Verbal Consent Script

Study Title: Validating the Use of Frailty Measurements to Predict Care Expectations and Deteriorations in Quality of Life Among People with COPD: A Prospective Cohort Study
Principal Investigator: Sunita Mulpuru, Respirology, 613-798-5555 ex 72772
OHSN-REB Number: 20200048-01H

Participant name:	**Person calling:**
Date Called:	**Time Called:**

Hello, may I please speak with [insert the name of the potential participant here].

- ***If respondent asks who the caller is:** My name is [name of caller] and I am calling from The Ottawa Hospital about a research study.
- ***If potential participant is unavailable:** Is there a better time to call back? Date/time:

- ***If potential participant indicates they are not interested:** Thank you for your time. Goodbye.
- ***If potential participant is respondent:** *Continue with script below*

Hi, [insert the name of the potential participant here] this is [insert your name here] calling from The Ottawa Hospital. Is this an ok time to talk?
☐ No → Is there a better time? Date/time:
☐ Yes → *Continue with script below*

We've been informed by a member of your circle of care that you have agreed to be contacted for research. The study is being conducted by Dr. Sunita Mulpuru, a lung doctor, at The Ottawa Hospital.

You are a candidate for this research because you have COPD.

The goal of the research study is to understand how people with COPD are functioning at home, how this affects their life, and what types of health services are desired by people with COPD.

Are you willing to hear more about the study?
☐ No → Thank you for your time. Goodbye
☐ Yes → *Continue with script below*

Conflicts of Interest:

There are no conflicts of interest to declare related to this study.

Research Activities:

Your participation in the study would involve: three telephone visits with a member of the research team and answering three surveys. The telephone visits will be scheduled shortly after this call, in 6 months, and 12 months after the initial visit.

During the first telephone visit, you will be asked questions about your ability to function at home and your overall health. During the 6-month and 12-month telephone visits, a member of the research team will speak with you about changes in your health since your last telephone visit and answer questions on your overall health. Each telephone visit would last no more than 10 minutes.

Prior to each visit, you will be asked to complete a survey (online) on your overall health, for a total of three online surveys for this study. This should not take you more than 10 minutes to complete.

If you do not have access to email or internet, or choose not to share your email with us, we are happy to go through the questions with you during our scheduled call. This will add a couple minutes to the call.

We will collect information on your quality of life, your lung health, and your care preferences. We may also review your health record at the Ottawa Hospital prior to your scheduled baseline visit and at the end of your participation in the study

Do you have questions about the activities this study involves?

☐ No → *Continue with script below*

☐ Yes → *Answer questions and document all questions and answers before continuing with script below*

Questions: _____

Answers: _____

Other Comments: _____

Voluntary Participation and Withdrawal:

Taking part in this study is voluntary.

You have the option to not participate at all, or you may choose to leave the study at any time (this is called withdrawal), without having to provide a reason. Your decision will not affect any healthcare services you are entitled to at The Ottawa Hospital. Please let the study team know if this is the case. We will no longer collect information about you but will use the information that was recorded before your withdrawal for the purpose of the study.

Do you have questions about the voluntary nature and ability to withdraw from of this study?

☐ No → *Continue with script below*

☐ Yes → *Answer questions and document all questions and answers*

before continuing with script below

Questions: _____

Answers: _____

Other Comments: _____

Potential Risks, Harms, Discomforts:

The information you provide is for research purposes only. Some of the questions are personal. You can choose not to answer questions if you wish.

Do you have questions about the potential risks this study involves?

☐ No → *Continue with script below*

☐ Yes → *Answer questions and document all questions and answers before continuing with script below*

Questions: _____
Answers: _____
Other Comments: _____

Potential Benefits:

You may not receive direct benefit from participating in this study. We hope the information learned from this study will help other people with COPD in the future.

Do you have questions about the potential benefits this study involves?

☐ No → *Continue with script below*

☐ Yes → *Answer questions and document all questions and answers before continuing with script below*

Questions: _____

Answers: _____

Other Comments: _____

Privacy/Confidentiality:

If you decide to participate in this study, we will only collect the information needed for this study. Records identifying you at this centre will be kept confidential and, to the extent permitted by the applicable laws, will not be disclosed or made publicly available, except as described in this consent document.

Authorized representatives of the following organizations may look at your original (identifiable) research records at the site where these records are held, to check that the information collected for the study is correct and follows proper laws and guidelines.

