INFORMED CONSENT FORM

1. Study Information

Protocol Title:

Strengthening Our Community's Resilience Against Threats from Emerging Infections (SOCRATEs)

Principal Investigator & Contact Details:

Dr Chen I-Cheng Mark
Head of Research Office
National Centre for Infectious Diseases (NCID)
16 Jalan Tan Tock Seng, Singapore 308442
E-mail: Mark_Ic_Chen@ncid.sg
Telephone: 6511 5048

Study Sponsor:
This research study is kindly sponsored by the Estate of Ong Tiong Tat and Irene Ong-Tan Liang Kheng.
(see https://www.straitstimes.com/singapore/education/chance-meeting-over-char-kway-teow-leads-to-friendship-and-legacy-of-giving).

2. Purpose of the Research Study

You are invited to participate in a research study. It is important to us that you first take time to read through and understand the information provided in this sheet. Nevertheless, before you take part in this research study, the study will be explained to you and you will be given the chance to ask questions. After you are properly satisfied that you understand this study, and that you wish to take part in the study, you must sign this informed consent form. You will be given a copy of this consent form to take home with you.

You are invited because you are a (1) Singapore Citizen or Singapore Permanent Resident, (2) aged 16 and above, (3) living within the targeted neighborhood, and with (4) access to a smartphone / tablet / any other internet-enabled device and willing to use it to fill out the surveys that will be conducted throughout this study.

As a travel hub and densely populated urban centre, Singapore is constantly at risk from outbreaks of infectious diseases. The SOCRATEs research programme was established to identify key gaps in the public's awareness and preparedness with regards to infectious disease outbreaks. The study will assess your knowledge, attitudes and perception of the risk posed by infectious diseases, as well as your opinions about interventions to control such outbreaks in Singapore. At the same time, this study also aims to explore the feasibility of an interactive application as a system of tracking common symptoms (like cough, fever and runny nose) that may indicate the spread of infectious diseases. Understanding how common these symptoms are, and whether there is any abnormal increase in these symptoms will allow us to track if diseases causing such symptoms may be spreading in the community in real time. It may also provide early warning that important infectious diseases, like Zika virus, are causing an outbreak.

This study will recruit up to 5,000 participants from households (up to 4 household members per household) living in various residential estates across Singapore and follow them over a period of 5 years. The data collection will be performed by students from National University of Singapore (NUS), the research study team from the National Centre for Infectious Diseases (NCID), and external survey companies

3. What procedures will be followed in this study

If you take part in this study, you will be part of a long-term cohort of individuals under the SOCRATEs research programme led by the National Centre for Infectious Diseases (NCID), and kindly sponsored by the Estate of Ong Tiong Tat and Irene Ong-Tan Liang Kheng.

You will first be asked to answer the demographic and registration surveys to capture your personal, household and registration details via pen and paper. You will then be asked to fill in the initial survey on outbreaks to assess your knowledge, attitudes and perception of the risk from infectious diseases, and your views about efforts to control outbreaks in Singapore, via pen and paper, or NHG REDCap Mobile Application using corporate mobile devices, or a via web-link. This will take about 30 to 45 minutes to complete.

In addition, you will be asked to download and install the SOCRATEs application onto your smartphone, tablet or any other internet-enabled device that you have access to. This will be done either on the day of enrolment into the study or at a later stage of the study. You will be asked to create a user account with a username of your choice, and you will then be guided through the functions of the SOCRATEs application, which may be used to launch future surveys. This will take about 5 to 15 minutes to complete. For participants who are asked to download the SOCRATEs application at a later stage of the study, the study team will assist you in the above-mentioned steps by giving step-by-step instructions, the unique activation code and your username (that you have chosen on the day of enrolment) via SMS, or telephone, or email, or in-person with a follow-up household visit.

Throughout the duration of the study, you will be notified via SMS, or telephone, or email, or via the SOCRATEs application, to visit the SOCRATEs web-link to receive information about future survey launches, future updates about the study or information about any infectious disease outbreaks that may arise during the duration of the study.

Throughout the duration of the study, you will be asked to complete follow-up surveys about infectious diseases up to twice a year. This will be via the SOCRATEs application, or by telephone, or via a web-link, or via pen and paper with follow-up household visits. The surveys will be limited to about 15 minutes each, and participants will be reimbursed $5 cash or voucher for each completed survey.

