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Pour l'amour des enfants

Université de Montréal

SUBJECT INFORMATION AND INFORMED CONSENT FORM

RESEARCH STUDY: *The Canadian Cohort Obstructive Lung Disease Study (CanCOLD)*

PRINCIPAL INVESTIGATOR: Dr. Jean Bourbeau, Montreal Chest Institute, Montréal

FUNDING AGENCY: CIHR/Rx&D Collaborative Research Program (IRO- 93326)
In partnership with Astra Zeneca, GlaxoSmithKline, Pfizer and Boehringer Ingelheim and the Respiratory Health Network of the FRSQ

PURPOSE OF THE SUBJECT INFORMATION AND CONSENT FORM:

The purpose of this form is to give you information on this research study and if you sign it, it means you agree to take part in the study. It is very important that you read and understand the following patient information. The form describes the purpose, procedures, benefits, and risks of the research study. It may contain words you do not understand. Please ask the study doctor or personnel to explain any words or procedures that you do not clearly understand. You may take this information home and discuss it with a family member or your family doctor. You may refuse to take part or withdraw from this study at any time.

INTRODUCTION:

You are being invited to take part in this research study because you were a participant in a previous study called Chronic Obstructive Lung Disease (COLD). The COLD study was designed to measure chronic obstructive pulmonary disease [COPD] in the community. You are being asked to participate because you indicated you would participate in future studies of COPD such as CanCOLD.

The present study, i.e., CanCOLD, is funded by the Canadian Institutes of Health Research (CIHR), a governmental body, as part of a collaborative research program with partners from the pharmaceutical industry. All the funds available for this study are being used for research coordination and assistant salaries, services of data management and analysis, and purchase of research equipment.

COPD stands for "Chronic Obstructive Pulmonary Disease"

- Chronic means it won't go away.
- Obstructive means partly blocked.
- Pulmonary means in the lungs.
- Disease means sickness.

COPD is the fourth leading cause of death in Canada. Our current knowledge of COPD and its consequences on patients' health and society is not complete.

This is a longitudinal study, involving men and women who are 40 years of age or older, who may be at risk of developing COPD or who have COPD. A longitudinal study allows researchers to study participants at regular intervals over time. The researchers want to characterize the disease and how the disease progresses over time. We will ask for one additional blood sample (35 mls or 6-7 teaspoons) if you agree to participate in the related genetic research study. The period of time for CanCOLD is 3 years or beyond.

There are 9 sites participating. Besides Montreal, the other research sites include: Calgary, Saskatoon, Toronto, Kingston, Ottawa, Vancouver, Québec (Ste Foy), and Halifax.

COPD is a common lung disease that obstructs the airways, making breathing difficult.

- COPD is usually caused by smoking or exposure to fumes or very dusty places.
- COPD can be prevented.
- When COPD develops, it can be treated, although it cannot be cured.
- The earlier it is detected, the better the results of treatment.

COPD is a major and growing world-wide public health problem:

- The World Health Organization [WHO] estimates that it caused 2.74 million deaths in the year 2000.
- In 1990, COPD was ranked 12th as a burden of disease; by 2020 it is projected to rank 3rd globally.

PURPOSE OF THE STUDY:

The purpose of this research study is to develop a framework to combat this major health problem (COPD), by better characterization of the population of men and women at risk and patients with early disease, by better understanding which factors modifiable through health interventions are related to health perception (health-related quality of life) and disease evolution.

PARTICIPANTS:

We hope to include 2000 persons from across Canada which will include 200-250 people from the Montreal center. You have been selected because you indicated in a previous study called COLD that you would be interested in receiving information on future research such as this study.

Subjects included in this study are in one of four groups:

1) Healthy subjects (no respiratory disease)
2) Subjects at risk (smoker without respiratory disease)
3) Subjects with mild COPD
4) Subjects with moderate-severe COPD

STUDY PROCEDURES:

The study staff or the doctor in charge of the study will carefully explain all procedures to you, and you should ask whenever you need more information. No procedure will be initiated before you provide consent to participate in this study. Your participation in this study will require visits to the Montreal Chest Institute and to the Hospital Ste-Justine.

