Māori Partnership Board, Capital & Coast DHB

RESEARCH ADVISORY GROUP MĀORI (RAG-M)

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04 April 2018

Dr. Max Berry and Dr. Angus Goodson

Tēnā Korua

Re: RAG-M #589 - (ROP-Ox) - Effect of retinopathy of prematurity screening on cerebral and gastrointestinal tract (splanchnic) regional oxygenation and cardiorespiratory stability in neonates

☑ Your application has been endorsed

RAG-M wishes you all the very best with your study.

Ngā mihi nui,

Jack Rikihana
Chairperson

District Health Board Māori Review of Research

Application Form

Date: 25 January 2018

Application: #589

Study title: Effect of retinopathy of prematurity screening on cerebral and gastrointestinal tract (splanchnic) regional oxygenation and cardiorespiratory stability in neonates	Documentation provided with this application: ☒ all patient information and consent forms ☒ documentation for collecting patient information ☒ study protocol ☒ ethics application form ☒ fee payment form or receipt ☐ other documentation, please describe:
Principal investigator: Dr. Max Berry Contact person: Dr Angus Goodson	
Contact details: Neonatal Intensive Care Unit (NICU) Wellington Regional Hospital Private Bag 7902 Wellington New Zealand	
Phone: 0211998263	email: angus.goodson@ccdhb.org.nz

For guidance on completing this form and meeting the minimum requirements of Māori consultation, please refer to:
***Simmonds S (2015) A Framework for Māori Review of Research in District Health Boards*:**
A Framework for Maori Review of Research

Other documentation that may help with this application process: CCDHB Tikanga Maori Guidelines

1. Details of Research

1a) Please provide a brief outline of your research project:

Retinopathy of prematurity (ROP) is one of the leading causes of preventable childhood blindness in developed countries, including New Zealand. Treatment for vision-threatening ROP has been highly effective. Timely screening for severe ROP among at-risk infants is essential to prevent unnecessary visual loss associated with ROP. Screening for ROP involves instillation of eye drops to reduce pain and dilate the pupils to allow examination of the retina.

The process of ROP screening has been shown to be associated with cardiorespiratory instability and with increased incidence of necrotizing enterocolitis, a potentially life-threatening complication. The mechanism of these adverse effects is poorly understood. In particular it is not known if these adverse effects are caused by the eye drops, by the examination, or by the combination of both procedures.

This study aims to develop better understanding of the mechanism by which ROP screening leads to these adverse effects. More specifically it will examine whether ROP screening decreases availability of oxygen to the brain and gastrointestinal tract. It also aims to examine whether such changes are related to the eye drops or the eye examination, and correlate such findings to markers of cardiorespiratory stability (frequency of peripheral desaturation, blood pressure stability and heart rate).

This is an observational study, and the decision to undergo ROP screening will be based on local guidelines. Once potential participants' are identified as requiring ROP screening, caregivers will be approached for enrollment in the study.

The study involves use of non-invasive devices to measure physiological parameters. The oxygen levels in the brain and gastrointestinal tract will be measured using near-infrared spectroscopy (NIRS), a portable and non-invasive device that is increasingly used in neonatal research and clinical practice. Parameters of cardiorespiratory stability will be measured using a pulse oximeter, doppler ultrasound and a non-invasive blood pressure monitor. Measurements will be taken before, during and after ROP screening.

1b) What type of research or trial design best describes your study? (tick any that apply)

☒ an observational study
☐ a minimal risk observational study
☐ an interventional study
☐ audit or related activities
☐ student-led research
☐ a multi-national study initiated outside NZ
☐ a clinical trial
☐ other, please detail *type or paste text here*

For definitions, please refer to: Standard Operating Procedures for Health and Disability Ethics Committees, version 1.0 2012
http://ethics.health.govt.nz/operating-procedures

1c) Which option best represents the current status of the study's ethical approval?

☐ received ethics
☒ applied for ethics
☐ not yet applied for ethics
☐ not applicable, please explain: *type or paste text here*

Please include copies of all ethics documentation with this application form

1d) What is the expected level of involvement for Māori in your research project? (either as participants, researchers or advisors)

☐ (1) no expected involvement
☐ (2) possible involvement
☒ (3) probable involvement
☐ (4) definite involvement
☐ (5) significant involvement (or exclusively Māori)

Please provide details: The study aims to recruit widely irrespective of participants' ethnic background. Maori infants represent 13% of total births in New Zealand (PSNZ data) and 35% of extremely premature births (local audit data). Extremely preterm infants are particularly at risk of developing retinopathy of prematurity and will require screening. Therefore we anticipate that our recruitment of Maori infants will be reflective of these statistics.

Note that if you have indicated levels 3-5, you may be requested to meet with the Research Advisory Group-Māori], and provide further detail of engagement with Māori. We will make contact with you if this is required.

Please refer to Simmonds S (2015) A Framework for Māori Review of Research in District Health Boards, table 1 to help identify levels of Māori involvement in a research project.