In the event of a major infectious disease outbreak arising during the study years, you may be asked to answer additional ad-hoc survey(s) about the specific outbreak. This will be via the SOCRATEs application, or by telephone, or via web-link, or via pen and paper with follow-up household visits. The surveys will be limited to about 15 minutes each, and participants will be reimbursed $5 cash or voucher for each survey completed.

In addition, as part of surveillance during infectious disease outbreaks, you may also be asked to answer a series of short weekly surveys to assess if you are experiencing any symptoms of significance. This will be via the SOCRATEs application, or by SMS, or by telephone, or via web-link. The surveys will be limited to about 1 to 5 minutes each, with the participants being reimbursed up to $10 cash or voucher in total depending on your participation rate.

Kindly note that telephone calls may be conducted by NCID staff, or staff and students working under the supervision of our collaborators at the National University of Singapore (NUS) or the Nanyang Technological University (NTU).

If you agree to take part in this study, the following will happen to you:

	Start of study period	**Study period** 0 to 5 years	**End of study period**
Informed Consent	X		
Demographic and registration surveys	X		
Initial survey about outbreaks	X		
Install SOCRATEs application	X (Date to be confirmed)	X (Date to be confirmed)	
Create user account	X (Date to be confirmed)	X (Date to be confirmed)	
Weekly survey		You will be informed if the need arises	
Follow-up surveys (up to twice a year)		You will be informed if the need arises	
Ad-hoc surveys		You will be informed if the need arises	
Final feedback survey			X
Delete SOCRATEs application			X

When your participation in the study ends, you will be asked to answer a final feedback survey to find out the barriers and facilitators for the sustained use of the surveillance system and get detailed feedback on each system feature and suggestions on how to improve them. This will be via the SOCRATEs application or a web-link. This will take up to 15 minutes to complete. Your SOCRATEs user account will then be closed and you will be asked to delete the SOCRATEs application from your personal electronic device.

The initial survey on outbreaks, weekly, follow-up, ad-hoc and final feedback surveys will not ask for any identifiable information (e.g. name, address, contact details). However, your identifiable information will be captured through the demographic and registration surveys and will be stored securely and separately. It is only used to allow the Principal Investigator and his research study team members to contact you when the need arises (e.g. reimbursement for weekly surveys completed). Any individually identifiable data obtained during the course of this study will be stored and analysed for the purpose of this study and will not be used for future research.

“Incidental findings” are findings that have potential health or reproductive importance to research participants like you / your child and are discovered in the course of conducting the study, but are unrelated to the purposes, objectives or variables of the study. This study will not result in any anticipated / unanticipated incidental findings; therefore, you will not be re-contacted for this reason.

4. Your Responsibilities in This Study

If you agree to participate in this study, your key responsibilities include:

1. On your day of enrolment:
    a. Complete demographic and registration surveys via pen and paper.
    b. Complete the initial survey on outbreaks via pen and paper, or NHG REDCap Mobile Application using corporate mobile devices, or via a web link.
    c. Download and install the SOCRATEs application on your smartphone, tablet or any other internet-enabled device that you have access to.
    d. Create a SOCRATEs user account with a username of your choice.
2. Throughout the study years:
    a. Download and install the SOCRATEs application on your smartphone, tablet or any other internet-enabled device that you have access to.
    b. Create a SOCRATEs user account with a username of your choice.
    c. Complete follow-up surveys via the SOCRATEs application, or by telephone, or via a web-link, or via pen and paper with follow-up household visits, up to twice a year throughout the study years.
    d. Complete a series of short weekly surveys via the SOCRATEs application, or by SMS, or by telephone, or via a web-link, if there is a reason to monitor infectious diseases throughout the study years.
    e. Complete ad-hoc survey(s) via the SOCRATEs application, or by telephone, or via a web-link, or via pen and paper with follow-up household visits, in times of infectious disease outbreaks arising during the study years.
    f. Complete a final feedback survey via the SOCRATEs application or via a web-link at the end of the study.

5. What Is Not Standard Care or is Experimental in This Study

The use of the application and completion of surveys via the SOCRATEs application, or by SMS, or by telephone, or a web-link, or via pen and paper with follow-up household visits, are carried out for the purpose of research only.

6. Possible Risks and Side Effects

There is a potential risk whereby your data transmitted via the cloud and storage on an external server can be intercepted, hacked or stolen in the event of a lost device or a system security breach. To minimize this risk, the data on the server will be encrypted such that it cannot be accessed by third parties. Most importantly, to safeguard against data breach, the SOCRATEs application will not contain your personal identifiers.

