Appendix B

Consent Forms English

INFORMATION AND CONSENT DOCUMENT

Study Title: Patients with COPD preferences, activities, and participation survey

MUHC or McGill Study Code: 15-203-MUHC

NCT Number: NCT02970422

Principal Investigator:
Shane Sweet, Ph.D., Department of Kinesiology & Physical Education, Faculty of Education, McGill University.

Dennis Jensen, Ph.D., Department of Kinesiology & Physical Education, Faculty of Education, McGill University.

Co-Investigators:
Emilie Michalovic, B.Sc., Department of Kinesiology & Physical Education, Faculty of Education, McGill University

Study Sponsor:
AstraZeneca Canada

INTRODUCTION

You have been invited to take part in this research study because you meet the criteria for a diagnosis of chronic obstructive pulmonary disease (COPD) and have expressed interest in answering a questionnaire.

It is important that you read and understand the following information. Please feel free contact the research staff with any questions that will help you understand the study and what we are asking you to do.

PURPOSE OF THE STUDY

Patient participation in health research has recently become an important step in determining the most important health outcomes of individuals diagnosed with chronic obstructive pulmonary disease (COPD). We would like to better understand: the activities that you can and cannot participate in (e.g., making the bed, dressing/undressing), how difficult it is to participate in these activities, and what prevents you from participating in these activities. Understanding these activities will help future researchers develop interventions to improve the care and management

of COPD. As well, we are interested in knowing what information you would like to be provided from your health care professionals and what topics you believe research in the field of COPD should focus on in the future. By understanding what people living with COPD want and need, we can better direct future COPD research that will benefit individuals living with COPD.

The purpose of this study is to assess the healthcare and research priorities of individuals living with COPD, as well as their participation in daily activities.

For this study, you will be asked to complete a questionnaire developed to gather the activities of people living with COPD, your research preferences, and what you would like to discuss with your health care providers. You will provide the researchers with your expert opinion as someone who lives with COPD. You will also be asked to complete additional questionnaires about your COPD status.

We are aiming to recruit 200 participants for this study who will be above the age of 18, are diagnosed with any stage of COPD, and able to read and write in English or French.

WHAT IS INVOLVED IN THE STUDY?

If you take part in this study, you will need to do the following:

- Be ready to spend 90 minutes responding to the Activities, Healthcare, Research Priorities Questionnaire and the additional questionnaires.
- Carefully read over the consent form and give your consent.
- Go through the questionnaire, answering the questions to the best of your ability.

VISITS AND PROCEDURES

The questionnaire will take place either online or via telephone. You must provide consent to participate in this study.

Prior to the start of the survey, you will be asked to complete the compensation form, demographic information (i.e., date of birth, ethnicity, educational status) as well as information on your COPD status (i.e., COPD disease severity, time since diagnosis, smoking status). Additionally, we will be asking for your name, date of birth, and mailing information, as it will be used to gather your medical charts. From your medical charts, we will be gathering your specific COPD measurements; such as, your COPD stage, your force vital capacity, comorbidities, height, weight, and smoking history. No other information will be taken from your medical chart.

The survey consists of three sections. Section 1 will ask you about the activities you participate in and why these activities may or may not be difficult for you to perform. As well, Section 1 will ask you which of these activities you would like to improve the most by having you rank the activities. Session 2 consists of two parts: (a) a list health care topics often discussed with health care providers and (b) a list of COPD research topics. In first part, you will be asked to assign a percentage of time (in increments of 10%) to the healthcare topics you would like to discuss most with your healthcare provider over the next year. The second part is focused on your priorities for COPD research. Similar to the first part, you will be asked to assign a percentage of

funds to the listed research topics. In Section 3, you will be responding to various questions pertaining to different COPD related topics (i.e., well-being, physical activity participation).

POTENTIAL RISKS ASSOCIATED WITH THE STUDY

You will not experience any pain or discomfort resulting from this study. There are no known risks associated with participating in this study. You are free to decline answering any question you do not feel comfortable with and leaving the questionnaire at any time, by simply closing the questionnaire or informing the research assistant on the telephone.

BENEFITS ASSOCIATED WITH THE STUDY

You will receive no direct benefit from participating in this study. We hope that the study results will contribute to the advancement of scientific knowledge in this field and help us better understand the needs of individuals living with COPD.

