

## **PARTICIPANT INFORMATION SHEET FOR DELPHI SURVEY PARTICIPANTS**

### Project title:

Enhancing New Zealand Clinical Trials

### Research team:

#### co-PIs

- Prof. Frank Bloomfield, Liggins Institute
- Ass. Prof. Matire Harwood, University of Auckland
- Prof. Lisa Stamp, University of Otago
- Prof. Katrina Sharples, University of Otago
- Prof. Stuart Dalziel, University of Auckland

### What does the study involve?

- There is the opportunity to significantly enhance clinical trials research in the public health system within Aotearoa New Zealand, addressing key infrastructure needs, inequity in access to and participation in clinical trials and enhancing capability throughout Aotearoa New Zealand. The primary focus of this project is on the infrastructure needed for clinical trials within the public healthcare space.
- We are seeking participation from individuals across the sector.
- Participants are invited to take part in a 3-round Delphi survey, where they will rate the importance of proposed infrastructure options for clinical trials in New Zealand. In round one, participants will also be able to propose additional infrastructure options for consideration in subsequent rounds.
- To participate, you will be sent a unique link to each survey. During the consecutive rounds, you will be asked to re-rate the infrastructure options you rated previously and, in rounds two and three, to rate new options suggested by participants in round one. To assist you in re-rating the options, you will be supplied with your previous rating and the median rating by the following groups: Māori respondents, consumer respondents, and all other respondents. None of the other participants will be able to see your previous rating.
- Participation in the survey is voluntary, and you are free to decline to participate or to withdraw from the research at any practicable time, without experiencing any disadvantage. During each round, you will be asked to consent to participate. After each Delphi survey round, you can request that your information be withdrawn within five working days after the round closing. Due to the nature of how the responses are calculated for inclusion in the subsequent rounds, only information from the current round will be withdrawn. Any data you submitted from previous round(s) cannot be withdrawn.
- After each Delphi round, you can request that your ratings be withdrawn up to five working days after the Delphi survey round closes. Due to the aggregated nature of the survey data, we will be unable to redact your ratings for any previous survey rounds.

- Each survey round should take approximately 15-20 minutes to complete. The entire process is expected to take place between October 2021 to March 2022.
- Individual responses will remain confidential; this includes ratings for the proposed options as well as proposing additional options.
- The scores for each proposed option will be averaged to indicate either group consensus for inclusion or exclusion. The following definition has been applied to the options to identify consensus:
  - **Consensus for Inclusion:** over 70% of all participants in each category score the option as "critical" (score 7 to 9), and fewer than 15% of all participants in each category score the option as "not important" (score 1 to 3)
  - **Consensus for Exclusion:** over 70% of all participants in each category score the option as "not important" (score 1 to 3), and fewer than 15% of all participants in each category score the option as "critical" (score 7 to 9)
  - **No Consensus:** anything else
- Following the three survey rounds and a review by the core group, survey participants will be sent the consensus findings for each proposed infrastructure option.
- No material that could personally identify you will be used in any reports produced for this scoping review project.
- No health information will be collected.

### Benefits and risks

- Participating in the Delphi survey will help us get your opinion on the importance of the various proposed infrastructure options for clinical trials in New Zealand. The survey findings will help us develop an infrastructure roadmap and operations model for clinical trials in New Zealand. This will be summarised in a final report, which will be submitted to the Ministry of Health (MoH) and Health Research Council (HRC).
- As a participant, there is a risk that you may feel uncomfortable answering the questions. You are free to withdraw from the survey at any practicable time without experiencing any disadvantage. You can request that your ratings be withdrawn up to five working days after each delphi survey round closes. After that point in time, we will be unable to redact your ratings due to how the results are aggregated.

### Who pays for the study?

- This scoping review project is being jointly funded by the Ministry of Health and Health Research Council.
- Unless previously indicated, all participants will not receive compensation to take part in the survey.

### Rights of the participant(s)

#### *Participation is voluntary:*

- Participation in the Delphi survey is voluntary, and participation or opting out of participating will not result in any disadvantage.

#### *Withdrawal from participation and withdrawal of data:*

- Participants have the right to withdraw from participation at any time without any disadvantage.

#### *Confidentiality and anonymity:*

- The participant's identity will remain confidential in any reports created as part of this scoping review project

#### What will happen after the study

- Delphi survey data will be stored on a University password-protected server until 6 years' time when it will be securely destroyed.
- The Delphi survey results will inform the final report submitted to the MoH and HRC. At a time that is practical, a summary of the final recommendation report will be made available to survey participants.
- The project will be completed May 2022.

#### Contact Details

Ass. Prof. Matire Harwood  
University of Auckland  
[m.harwood@auckland.ac.nz](mailto:m.harwood@auckland.ac.nz)

If you require Māori cultural support, talk to your whānau in the first instance. You may also contact the administrator for He Kamaka Waiora (Māori Health Team) by telephoning 09 486 8324 ext 2324, or contact the Auckland and Waitematā District Health Boards Māori Research Committee or Māori Research Advisor by phoning 09 4868920 ext 3204 to discuss any questions or complaints about the study.

AHREC Chair contact details:

For concerns of an ethical nature, you can contact the Chair of the Auckland Health Research Ethics Committee at [ahrec@auckland.ac.nz](mailto:ahrec@auckland.ac.nz) or at 373 7599 x 83711, or at Auckland Health Research Ethics Committee, The University of Auckland, Private Bag 92019, Auckland 1142.

Approved by the Auckland Health Research Ethics Committee on 27/08/2021 for three years. Reference number AH23158.