There is a potential risk whereby paper demographic and registration surveys, which contains your personal identifiers, may be misplaced during the recruitment process. To minimize this risk, the recruitment team will count and keep the paper demographic and registration surveys in secured file prior to leaving your house. These surveys will then be brought back to NCID at the end of the day and kept in a locked cabinet.

7. Possible Benefits from Participating in the Study

There is no assurance you will benefit directly from participation in this study. However, your participation in this study may help in the identification of potential areas for improvement in our preparedness against future infectious disease outbreaks. The SOCRATEs application may have other interactive features such as useful information on disease outbreak or pandemics that you may benefit from.

8. Important Information for Women Subjects

The study will involve the completion of questionnaires via SOCRATEs application installed onto your smartphone, tablet or any other internet-enabled device that you have access to, or by SMS, or by telephone, or via a web-link, or via pen and paper with follow-up household visits. This does not involve any invasive procedures or therapeutic products and hence the risk to pregnant women / breast-feeding women / foetus / neonate is minimal.

9. Costs & Payments if Participating in the Study

How much will you be paid?

On the day of enrolment into the study, you will receive $15 cash or voucher for the completion of the demographic and/or registration surveys, and initial survey on outbreaks, and/or the successful download and installation of the SOCRATEs application onto the smartphone, tablet or any other internet-enabled device that you have access to and creation of a user account. You may also receive a non-cash gift, such as a digital thermometer, costing no more than $5.

Reimbursement for subsequent study participation (i.e. completion of weekly, follow-up and/or ad-hoc surveys) is dependent on your participation rate. For the weekly surveys, you will receive up to $10 cash or voucher for the completion of a series of weekly surveys that you complete. For the follow-up and ad-hoc surveys, you will receive $5 cash or voucher for each survey that you complete.

When you are asked to answer the surveys via the SOCRATEs application on your personal smart electronic device, you may incur a very small cost on your device's data plan. You can avoid this by using the SOCRATEs application when you have access to free Wifi.

When and how will you be paid?

Reimbursement for subsequent participation (i.e. completion of follow-up and/or ad-hoc surveys) will be done twice a year, approximately every 6 months. The type of payment (i.e. cash or voucher) for subsequent study participation is dependent on the payment mode that you have chosen. You will be notified about your reimbursement through the SOCRATEs application and/or your indicated email address / mobile number.

On the day of enrolment into the study, you will be asked to select your choice of payment mode from the four options below. **Kindly note that once you have selected your preferred payment mode, you will not be allowed to change your choice.**

1. If you have selected **iBanking**, a secured payment web link will be emailed to your indicated email address during the payment months. You will be asked to fill in and submit your bank account details to receive your reimbursement(s). You will be notified via SMS or email when your reimbursement is issued.
2. If you have selected **authorize someone for iBanking**, you will be asked to fill the details of the authorized person on our authorization form on the day of your enrolment. You and the authorized person will be asked to sign on the same authorization form to acknowledge this agreement. You and the authorized person will be notified via SMS or email when your reimbursement is issued.

3. If you have selected **mailing**, your reimbursement will be sent out to your indicated mailing address during the payment months. Please note that the actual duration to receive the reimbursement may be longer due to delivery schedule of Singpost. You will be notified via SMS or email when your reimbursement is mailed out.
4. If you have selected **self-collection at National Centre for Infectious Diseases (NCID)**, you will be contacted by a member of the study team during the payment months to arrange for an appointment from Monday to Fridays between 9am to 4pm.

Kindly note all unsuccessful bank transfer / lost mail reports will be investigated and resend of reimbursement(s) will be done only for all approved unsuccessful bank transfer / lost mail exceptions.

10. Voluntary Participation

Your participation in this study is voluntary. You may stop participating in this study at any time. Your decision not to take part in this study or to stop your participation will not affect your medical care or any benefits to which you are entitled. If you decide to stop taking part in this study, you should tell the Principal Investigator or his/her representative.

However, the data that have been collected until the time of your withdrawal will be kept and analyzed. The reason is to enable a complete and comprehensive evaluation of the study.

In the event of any new information becoming available that may be relevant to your willingness to continue in this study, you (or your legally acceptable representative, if relevant) will be informed in a timely manner by the Principal Investigator or his representative.

11. Compensation for Injury

You are only required to complete surveys via the SOCRATEs application or by telephone as part of your participation in this study. Therefore, the risks of injury arising from your participation in this study are minimal. By signing this consent form, you will not waive any of your legal rights or release the parties involved in this study from liability for negligence.

