

Participant Information Sheet

A Delphi consensus study for an Australian Clinical Research Competency Framework

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Participant Information and Consent Form	
Short Name of Research Project	Competency Delphi
Full Name of Research Project	A Delphi consensus study for an Australian Clinical Research Competency Framework
Principal Investigator	Kathleen Irish
Project Sponsor	NSW Health
Site Name	Not Applicable

What am I being invited to do?

The research team invite you to take part in a project that aims to generate a consensus for a competency framework to train, recruit, manage, and develop the Australian clinical research workforce.

The research team are seeking experts, workforce representatives, and consumers in the fields of clinical research, education, and workforce. You have been invited to take part because you have:

Been identified or have self-nominated as having professional expertise in the clinical research sector and / or the education and workforce sectors, and/or

Are a clinical research workforce Representative member, and/or

Are a clinical research consumer

If you take part, we will ask you to complete pre-readings, participate in 3 or 4 online meetings, and complete an online survey for each meeting.

Many people will be eligible to take part in this project. They will be from all states and territories of Australia and from different parts of the clinical research sector. We expect there will be at least 50 people who take part in this project, and up to several hundred.

Please read this information and ask the research team any questions. You can take some time to make up your mind.

What is the purpose of this project?

In this research project, we are seeking to develop expert consensus on an agreed competency framework for employing appropriately skilled people to clinical research roles in Australia.

There are currently no national or state industrial awards specific to this workforce. Multiple competency frameworks are available for use in Australia, including through International and National organisations. This results in variations in training quality, and difficulty in transferring job roles across different organisations.

An agreed Clinical Research Competency Framework will form a standardised way to determine the suitability of people for employment to clinical research roles, and describe a career path for that workforce.

Do I have to take part and can I change my mind?

Taking part is up to you

You get to decide whether to take part in this research project. You can say yes or no. your decision will not affect any relationship you have with NSW Health, the University of NSW, University of Sydney.

You can change your mind at any time

If you do take part, you can stop at any time. If you want to stop, please tell someone in the project team. You do not have to tell us the reason.

Once you stop taking part, we will not include you in any further research activities. The research team will keep the information we have already collected from any completed Delphi rounds. This is so we can measure the project results properly, as each stage of the Delphi process builds on information gathered from previous rounds. The survey results are anonymous. We would not be able to tell which responses belong to you.

Please only join this project if you are happy with this approach.

The project might stop for other reasons

We might need to stop the project while you are taking part. If this happens, we will explain the reasons to you.

What do I have to do if I take part?

If you take part in this research project, you will be in it for approximately 4 months.

Be aware that during the 4 months, you will be asked to participate in 3 or 4 rounds of online meetings, and complete an online survey of opinion after that meeting.

This table below outlines what you need to do in this project. For more information, please contact the Lead Researcher.

What part of the research project?	What do I have to do?
When you start the research project	If you want to participate in this Competency Delphi, you will be invited to complete an Expression of Interest form, submitting details of your professional expertise. This Expression of Interest form will include a declaration from you that you are agreeing to participate. The Research team will allocate you to the Expert Panel, the Workforce User and Consumer Panels based on your background. This information will be collected and stored in a secure online database.
When the Delphi Rounds commence	The Panels will complete Delphi Round 0 to form an agreed starting point for an Australian Clinical Research Competency Framework. If you are eligible to join the Expert Panel, you will need to complete pre-reading prior to the online meeting. Delphi Round 0 will be conducted by an online meeting, with a live survey to determine if there is a consensus to develop a competency Framework. Consensus on commencing this process is required to give credibility to the following rounds, and because using a competency framework will require organisations to commit to this. This meeting will be followed by an offline survey.
During the Delphi rounds	If Delphi Round 0 demonstrates agreement, both the Expert Panel and the Workforce User and Consumer Panels will progress to Delphi Rounds 1 through 3. These rounds will determine the structure and details that will form an Australian Clinical Research Competency Framework. You will need to complete some pre-reading prior to the online meeting for each Delphi round. You will need to attend the online meeting, and vote anonymously after the end of each Delphi round.
At the end of the Delphi rounds	You will need to maintain confidentiality until the consensus information is made publicly available
After the project completes	The research team will send you a summary of the results of the project A plain language summary and links to any publications will be available on the NSW Health, University of NSW, and the University of Sydney.

