

**LETTER OF INFORMATION AND CONSENT TO PARTICIPATE IN THE HPS
DATABASE**

St. Michael's Hospital Hepatopulmonary Syndrome (HPS) Database

Database Investigator

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Sponsor and Funding

This database is maintained by Dr. Samir Gupta and it is funded by donations made to the HPS program.

Introduction

You are being asked to consider taking part in the HPS database because you have been assessed for HPS. Before you agree to participate in this research database, it is important that you read and understand the following explanation of the database. It describes the purpose, procedures, possible benefits, risks and discomforts, associated with the database. It describes your rights as a participant, including the right to withdraw from the database at any time. It is also important that refusal to participate will not influence the standard care you and your family may receive at St. Michael's Hospital. This consent may contain words that you do not understand. Please ask the database investigator or staff to explain any words or information that you do not understand. You should not sign this form until you are sure you understand the information. Participation is voluntary. You may also wish to discuss the database with your family doctor, a family member or close friend.

Purpose of the HPS Database

HPS is a rare disease and there is little known about this disease. St. Michael's Hospital has one of the largest HPS programs specializing in this disease. The HPS database is an electronic list of patients who have been assessed for hepatopulmonary syndrome (HPS) at St. Michael's Hospital. We estimate that we will enroll approximately 30 patients per year in the HPS database.

The purpose of the HPS database is to: (1) maintain an electronic registry of standardized information on patients assessed for HPS; (2) use patient data in the database for research studies and (3) contact patients for future research studies (where applicable). The database is confidential and will only be used by the database

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investigator and authorized research staff. Your information will not be given to any other doctors, drug companies, government agencies, or insurance companies.

Obligations

There are no obligations. You are being asked for your permission to be included in the HPS database.

Potential Harms

Participation in this database does not pose any risk to your health. The only consideration is potential for breach of confidentiality and this will be minimized by limiting access to your health data to authorized research personnel.

Potential Benefits

The information that will be collected may help us to better understand HPS and liver disease.

Duration/Follow-up

Your health information will be included and updated in the database until you are no longer seen at St. Michael's Hospital.

Participation and Withdrawal

If you decide not to participate in this database, you and your family's standard medical care will not be affected in any way. If you withdraw from the database, your health information will be kept in the database however we will no longer collect your health information in the future. If you withdraw, you will no longer be contacted for future study participation. If you want to withdraw your information from the database at any time, you may call the research coordinator or Dr. Gupta.

Potential Costs and Reimbursement

There are no costs to you for participation in this database. You will not be paid for your participation in this database.

Data Storage and Retention

Your health information will be stored in the database indefinitely. The database will be stored on an onsite, secure internal server. If you withdraw from the database, your health information will be kept in the database however we will no longer collect your health information in the future.

Protecting Your Personal Health Information

Personal health information is any information that could be used to identify you and includes your name, address, date of birth, and new or existing medical records, including types, dates and results of medical tests or procedures. Database data is any information about you that is generated by and/or collected for this database. It does not include any identifying information. All St. Michael's Hospital (SMH) database staff (database investigators, coordinators, nurses and delegates) is committed to respecting your privacy. No other persons will have access to your personal health information or identifying information without your consent, unless required by law. The database staff will make every effort to keep your personal health information private and confidential in accordance with all applicable laws, regulations, guidelines and privacy legislations, including the Personal Health Information Protection Act (PHIPA) of Ontario.

Our guidelines include the following:

- All information that identifies you, both paper copy and electronic information, will be kept

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confidential and stored and locked in a secure place that only the database staff will be able to access.

- Electronic files will be stored securely on hospital or institutional networks.
- No information identifying you will be allowed off site in any form. Examples include your hospital or clinic charts, copies of any part of your charts, or notes made from your charts.

It is important to understand that despite these protections being in place, there continues to be the risk of unintentional release of information. The SMH database staff will protect your records and keep all the information in your database file confidential to the greatest extent possible. The chance that this information will be accidentally released is minimal.

Although all of your database data will be kept confidential, your medical records or database records may be accessed by the database staff or authorized representatives of the St. Michael's Hospital, including members of the Research Ethics Board. Such access will be used only for the purpose of verifying the authenticity and accuracy of the information collected for the database, without violating your confidentiality to the extent permitted by applicable laws and regulations.

Federal and Provincial Data Protection regulations, including the Personal Information Protection and Electronic Documents Act (PIPEDA 2000) and the Personal Health Information Protection Act (PHIPA 2004) of Ontario, protect your personal information. They also give you the right to control the use of your personal information (including personal health information) and require your written permission for this personal information to be collected, used, or disclosed for the purposes of this database, as described in this consent form. You have the right to review and copy your personal information collected in this database. However, if you decide to be in this database or choose to withdraw from it, your right to look at or copy your personal information related to this database will be delayed until after the research is completed.

Database Results

Research studies that result from the maintenance of this database will be published in journal articles and conference presentations. The research publications/presentations will not contain information that is identifiable to you. You can ask us to send you a copy of the article when it is published by contacting the database investigator.

New Findings

You will be told of any significant new findings obtained from subsequent research studies resulting from the maintenance of this HPS database that may impact you and your family.

Future Use of Research Data

Your data will be strictly accessible to the authorized research team. Your health information from the database will be used to perform studies in this disorder. In addition, you may be contacted and invited to participate in future research studies.

Research Ethics Board Contact

If you have any questions regarding your rights as a research participant, please contact Dr. David Mazer, Chair Research Ethics Board at 416 864 6060 ext. 2557, business hours-weekdays 9 to 5 pm.

Database Contact

If you have any questions regarding this database, please contact the research coordinator, Madina Naimi, at 416-864-6060 ext. 2045, business hours-weekdays 9 to 5 pm.

St. Michael's Hospital Hepatopulmonary Syndrome Database

Consent to Participate in Database:

By signing this consent form, I acknowledge that the research database has been explained to me. I have been given an opportunity to ask questions and any questions I have asked have been answered to my satisfaction. I have been informed of the alternatives to participation in this database, including the right not to participate and the right to withdraw without compromising the quality of medical care at St. Michael's Hospital for myself and for other members of my family. As well, the potential risks, harms, and discomforts have been explained to me as well as the possible benefits to participating in the database.

I understand that by consenting to be in the HPS database, I acknowledge (give permission) that:

- (1) My personal health information will be included in the database**
- (2) My health information may be used in research studies to gain a better understanding of HPS and liver disease.**
- (3) I may be contacted in the future for participation in research studies.**

I understand that I have not waived my legal rights nor released the investigators, sponsors, or involved institutions from their legal and professional duties. I understand that I may now, or in the future, ask any questions I have about my participation in the database. I have been assured that records relating to me and my care will be kept confidential and that no information will be released that would disclose personal identity without my permission unless required by law. I have been given sufficient time to read and understand the above information. By signing this consent, I agree to participate. I will be given a signed copy of this consent form.

Participant's Name Participant's Signature Date (dd/mmm/yyyy)

I confirm that I have explained the nature and purpose of the database to the participant named above. I have answered all questions.

Signature of Database Personnel Obtaining Consent Date (dd/mmm/yyyy)

Name of Person Obtaining Consent (Please print)