/s that you will be using.

The NAVMAN trial is a multi-centre, staggered entry, waitlisted randomised controlled trial that assesses the health benefits and costs of a patient navigator program in children with chronic kidney disease (CKD) stages 3-5, on dialysis (CKD-D) and with kidney transplants (CKD-T) and of low socioeconomic backgrounds.
Patient navigators are trained non-medical personnel who assist patients with complex and/or chronic conditions journey through the continuum of care and transit across different care settings. A patient navigator is an intervention that addresses the disparities in health among medically underserved population.
The roles of the patient navigators are diverse, but they have the key objectives of facilitating patients' receipt and access to care to improve the overall health of patients from low SES backgrounds.
In the context of children with CKD, their responsibilities may include helping patients to keep track of appointments, particularly when the organisational and executive skills of the child are affected, provide social support, interpret health information provided by the clinicians and facilitate communication within the families when parents are separated. Navigators may help patients to forge a more participatory dialogue with their clinicians, and guiding the patients to ask the right questions, enhancing patient autonomy. Patient navigators can also provide support for caregivers; e.g. managing transport to and from the hospital or coping with the complex organisational network within the hospital, particularly for those of lower literacy, low SES and families from non-English speaking backgrounds.
The intervention arm will receive the intervention (patient navigator program) immediately after randomisaton for 24 weeks. Children being randomised to the wait-list arm will wait for 23 weeks but receive the standard care during the 'wait-period' and commence the intervention (patient navigator program) in week 24.

M6.2. Is your intervention related to the prevention, diagnosis, treatment or management of a health condition?

(•) Yes ( ) No

M6.2.1 Do you consider that you are conducting a clinical trial?

(•) Yes ( ) No

M6.2.1.1 What does the clinical trial involve the use of?

[ ] Drug/s
[ ] Device/s
[x] Other

M6.2.1.2 Does the clinical trial differ from standard care?

(•) Yes ( ) No

M6.2.1.2.1 How does the clinical trial differ from standard care?

The intervention is an adjunct to standard treatment.
Patient navigators are trained non-medical personnel who assist patients with complex and/or chronic conditions journey through the continuum of care and transit across different care settings.
In the context of children with CKD, their responsibilities may include helping patients to keep track of appointments, particularly when the organisational and executive skills of the child are affected, provide social support, interpret health information provided by the clinicians and facilitate communication within the families

when parents are separated. Navigators may help patients to forge a more participatory dialogue with their clinicians, and guiding the patients to ask the right questions, enhancing patient autonomy. Patient navigators can also provide support for caregivers; e.g. managing transport to and from the hospital or coping with the complex organisational network within the hospital, particularly for those of lower literacy, low SES and families from non-English speaking backgrounds.

M6.2.1.3 Will trial participants be exposed to ionising radiation to which they would not have been exposed to if they did not participate in the trial?

○ Yes ◉ No

M6.2.1.2.4 Will your clinical trial be conducted under either the Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) schemes?

Neither

M6.2.1.2.5 Who is the sponsor of the clinical trial?

Currently, seed funding has been secured through the Ludwig Engel Research Fellowship for a pilot study. An NHMRC project graft application for funding in 2019 has been submitted.

M6.2.1.2.6 Provide the following details for each site where the clinical trial will be conducted.

Site 1

M6.2.1.2.6.1 Name of Site:

Children's Hospital at Westmead

M6.2.1.2.6.2 Individual responsible at site:

Steven Alexander

Site 2

M6.2.1.2.6.1 Name of Site:

Sydney Children's Hospital Randwick

M6.2.1.2.6.2 Individual responsible at site:

Fiona Mackie

Site 3

M6.2.1.2.6.1 Name of Site:

Lady Cilento Children's Hospital

M6.2.1.2.6.2 Individual responsible at site:

Steve McTaggart

Site 4

M6.2.1.2.6.1 Name of Site:

Royal Children's Hospital Melbourne

M6.2.1.2.6.2 Individual responsible at site:

Amanda Walker

M6.2.1.2.7 Select the phase of your clinical trial.