Visit to the Montreal Chest Institute (1 visit every 18 months, over the next 3 years)

- **Questionnaires:** You will be asked questions concerning your medical history, such as the presence of respiratory symptoms (cough, sputum, wheezing, shortness of breath), exposure to potential risk factors, respiratory diagnoses (asthma, emphysema, COPD, chronic bronchitis, etc.), and other illnesses. You will also be asked about your occupation, health care utilization, your medication use, activity limitation, state of health and nutrition. These questionnaires take about 3 hours to be completed. To reduce your time spent at the Montreal Chest Institute, we will give you the choice of answering some of the questionnaires at a later date over the phone with the Coordinator.
- **Tests**: we will ask you to do some tests
  - a pulmonary lung function test (PFT). This test takes approximately 20 min, and will be done at the initial visit and at 3 years.
  - a cardiopulmonary exercise test (CPET). This test takes approximately 45 min, and will be done at the initial visit and at 3 years.
  - a blood draw, if you agree to participate in the related genetic research study. This test takes approximately 10 min, and will be done at the initial visit, 18 months and at 3 years.
  - a simple breathing test (spirometry). This test takes approximately 15 min, and will be done at the initial visit, 18 months and at 3 years.
  - an exercise test called the 6-minute walk. This test takes approximately 6 min, and will be done at 18 months.

Visit to the Hospital Ste-Justine for a CT Scan

We will ask you to complete a multi-detector computer tomography scan (MDCT Scan) of your lungs. This test will only take place at the initial visit if you are a healthy participant with no respiratory disease; otherwise, at the initial visit and at year 3.

Blood draw and bank

At every visit blood from your vein will be collected to measure proteins (e.g. Surfactant Protein-D (SPD) and C Reactive Protein (CRP)) and to measure other inflammatory substances (e.g. Interleukin-6 (IL-6) and Clara cell secretory protein (CC16)). The amount of blood that will be collected from a vein at a given visit is 35 mls or 6-7 teaspoons.

Also, we will ask that you consent to deposit your blood and personal data in a "blood bank" which will serve for future research on COPD disease only. If you are interested, you will be asked to sign a separate consent form for this specific matter. The samples will be stored for additional future work to discover genetic aspects and potential new targets of therapy for people with COPD. Two genetic components, the DNA and the RNA, will be extracted from your blood cells and saved in the 'blood bank'. The DNA is the molecule that contains the genetic code of all organisms. The RNA is the nucleic acid that is used in key metabolic processes for all steps of protein synthesis in all living cells. **It is important to understand that you can take part in the main study and not take part in this option of long-term banking.**

Administrative data base from provincial health care administrative databases

You will be asked to provide permission to follow your health care utilisation (including use of medications) and health outcomes by allowing the researchers to obtain data from the provincial health care data banks. The Province of Quebec collects data for everyone who has a medicare card. Every time you receive medical service or obtain prescription medication, the details of these contacts are stored by the provincial health system (Régie de l'assurance maladie du Québec or RAMQ) in computer files. With Your permission, this information collected on how you used the health care system in the last five years, and the information to be collected on how you will use the health care system in the next 15 years – all of this information will be sent by the RAMQ to the study doctor. This information would be used to see how your health is affected by COPD or by other illnesses you may develop in the future. This information about you will be coded so that you cannot be identified. If you agree, you will be asked to sign a separate consent form for this specific matter. **It is important to understand that you can take part in the main study and not take part in this optional administrative database.**

PARTICIPANT RESPONSIBILITIES

If you take any respiratory medication, we will ask you to withhold them before some of the tests (pulmonary function test, spirometry, cardiorespiratory pulmonary exercise test and 6-minute walk test). However, if you feel you need to use your medications, you should use them as you would normally do.The study coordinator will provide you a table that explains how many hours before each test you should withhold your respiratory medications. You will be able to take them once the tests are completed.

DESCRIPTION OF THE QUESTIONNAIRES AND TESTS:

Questionnaires:

The CanCOLD research study involves the administration of questionnaires.
We will ask you questions about your medical history, the medicines you are using, occupational exposures, smoking history, quality of life, nutrition, how you feel in daily life and physical activities.

