

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

(Healthcare Professionals)

You are being invited to participate in a research study. Your participation in this study is entirely voluntary. Before you take part in this research study, the study must be explained to you and you must be given the chance to ask questions. Your questions will be answered clearly and to your satisfaction. Please read the information provided here carefully. If you agree to participate, please sign the consent form. You will be given a copy of this document.

STUDY INFORMATION

Study Title:

Developing a gout action plan in primary care setting in Singapore

This research study is recruiting at the following SingHealth institution(s). Please note that the word “SingHealth” refers to the institution where you are recruited into the study.

SingHealth Polyclinics

Principal Investigator:

Dr Liew Siew Lee

SingHealth Polyclinics- 6 Pasir Ris Drive 8 #1M-01, 519466 Singapore

Tel: 6340 7436

Institutional Hotline: 6350 7600

PURPOSE OF THE RESEARCH STUDY

The purpose of this research study is to understand healthcare providers (HCPs) who treat gout, so that their perspectives can be incorporated into developing a gout action plan in primary care setting in Singapore. This research aims to understand primary care HCPs who manage patients with gout, their understanding on gout and its management, experiences of treating patients with gout, their views of self-management, their views on the acceptability and usability of prototype gout action plan. We hope to collect enough knowledge to create an action plan for patients with gout.

You were selected because you manage patients with gout in your practices.

For this study, it targets to recruit 15 healthcare providers participants from Pasir Ris Polyclinic and other various primary care practices.

STUDY PROCEDURES & YOUR RESPONSIBILITIES IN THIS STUDY

If you agree to take part in this study, you will be asked to either attend an interview or a focus group discussion. The interview or focus group discussion will be audio-recorded for transcription and analysis.

Your participation in the study will last for 60 minutes. Your demographics information (age, gender, ethnic, place and years of practice, qualification, seniority level) will be collected. You will be asked questions on your understanding on gout and its management, experiences of treating patients with gout, views of self-management, your opinion on the prototype gout action plan developed for gout treatment, your views of the acceptability and usability of prototype gout action plan. Prototype gout action plan developed for gout treatment will be provided on the day of the interview or focus group discussion.

If you agree to participate in this study, you should:
Follow the advice and directions given to you by the study team.

WHAT IS NOT STANDARD CARE OR IS EXPERIMENTAL IN THIS STUDY

The study is being conducted because the gout action plan has not been previously developed and not yet proven to be feasible or acceptable to complement gout management in patients with gout. We hope that your participation will help us to determine whether the gout action plan is equal or superior to usual clinical care for gout management.

In this study, the interview, focus group discussion and prototype gout action plan are being used for the purposes of the research.

POSSIBLE RISKS, DISCOMFORTS OR INCONVENIENCES

Questionnaires/ surveys/ interviews:

Some of the questions might make you feel uncomfortable or upset. You may refuse to answer any of the questions and/or take a break at any time during the study.

Personal privacy and confidentiality:

This study uses information that may affect your privacy. To protect your confidentiality, only a unique code will be used to identify data that we collected from you.

As there will be a link between the code and your identifiable information, there is still a possibility of data breach. A data breach is when someone sees or uses data without permission. If there is a data breach, someone could see or use the data we have about you. Even without your name, there is a chance someone could figure out who you are. They could misuse your data. We believe the chance of this is very small, but it is not zero.

POTENTIAL BENEFITS

There is no known benefit from participation in this study. However, your participation in this study may add to the medical knowledge about physicians who treat gout and the eventual creation of gout action plan that will help patients with gout in self-management and improving gout care.

ALTERNATIVE IF YOU DO NOT PARTICIPATE IN THE STUDY

There is no alternative to the study procedures. You can choose not to take part in this study. The study procedures will not be carried out.

COSTS & PAYMENTS IF PARTICIPATING IN THIS STUDY

There is no cost to you for participating in this research study.

You will be reimbursed for your time, inconvenience and transportation costs. If you complete the study, you will receive \$20 in total.

INCIDENTAL FINDINGS

There will not be any incidental findings arising in this research. “Incidental findings” are findings that have potential health or reproductive importance to research participants like you and are discovered in the course of conducting the study, but are unrelated to the purposes, objectives or variables of the study.

PARTICIPANT’S RIGHTS

Your participation in this study is entirely voluntary. You have a right to ask questions, which the study team will do their best to answer clearly and to your satisfaction.

In the event of any new information becoming available that may be relevant to your willingness to continue in this study, you (or your legal representative, if relevant) will be informed in a timely manner by the Principal Investigator or his/her representative and will be contacted for further consent if required.

WITHDRAWAL FROM STUDY

You are free to withdraw your consent and discontinue your participation in the study at any time, without giving any reasons and without your medical care being affected. If you decide to stop taking part in this study, you should tell the Principal Investigator.

If you withdraw from the study, further data collection pertaining to the study will be stopped. However, any research information or data obtained before your withdrawal of consent will be retained and may continue to be used. This is to allow a complete and comprehensive evaluation of the research study.