Phase 0/Pilot

M6.2.1.2.8 Has this clinical trial been registered on a Primary Registry in the World Health Organization Registry Network?

◯ Yes ◉ No

M6.2.1.2.8.2 Do you want to register your clinical trial on the Australian New Zealand Clinical Trials Registry (ANZCTR) now?

◯ Yes ◉ No

M6.2.1.2.9 Do you intend to make the trial intervention available to participants after the completion of the trial?

◯ Yes ◉ No

M6.2.1.2.10 Explain how and when participants will be informed about post-trial access to the trial intervention.

The participants with not have access to the trial intervention. At the time of consent, the participants will be made aware of this.

M6.3. With regard to your answers above, describe any ethical considerations related to your use of the intervention/s in this research project and your plans for addressing these issues.

Nil.

OBSERVATIONAL RESEARCH

SURVEY/INTERVIEW/FOCUS GROUP RESEARCH

TEXTUAL ANALYSIS RESEARCH

Participant Specific Questions

Pregnant women and human fetus

Children and young people

P2.1. How will the children or young people participate in this research?

The navigator will work with patients, caregivers, health professionals to achieve better care, and access to care and improved health through involvement in the social, community and health organisational network.

P2.2. Explain how the research is likely to advance knowledge about the health or welfare or other matters relevant to children or young people.

Given the complexity and chronicity of the disease process and growing concerns that current model of care in paediatric nephrology may not be equipped to support the provision of high level care in children with CKD from socio-economically disadvantaged backgrounds a patient-navigation program may lead to improvement in the provision of care and overall health of children with CKD.

P2.3. Explain how the children's or young people's participation is indispensable to the conduct of the research.

Participation is not indispensable, but it is important for children and young people to participate in this research because it is envisage the 'intervention', which is of low risk, could provide improved care and access to care for children with CKD. The NAVMAN trial aims to asess the impact of a patient navigator program on the overall health

and well-being of children with CKD. The patient navigator will work with both the child and parent/caregiver to to better understand their diagnoses, treatment options, and available resources, to guide them through the very complex medical system and to overcome barriers to health care access and bridge gaps in transitions of care.

P2.4. How will you ensure that the children's and/or young people's safety, emotional and psychological security and wellbeing are protected?

The investigators of this project has ample experience with working with children. Professors Alexanders, Mackie, Walker and McTaggart are head of units of the three largest paediatric nephrology units in Australia. Associate Professor Wong is an adult nephrologist but heads the transition service for young people with CKD at Westmead Hospital. Researchers and staff working with children on this project will require clearance from 'Working with Children Check'. It is anticipated that this research involves no greater than minimal risk to the children. It is also anticipated that the benefit of this research in relation to the risk is least as favourable as that presented by standard care. All adverse effects/ harms (if any) will be reported to the DMSB. The DMSB will work independently to evaluate the consideration of risk/benefits and has right to terminate the study if consider it is harmful to the participants. However, given the nature of the intervention, it is expected the risk to be of low - negligible in this case.

P2.5. How will you establish that participation in the research is not contrary to the best interests of the children or young people?

The investigator team will ensure this research is of the best interests for the child/young person. Given the perceived benefits as shown in the field of oncology, the staggered sntry, waitlisted design will ensure the intervention is applied to all children and caregivers enrolled in the study. However, a child/young person (an in consultation with their parents/caregivers)refusal to participate or continue in the research will be respected.

People highly dependent on medical care who may be unable to give consent

People with a cognitive impairment, an intellectual disability, or a mental illness

People in dependent or unequal relationships

People who may be involved in illegal activities

People in other countries

Aboriginal and Torres Strait Islander Peoples

Recruitment - General

Q2.1.1. Indicate how you will identify and recruit participants for your research, referencing any relevant section/s of your Project Description/Protocol.