Breathing Tests (Spirometry and full pulmonary function tests "PFT"):

- **Spirometry** is the name for lung function testing and is carried out both before and after administration of an inhaled bronchodilating drug, which are standard procedures for lung function testing. You will perform the breathing test twice, before and 15 minutes after inhaling 2 puffs of a bronchodilator called salbutamol [Ventolin®]. This inhaled drug is the standard drug used by asthmatic and COPD patients to relax the airways and relieve symptoms. In this case, the use of this drug is part of the routine procedure for spirometry testing in all subjects, as it allows us to measure your personal best lung function, when the airways are fully relaxed.

- You will be asked to perform a **Full Pulmonary Function Test (PFT)** in addition to the breathing test described above. This involves breathing on a mouthpiece while sitting inside a glass body box. This will give us complete information on the state of health of the lungs, including the presence of airway obstruction or changes in lung volumes, and how well the lungs are able to exchange oxygen and carbon dioxide.

Exercise Tests:

There are two tests that we will use to measure your ability to exercise. The tests are:

1. **6-Minute Walk:** The object of this test is to walk for as far as possible for 6 minutes. You will walk back and forth on a flat surface such as a hallway. Six minutes is a long time to walk, so you will be exerting yourself.
2. **Cardiopulmonary Exercise Test (CPET):** This test will measure the oxygen use (O_2) and carbon dioxide production (CO_2) of the lungs during a period of exercise. Exercise will be performed on a stationary bicycle. In addition, your heart function will be assessed using the Physioflow device. For this evaluation, we will place 6 electrodes, 2 on your neck and 4 on your body which will allow the machine to monitor your heart response continuously during exercise. Diseases that affect the heart, lungs, circulation, or blood, will cause an abnormal response to exercise. Exercise testing is useful to help evaluate the cause of shortness of breath that otherwise cannot be determined at rest (heart vs. lungs). It also evaluates the physical fitness of the heart and lungs. The test is also more sensitive for detecting early disease than are less comprehensive tests that are done at rest.

Multi-Detector Computed Tomography (or CT scan):

The MDCT test will take place at the Ste-Justine Hospital. For the CT scan you will be required to remove your upper clothing and wear a hospital gown. You will then lie on a table with your arms extended above your head. The table will then be moved through a "doughnut" shaped

apparatus to obtain the CT scan. The whole CT procedure including the change of clothing, positioning on the table, the scan and the re-dressing will take approximately half an hour. The actual CT scan will take approximately 5 minutes. A registered CT technologist will perform all of the CT scans Participants who have no respiratory illness (healthy subjects) will have only one CT scan.

POTENTIAL RISKS AND DISCOMFORTS:

Questionnaires: You do not have to answer any questions that you do not feel comfortable with. Everything that you talk about with the research staff is completely confidential, meaning that you will not be identifiable.

Symptoms: As mentioned, we will ask you to withhold some of your respiratory medications (if you have any) before the tests. As a result, you could feel more short of breath. This is temporary and could be quickly relieved by using your usual rescue bronchodilators if it becomes too severe. Please inform the study doctor(s) or the coordinator if you were unable to withhold your respiratory medication(s).

Breathing Tests (Spirometry and Full Pulmonary Function Tests "PFT"): Discomfort is unusual; however, some people experience headache and/or a sense of dizziness when performing these tests; these feelings are usually temporary. Spirometry is the standard test of lung function and has been performed in patients and normal subjects all over the world for the last 50 years. Spirometry and PFT procedures are very safe and do not involve needles. However, the breathing test (spirometry) involves maximum effort breathing out and this may cause you to feel dizzy or lightheaded. To reduce the risk of this, the breathing test is performed as you are seated in a chair. The personnel who administer the test are specially trained and certified in this procedure. If you already have doctor-diagnosed COPD, you will be asked to delay your bronchodilator medications until after the interview. However, if you feel you need these bronchodilator medications, you should use them as you would normally do.