Your study doctor, the Principal Investigator of this study may stop your participation in the study at any time for one or more of the following reasons:

- Failure to follow the instructions of the Principal Investigator and/or study staff.
- The Principal Investigator decides that continuing your participation could be harmful to your health or safety.
- The study is cancelled.

RESEARCH RELATED INJURY AND COMPENSATION

If you follow the directions of the Principal Investigator of this research study and you are injured due to the research procedure given under the plan for the research study, our institution will provide you with the appropriate medical treatment.

Payment for management of the normally expected consequences of your treatment (i.e. consequences of your treatment which are not caused by your participation in the research study) will not be provided.

You still have all your legal rights. Nothing said here about treatment or compensation in any way alters your right to recover damages where you can prove negligence.

CONFIDENTIALITY OF STUDY AND MEDICAL RECORDS

Your participation in this study will involve the collection of Personal Data. "Personal Data" means data about you which makes you identifiable (i) from such data or (ii) from that data and other information which an organisation has or likely to have access. Examples of personal data include name, national registration identity card (NRIC), nationality, passport information, date of birth, and telephone number.

Personal Data collected for this study will be kept confidential and stored in Singapore. Your study records and medical records (if applicable), to the extent required by the applicable laws and regulations, will not be made publicly available. To protect your identity, your Personal Data will be labelled with a unique code. The code will be used in place of your name and other information that directly and easily identifies you. The study team will keep a separate file that links your code to your Personal Data. This will be kept in a safe place with restricted access. In the event of any data sharing with third parties (e.g. funding agencies, research collaborators) whether locally or overseas and publication regarding this study, your identity will remain confidential.

However, the monitor(s), the auditor(s), the Institutional Review Board, and the regulatory authority(ies) will be granted direct access to your original medical records (if applicable) and study records to verify study procedures and data, without making any of your information public.

By signing the Consent Form, you consent to (i) the collection, access to, use and storage of your Personal Data by SingHealth, and (ii) the disclosure of such Personal Data to our authorised service providers and relevant third parties as mentioned above. To the fullest extent permitted by applicable law, under no circumstances will SingHealth and/or its affiliates be liable for any direct, indirect, incidental, special or consequential loss or damages arising out of any data breach event.

All data collected in this study are the property of SingHealth. The data will be used for the purpose of this research study only. The data will be used for the purpose of this research study only, unless you give permission for your data to be made available for future use in other research studies. For this purpose, consent for future research will be sought from you.

By participating in this research study, you are confirming that you have read, understood and consent to the SingHealth Data Protection Policy, the full version of which is available at www.singhealth.com.sg/pdpa.

WHO HAS REVIEWED THE STUDY

This study has been reviewed by the SingHealth Centralised Institutional Review Board for ethics approval.

If you have questions about your rights as a participant, you can call the SingHealth Centralised Institutional Review Board at 8126 3660 during office hours (8:30 am to 5:30pm).

WHO TO CONTACT IF YOU HAVE QUESTIONS REGARDING THE STUDY

If you have questions about this research study or in the case of any injuries during the course of this study, you may contact your study doctor, the Principal Investigator listed under STUDY INFORMATION section, at the beginning of this document.

If you have any feedback about this research study, you may contact the Principal Investigator or the SingHealth Centralised Institutional Review Board.

CONSENT FORM FOR RESEARCH STUDY

Protocol Title:

Developing a gout action plan in primary care setting in Singapore

Declaration by Research Participant

(i) I agree to participate in the research study as described and on the terms set out in the Participant Information Sheet. The nature, risks and benefits of the study have been explained clearly to me and I fully understand them.

(ii) I understand the purpose and procedures of this study. I have been given the Participant Information Sheet and the opportunity to discuss and ask questions about this study and am satisfied with the information provided to me.

(iii) I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reasons and without my medical care being affected.

(iv) By participating in this research study, I confirm that I have read, understood and consent to the SingHealth Data Protection Policy.

Name of participant

Signature/Thumbprint (Right / Left)

Date of signing

To be completed by witness, where applicable

I, the undersigned, certify that:

- I am 21 years of age or older.
- To the best of my knowledge, the participant or the participant's legal representative signing this informed consent form had the study fully explained to him/her in a language understood by him/ her and clearly understands the nature, risks and benefits of the participant's participation in the study.
- I have taken reasonable steps to ascertain the identity of the participant or the participant's legal representative giving the consent.
- I have taken reasonable steps to ascertain that the consent has been given voluntarily without any coercion or intimidation.

Witnessed by: _____

Name of witness

Date of signing

Signature of witness

1. An impartial witness (who is 21 years of age or older, has mental capacity, who is independent of the research study, and cannot be unfairly influenced by people involved with the research study) should be present during the entire informed consent discussion if a participant or the participant's legal representative is unable to read, and/or sign and date on the consent form (i.e. using the participant's or legal representative's thumbprint). After the written consent form and any written information to be provided to participant is read and explained to the participant or the participant's legal representative, and after the participant or the participant's legal representative has orally consented to the participant's participation in the study and, if capable of doing so, has signed and personally dated the consent form, the witness should sign and personally date the consent form. This is applicable for Clinical Trials regulated by HSA and Human Biomedical Research under the HBRA.