What are the benefits of taking part?

By taking part, you will help the research team demonstrate a consensus view on an Australian Clinical Research Competency Framework. This knowledge may help people in the future to develop workplace policies to support a professional clinical research workforce in Australia. This information is expected to help inform professional standards for the Clinical Research workforce.

You may not directly benefit from taking part in this project.

What are the risks and discomforts of taking part?

There are no direct costs to taking part in this project

Taking part in this project will require you to contribute your time.

Breach of confidentiality

If you are an Expert, your participation will be known by others in the Expert Panel. In this Competency Delphi, there is a chance that other people in the Expert Panel could share details from the discussions and voting results with others outside of this project. We will remind everyone who takes part that they must keep what they hear in these meetings and voting rounds confidential, and not share it with others.

If you are in the User or Consumer panels, you can choose to participate anonymously. To maintain anonymity, we will ensure you are able to log into the online platform using a pseudonym. You will be able to dial in to the MS Teams by two methods to provide anonymity:

- You can dial in to the MS Teams meeting from your phone and hide your number as you join the meeting.
 - You can dial in to the MS Teams meeting from a private browser, or incognito window, and you can use a pseudonym to join the meeting.
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How will my information be used for this project?

This section tells you how this research project will collect, store, use, share and dispose of your information. If you do not want us to collect this information, you will not be able to participate in this project.

Collecting your information

We will collect information for this project directly from you.

Where we will collect your information from	What kind of information we will collect
Directly from you	Your Name Your professional expertise to determine eligibility to participate as a voting member of the Delphi Panel.
Through the research process	Meetings will be audio-recorded and transcribed for analysis purposes. The chat and Q&A sections of these meetings will be retained. This recording will be completed on MS Teams, where you can enter a meeting anonymously. This recorded information will be disposed securely after the end of research project.

Where we will collect your information from	What kind of information we will collect
	We will keep the information we collect for this study in perpetuity and may use it for future projects.

Keeping your information safe

To keep your information safe, we will:

- Follow all relevant privacy requirements
- Store information securely on an electronic database
- Take steps to prevent anyone from accessing information that identifies you unless they are authorised to do so

If you have any complaints about how we are managing your personal information, you can contact the NSW Health Data Custodian.

Publishing project information

We will share information from this project so that others can use it and understand the study findings.

This information can be shared in two ways.

If you prefer to not be identified, we will not include your name in the report or other publication.

If you consent, we will include your name and your place of employment in the report and any other publications.

By being in this project, you agree to us sharing project information for these purposes. If you will be identified in any publicly available reports, we will ask for your consent before publication.

How will my information be shared for future research?

Your expertise may help with new research projects in the future. We will ask you to consider sharing your name and contact details for future research. When we share your name and contact details, we will check with you before we do this.

You can choose the kinds of research projects for which we share your name and contact details.

Who is running and paying for this project?

This project is being run by the NSW Ministry of Health, as part of the sustained membership of the Australian Government Department of Health, Disability, and Ageing (DHDA) Inter-Governmental Policy Reform Group (IGPRG). The IGPRG leads national reforms to strengthen and streamline the health and medical research regulatory and operating environment.

The DHDA have a federal funding agreement with all state and territory governments in Australia designed to support the activities of the enduring IGPRG for health and medical research.

NSW Health is leading this Competency Delphi as part of the IGPRG national reform agenda workplan.

Researchers from the University of NSW and the University of Sydney who are experts in Delphi methods and in competency frameworks are part of the research team.

Who has reviewed and approved this project?

The IRIS Ethics Committee has approved this project. This is an independent committee that makes sure that this project meets Australian ethical standards for research that involved people.

Comments and complaints about how this project is being run

If you have any comments or complaints about this project, please contact:

Iris Human Research Ethics Committee:

info@irisethics.com.au

Key contacts and where to find more information

Thank you for taking the time to read this information about our project. You can contact a member of the project team at any time to ask questions.

Kathleen Irish – Project Lead:

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