- The Ottawa Health Science Network Research Ethics Board who oversees the ethical conduct of this study.
- Ottawa Hospital Research Institute to oversee the conduct of research at this location.

Information that is collected about you for the study (called study data) may also be sent to the organizations listed above. Your name, address, email, or other information that may directly identify you will not be used. The records received by these organizations may contain your gender and age.

Communication via e-mail is not absolutely secure. We do not recommend that you communicate sensitive personal information via e-mail.

If the results of this study are published, your identity will remain confidential. It is expected that the information collected during this study will be used in analyses and will be published/ presented to the scientific community at meetings and in journals.

Your de-identified data from this study may be used for other research purposes. If your study data is shared with other researchers, information that links your study data directly to you will not be shared. Even though the likelihood that someone may identify you from the study data is very small, it can never be completely eliminated.

Do you have questions about the how your privacy will be protected?

☐ No → *Continue with script below*

☐ Yes → *Answer questions and document all questions and answers before continuing with script below*

Questions: _____

Answers: _____

Other Comments: _____

Cost to participation:

Participation in this study will not involve any additional costs to you.

Payment or Reimbursement:

As a token of our appreciation, you will be given a 20$ coffee gift card. The gift card will be sent to you by mail after completion of each study visit.

Do you have questions about the costs of participation or payment/reimbursement?

☐ No → *Continue with script below*

☐ Yes → *Answer questions and document all questions and answers before continuing with script below*

Questions: _____

Answers: _____

Other Comments: _____

Participant Rights:

You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this study.

You have the right to be informed of the results of this study once the entire study is complete. If you would like to be informed of the results of this study, please let the research team know.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

Questions:

In case you have any questions, here are some contact numbers that are good to have. Do you have a pen and paper ready?

For questions about your rights as a research participant or about ethical issues related to the study, you can contact The Ottawa Health Science Network Research Ethics Board at 613-798-5555, extension 16719, and speak to someone who isn't involved in the study at all.

I can answer any questions that you may have about the research study right now, but if you think of additional questions later on, you can contact me, my name is at 613-798-5555 ext 16054.

Have all of your questions been answered?

☐ No → *Answer questions and document all questions and answers before continuing with script below*

Questions: _____

Answers: _____

Other Comments: _____

☐ Yes → *Continue with script below*

Consent:

Based on the description of the study, would you like to participate? Or would you like some time to think about it?

☐ No ☐ Yes ☐ More time to think about it

- ***If they do not want to participate:** Thank you for your time. Goodbye.
- ***If they do want to participate:** *Continue with script below*
- ***If they would like more time:** *Continue with script below*

For your records and to help in making your decision, I can send you the Information Sheet by mail or email. What is your preference?

☐ *Mail, confirm address: _____*

Before I can initiate email contact with you, I'm required to inform you of the risks associated with use of email. I'm going to read a series of statements to you. Please stop me at any time if you have questions. ***Read the 'Research Participant Consent to Communicate by Email'***

Discussed on: _____/____/____ Time: _____

Consenting Process completed by: _____
Date: _____/____/____

☐ *Email, record and confirm email: _____*

***If they wanted more time:** When would be a good time for me to call you back to answer any further questions you may have and obtain your decision? Date/time:

If consented, next steps

Now, let's schedule your first telephone visit. What time would work best for you? Date/time of baseline visit: _____.

Is the number I called you today the best to reach you?
☐ No ☐ Yes

Would you like to complete the survey beforehand? This will be sent to you by email
☐ No ☐ Yes

Wrap up with a reminder of the next steps and end the call.

Documentation of Verbal Consent

Study Title:

OHSN-REB Number:

Name of Participant: _____

Date of Discussion: _____

Duration of Discussion: _____

SIGNATURES

- The participant's questions have been answered,
- The participant understands the information within this Verbal Consent Script,
- Each page of the Verbal Consent Script has been read to the participant.
- The participant will allow access to medical records and/or specimens as explained in this consent form,
- The participant understands that their family doctor/health care provider may be informed of their participation in this study,
- The participant agrees to take part in this study.

Investigator or Delegate Statement

I have carefully explained the study to the study participant. To the best of my knowledge, the participant understands the nature, demands, risks and benefits involved in taking part in this study.

_____	_____	_____
Signature of Person Conducting the Consent Discussion	Printed Name and Role	Date