2. WHAKAPAPA. Research should involve the development and maintenance of respectful relationships and clear, appropriate communication

2a) Please detail how participants are recruited for this study, and strategies to ensure appropriate recruitment of Māori:

Infants who meet the criteria for ROP screening according to the local guideline will be identified through daily discussion with clinicians in Wellington NICU. I (coordinating investigator) will personally approach parents and Whanau of potential participants and explain the study prior to recruitment.

The majority of potential participants will be long-term patients in Wellington NICU (premature infants or infants with significant health conditions), whose parents and Whanau will have developed relationships with the local Whanau care services and social service. We will endeavour to involve these services during recruitment and throughout the study period.

2b) Please provide the following details for each of your patient information and consent forms:

Consent form	Flesch reading score	Number of words	Number of pages
Participant information sheet	48	1895	5
Consent form	46	305	2

2c) What steps have you taken to ensure your patient information and consent forms are appropriate for Māori?

The participant information sheet and consent form were reviewed by two Maori parents without any medical background, whose infants are currently inpatients in Wellington NICU.

2d) Does this study involve the collection of tissue samples?

☒ No. Continue to question 2g.

☐ Yes. Please provide all details of the nature and amount of samples, storage and transport, overseas transport and method of disposal:

type or paste text here

2e) Please confirm that separate consent forms are supplied for storage of samples for future unspecified use

☐ Yes ☒ Not applicable (not part of this study)

2f) Please confirm that separate consent forms are supplied for use of samples for genetic analysis

☐ Yes ☒ Not applicable (not part of this study)

Please include copies of all patient information and consent forms with this application

2g) Please detail how study results will be disseminated to study participants and whānau

As part of informed consent parents and Whanau of participating infants will be asked whether they wish to receive a written lay summary of the study findings. The written lay summary will be prepared by myself (coordinating investigator) after data collection is completed for the study. Parents and Whanau will also be informed of any publication based on the study findings.

2h) Please confirm that the dissemination plan for the study includes a full report of study results to be sent to the Māori DHB reviewing team: ☒

2i) Please confirm that the dissemination plan for the study includes a locality report to be provided to the Māori DHB reviewing team: ☒

The locality report will detail the numbers of Māori recruited and any specific issues or concerns recruiting or maintaining Māori in the study. This may be submitted following the completion of local involvement in the study.

3. TIKA. Researchers should have the appropriate skills and experience required to design research that contributes to equity and to Māori health development

3a) Please confirm that ethnicity data is collected, stored and handled using the standard ethnicity question as recommended by the Ministry of Health

Yes ☒ comment: *type or paste text here*

Please include copies of all documentation for collection of patient details with this application. Refer to ethnicity data protocols: http://www.health.govt.nz/publication/ethnicity-data-protocols-health-and-disability-sector

3b) Will the study undertake an analysis of results by ethnicity?

☐ Yes, please describe:

☒ No, please explain: The power calculation for the study is done based on the total number of patients recruited. The study will not be powered to do a sub-analysis using ethnicity. Instead ethnicity will be presented as part of the demographic information of the study participants.

3c) The proportion of Māori participants in the study should reflect the proportion of Māori in the community with the health condition of interest. Please detail the following:

- Total number of study participants in this locality: 30
- Total number of Māori participants expected: 5
- Proportion of Māori participants expected: 30 -35%

3d) Please explain your calculations for 3c above, and provide the source of any data used:

Maori infants represent 13% of total births in New Zealand (PSNZ data) and 35% of extremely premature births (local audit data). Extremely preterm infants are particularly at risk of developing retinopathy of prematurity and therefore require screening. We therefore anticipate the proportion of Maori participants to be approximately 30-35%.

Useful sources of data for these calculations include stats NZ population data and projections (www.stats.govt.nz), Health Needs Assessments for DHBs or Māori Health Profiles 2015 (www.health.govt.nz), Māori health plans and strategies for each DHB (available on DHB website)

3e) Researchers are strongly encouraged to attend the CCDHB Tikanga Māori-Research Specific education offered monthly at Wellington Hospital. Please contact ragm@ccdhb.org.nz for further information. Please provide the details of all researchers and their attendance at training:

Researcher name	Research role	Training attended	Attendance date
Dr. Angus Goodson	Coordinating investigator (data collection and analysis)	CCDHB Tikanga Māori-Research Specific education	To attend early 2018
Dr. Max Berry	Co-investigator (data analysis)	CCDHB Tikanga Māori-Research Specific education	2014
Dr. Shieak Tzeng	Co-investigator (data analysis)	n/a (based at University of Otago)	
Dr Maria Saito-Benz	Co-investigator (data analysis)	CCDHB Tikanga Maori Research Specific Education	29th March 2016
Dr Vaughan Richardson	Co-Investigator		

3f) Please provide the details of previous or current involvement by your research team in other research projects of particular importance to Māori:

In 2015, our research team conducted a clinical audit on the outcomes of extremely preterm infants (23 weeks and 24 weeks gestation). Through this audit we identified that Māori infants are over-represented in this vulnerable cohort of patients who are at risk of long-term neurodisability.