Participants will the recruited from 5 different sites across Australia: The Children's Hospital at Westmead (AI McCarthy), Sydney Children's Hospital, Randwick (AIs Mackie), Lady Cilento Hospital, Queensland (AI McTaggart), and Royal Children's Hospital in Melbourne (AI Walker). Recruitment is highly feasible as participants will be identified and recruited from the existing KCAD cohort. New and incident patients will also be recruited from these sites. The AI from each site will identify eligible participants within their hospital databases. The trial coordinator will provide the eligible participants (and caregivers) an information brochure and informed consent form to review. The coordinator will obtain written consent from the caregivers and adolescent assent (for children ≥ 16 years), and baseline data including patient demographics, clinical data including comorbidities, CKD stage, serum creatinine measures (for CKD 3-5 and CKD-T), dialysis modality, medication use and SES details at screening.

Q2.1.2. How will your recruitment strategy take account of the ethical considerations relevant to the specific people you are recruiting?

The KCAD study, a multicentre, prospective cohort study of children with CKD (n = 377), has informed the: 1. Study design, 2. Inclusion criteria, 3. Intervention of choice and 4. Choice of outcomes measures of the NAVMAN trial. At least 50% of the participants from the KCAD study will satisfy the inclusion criteria for the NAVMAN trial. Recruitment

is therefore highly feasible as we will be able to fulfil 90% of our sample size by inviting participants from the KCAD study alone.

Recruitment - Action Research

Recruitment - Observational Research

Consent

Q2.2.1. Indicate the relevant section/s of your Project Description/Protocol that address/es consent.

The researcher will discuss the study to the child and their parents/caregivers and obtain verbal and written consent. Information sheets and consent forms will be provided which will explain the study, including the potential risks and benefits. The caregivers are encouraged to take their time to make a decision about participating in the study and they are welcome to discuss with their treating physician.

Q2.2.2. Will you be obtaining consent from some or all participants to participate in the research?

- (•) Yes for all participants
- ( ) Yes for some participants
- ( ) Not for any participants

Q2.2.2.1 What is the scope of consent that you will be seeking?

- [x] Specific
- [ ] Extended
- [ ] Unspecified

Q2.2.2.2 How will consent be obtained?

- [x] Written
- [x] Verbal
- [ ] Implied

Q2.2.2.3 Are you proposing to obtain consent using limited disclosure?

( ) Yes (•) No

Q2.2.3. Are family members, authorised representatives or any others involved in the participants' decision to participate in the research?

( ) Yes (•) No

Q2.2.4. Will there be an opportunity to confirm or re-negotiate consent during the research project?

(•) Yes ( ) No

Refer to the relevant section/s of your Project Description/Protocol that detail the process for confirming or re-negotiating consent at Q1 (Consent - General)

Q2.2.6. Describe any ethical considerations related to the approach to consent that you will be seeking and your strategies for addressing and managing these issues.

For non-English speaking patients and their parents/caregivers, a health care interpreter will translate the

information sheets into their native language. The PI overseeing the studying at the particular site will consent the partipants, if necessary, with a health care interpreter.

Q2.2.7. Are you proposing to use an opt-out approach with respect to some or all of the participants?

◯ Yes ◉ No

Q2.2.8. Are you requesting a waiver of the requirement for consent with respect to some or all participants?

◯ Yes ◉ No

Consent - Ethnographic Research

Consent - Children and young people

Q2.2.P2.1. From whom are you obtaining consent?

- ☐ The child or young person themselves
- ☑ One parent
- ☐ Both parents
- ☑ The guardian or primary care giver
- ☐ An organisation required by law

Q2.2.P2.2. Will the research involve the participation of any children who are not of sufficient maturity to consent?

◉ Yes ◯ No

Q2.2.P2.3. Explain how the children or young people's capacity to consent will be judged.

