Information leaflet and informed consent for Adults: potential participants for CoughWatchSA

STUDY TITLE: Digital Participatory Surveillance for Respiratory Illness in South Africa - CoughWatchSA

Each participant must read this document and sign the attached informed consent before any further study-related procedure is done

This consent will apply to for prospective participants.

Institution: National Institute for Communicable Diseases (NICD), South Africa; funded by a grant from the Centers for Disease Control and Prevention (CDC), Atlanta, United States of America and Sanofi Pasteur

Investigator: Prof Cheryl Cohen 011 386 6593, daytime and 082 803 8093, afterhours

Hello, my name is Prof Cheryl Cohen. I am the Head of the Centre for Respiratory Disease and Meningitis (CRDM) at the NICD) in Johannesburg. I would like to invite you to think about participating in our study. I would like to thank you for considering participating in this study.

- Before you agree to take part in this study**,** we would like you to read this information sheet about the study.
- Please make sure you understand what you need to do.
- You should also make sure you understand the purpose of the study, the study procedures, benefits, risks, discomforts, and precautions as well as the alternative procedures that are available to you, and your right to withdraw from the study at any time.
- This information leaflet is to help you to decide if you would like to participate. You need to understand what is involved before you agree to take part in this study.
- If you have any questions, do not hesitate to contact me.
- You should not agree to take part unless you are satisfied with all the procedures involved.
- If you decide to take part in this study, you will be asked to accept the terms and condition by checking the accept checkbox at the end.

Background/Purpose

Surveillance (looking out for diseases) allows us to obtain laboratory confirmation of cases of respiratory illness (like influenza (flu)) from patients consulting primary health care facilities. This data is useful for quantifying the burden and severity of respiratory illness in South Africa. We also use this information to document the timing of the flu season and what other respiratory pathogens are circulating (like COVID19). However, many people do not consult a clinic or general practitioner for their flu like symptoms. Because of this we may underestimate the number of cases of flu and other respiratory illness each year. We are introducing a new and innovative way to collect information on flu like symptoms from people in the community. In this study we want to collect information on symptoms related to respiratory illness, including demographic data (age, gender, area you live in), symptoms (cough, fever, runny nose, chest pains fatigue and the like), underlying

medical conditions (like high blood pressure, diabetes), and vaccines you may have had (influenza and COVID19). After you have agreed we will ask you to complete a simple questionnaire at baseline and then every week for the 6 months of the flu seasons.

Length of study and number of participants

- The study is only being performed in South Africa only.
- The surveillance will run over three winter influenza seasons between April – October over the following years: 2023, 2024 and 2025.
- The study may be extended if there is a new respiratory virus outbreak
- At least 1500 participants will be enrolled in the study
- If you live in South Africa and are at least 18 years old, you are eligible for enrolment. You will also have the opportunity to enrol your children in the study

Study procedures:

- If you agree to take part in this study, you will first be asked questions about your age, gender, occupation, underlying medical conditions, whether you smoke or drink, influenza and COVID19 vaccination status
- Only a weekly basis, once you have agreed to participate in the study we will send you a symptoms questionnaire where we will ask you to provide us with information on whether you have experienced any symptoms related to respiratory illness, like cough, headache etc.
- If you have experienced any symptoms, we will ask you questions about when the symptoms first appeared, what kind of medical or alternative help did you seek, whether you had a test for influenza or COVID19 and the result if you did.
- We will ask you to register on the web application if you agree to participate in this study using your email address and we will provide you with an opportunity to use your Whatsapp number to receive notifications on your phone. We would like to use your email address or Whatsapp number to send you a weekly reminder to complete the symptoms questionnaire.
- The questionnaire will not take approximately 10 minutes of your time to complete.

Your rights as a participant

Your participation in this study is entirely voluntary and you can decline to participate, or stop at any time, without stating any reason.

Expected duration of participation

We will request that you participate in the study for the duration of the study period i.e. April – October in 2024 and the same period in subsequent years. The total amount of time requested for your participation in this study is approximately of 10 minutes a week for completing the short questionnaire.

Risks of this study

In this study, we are collecting your email address and/or Whatsapp number, which may potentially identify you. Both the email address and/or your Whatsapp number will be stored in an access-controlled database, where only the database administrators will have access to it. The email address and Whatsapp number will be stored in a separate table and separated from the study data. Our collaborators are a team of researchers at the Institute for Scientific Interchange in Italy. Your email address and/or Whatsapp number will not be shared with collaborators and confidentiality will be maintained by separating your email address from the data you provide in the program.

Benefits of this study

There is no direct benefit to you for participating in the study. However, your participation in this study may contribute to information about flu and other respiratory infection in your community. This may allow us to potentially respond earlier to increases in suspected cases.

Confidentiality

We will keep your information confidential by doing the following: All information obtained during the course of this study, including personal data and research data will be managed and stored confidentially. Your email address will be stored as a masked-input in a separate table from the analysis data. Your data will be stored and linked to a unique studyid, separate from the email address. The database is a password protected database with only the study team having access to the data. Data that may be reported in scientific journals will not include any information that identifies you as a participant in this study. Your data will be collected, processed and stored according to the South African Protection of Personal Information (POPI) Act of 2013.

Withdrawal from the study

Your participation in this study is entirely voluntary and you can decline to participate, or stop at any time, without stating any reason. Your withdrawal will not affect your access to other medical care.

Reimbursement for Participation

You will receive a R 10 airtime voucher for each weekly symptoms questionnaire submitted.

Incentives

If you submit all 4 surveys in a month you will be entered into a lucky draw. 8 lucky people will win R1000 each every month.

Ethical approval

- This study protocol has been submitted to the University of the Witwatersrand, **Human Research Ethics Committee (HREC)** and written approval has been granted by that committee.
- This study is sponsored by Centre for Diseases Control and Prevention (CDC) Atlanta. I do not have any financial or personal interests with this organisation that may bias my actions
- If you want any information regarding your **rights as a surveillance participant, or complaints regarding this surveillance programme**, you may contact Prof. Paul Ruff, Chairperson of the University of the Witwatersrand, Human Research Ethics Committee (HREC), which is an independent committee established to help protect the rights of research participants at (011) 274 9200.
- For **surveillance information** you can contact Prof Cheryl Cohen, National Institute for Communicable Diseases at +2711 386 6593 and +27 82 803 8093

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- I hereby confirm that I have read and understood the terms and conditions for my participation in the CoughWatchSA study – Digital Participatory Surveillance (DPS) for Respiratory Illness for South Africa
- I am aware that the results of the study, including confidential information will be anonymously processed into a study report.
- In view of the requirements of research, I agree that the data collected during this study can be processed by NICD or research partners.
- I may, at any stage, without prejudice, withdraw my consent to participate in the program.
- I agree to use my WhatsApp number if I would like to receive notifications for the surveys. I also acknowledge that I am not required to use my WhatsApp number and may refuse to do so, without prejudice.
- I have had sufficient opportunity to ask questions through provided support email and communications channels from NICD, and (of my own free will) declare I am prepared to participate in the study
- I am aware that I will not be paying for my own mobile data to access the online survey
- By clicking Accept, I agree to:
    - Fill in the intake questionnaire which includes basic demographic information, lifestyle related questions and medical related questions like vaccine history and comorbidities.
    - Complete and submit a weekly follow-up symptoms questionnaire that will include symptoms related to acute respiratory tract infections (ARI).

☐ I accept the terms above and provide consent to participate in the CoughWatchSA application