PARTICIPANT INFORMATION SHEET

RELOAD: REspiratory disease progression through LOngitudinal Audio Data machine learning

We invite you to participate in our research study. Before you decide, you must understand why the research is being done and what it will involve. Feel free to discuss it with others if you wish. Use the contact details at the bottom to ask us if anything is unclear or if you want more information. Please take your time to read the following information carefully and decide if you wish to participate.

1. What is the purpose of the study?
Respiratory Tract Infections (RTIs) (coughs and colds) are the most common cause of illness and the most common reason for seeing a GP. Most RTIs will get better by themselves and do not require medical treatment.

Identifying patients who are likely to experience serious progression of illness and require medical assessment, or those who can be safely reassured that they do not currently need healthcare assessment, is an important priority. Rapid breathing is associated with increased risk of serious progression and other features detectable by breathing and speaking sounds may also be useful in predicting how the illness is likely to progress.

The main goal of this study is to explore the value of using sounds collected over time using a mobile device to predict clinical progression in people with respiratory tract infections (RTI) with a cough.

2. Why have I been invited?
Two groups of people are being invited to take part in this study: 1) adults who are willing to provide information about themselves and breathing/speaking sounds when they are healthy, and again if they develop a cough caused by infection; 2) adults who have consulted a healthcare professional about an infection associated with a cough. You have been invited to take part in our study because you may fit into one of these two groups.

3. Do I have to take part?
No. Participation in this study is entirely voluntary, and you are under no pressure to participate. If you decide to participate, we will ask you to download the app we have designed for the study (if you have not done so already) and complete the consent form it will show you. If you later change your mind, you are free to withdraw from the study at any time without having to explain why. If you do not wish to participate in this study, the standard of care you receive will not be affected.

4. What will happen to me if I take part?
If you are interested in participating in this study after reading this information sheet, taking the time to discuss it with anyone you wish, and asking any questions you may have, you will first need to download the app we have designed for the study (if you have not already done so) and complete a consent form.

After you have provided consent, you will be asked to answer some questions about yourself on the app, including information such as age, sex, gender and ethnicity, and information about your current health and past health conditions. You will not need to provide any identifiable information, such as your name, date of birth or address.

After that, you will be asked different information depending on whether you are in group 1 (no current infection) or group 2 (currently ill with an infection causing a cough).

Group 1 (no current infection)
You will be asked to record some breathing and speaking sounds when you first enter the study (and do not have an infection). You will also be asked to record some information if you develop a cough that you think is likely to be caused by an infection. You will then be asked to answer some questions about your illness and record more sounds every day until you have recovered (or for a maximum of four weeks). This will take no more than 10 minutes every day.

To help you remember to record more information if you develop a cough, we will ask your permission to send you a reminder through the app once a week.

Group 2 (currently ill with an infection causing a cough).
You will be asked some questions about your illness and asked to record some sounds on your phone every day until you have recovered from your illness (or for a maximum of four weeks). The recordings will include sounds of you breathing, and doing some tasks, such as speaking or coughing.

A research team will analyse this data to try and identify whether these sound recordings can be used to help identify progression of coughing illness.

When recording sounds, please make sure that you:

- Only make recordings when you are alone, so that other people are not recorded without their consent.
- Only record the sounds requested by the app.
- Do not record your name or any other identifying details.

5. Expenses and payments
Aside from the requirement that you have a smartphone capable of running our app and connecting to the internet. We do not anticipate that you will incur any additional expenses and are not able to reimburse you any expenses that do occur. There is no payment for taking part in this study.

6. What are the possible disadvantages and risks of taking part?
There are no serious disadvantages or risks associated with taking part in this study. The only potential disadvantage is that it will take some of your time. You will also need to share some of your data with us, but we will keep this data secure.

7. What are the possible benefits of taking part?
There are no direct clinical benefits to you from taking part in this study. The study will not influence how you are treated.

8. What will happen if I don't want to carry on with the study?
You can withdraw from the study at any time by deleting the app or by just not answering any further questions through the app. It will not affect any health care that you are receiving.

9. What if there is a problem?
If you are concerned about any aspect of this study, ask to speak to one of the researchers (contact details below), who will do their best to answer your questions. If you remain unhappy or have a

complaint about any aspect of this study, please contact the University of Southampton Head of Research Ethics and Governance (023 8059 5058, rgoinfo@soton.ac.uk).

If something goes wrong, and you are harmed during the study due to someone's negligence, you may have grounds for legal action for compensation against the university, but you may have to pay your legal costs. The normal complaints mechanisms will still be available to you.

10. Will my taking part in this study be kept confidential?

Your general practice may have used your contact details to let you know about the study but they will not pass on this information to the research team. All data collected by the study team will be collected through the app. We will not ask you for any identifiable data so your data will be anonymous, with an ID number assigned to all the data from you.

You will be recording your voice, and it is possible that one of the researchers may identify you via your voice. However, your recorded data will be stored securely and primarily analysed using computer algorithms.

We will keep the data you provide as part of this study for 10 years.

11. How will we use information about you?

This study is sponsored by the University of Southampton and for the purposes of data protection law is the 'Data Controller' for this study. We will need to use information from you for this research project.

This information will include:

- Information about you (age, sex, gender, ethnic group, socioeconomic status, weight and height)
- Information you provide about your medical history (medical conditions, use of medications, any recent hospital admissions)
- Recordings you make while breathing, speaking and coughing
- Information you provide about any coughing illnesses (symptoms, diagnosis (if given one), healthcare assessments, use of medications)

People will use this information to do the research or to check your records to make sure that the research is being done properly.

Members of the research team will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

12. What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- We may make anonymous data collected as part of this study available to other researchers. As we will not have your contact details we will not be able to ask your permission and so by taking part in this study you are consenting to us making your anonymous data available to other researchers in the future.

13. Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- the leaflet available from [**www.hra.nhs.uk/patientdataandresearch**]
- by sending an email to University's Data Protection Officer (data.protection@soton.ac.uk).
- by asking one of the research team
- by sending an email to RELOAD_RA@soton.ac.uk

14. What will happen to the results of the research study?

The results of the research study will be published in scientific journals and conferences. Once the study is finished you can read a summary of the results on the study website reloadstudy.co.uk

15. Who is organising and funding the research?

UK Research and Innovation (UKRI) are funding the research.

16. Who has reviewed the study?

This study has approval from the University of Southampton and a Favourable Research Ethics Committee (REC) Opinion.

17. Further information and contact details

For further information, you can speak to one of the study team:

Study Manager: Jackie Seely
Email: RELOAD_RA@soton.ac.uk

Chief investigator: Professor Nick Francis
Email: Nick.Francis@soton.ac.uk Faculty of Medicine, University of Southampton

If you have a complaint, please contact the study team.
Alternatively, you can speak to an independent contact: Patient Advice and Liaison Service (PALS).

You can find your nearest PALS office on the NHS website.

You can also ask your GP surgery, hospital or phone NHS 111 for details of your nearest PALS.

GDPR Statement:

The University of Southampton is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Southampton will keep identifiable information about you for 10 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information: https://www.southampton.ac.uk/~assets/doc/legal-services/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf

Thank you for considering taking part in this study.

If you decide to participate you will be asked to complete a consent form in the app. A copy of this will be kept by the study team. If you choose to withdraw consent you can delete the app.