Consent of the child/young person will be sought. For children under the age of 16 consent will be sought from parents or caregivers. Assent will be sought for children over the age of 16.

Q2.2.P2.4. >Describe how you plan to discuss the research project with children at their level of comprehension.

The research study will be discussed in lay language to the child and their caregiver. They will also be provided with an information sheet which will also have important information about the study processes, impact to the patient and potential risks and benefits. The child and their parent and/or caregiver will be encouraged to ask any questions or concerns and the researcher will address.

Q2.2.P2.5. Are you proposing to obtain consent using standing parental consent for the participation of the children or young people?

◯ Yes ◉ No

Consent - People highly dependent on medical care

Consent - People with a cognitive impairment

Consent - Involvement in illegal activities

Risk - General

Q2.3.1. Describe the risks and burdens associated with your research, referencing any relevant sections of your Project Description/Protocol as appropriate.

There is low to negligible risk of harm to both the participant and their caregivers. The intervention is unlikely result in significant discomfort of inconvenience to the patients. The patient navigator will all undergo standard Working With Children Checks. They will also be supervised by at least one of the investigator at each site. The navigator is required to provide a daily record of their activities to their supervisors and feedback will also be obtained from the participants and their caregivers fortnightly, and as needed. It is envisaged that the navigator will work with the families on a one-to-way basis and that professional relationship may develop. However, the DSMB will have responsibility of monitoring for adverse events and will ensure the safety of children and families is protected to ensure there will be no breach of confidentiality and contract between the participants, caregivers and researchers. One potential but low risk may be inconvenience, and may include filling in a form, participating in a street survey, or giving up time to participate in research.

Q2.3.2. Describe how these risks will be mitigated and managed.

To mitigate the very low and negligible risk of potential inconvenience, the researcher will provide guidance and support for the participants and caregivers at all levels.

Risk - People in dependent or unequal relationships

Benefit

Q2.4.1. Describe the benefits associated with your research, referencing any relevant sections of your Project Description/Protocol as appropriate.

This trial will test a novel intervention, which has the potential to improve the patients' overall health and well-being, particularly among the undeserved and most vulnerable paediatric population. The NAVMAN trial will provide clear evidence of the effectiveness and cost-effectiveness of a new intervention, through a high quality, well-powered clinical trial. It is informed by our extensive observational and qualitative data that reflect the current research gaps and leverages relationship and goodwill from our existing observational study. This trial also has a number of innovative features. It is enriched by involving participants of low SES backgrounds, as prior work has shown that patient navigation interventions focused on communities-at-risk demonstrated a much greater impact of patient navigation. The staggered entry, wait-listed controlled trial not only ensures trial efficiency, but also allows adjustment for other external seasonal events, which are potential confounders to the intervention effects. As the infrastructure for the program will be developed during course of the trial, if proven effective, the navigator program can be rapidly implemented into clinical care, within 12 months of trial completion.

Q2.4.2. Explain how the benefits of this research justify any risks or burdens associated with the research.

Children with CKD suffer from significant physical, cognitive and psychological complications. This proposal will test a novel intervention, which has the potential to improve the patients' overall health and well-being, particularly among the undeserved and most vulnerable paediatric population. Apart from inconvenience and potential time spent in research, which are of low risk to the participants, it is anticipated that the benefits of the research will outweigh this very low risk.

Q2.4.3. How will you manage participants' expectations of the perceived benefit of participating in the research?

Detailed explanation will be provided to the participants regarding the perceived benefits of this research. However, the researcher will also inform participants regarding the potential 'null' effects of the intervention. Participants will undergo three-monthly follow-up, ensuring all outcomes are measured and any concerns relating to any aspects of the trial are communicated with the researchers. Any unexpected outcomes will be reported to the DSMB.

Section 3 - Data and Privacy

Data and Privacy - Data Characteristics

Q3.1. Indicate the type of information/data you will be collecting for this project.

