

# Subject information for participation in medical research

## SPEAKtoCOPD (Speaking uP to dEtect lung AttACKs for COPD) the flashmob research at World COPD Day

### Introduction

Dear Sir/Madam,

With this letter we would like to ask you to take part in a medical study. Participation is voluntary. This study is set up by the Maastricht University Medical Center+ (MUMC+). The study will take place online at the SPEAKtoCOPD website.

You can read through this information in your own pace and contact the researcher ([loes.vanbommel@maastrichtuniversity.nl](mailto:loes.vanbommel@maastrichtuniversity.nl)) for any questions, before you decide to participate in this study. You can also discuss this with your partner, friends or family.

### 1. Purpose of the study

People with COPD can suffer from lung attacks. These are periods of acute worsening of symptoms, like dyspnea, coughing and sputum. These lung attacks are usually treatable with medicine, but can sometimes lead to hospitalization. Early detection of a lung attack can prevent the worsening of symptoms. Detection of these lung attacks is currently also possible at home.

In the SPEAK study we want to develop an app where lung attacks can be detected early by using your voice and your phone. By talking to this app on your phone, the app is able to predict whether you will get a lung attack. To ensure the app is compliant to your needs, we want to develop this app together with COPD patients, COPD caretakers and app developers. Your speech is also needed to develop the algorithm that can predict lung attacks.

In the SPEAKtoCOPD study we want to collect as many voices as possible around World COPD Day (20 November 2024) to develop algorithms that can predict lung attacks. We made a site for this purpose. If you participate in this study, you will record your speech on the SPEAKtoCOPD site.

## **2. What happens during the study**

If you want to participate in this study, you can go to the SPEAKtoCOPD site online and record your speech. There is also a questionnaire about you and your current health status.

The questionnaire can be filled online on your mobile phone, tablet or pc. You can check the answer options that apply to you. You can ask someone else to help.

To record your voice, your device needs a microphone. We recommend participating in this study with a mobile phone.

The study will fully take place online and there will be no influence on your regular care. There are no costs involved in participating in this study. You do not have to prepare anything. We estimate participation will take around 10 minutes.

## **3. Possible pros and cons**

The risks of participating in this study are negligible. It is important that you consider the pros and cons before participation. There are no pros in participating in this study. Your participation helps to collect more voices and in turn create a better algorithm to predict lung attacks. Participation in this study will take around 10 minutes.

## **4. What happens if you do not want to participate or want to stop the study**

It is your own decision whether you want to participate in this study. Participation is voluntary. If you decide not to participate, there is no further action required. You do not have to sign anything. You do not have to mention why you do not want to participate. If you are a patient, your treatment is not changed.

If you do want to participate, you are always free to change your mind and stop during the study. If you are a patient this does not influence your treatment. You do not have to give a reason to stop.

The data that is collected up to that moment will not be used in the study. You can close the SPEAKtoCOPD site without sending your data. If the data is sent already and you want to stop your participation, you can use your unique ID (seen on the site) and write it with a mail to the researcher ([loes.vanbemmel@maastrichtuniversity.nl](mailto:loes.vanbemmel@maastrichtuniversity.nl)) with a request to delete your data. You can also ask to request your data or change your data.

## **5. Collection and processing of your data**

For this study, your personal data is collected, processed and stored. This personal data is only the data you yourself provide in the site, like your gender, age category, first language and data about your health. Your speech is also personal data. The collection, processing and storage of your data is necessary to answer the questions we have in this study and to publish results. We ask permission of you to use your data. There is also an option to store your data in a repository for other researchers to be used in the future for research. You can decide whether you want to add your data to this repository yourself and it is not necessary for participation in the study.

### **Confidentiality of your data**

To protect your privacy we will encode your data. Only the key of this encoding can be used to trace back your data to you. The key of this encoding will be safely stored in the local research institution. Reports and publications of the study will not be able to trace your data back to you. Data such as your name and (ip) address will not be asked for, processed, or stored. These will also not be added to the database.