CONFIDENTIALITY

All the information collected about you during the study will remain confidential, as the law requires. To protect your privacy, an identification number will be created for each participant. Any personal information collected (i.e., mailing information) will not be attached to the questionnaire and will be used for compensation purposes and to identify individuals' medical chart information, in the event they have the same name as someone else. Only the investigators in charge of the study, their research assistants, and McGill Finance (mailing information for compensation purposes) will have access to the mailing information you provide. The study investigators will use the study information collected from you for research purposes, only to reach the study goals as they are explained in this information and consent document.

The study investigators and team will also collect and take down information about you from your medical file to create a research study file. Only information necessary for the research study will be collected. The information will consist of your forced expiratory flow volumes, your COPD stage, comorbidities/other diagnoses and demographic information such as height and weight. This information will be collected from your medical file at your corresponding hospital/rehabilitation program (MUHC Chest Institute, Mount Sinai, and the West Island Health and Social Services Centre at the Lakeshore General Hospital). No identifiable information will be added to the research study file.

As part of the compensation we would like to provide you for your time, we will require you to provide your mailing information. Your mailing information will only be used for compensation purposes and to help retrieve your medical file. Your mailing information will be kept separate from your questionnaire data.

The results from this study will be published in academic journals and presented at scientific conferences and could be distributed to the larger COPD community or health care professionals. Your name will not be disclosed in either of these circumstances.

The investigator(s) in charge of the study will keep your study information for 7 years from the date of publication.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

This is a voluntary study. As a volunteer, you are free to choose whether or not you would like to participate in this study. As well, you may withdraw from the study at any time by: not responding to the remainder of the questionnaire, by informing the researcher on the phone, or leaving the questionnaire by closing the browser. You may also exercise your right to remove your data from the study. To exercise this right, you will need to contact the research staff. You can refuse to answer any of the study's questions at any time, without any consequences, while still remaining in the study.

The investigator(s) in charge of the study or the Research Ethics Board of the McGill University Health Centre may take you off the study without your consent at any time if:

- New information shows that taking part in the study is not right for you;
- You are unable to follow the requirements of the study;
- The study must be stopped for safety or administrative reasons.

If you choose to stop taking part or are taken off the study, the information that was already collected from the study will be stored as long as needed to ensure your safety as well as that of other participants in the study and for as long as legally required.

Compensation/Reimbursement

You will be compensated $50 for you time and any inconvenience answering the questionnaire may have caused you. If you do not complete the questionnaire in its entirety, you will not be eligible to receive this compensation.

Persons Responsible for the Study and Contacts

If you have any questions about the research project or if you have a problem that you believe is related to your participation in the research project, you can contact the researchers responsible for the project at the following numbers:

- Shane Sweet, Ph.D. (Principal investigator)
  - Telephone: (514) 398-4184 ext. 09903
  - Email: shane.sweet@mcgill.ca
- Dennis Jensen, Ph.D. (Principal Investigator)
  - Telephone: (514) 398-4184 ext. 0472
  - Email: dennis.jensen@mcgill.ca
- Emilie Michalovic (Research Assistant)
  - Telephone: (514) 398-4184 ext. 0481
  - Email: emilie.michalovic@mail.mcgill.ca

For any questions about your rights as a study subject, please contact the Ombudsman of the:

- McGill University Health Centre (1-514-934-1934 ext. 35655)
- Lakeshore General Hospital (Sarah-Beth Trudeau; 1-844-630-5125; commissariat.plaintes.comtl@ssss.gouv.qc.ca)
- Mt. Sinai Hospital (Hong Hanh Vo; 1-514-369-2222; hong.hanhvo@ssss.gouv.qc.ca).

MONITORING OF ETHICAL ASPECTS OF THE PROJECT

The Research Ethics Board of the McGill University Health Centre approved and monitors this research project. In addition, it will approve beforehand any revision and amendment to the information and consent form and the research protocol.

PARTICIPANT INFORMED CONSENT FORM

Patients with COPD preferences, activities, and participation survey: development of a questionnaire in focus group sessions

- I have read the information in this form.
- I may refuse to participate or may discontinue participation at any time during the study without penalty and without affecting my future medical care.
- Having read all pages of this consent form and understanding the requirements of the study, my selection of 'next' below indicates that I voluntarily consent to participate in this study.

By clicking on the Next button below you are consenting to participate in this research study.
Before indicating your consent, you can print this document to keep for your own reference.