Australian Rheumatology Association

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Participant Information Sheet

Project Title: **Development of an Australian quality standard for giant cell arteritis (GCA)**

Project Sponsor: Australian Rheumatology Association (ARA)

Principal Investigator:
Professor Catherine Hill, Director Rheumatology Unit, The Queen Elizabeth Hospital, Catherine.Hill@sa.gov.au, ph: (08) 8222 6688.

Associate Investigators:
Associate Professor Helen Keen, ARA Vice President, Rheumatologist
Dr Claire Owen, Rheumatologist
Dr Charlotte Woollard, Rheumatology Advanced Trainee
Dr Maria Sukkar, ARA Project Officer
Kathryn Dyer, Research Assistant

CALHN HREC Reference: 20976

You are invited to take part in this survey because you have GCA. However, before you decide whether or not you wish to participate, we need to be sure that you understand

why we are doing this survey, and
what it would involve if you agreed.

We are therefore providing you with the following information sheet. Please take the time to read it carefully and be sure to ask any questions you have. The researchers conducting the research will be happy to discuss it with you and answer any questions that you may have. You are also free to discuss it with others if you wish (i.e. family, friends and/or your local doctor).

What is the purpose of the study

The ARA is developing a quality standard, called the GCA Clinical Care Standards (CCS). The aim is to improve the quality of care for people living with GCA in Australia. A quality standard is a document that sets out the standard of care that all people with GCA should be offered or receive. It does not cover every aspect of care, rather it focusses on specific areas of care where increased investment in resources can be predicted to lead to the greatest improvements in patient outcomes. The quality standard consists of a small number of concise statements that describe the care patients should be offered by health professionals and health services, in line with current best evidence. Each statement is accompanied by one or more

quality measures, which provide criteria for assessing, measuring, and monitoring the quality of care as specified in the statement.

Why have I been approached for the study?

People living with GCA, and people caring for people living with GCA, will be invited to participate in the study.

Do I have to take part?

This is a research project and you do not have to be involved. If you do not wish to participate, this will not affect the clinical care or treatment you receive in any way. Also, you may withdraw from the project at any time after you have commenced.

What will I be asked to do if I take part?

The ARA has been working with a group of health professionals and people living with and caring for people with GCA to develop the quality standard. The group prioritised specific areas of care that should be targeted for quality improvement efforts. Once the priority areas were decided, the group formulated quality statements that describe the standard of care that people with GCA can expect to be offered or receive. In addition, the group established guiding principles that apply to the care of all people living with GCA at all times.

If you agree to take part in this study, you will be asked to participate in an online survey where you will be asked to review each quality statement and indicate the extent to which:

1. You agree or disagree that the area of care described in each quality statement is a priority area for quality improvement

2. You agree or disagree with the content and wording of each quality statement

A rationale and supporting explanation are provided for each of the quality statements. This includes, where available, the clinical practice guidelines upon which the statement is based and explains how the statement aligns with or differs from international quality standards for GCA for your reference. You will also have the opportunity to offer written comments if you wish to do so.

To help us understand the context of your response to each statement, we will also ask you to complete a few questions about yourself. The survey will take approximately 30 to 45 minutes to complete. You do not need to complete the survey all at once, you can save your responses and come back to the survey at another time.

Once the quality statements are finalised the group will formulate a set of quality measures that may be used to assess and monitor the quality of care for people with GCA, to ensure it meets the standard of care described in each statement.

There are no costs associated with participating in this research project, nor will you be paid. If you don't wish to take part, you don't have to. You can withdraw from the study at any time. If you choose to withdraw your relationship with the ARA or the researchers will not be affected.

What are the possible benefits of taking part?

In Australia, there are currently no available quality standards by which to assess the quality of care for people living with GCA. The quality statements in this survey will be used by the researchers to formulate measurable indicators that can then be used to assess the care as specified in each statement and make improvements if necessary. Thus, the quality standard generated as an outcome of this study will provide an invaluable tool to improve the quality of care for people with GCA.

The quality standard will also be used to inform the development of a consumer-focused care guide which will help people with GCA to better understand the standard of care they should receive from their health care providers.

What are the possible risks of taking part?

Participation in the study involves completing a survey and providing feedback about several statements related to the care that people with GCA should receive. Participation in the survey will not affect your relationship with the ARA or the investigators.

What will happen to research information about me?

All information that is collected about you will be de-identified. Please note the following in relation to the study's confidentiality and security measures:

I. **Form of stored data:** De-identified information will be stored electronically in Microsoft Office Excel spreadsheets

II. **Location of storage:** Research information collected about you will be stored on a secure server owned by the ARA.

III. **Who has access:** All study investigators will have access to de-identified information collected from you. The study investigators directly responsible for processing the information collected from the survey, Kate Dyer and Charlotte Woollard, will have access to identifiable information about you, however, this information will be treated as strictly confidential.

IV. **How it is secured:** Research information collected about you will be stored in password protected files on the ARA server.

V. **Duration of storage:** 5 years from the time the study results are published.

VI. **Method of destruction:** Files in which research information is stored will be permanently deleted from the ARA secure server 5 years after publication of the study results.

Study results will be disseminated via publication in an academic journal. In addition, results will be published on the ARA website, and the websites of other stakeholder organisations, if appropriate. No participants will be identified through publication of study results.

In accordance with relevant Australian and/or South Australian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

What happens if I withdraw from the research?

Participants are free to withdraw from the study at any time. Participants may elect to allow researchers to use data that has been collected to date or may elect to remove their data from all the analysis.

Withdrawal from the study will not affect your relationship with the ARA, or the investigators.

Complaints and contacts (Investigators and Ethics Committee)

If you would like further details about this study or if you have a concern about any aspect of this study, please contact the relevant person below:

Questions and Information Contact	
Name:	Charlotte Woollard
Position:	Project Coordinator
Telephone:	08 6151 1154
E-mail:	Charlotte.Woollard@health.wa.gov.au
Reviewing HREC approving this research, HREC Executive Officer details and Complaints Contact	
HREC Name	Central Adelaide Local Health Network Human Research Ethics Committee (CALHN HREC)
Contact	HREC Support Officer
Telephone:	08 7117 2229
E-mail:	Health.CALHNResearchEthics@sa.gov.au

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2023) incorporating all updates. This statement has been developed to protect the interests of people who agree to participate in human research studies.

The study has been approved by the Central Adelaide Local Health Network Human Research Ethics Committee. If you wish to speak to someone not directly involved in the study about your rights as a volunteer, or about the conduct of the study, you may also contact the CALHN HREC Chairperson, on 08 7117 2229.

By continuing with the survey, you indicate that you have read and understood the information provided in this Participant Information Sheet. Your participation in this study is voluntary, and

you consent to take part under the conditions outlined above. By completing this survey you are providing your implied consent.