**Wellbeing and Healthy Lifestyle Program  
for People with Rheumatoid Arthritis.**

**Participant Information**

You have been provided with this information as you may be eligible for this research. This information may help you to decide whether you wish to be involved or not. Please feel free to discuss your participation, or any information in this document, with a team member or your health professional.

***What is this Program About?***

Positive wellbeing and healthy lifestyle behaviours are key predictors of severity and progression of rheumatoid arthritis (RA). However, it is important to understand how to effectively assist people with RA to start and/or maintain health and wellbeing activities. This work will deliver and evaluate a wellbeing and healthy lifestyle program for people with RA. The program aims to improve knowledge, confidence and capability to effectively respond to thoughts and emotions, access support networks, self-direct exercise, eating healthily, and (if required) stop smoking.

***What is Involved***

All participants will continue to receive usual care from their health care team.

All participants will be asked to attend two assessment sessions over six months. This will include

* online questionnaires to measure wellbeing, quality of life, exercise, diet and smoking. There will also be some demographic questions (e.g., living situation, age, gender) so that we can describe the people involved in the research.
* wearing an activity monitor for one week: This assesses the amount and intensity of movement you do, but not where you are or what you are doing
* a telephone/online interview and online three day diary about the types of food you eat
* physical measures such as walking for 6 minutes or stepping in place for 2 minutes, grip strength, standing up from a seated position
* measures of height, weight, waist circumference

Participants who are also part of the Australian Arthritis & AutoImmune Biobank Collaborative (A3BC) study (HREC/17/HAWKE/339) will be asked permission for their A3BC data (disease activity scores) to be used in this project. That data will be requested at the end of the current project.

Participants in the current study will be randomly allocated to one of two groups. One group will continue to receive usual care from their healthcare professionals and have no additional requirements other than the two assessments sessions. The other group will receive the RA program over 5- 6 months which will include

* Six two hour in person small group emotional and social resilience sessions (12 hours total).
* One individual in person session to develop an individualised exercise plan (75 mins), and eight in person small group (maximum 5 people) supervised exercise sessions (5-6 hours in total). Program participants will also be provided with an activity tracker
* One individual teleconference session to plan for healthy eating (45 mins), and four individual teleconference sessions (2 hours total)
* Four in person small group behaviour change support sessions (4 hours total)
* (if relevant) one in person two hour small group session and five individual teleconference stop smoking help sessions, (3.25 hours total)

RA program participants will also be asked to provide feedback on the program. Please note that the delivery of in person assessment and program sessions may change to online in response to Covid19 restrictions.

Page 1

The program is free, and relevant materials (e.g., session notes, exercise aids, activity monitor, food shopping and meal preparation guides, some stop smoking aids) will be provided at no cost. Assessment and program sessions will be conducted at either Griffith University School of Applied Psychology (Mt Gravatt campus) or the Princess Alexandra Hospital. Groups will be limited to ~5 people, with sessions led by staff with expertise and training in Clinical/Health Psychology, Exercise Physiology, Nutrition and Dietetics (ND), or Tobacco Treatment Specialisation (TTS).

***Benefits and Risks***

All participants will be helping the research team to understand how people with RA can be assisted to start and maintain health and wellbeing activities which can help manage RA symptoms and experiences.

For those participants who attend the program, we hope that you will become more knowledgeable, confident and capable to manage RA, including how to exercise safely and eat healthily. This can provide benefits for wellbeing, physical function, RA symptoms and quality of life. During the program, you may be asked to think about stress and emotions. If this causes you concern, the program staff will help you, and you may also seek assistance from outside the program. If you are unused to exercise, you may experience some initial breathlessness, discomfort and muscle soreness. You may also have some physical or psychological experiences from changing your diet or stopping smoking. All of these should go away over time. Any lasting effects should be discussed with the project team or with a health professional. It may be, however, that you receive no direct benefits from the program.

Those participants not allocated to receive the program will be providing valuable information for comparison purposes to improve understanding of the management and experiences of people with RA.

If you become unwell or have an injury as a result of the assessment or program, please contact our project team as soon as possible.

***The People***

This research is being overseen a team of experienced health professionals and researchers: Professor Ranjeny Thomas and Dr Helen Benham (Rheumatologists), Associate Professor Nicola Burton (Clinical and Health Psychologist), Professor Jeff Coombes (Exercise Physiologist); Associate Professor Coral Gartner (Tobacco control policy and smoking specialist), Dr Veronique Chachay (Accredited Practising Dietician) and Dr Hannah Mayr (clinical research dietician).