Exercise Tests:

1. **The 6-Minute Walk:** If you become fatigued or tired, you will be allowed to slow down, to stop, and to rest as necessary. You may lean against the wall while resting, but resume walking as soon as you are able.
2. **Cardiopulmonary Exercise Test (CPET):** Exercise may make your muscles tired and possibly sore in the days following the exercise. This is generally temporary and is not harmful. As with any type of strenuous physical activity there is a very slight risk of a serious event (e.g. heart attack) during the exercise tests that you will perform, but this risk is no different than if such exercise were performed at home or local gym. In fact, it is probably safer in that you are being closely watched and exercise will be stopped immediately if there are any signs of a problem. Patients without heart disease should not experience chest pain, dizziness, or irregular heart rhythm during the exercise tests. Your heart rate, heart rhythm tracing (ECG) and amount of oxygen in your blood will be closely monitored during all tests. If, at any time during the exercise tests, you do not wish to continue for any reason, you may stop exercising. A study physician will always be available during the exercise tests to monitor you and will be available should there be

any complication or if you have any questions. Emergency equipment will always be available in case of a serious event. The supervising physician may decide to terminate the exercise test at any time.

Multi-Detector Computed Tomography (or CT scan): The CT scans will be used to measure the structure of your lungs. While there will be information obtained from these scans, the number of images that are generated are too small for an effective "clinical" assessment of your lungs. Therefore, unless there is something dramatically wrong with your lungs that the study doctor believe requires further clinical investigation, you will not be informed of the results of this exam.

The radiation you will experience from the CT scan is comparable to the radiation one would experience annually from all natural sources of irradiation. As of now, there are no known side effects from this CT scanning procedure.

Some people who are afraid of confined spaces find the lung function box and the CT scan uncomfortable. The lung function box is constructed of clear plastic so you can always see out and the technician will allow you to enter and leave the box as you need. The CT scanner is relatively narrow and you will always be able to see the room around you. Also, a microphone allows you to communicate with the radiology technician at all times, and you will be removed from the scanner if you become too uncomfortable.

Blood Tests: Drawing blood may cause some pain and carries a small risk of bleeding, light headedness, bruising, and/or infection (less than 1% of patients experience it) at the site where the blood is drawn. When taking blood tests we understand that some bruising may occur but this is not harmful and will disappear. The amount of blood that will be taken will not cause any symptoms or anemia (low red blood cell count).

POTENTIAL BENEFITS:

There are no direct benefits to you from participating in this study.

The indirect benefits associated with participation in the study include:

- You may have undiagnosed COPD, which may be detected in this study. If so, you wil be encouraged to see your physician for medical treatment.
- You will learn the current state of your lung function which, like knowing your blood pressure or blood sugar, is of value to your health.
- You may have the satisfaction of participating in an important study of lung health with wide public health implications.

What are the benefits to society?

The results of this study will for the first time provide precise information about:

- The prevalence and the evolution of all grades of COPD in the community.
- The role of smoking and non-smoking risk factors for development of COPD.
- The role of modifiable factors (exercise, nutrition) on COPD evolution and the potential for new health interventions.
- The extent of the impact of COPD on the subjects' quality of life.
- Both the direct [hospitalization, clinic visits, medications] and indirect [time loss from work by subject and caregiver, and disability compensation] economic burden of COPD in the community, and projection for the future.

FINANCIAL COMPENSATION:

As compensation towards your time, effort and travel costs you will receive $25 per yearly visit at the Montreal Chest Institute. You will also receive $20 for your visit to the Ste-Justine Hospital for your MDCT Scan.

CONFIDENTIALITY:

Your confidentiality will be respected. No information that discloses your identity will be released or published without your specific consent to the disclosure. However, research records and medical records identifying you may be inspected in the presence of the Investigator or his or her designate, a representative of Health Canada and/or the MUHC Research Ethics Board and by the Research Ethics Board of Sainte-Justine University Health Center (CHU Sainte-Justine) for the purpose of monitoring the research. We will also ask you to provide us with a second phone number of a relative who doesn't live with you (parent, sister or brother) where we will be able to reach you for the time of the study.

On papers, questionnaires, files and tests for the study, you will be identified only by a research number.

For this study, the study doctor may need to access your personal health records for health information such as past medical history and test results. He/she may also need to contact your family physician and your other health care providers to obtain additional medical information.

The health information collected as part of this study will be kept confidential unless release is required by law, and will be used only for the purpose of the research study. By signing the consent form you give permission to the study staff to access any personally identifiable health information which is under the custody of other health care professionals as deemed necessary for the conduct of the research. Information furnished from the RAMQ and MedECHO data bases will be coded to ensure confidentiality.

The questionnaire(s) and the sample(s)/data collected will be used for this study only and will be kept for 25 years after completion of the study as required by Health Canada. Computer information will be password protected.