- [x] Personal information
- [x] Sensitive information
- [x] Health information
- [ ] Not personal information

Q3.2. Indicate the type of information/data you will be using in this project.

- [x] Personal information
- [x] Sensitive information
- [x] Health information
- [ ] Not personal information

Q3.3. Indicate the degree of identifiability of information/data you will be collecting for this project.

- [x] Individually identifiable information
- [x] Re-identifiable (coded) information
- [ ] Non-identifiable information

Q3.4. Indicate the degree of identifiability of information/data you will be using in this project.

- [x] Individually identifiable information
- [ ] Re-identifiable (coded) information
- [ ] Non-identifiable information

Q3.5. Describe any ethical considerations relating to the collection and/or use of the information/data in this project.

Information collected about the participants will be published in a non-identifiable manner. Data collected via questionnaires will be stored as paper copies in a locked cabinet accessible to only the researchers as well as a computer file which is password protected.

Q3.6. Identify the source/s of the information/data that you will be collecting and/or using in this project.

- [x] Individual participants
- [x] Relatives or associates of participants
- [x] Medical/health/mental health record
- [ ] Electoral roll
- [ ] Held by a law enforcement agency or judicial body
- [ ] Publicly held database (Commonwealth)
- [ ] Publicly held database (State or local)
- [ ] Privately held database

Q3.7. Describe any ethical considerations relating to the source of information/data as indicated in the response to the previous question.

The information will be sought from the individual or caregiver. If biochemistry results are needed to determine their CKD stage or renal function, this will be collected from their medical record.

Q3.8. Was the information/data that you are using previously collected for a purpose other than research?

○ Yes ◉ No

Data and Privacy - Activities with Data

Q3.9. Do you plan to disclose any personal information/data in this project to a third party?

○ Yes ◉ No

Q3.10. How will you protect the privacy of participants and non-participants in any notes and/or publications arising from your research.

The named investigators on this study will have access the data for the purposes of monitoring and analysis of the data. The study coordinators and research assistants will have access to the identifiable data for the purposes of patient recruitment, follow up and data collection and data management. The survey data will be stored and uploaded electronically in a web-based database. Only authorised personnel will have access to the data.

Q3.11. Are there any restrictions on your ability to assure the confidentiality of participants?

○ Yes ◉ No

Q3.12. Do you plan to share any individual research results obtained during this research to the participants?

○ Yes ◉ No

Q3.13. Describe how you will handle any secondary or incidental findings that arise from the analysis of personal information/data.

Confidential and incidental findings that relates to the safety of the child will be reported to the relevant authorities.

Q3.14. Describe how the information/data will be stored, accessed, archived and/or destroyed.

Any identifiable information that is collected will remain confidential, and will be disclosed only with permission, or except as required by law. Data will be stored as paper copies in a secure location within the recruiting site or at the Centre for Kidney Research at The Children's Hospital at Westmead, as well as on a password protected computer for 15 years once the study has been finalized. Electronic records will be securely destroyed, and paper documents will be shredded. In addition, all computer files will only be accessed via a password protected file.

Q3.15. Describe any ethical considerations relating to the storage of, access to or destruction of information/data in this project.

All participants will be informed regarding the nature of the study and how the stored data will be handled. All research assistants and study co-ordinators are fully trained clinical researchers and are fully aware of the privacy issues and data handling issues within this project. All researchers are also aware of the identifiable or sensitive information that are being handled in this project and are made fully aware of their responsibilities and obligations to respect participants confidentiality in compliance with market standards and best practices.

Q3.16. Will the outcomes of this project be disseminated to the participants?

◉ Yes ○ No

Q3.16.1.1 Describe how the outcomes of the project will be disseminated to the participants, or refer to the relevant section/s of your Project Description/Protocol which deals with this matter.

The outcomes of this project will be distributed to the participants in the form of newsletter and the NAVMAN website. All participants will have access to the NAVMAN website.

