GP INFORMATION STATEMENT AND CONSENT FORM

eHealth Tool for People with Gout

ID: | | | | | - | | | ☒ | ☒ |

This study is being carried out by Professor Richard Day (The University of New South Wales), and a team of researchers, and is funded by the National Health and Medical Research Council and partners.

What is the research study about?

You are invited to take part in this research study, which aims to determine the effectiveness of an electronic health (eHealth) tool, designed for people with gout. This eHealth tool is a mobile application (app). You were selected as a possible participant in this study because you are a general practitioner (GP) who treats patients with gout.

To participate in this project, you need to have seen patients with gout in the last year.

Your gout patients, who provide consent to participate in the study, will be randomly assigned to receive one of two versions of a mobile app, designed for patients with gout. They will be asked to:

- Use this mobile app for one year, and record gout attacks using this tool,
- See you for routine gout check-ups and the pathology service for blood tests at the start, 6 months and 12 months of the study, and
- Complete 3 surveys, including questions about themselves, their gout and gout treatment, and how gout affects their work and quality of life.

Do I have to take part in this research study?

Participation in this research study is completely voluntary, and your decision to not participate will not affect your relationship with The University of New South Wales.

If you decide you want to take part in the research study, you will be asked to:

- Read this Participant Information Statement carefully (ask questions if necessary),
- Sign and return one copy of the consent form, and
- Keep a copy of this Participant Information Statement and another copy of the consent form.

What does participation in this research study require, and are there any risks involved?

If you decide to take part in the research, we will request:

- Your help with recruiting your gout patients into the study,
- That you see participating patients for routine gout check-ups and refer them to pathology services for blood tests at the start, 6 months, and 12 months of the study, and
- That you provide some medical information related to the patients' gout, with their consent, following each check-up (optional).

Additionally, we may interview you at the end of the study about your experiences with gout and using the mobile app. Participation in the interview is optional. The interview can be conducted by telephone or online via a video chat. Alternatively, the interview can take place at a convenient location for you or at St Vincent's Hospital Sydney. The interview will take approximately 30 minutes. With your permission, we would like to digitally record the interview (audio only).

With the exception of your time, we do not expect there to be any risks or costs associated with taking part in this study.

To participate in this project, gout patients need to:

- Have had at least two attacks of gout in the past year,
- Have access to a smartphone or tablet device with the internet, and
- Be receiving or eligible to receive urate-lowering therapy to prevent attacks.

With permission from your gout patients, who provide consent to participate in the study, we would like to gain access to the following:

- Their medical examination and medical history relevant to their gout, and
- Their blood test results to track uric acid and creatinine concentrations.

Will I be paid to participate in this project?

Your practice will be reimbursed for your participation in this study with a $300 gift voucher.

What are the possible benefits to participation?

We hope to use information from this research study to benefit patients with gout, who are currently experiencing problems managing their gout. At the completion of the study, you and participating patients will have access to the most-effective version of the mobile app free of charge.

What will happen to information about me?

By signing the consent form you allow the research team to collect and use information about you for the research study. We will keep your data for 15 years at St Vincent's Hospital Sydney. Your information will only be used for the purpose of this research study, and it will only be disclosed with your permission.

It is anticipated that the results of this research study will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be presented in such a way that you will not be individually identified.

You have the right to request access to the information about you that is collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. You can do this by contacting a member of the research team.

If you take part in an interview, a digital audio recording of your interview will be taken for the purposes of the research study. After the interview, we will transcribe and then delete your digital audio recordings. We will keep the de-identified transcription of your interview for 15 years on a password-protected server at St Vincent's Hospital Sydney.

Data will be managed using Microsoft Office Excel, and stored in a password-protected file in the study's password-protected computers (which are not for public use). To ensure that your personal identifiers and relevant data are de-identified, you will be allocated an identification number instead of your name for analysis. This ensures that your confidentiality is maintained throughout the study. The consent form you signed will be stored in a locked filing cabinet in a secure room at the St. Vincent's Hospital in Sydney separately from other data collected in paper forms.

How and when will I find out what the results of the research study are?

You have a right to receive feedback about the overall results of this study. You can tell us that you wish to receive feedback by contacting a member of the research team. This feedback will be in the form of a written summary of our study findings. You will receive this feedback after the study is finished.

What if I want to withdraw from the research study?

If you consent to participate, you may withdraw at any time. If you do withdraw, you will be asked to complete and sign the 'Withdrawal of Consent' form which is provided at the end of this document. Alternatively, you can contact the research team and tell them you no longer want to participate.

If you take part in an interview, you are free to stop the interview at any time. Unless you say that you want us to keep them, any recordings will be erased, and the information you have provided will not be included in the study results. You may also refuse to answer any questions that you do not wish to answer during the interview or in the surveys.

If you decide to withdraw from the study, we will not collect any more information from you. Please let us know at the time when you withdraw what you would like us to do with the information we have collected about you up to that point. If you wish, your information will be removed from our study records and will not be included in the study results, up to the point that we have analysed and published the results.

What should I do if I have further questions about my involvement in the research study?
The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if you have any problems that may be related to your involvement in the project, you can contact the following member/s of the research team:

Research Team Contact

Name	Jacob Bechara
Position	Research Assistant
Telephone	1800 931 544
Email	med.gout.app@unsw.edu.au

What if I have a complaint or any concerns about the research study?
If you have any complaints about any aspect of the project, the way it is being conducted, then you may contact:

Complaints Contact

Position	Human Research Ethics Coordinator
Telephone	02 9385 6222
Email	humanethics@unsw.edu.au
HC Reference Number	15199

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UNSW SYDNEY

Consent Form – Participating GP providing own consent

Declaration by the participating GP

☐ I have read the Participant Information Statement or someone has read it to me in a language that I understand;

☐ I understand the purposes, study tasks and risks of the research described in the project;

☐ 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 project and withdrawal will not affect my relationship with any of the named organisations and/or research team members;

☐ I understand that I will be given a signed copy of this document to keep;

Y / N ■ ☐ I consent to being contacted about further research studies. By circling "Y" you are giving consent for information about your name, and contact details to be kept indefinitely, unless you withdraw your permission. If a study in primary care needs participants, you may be contacted to ask if you would like to participate.

Participating GP Signature

Name of GP (please print)	Dr
Signature of GP	
Date	

Declaration by Researcher*

☐ I have given a verbal explanation of the research study, its study activities and risks and I believe that the participant has understood that explanation.

Researcher Signature*

Name of Researcher (please print)	
Signature of Researcher	
Date	

***An appropriately qualified member of the research team must provide the explanation of, and information concerning the research study.**
Note: All parties signing the consent section must date their own signature.

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Form for Withdrawal of Participation

I wish to **WITHDRAW** my consent to participate in the research proposal described above and understand that such withdrawal **WILL NOT** affect my relationship with The University of New South Wales.

Participating GP Signature

Name of GP (please print)	Dr
Signature of GP	
Date	

The section for Withdrawal of Participation should be forwarded to:

CI Name:	Prof Richard Day
Email:	r.day@unsw.edu.au
Phone:	02 8382 2331
Postal Address:	Department of Clinical Pharmacology & Toxicology Therapeutics Centre, Level 2 Xavier Building St Vincent's Hospital Sydney 390 Victoria St Darlinghurst NSW 2010 Australia