The results of your lung function tests will only be sent to your family doctor upon your request because the tests are strictly performed for research purposes.

VOLUNTARY PARTICIPATION AND WITHDRAWAL:

Your participation in the study is voluntary. You may refuse to take part or you may decide to stop at any time. If you decide to withdraw from the study, it is important that you inform the study doctor or coordinator. The doctor may also withdraw you from the study if you do not follow the study instructions, or in the unlikely event that you have a serious side effect from the study procedures. This will not affect your relationship with the study doctor, or with your regular doctor, who will continue to give you the best treatment he/she can offer. Your data will be kept but no new data will be collected.

If new information arises that may affect your willingness to remain in this study, you will be advised of this information promptly.

LEGAL RIGHTS:

You are not waiving any of your legal rights by participating in this research study, or by signing this consent form, including, for example, the right to seek damages under civil law for any research related injury.

If you suffer any injury due to a study procedure required as part of this research, you will receive all care and services needed to treat you covered by the Quebec Medicare health care system and by your drug insurance plan.

PRINCIPAL INVESTIGATOR AND RESOURCE PERSONS

Principal Investigator:
Dr. Jean Bourbeau. Telephone: 514 934-1934, ext. 32185

Research Coordinators:
Palmina Mancino. Telephone: 514 934-1934, ext. 32116.
Katrina Metz. Telephone: 514 934-1934, ext. 32489.

PATIENT REPRESENTATIVE OF THE HOSPITAL:

For all other questions concerning your rights pertaining to your participation in a research project, you can contact the ombudsman of the McGill University Health Center at 514 934-1934 ext. 35655. If you believe that you have been injured while participating in this study, you can contact the Director of Professional Services at 514 934-1934 ext. 34329.

SUBJECT INFORMED CONSENT- Signature Page

RESEARCH STUDY: *The Canadian Cohort Obstructive Lung Disease Study*

PRINCIPAL INVESTIGATOR: Dr. Jean Bourbeau, Montreal Chest Institute, Montréal

1. I understand that this is a research study.
2. I have read all the pages of the consent form. The research personnel have explained the information and procedures involved in the study. I have had the opportunity to ask questions and my questions have been answered satisfactorily. I have been given time to consider the information carefully and to decide whether or not to participate in this study.
3. I have been informed that my participation in this study is entirely voluntary and that I may refuse to participate, or withdraw at any time, without any consequences to my ongoing and future medical care in this institution.
4. I authorize the release of my medical records to the regulatory authorities and the ethics committee of this institution for purposes of this study only. This authorization will be valid for a period of 25 years.
5. I understand that I will be given a copy of this informed consent to keep for my own information, once it is signed.
6. I understand that I do not give up any of my legal rights by signing this form nor am I freeing the investigators, sponsors, or the health establishment where the study takes place from their civil and professional responsibilities.
7. My signature below indicates that I voluntarily agree to take part in this study.

_____	_____	_____
Subject's signature	Name (in block letters)	Date
_____	_____	_____
Signature of Person Administering Informed Consent	Name (in block letters)	Date
_____	_____	_____
Investigator's Signature	Name (in block letters)	Date

SUBJECT INFORMED CONSENT- Signature Page

PROVINCIAL ADMINISTRATIVE DATABASE

RESEARCH STUDY: *The Canadian Cohort Obstructive Lung Disease Study*

PRINCIPAL INVESTIGATOR: Dr. Jean Bourbeau, Montreal Chest Institute, Montréal

The researchers from the CanCOLD study would like to have access to your RAMQ and MED ECHO data to validate their research data. Therefore, you are being asked to give the CanCOLD researchers access to your RAMQ and MED ECHO of the previous 5 years and of next 15 years from the start of the study.

Yes, I agree that you may access my RAMQ and MED ECHO of the previous 5 years and of the 15 years from the start of the study. ☐

Medicare Number: _____

No, I **do not** agree that you may access my RAMQ and MED ECHO. ☐

_____	_____	_____
Subject's signature	Name (in block letters)	Date

_____	_____	_____
Signature of Person Administering Informed Consent	Name (in block letters)	Date

_____	_____	_____
Investigator's Signature	Name (in block letters)	Date