Q3.16.1.2 Describe any ethical considerations relating to any dissemination of outcomes to the participants.

There is a risk that some psychological upset may occur relating to finding out the overall health an quality of life assessment of standardised testing. Patients and carers will be provided with access to the psychologist or social worker for further advice and offered advice or referral as appropriate as available in standard care in the hospital setting.

Q3.17. Describe any foreseeable future activities for which information/data collected and/or used in this project may be made available.

Information collected and outcomes of this research project will be published in peer-reviewed journals and presented in national and international conferences. Publications will be limited to those who have ethical approval to access the dataset. A/Prof Germaine Wong and the Centre for kidney research will have the right to impose limitations or conditions on the publication of the results of this project to ensure all obligations are met in terms of funding bodies, research collaborative agreements and institutional codes, regulations and guidelines.

Q3.18. Describe any ethical considerations relating to the planned or possible future use of information/data in this project.

It is anticipated that only work specified in the proposal will be published and used for future research. In addition, only group data will be reported and disseminated in findings and no participants will be identified.

Section 4 – Attachments and Declarations

ATTACHMENTS

The following documents have been attached to this HREA.

Document Type	Attachment File Name	Attachment Description
Interview Schedules / Topic Guides	9.NAVMAN_QualitativeInterviewGuide_200618.docx	
Participant Information Sheet/Consent Form	3. NAVMAN_PatientInformationSheetConsent Form_v1_18_06_2018.doc	
Participant Information Sheet/Consent Form	4_YoungPersonInformationSheet_v1_18_06_2018.doc	
Protocol	2. NAVMAN_Protocol_v1_18_06_2018.docx	
Questionnaire	7. Caregiver_Satisfaction_Questionnaire_v1_18_06_2018.docx	
Questionnaire	5. NAVMAN_CRF_version1_18_June_2018.doc	
Questionnaire	8. NAVMAN_PatientNavigatorSatisfactionQuestionnaire_PN_v1_18_06_2018 .docx	
Questionnaire	6. NAVMAN_CRF_version1_18_June_2018_WAIT.doc	

DECLARATIONS

1. DECLARATIONS

I/we certify that:

- All information in this application and supporting documentation is correct and as complete as possible;
- I have read and addressed in this application the requirements of the National Statement and any other relevant guidelines;
- I have familiarised myself with, considered and addressed in this application any relevant legislation, regulations, research guidelines and organisational policies;
- All relevant financial and non-financial interests of the project team have been disclosed; and
- In the capacity of a supervisor, as applicable, I have reviewed this application and I will provide appropriate supervision to the student(s) in accordance with the arrangements specified in this application and those associated with the student's educational program.

Chief Investigator/Researcher, Co-ordinating Principal Investigator/Researcher, Lead Investigator

Chief Researcher section was signed electronically by A/Prof Germaine Wong on 09/07/2018 21:18

Job Title/Post:

Organisation:

Email:

Decision/Comments:

Chief Investigator/Researcher
Associate Professor Germaine Wong ..... Signature ...../...../..... Date

Principal Investigator

Principal Researcher section was signed electronically by A/Prof Germaine Wong on 09/07/2018 21:28

Job Title/Post:

Organisation:

Email:

Decision/Comments:

Principal Researcher section was signed electronically by A/Prof Germaine Wong on 09/07/2018 21:17

Job Title/Post:

Organisation:

Email:

Decision/Comments:

Principal Investigator
Doctor Hugh McCartney ..... Signature ...../...../..... Date

Principal Investigator
Doctor Fiona Mackie ..... Signature ...../...../..... Date

Principal Investigator
Associate Professor Amanda Walker ..... Signature ...../...../..... Date

Principal Investigator
Associate Professor Steve McTaggart ..... Signature ...../...../..... Date

Associate /Assistant/Sub-/Co- Investigator

Investigator and Other