### **Retention period of your data**

Your data will be stored for 15 years in the research institute. If you give permission to add your data to the database, these data could be retained for a longer period.

### **Storage and use of your data**

#### *During the study*

We collect, process and store your data to answer the questions in this study and to publish our results.

#### *After the study*

Your data can be used for other scientific research in the future. You are able to independently state whether you agree with the use of your data for future research. This future research could take place in the MUMC+ or other research institutes (i.e. hospitals, university centers) that collaborate with the MUMC+.

#### *Repository for other researchers*

Additionally, there is the option to store your data in a repository (database). This repository is meant for other researchers to perform more research in speech analysis. These researchers could be outside of the MUMC+ or University of Maastricht. You can independently agree whether you want to add your data to this repository. It is not necessary for participation in this study. This database will also be available for researchers outside of the EU/EEA. These countries could have less strict privacy rules than in the Netherlands. Keep this in mind when giving permission whether to store your data in this database.

### **Withdrawal of permission**

You are able to withdraw the use of your data at any moment. You are able to do this for this study or for future studies. You can withdraw permission with the unique ID you have received at the SPEAKtoCOPD site during the study. If you contact the researcher ([loes.vanbemmel@maastrichtuniversity.nl](mailto:loes.vanbemmel@maastrichtuniversity.nl)) with this number, you can ask to show, change, or delete your data and they will not be used in this study.

### **Additional information about your rights with processing of your data**

For general information about your rights with processing of your data you can consult the site of the MUMC+ and Autoriteit Persoonsgegevens (Dutch Data Protection Authority). If you have questions about your rights, you can contact the responsible party that processes your personal data, the researcher: ([loes.vanbemmel@maastrichtuniversity.nl](mailto:loes.vanbemmel@maastrichtuniversity.nl)). With questions or complaints about the processing of your personal data, we recommend contacting the principal investigator first. You can also contact the Functionaris voor de Gegevensbescherming (Dutch Data Protection Officer; mrs. C. Buursink, 043-3875910, [fg@mumc.nl](mailto:fg@mumc.nl)).

### **6. No compensation for participation**

There is no compensation for participating in this study.

### **7. Do you have a question or complaint?**

If you have a question or complaint about this study, you can discuss this with the researcher or your treating doctor. Would you prefer not to, you can also go to someone of the independent klachtencommissie (complaints committee) of the MUMC+, tel: 043-3874204 or [klachten@mumc.nl](mailto:klachten@mumc.nl)

### **8. Signing the informed consent form**

If you agree to participate in this study, we ask you to confirm this in the informed consent form online. You can find this form on the SPEAKtoCOPD site. By giving permission to participate in this study you indicate that you understood the information provided in this form and you agree to participate in this study.

Thank you for your attention.

### **Appendix to this information**

[1] Consent form

## Appendix [1]: consent form participant

### SPEAKtoCOPD the flashmob research at World COPD Day

- I have read the information letter. I was able to ask questions and these were answered sufficiently. I have had enough time to decide whether I want to participate.
- I am aware that participation is voluntary. I know I can decide at any given moment to stop with the study. I do not have to give a reason to stop. Using my unique ID on the SPEAKtoCOPD site, I can ask the researcher ([loes.vanbemmel@maastrichtuniversity.nl](mailto:loes.vanbemmel@maastrichtuniversity.nl)) to remove, correct, or show my data. If my data is deleted, they will not be used for analysis.
- I give permission to collect and process my data in order to answer the research question in this study.
- I  **do**  
 **do not** consent to share my data with other researchers in the UM and MUMC+ for other research in the area of COPD, speech, or digital care.
- I  **do**  
 **do not** consent to share my data with other organizations or institutions (i.e. hospitals, university centres) for other future research.
- I  **do**  
 **do not** consent to storing my data in a repository for other researchers for other future research within and outside of the EU/EEA. I am aware their privacy laws might be less strict than the laws in the Netherlands.
- I want to participate in this study.

Name participant:

Signature:

Date : \_\_ / \_\_ / \_\_

-----