12. 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. This includes medical conditions, medications, investigations and treatment history.

Information and “Personal Data” collected for this study will be kept confidential. Your records, to the extent of the applicable laws and regulations, will not be made publicly available. Any individually identifiable data obtained during the course of this study will be stored and analysed for the purpose of this study and will not be used for future research.

However, the NHG Domain Specific Review Board and Ministry of Health will be granted direct access to your original medical records to check study procedures and data, without making any of your information public. By signing the Informed Consent Form attached, you or your legally acceptable representative are authorizing (i) the collection, access to, use and storage of your “Personal Data”, and (ii) the disclosure to authorized service providers and relevant third parties.

Data collected and entered into the survey forms are the property of National Centre of Infectious Diseases. In the event of any publication regarding this study, your identity will remain confidential.

Research arising in the future, based on your “Personal Data”, will be subject to review by the relevant institutional review board.

By participating in this research study, you are confirming that you have read, understood and consent to the Personal Data Protection Notification available at http://www.ttsh.com.sg/patient-guide/page.aspx?id=4468

13. Who To Contact if You Have Questions

If you have questions about this research study, you may contact the Principal Investigator, Dr Chen I-Cheng Mark, Head of Research Office, National Centre for Infectious Diseases at Tel: 6511 5048. Alternatively, you may also contact his representatives, Ms Brenda Ong Wei Ling or Mr Alexius Matthias Soh Sheng En at Tel: 6511 5081.

The study has been reviewed by the NHG Domain Specific Review Board (the central ethics committee) for ethics approval.

If you want an independent opinion to discuss problems and questions, obtain information and offer inputs on your rights as a research subject, you may contact the NHG Domain Specific Review Board Secretariat at 6471-3266. You can also find more information about participating in clinical research, the NHG Domain Specific Review Board and its review processes at www.research.nhg.com.sg.

If you have any complaints or feedback about this research study, you may contact the Principal Investigator or the NHG Domain Specific Review Board Secretariat.

14. Consent to be Contacted for Future Research

You will be asked for permission to be re-contacted in the future for participation in research studies that you may be suitable for.

If you agree to be re-contacted, your information and contact details will be stored in a secured database within National Centre for Infectious Diseases. Your information and contact details will not be released to any parties outside the National Centre for Infectious Diseases without your permission. When investigators from the National Centre for Infectious Diseases identify you to be suitable for a particular research study, the investigators or authorized personnel from the National Centre for Infectious Diseases will contact you to inform you about the research study. Your decision to be contacted for future research studies is completely voluntary and separate from your decision to participate in this study.

Your decision will not affect your medical care or any benefits to which you are entitled. You may change your mind at any time by contacting the Principal Investigator, Dr Chen I-Cheng Mark at Tel: 6511 5048, or his representatives, Ms Brenda Ong Wei Ling or Mr Alexius Matthias Soh Sheng En at Tel: 6511 5081.

CONSENT FORM

Protocol Title:

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Principal Investigator & Contact Details:

Dr Chen I-Cheng Mark
Head of Research Office
National Centre for Infectious Diseases
16 Jalan Tan Tock Seng, Singapore 308442
E-mail: Mark_Ic_Chen@ncid.sg
Telephone: 6511 5048

Consent to Participate in the SOCRATEs study

□ Yes, I voluntarily consent to take part in this research study. I have fully discussed and understood the purpose and procedures of this study. This study has been explained to me in a language that I understand. I have been given enough time to ask any questions that I have about the study, and all my questions have been answered to my satisfaction. By participating in this research study, I confirm that I have read, understood and consent to the National Centre of Infectious Diseases Personal Data Protection Notification.

Consent to be Contacted for Future Research

□ Yes, I agree to be for contacted for future research that I may be eligible for.

I agree to be contacted via:

□ Phone _____

□ Mail _____

_____

_____

□ Email _____

□ Others _____

□ No, I do not agree to be contacted for future research.

Name of Participant (as stated in NRIC / FIN)	Signature	Date

NOTE: parental consent is required for the recruitment of minors

Name of Parent/Legal Guardian (as stated in NRIC / FIN)	Signature	Date

Investigator Statement

I, the undersigned, certify that I explained the study to the participant and to the best of my knowledge the participant signing this informed consent form clearly understands the nature, risks and benefits of his / her participation in the study.

Name of Investigator / Person administering consent (as stated in NRIC / FIN)	Signature	Date