***Online Data***

The online questionnaires will be administered using the REDcap (Research Electronic Data Capture) data collection tool. Griffith University hosts and manages a secure instance of REDcap, and all surveys and data collected are stored in university servers administered by university staff. No data is ever transmitted by REDcap to another institution or organisation. Once research is completed, survey data is automatically stored and archived according to Griffith’s Schedule of Retention Periods for Research Data. Storage of electronic data within Griffith University (e.g., OneDrive) can involve the cloud (i.e., sometimes outside of Australia) and the University has entered into arrangements to protect the privacy of this data.

All assessment information will be confidential, de-identified and stored using a unique identification number. We will ask for your name and date of birth which will then be replaced by a code to compare data obtained at the start and end of the study. At the start of the research we will request your contact details (email or telephone) to remind you of scheduled sessions and advise of any changes to the research. After study completion we will delete your personal information. Your name will not be reported in any output from the study although anonymous comments reflecting your experiences may be included. Your data may be used in future related research, in which case it will be de-identified, so that your name and contact details are not included.

Page 2

***The Ethics***

This program has been awarded clearance by Metro South Human Research Ethics Committee (HREC/2020/QMS/70435), Griffith University (2021/684), and University of Queensland (2021/HE001971) and is conducted in accordance with National Health and Medical Research Council's guidelines.

Participation is completely voluntary. If you wish to withdraw from the study after it has started, you can do so at any time without having to give a reason. There are no consequences to you for withdrawing from the study and it will not affect the type of care you receive from any member of the program team, The University of Queensland or Griffith University, or your health care now or at any time into the future.

If you choose to withdraw you will be provided with a withdrawal form to sign. On the form you can select whether all your personal data already collected is destroyed or whether it can be kept by the researchers. The reason for keeping your data is to accurately detail the characteristics of all participants initially involved.

Should you wish to discuss the study with someone not directly involved, in particular in relation to matters concerning study policies, information about conduct of the study or your rights as a participant, or should you wish to make an independent complaint, you can contact any of following

* Metro South Human Ethics Committee Manager on 07 3443 8047 or email MSH-Ethics@health.qld.gov.au
* Griffith University Ethics Coordinators on 07 3735 4375 or [research-ethics@griffith.edu.au](mailto:research-ethics@griffith.edu.au)
* The University of Queensland Ethics Coordinators on 07 3365 3924 or 07 3443 1656 or email [humanethics@research.uq.edu.au](mailto:humanethics@research.uq.edu.au).

Page 3

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**Participant Consent Form**

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| ***Names and Contact Details of Investigators*** |
| Professor Ranjeny Thomas, Rheumatologist, The University of Queensland Diamantina Institute, [Ranjeny.thomas@uq.edu.au](mailto:Ranjeny.thomas@uq.edu.au)  Associate Professor Nicola Burton, Clinical and Health Psychologist, Griffith University School of Applied Psychology n.burton@griffith.edu.au  Dr Helen Benham, Rheumatologist, Princess Alexandra Hospital, helen.benham@health.qld.au  Professor Jeff Coombes, Exercise Physiologist, The University of Queensland School of Human Movement and Nutrition Sciences, jcoombes@uq.edu.au  Associate Professor Coral Gartner, Tobacco control policy and smoking specialist, The University of Queensland School of Public Health, c.gartner@uq.edu.au  Dr Veronique Chachay, Accredited Practising Dietician, The University of Queensland School of Human Movement and Nutrition Sciences, [v.chachay@uq.edu.au](mailto:v.chachay@uq.edu.au)  Dr Hannah Mahr, Clinical Research Dietician, Princess Alexandra Hospital, Hannah.Mahr@health.qld.gov.au |

**Declaration by the participant**: I have read the Participant Information for this program, or have had it read to me.

I understand the purposes, procedures, potential benefits and risks of the research described.

I have had an opportunity to ask questions, and I am satisfied with the answers I have received.

I freely agree to participate in this research study as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that all assessment information will confidential, de-identified and stored securely using a unique identification (ID) number.

I understand that if I am also enrolled in the A3BC study (HREC/17/HAWKE/339) my assessment data (disease activity scores) will be used as part of the evaluation for the current study.

I understand that the data from this study may be used in future related research, in which case my personal and contact details will not be made available, and my anonymity will be protected.

I understand I will be given a copy of my signed consent form to keep for my records.

**Full Name of Participant \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature (Where possible) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date and Time of Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Researcher Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Researcher Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**