Since then we have conducted a number of research projects in NICU with the aim to improve the long-term neurological outcomes of premature infants. Earlier this year, my co-investigators have successfully completed one HDEC-approved project 'Effects of elective blood transfusion on cerebral, hepatic and muscle regional oxygenation and cardiorespiratory stability in neonates (ref: 16/CEN/18), and achieved 30% Maori participation in this study. We are currently running two HDEC-approved projects 1) Near Infrared spectroscopy for Monitoring brain Oxygenation in Premature infants (NIMO-Prem) (ref: 16/NTA/209), and 2) Near Infrared spectroscopy for Monitoring brain Oxygenation: A single centre randomised controlled trial of freshly irradiated versus standard red blood cells for treatment of anaemia of prematurity (NIMO-Rad) (ref: 17/CEN/202)

As a research team we have experience in working with vulnerable infants and their whanau, many of whom are of Maori descent. We have always valued support from the CCDHB Whanau care service, and we are also fortunate to have a group of Maori 'ex-NICU' parents who provide us with parents' perspective on research in Neonatal Intensive Care Units.

4. MANAAKITANGA. Research should be conducted with respect for all persons involved and respect for their culture

Please confirm the following:

4a) ☒ contact details for Whanau Care Services are provided on your patient information and consent form

☐ No, please explain: *type or paste text here*

4b) ☒ provision has been made for the participant's whānau to be involved in the study

☐ No, please explain: *type or paste text here*

4c) ☐ provision has been made for participants to undertake the study in te reo Māori if desired

☒ No, please explain: All Maori parents will be asked whether they wish to have involvement of the Whanau care service during informed consent and subsequent communications. The study itself involves non-invasive physiological monitoring of infants only.

4d) ☒ provision has been made for appropriate tikanga Māori protocols to be carried out when required Yes

☐ No, please explain: *type or paste text here*

4e) Please describe how measures to ensure privacy and confidentiality are provided for participants and whānau:

To identify potential participants, study investigators will verbally discuss with clinicians in Wellington NICU whether any patients are due for ROP screening. There will be no written documentation of the potential participants, and I will be responsible for ensuring the confidentiality of this information.

All health information of participants (see participants characteristics spreadsheet included in this application) will be stored in the Research Electronic Data Capture (REDCap) application, a secure online database system specifically designed to support handling of confidential information in research studies.

All physiological data will be recorded anonymously and directly into the SenSmart and LabChart data recording system.

4f) Does your research team have a support agreement with Whanau Care Services or an equivalent provider?

☐ No. ☒ Yes. Please provide details: In the past we have had full support of the local Whanau care services and social services in all research based in Wellington NICU. I (coordinating investigator) will be approaching them for their support specifically for this project prior to initiation of the study.

Please include copies of any support agreements with this application.

5. MANA. Research relationships should be reciprocal and equitable and acknowledge the rights, roles and responsibilities of all involved.

5a) Describe the process for obtaining consent from participants (and whānau):

The parents of potential participants will be identified based on their eligibility for ROP screening according to local guidelines. A research team member with clinical expertise in neonatal care will arrange to meet them in person on the Neonatal Unit and explain about the study. They will be provided with a written information sheet and an opportunity to ask questions at this stage. A signed consent form will be collected by an investigator prior to start of data collection, and parents and Whanau will be given a further opportunity to ask questions then.

5b) Describe how this research project can contribute to improving health literacy for Māori participants and whānau:

This study will improve health literacy for Maori participants and Whanau by informing them of screening for and treating retinopathy of prematurity, what guideline is used locally and how such guideline could be improved through clinical research.

Useful reference: http://www.hqsc.govt.nz/publications-and-resources/publication/2046/

5c) Describe how this research project can contribute to Māori research capacity development:

Wellington NICU has an established working relationship with the CCDHB Whanau care service, ranging from providing social support for Whanau to conducting clinical research involving Maori infants. This study aims to build on this existing collaboration to ensure that the needs of Maori infants and their Whanau are heard.

The study will facilitate awareness of clinical research among Whanau, and gives them an opportunity to participate in a study which could lead to improved clinical care for Maori infants in the future.

Although none of our research group are of Maori descent, we would welcome the opportunity for additional Maori collaboration and are actively working with our colleagues to enable this.

5d) Describe any contribution of koha (gift) to participants, or reimbursement of costs for study participation:

None. There will be no additional cost for study participants or Whanau. The participating infants will be inpatients in Wellington NICU, and their parents and Whanau will be approached for recruitment when they are visiting their infants in Wellington NICU.

5e) Describe any other provisions you have made in your study to ensure the cultural preferences of Māori have been considered:

We will be working closely with the CCDHB Whanau care service and any recommendations from them will be incorporated in our study.

Thank you for taking the time to complete this form. Please save as a word document and email with all other required documentation to: ragm@ccdhb.org.nz

Kia ora.

Office use only	Date	Comment
Date received:		
Date acknowledged:		
Proposal sent to review:		
Next committee date:		
Due date for feedback:		
Provisional endorsement:		
Response received:		
Final endorsement:		