2. For HBRA studies, the witness may be a member of the team carrying out the research only if a participant or the participant's legal representative is able to read, sign and date on the consent form.

Investigator's Statement

I, the undersigned, certify to the best of my knowledge that the participant/ participant's legal representative signing this consent form had the study fully explained to him/her and clearly understands the nature, risks and benefits of the participant's participation in the study.

Name of Investigator/
Person obtaining consent

Signature

Date

INFORMATION & CONSENT FORM FOR FUTURE RESEARCH

This is an optional component that is separate from the research study. You may still participate in the research study if you say “No” to this. Please ask questions if you do not understand why we are asking for your permission.

In this Consent Form for Future Research, we seek your permission to keep all information collected about you (Personal Data and research data) for Future Research. Except if you withdraw your consent or there are limits imposed by law, there is no limit on the length of time we will store the data. Researchers will use the data for research long into the future.

This is what will be done with the data:

- We may use the data to answer additional research questions in other research studies which are outside the scope of the research study (“Future Research”). We may also share the data with other researchers within and/or outside of Singapore, for use in Future Research.
- You should not expect to get personal test results from Future Research. However, it may be possible that incidental findings will be detected in the course of conducting Future Research. If this happens, we may contact you to find out if you would like to learn more. Only medically actionable incidental findings (where medical treatment is available) will be disclosed. You will be asked to indicate whether you wish to be re-identified and notified in the event of an important incidental finding that is related to you.
- We may also use the data for purposes other than research such as teaching, or training future researchers, development of health policy.

This is what will be done to protect confidentiality of the data:

- Any information that could identify you will be removed (de-identified) before this de-identified data is used and/or shared with other researchers.
- If you decide at a later time that you do not want the data to be used for Future Research, you can contact the Principal Investigator or study team at any time. All the data that has not been used or shared with other researchers will be removed and discontinued from further use, unless this information has already been included in analyses or used in publications.

The use of your data in Future Research may result in intellectual property rights and commercial profits. If this should occur, you will not be compensated and will not receive any financial benefits or proprietary interest.

CONSENT FORM FOR FUTURE RESEARCH

This component is optional. You do not have to agree to it in order to participate in the research study.

Please indicate your choice using the relevant checkbox.

- ☐ I do not agree to have my data stored for future use in other research studies.
- ☐ I agree to have my data stored for future use in other research studies, as described above. I understand that I will not be contacted again personally, for approvals to use and share my data for such Future Research. Research arising in the future, will be subject to review by the relevant institutional review board, where applicable.

Disclosure of incidental findings arising from Future Research

- ☐ I wish to be re-identified and notified of any incidental findings that are medically actionable (with available treatment options).
- ☐ I do not wish to be re-identified and notified of any incidental finding that are medically actionable (with available treatment options). However, I understand that in exceptional or rare situations such as discovery of life-threatening findings, I may be contacted to confirm my decision whether to learn more about the incidental findings.

I understand the purpose and nature of this optional component (storage of data for future use). I have been given the Information & Consent Form for Future Research and the opportunity to discuss and ask questions about this optional component and am satisfied with the information provided to me.

I confirm that I have read, understood and consent to the SingHealth Data Protection Policy.

Name of participant

Signature/Thumbprint (Right / Left)

Date of signing

To be completed by witness, where applicable

I, the undersigned, certify that:

- I am 21 years of age or older.
- To the best of my knowledge, the participant or the participant's legal representative signing this Information & Consent Form for Future Research had the optional

component fully explained to him/her in a language understood by him/ her and clearly understands the purpose and the nature of this optional component.

- I have taken reasonable steps to ascertain the identity of the participant or the participant's legal representative signing this Information & Consent Form for Future Research.
- I have taken reasonable steps to ascertain that the participant or the participant's legal representative has not been coerced into giving consent.

Witnessed by: _____
Name of witness Date of signing

Signature of witness

1. An impartial witness (who is 21 years of age or older, has mental capacity, who is independent of the research study, and cannot be unfairly influenced by people involved with the research study) should be present during the entire informed consent discussion if a participant or the participant's legal representative is unable to read, and/or sign and date on the consent form (i.e. using the participant's or legal representative's thumbprint). After the written consent form and any written information to be provided to participant, is read and explained to the participant or the participant's legal representative, and after the participant or the participant's legal representative has orally consented to the participant's participation in the study and, if capable of doing so, has signed and personally dated the consent form, the witness should sign and personally date the consent form. This is applicable for Clinical Trials regulated by HSA and Human Biomedical Research under the HBRA.

2. For HBRA studies, the witness may be a member of the team carrying out the research only if a participant or the participant's legal representative is able to read, sign and date on the consent form.

Investigator's Statement

I, the undersigned, certify to the best of my knowledge that the participant/ participant's legal representative signing this Information & Consent Form for Future Research had the optional component (storage of data for future use) fully explained to him/her and clearly understands the purpose and the nature of this optional component.

Name of Investigator/
Person obtaining consent

Signature

Date