



**Centre universitaire de santé McGill
McGill University Health Centre**

*Les meilleurs soins pour la vie
The Best Care for Life*

SUBJECT INFORMATION AND INFORMED CONSENT

**LONG-TERM BANKING OF HEALTH DATA AND BLOOD SAMPLES FOR
GENETIC TESTING AND FOR FUTURE TESTING OF BLOOD SUBSTANCES**

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

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

Purpose of the Subject Information and Consent Form:

The purpose of this form is to give you information about this research study and if you sign it, it means you will have to agreed to take part in the study. The form describes the purpose, procedures, benefits, risks and side effects of the research study. Please ask the study doctor or personnel to explain any words or procedures that you do not clearly understand. You may refuse to take part or withdraw from this study at any time, without affecting your medical care at this institution.

Introduction:

The Montreal Chest Institute Tissue Bank of the « Réseau en santé respiratoire du Fonds en recherche et en santé du Québec » (FRSQ) conserves human tissue specimens from subjects who agree to participate in the collection of blood samples for the CanCOLD project. We ask that you consent to deposit these blood samples, with appropriate health data, into storage so we can undertake genetic testing and future testing of substances in your blood such as proteins and inflammatory substances.

Purpose of the tissue (blood) banking:

At the end of a research project such as CanCOLD, all samples and health data obtained are usually destroyed. However, instead of destroying these samples, it would be very helpful to have these samples and data available for future studies. These studies will help us learn more about COPD. Environmental exposures such as smoking and your genes can also influence the development of a variety of diseases such as COPD.

We ask that you consent to deposit your blood, and data in a “tissue bank” which will serve for future research on COPD disease only. The samples will be stored for additional future work to discover the genetic aspects that potential targets the therapy for people with COPD. Two genetic components, the DNA and RNA, will be extracted and banked. 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.**

Other Uses of Biological Material:

In addition to the research carried out by our laboratory, some of the material may be shared in collaborative research at other universities, or pharmaceutical or biotechnology companies, for development of new diagnostic tools and therapies to diagnose and/or treat lung disease. In the long term, the results of this study may be valuable for

commercial and /or intellectual property (for example patent purposes). The investigators, following university guidelines, may derive personal benefit from this potential intellectual property. It is important that you realize that you will not have any claim on products that may result from this long-term research.

Procedure:

Method and duration of sample storage:

Your blood specimen will be stored in order to facilitate current and future studies for lung health and may be kept for 25 years. Blood samples and data will be kept for 25 years as long as the Principal Investigator, Dr. Jean Bourbeau or appointed study investigators can guarantee their proper management. You have the right to withdraw from the bank by informing the investigator or the resource person at any time.

Use of banked samples:

Samples will be accessible to researchers for use in biological and genetic analyses related to research in COPD. To be granted access to any samples, researchers (same researchers in a similar study or other researchers in similar or different studies) are required to obtain authorization from the Research Ethics Board, The McGill University Health Center, or another appropriately constituted Ethics Committee involved in the CanCOLD study.

Any samples that are left at the end of 25 years will be kept anonymous unless you indicate that you would like your samples destroyed. This is following the procedure in place from the provincial bank of the Réseau en santé respiratoire du Fonds de la recherche en santé du Québec (FRSQ).

There is no physical risk involved in allowing long term storage of samples. It does not require any additional visits, or any additional samples. You will not receive financial compensation for discoveries made using specimens held in storage. By accepting, you contribute to an important resource for health researchers.

It will not be possible to inform you, your family, or your doctors of the results of the genetic or biological analyses on your blood samples. You will, however, have access to the general results and will be informed of publications arising from the research.

Potential Risk and Discomforts:

Non-Physical Risks: There are also possible non-physical risks associated with taking part in this study such as the possibility of loss of confidentiality and the subsequent effects. For example, the accidental disclosure of genetic or tissue marker research data could result in discrimination by employers or insurance providers. There are multiple safeguards in place to prevent this from happening (for example, all information that could identify you is removed and samples are assigned a code number.)

Potential Benefits:

There may not be any direct benefit to you from participation in this part of the project. However, the information that may be gathered from this project may help researchers to better understand and treat lung diseases such as COPD.

Financial Compensation:

Your participation is entirely voluntary and will include no financial compensation.

Confidentiality:

Each sample will be labeled by a code. This means that the sample won't be identify with your name or any information that could identify you. However, we will have the possibility to link clinical information (demographic, clinical and pulmonary function tests or CTScan) to the blood sample using a predefined study number. No information that discloses your identity will be released or published without your specific consent to the disclosure. The blood samples will be store at the Montreal Chest Institute Tissue bank of the Réseau en santé respiratoire du Fonds de la recherche et en santé du Québec (FRSQ) for 25 years. Only the research personel at the Montreal Chest Institute will have access to the study documents.

Biologic samples from yourself will be frozen and stored in a laboratory of the investigators according to local and provincial regulations. These samples will be labelled by a number only so as to not identify you. Some of these samples will be shipped to various laboratories elsewhere. Some of these samples will remain in long term storage for later testing of factors that may become important as we learn about them in the future and develop new methods of testing.

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.

Withdrawal of Samples:

If you wish that your specimens be removed from the Tissue Bank, you should communicate with the resource person for the Tissue Bank at the phone number below. The specimens will then be destroyed as well as all personal information about you in the data bank.

Principal investigator and resource person for the tissue bank:

Principal Investigator:	Dr. Jean Bourbeau Telephone: (514) 934-1934 ext 32185
Resource person for the tissue bank:	Andrea Mogas Telephone: (514) 934-1934 ext 32124
Resource person for the study:	Palmina Mancino Telephone: (514) 934-1934 ext 32116

Persons to Contact:

For all other questions concerning the subject of your rights regarding 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 participated in this study, you can contact the Director of Professional Services at (514) 934-1934 ext.

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SUBJECT INFORMED CONSENT- Signature Page

RESEARCH STUDY: *The Canadian Cohort Obststructive 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 Dr. Bourbeau and his designated assistants, as well as 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 Name (in block letters) Date
Administering Informed Consent

Investigator's Signature Name (in block letters) Date