McMaster University
Health Sciences

LETTER OF INFORMATION AND CONSENT: PERSON WITH HEMOPHILIA

STUDY TITLE: Outcomes, Equity, Acceptability, Feasibility: A qualitative approach to identify and understand stakeholder perceptions and experiences of models of care for hemophilia management in the US

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STUDY FUNDER: National Hemophilia Foundation

INSTITUTION: McMaster Transfusion Research Program (MTRP), McMaster University

You are being invited to participate in a research study because you are a **person with hemophilia (PWH)** who has experience receiving hemophilia related treatment and care.

Who can participate in this study?

Adults (≥19 years old), living with hemophilia A or B (any severity) who receive treatment and care for hemophilia in the United States.

Study Purpose

The purpose of this study is to explore and understand the perspectives of stakeholders (i.e. people with hemophilia, parents of people with hemophilia 18 years of age and under, healthcare providers including physicians, nurses, social workers, physical therapists, people involved in hemophilia policy and people involved in insurance provision), with experience that relates to *providing* or *receiving* hemophilia related care and services in the US in one or more of the following ways: through a Hemophilia Treatment Center, through a specialty pharmacy or through a physician (who may or may not have expertise in hemophilia) in a non-specialized setting. We are specifically interested in understanding:

- the health outcomes that are important to stakeholders,
- the acceptability of different ways of receiving and providing care
- how different ways of receiving care might impact health inequities
- the feasibility of different ways of receiving and providing care

What does giving consent mean?

This consent form describes the purpose, procedures, potential risks (side effects) and benefits, which go along with your participation in this research study. In order to decide whether or not you

want to be part of this research study, you should understand what is involved and the potential risks and benefits of participation. This form gives detailed information about the research study, which will be discussed with you. Once you understand the study, you will be asked to sign this form if you wish to participate.

What do you have to do on this study?
You will be asked to participate in a one-on-one telephone interview that will last approximately 20-30 minutes, with a researcher from McMaster University in Hamilton, Ontario, Canada. The interviewer will ask you questions about your experiences and point of view regarding receiving care for hemophilia. Before the interview takes place, you will be asked to read this information sheet and to ask any questions that you might have regarding the study. If you decide to participate, you will need to sign this consent form and return it to the study coordinator. A copy of the form will be kept by the McMaster Transfusion Research Program (MTRP) and one will be sent to you for your records.

How many other participants are there in the study?
The total number of participants in this study will depend on the number of individuals who qualify and agree to participate. It is anticipated that approximately 90 individuals will participate in the research study.

Potential Benefits
You will not directly benefit from participating in this study.

What are the possible risks of the study?
It is unlikely that there will be any harm or discomfort associated with participation in this study. However, if you feel uncomfortable with certain questions you do not need to answer them. You also have the right to withdraw from the study.

Withdrawal from Study
During the interview you may choose not to answer certain questions. You may also choose to end the interview at any time. Should you change your mind about participating in the interview you are free to withdraw from the study up until one week from the date the interview is conducted. At your request, any data you contributed in the interview will be removed from the study transcript and will not be used in the study results.

Who will have access to my interview recording, electronic and printed transcript?
Your confidentiality will be respected. When the audio recording of the interview is transcribed your name will be removed from the transcript and will be replaced with a code (i.e.: P-01). The only person who will have access to both your name and the code is the research coordinator who will keep this information secure in a locked office in the institution where this research is being conducted. No records that identify you by name or initials will be allowed to leave the research coordinator's office. Information that discloses your identity will not be released without your consent unless required by law or regulation. However, research records and medical records identifying you may be inspected in the presence of the investigator or his or her designate, by representatives of Health Canada, and the Research Ethics Board for the purposes of monitoring the research. Audio recordings of the interview will be deleted after verification of the accuracy of transcribed interviews. Printed and electronic interview transcripts will be retained for 10 years and will then be destroyed and deleted.

What payments will be made for the study?
You will not be paid for your participation in the study. Your participation within the study is voluntary.

Who should you contact to answer any questions on the study?
If you have questions or require more information about the study itself, please contact the Project Coordinator, Shannon Lane by phone: (905) 525-9140 extension, 21788 or email: lanesj@mcmaster.ca

What are my rights as a Research Subject?
If you have any questions regarding your rights as a research participant you can contact the Office of the Chair of the Hamilton Integrated Research Ethics Board at (905) 521-2100 Ext. 42013.

Contact Information
The name and contact information of the Principal Investigator of this study are listed at the top of the first page of this document. You may contact the investigator for information on the study procedures, or for any other study related questions.

SUBJECT'S STATEMENT OF CONSENT

I have read and understood the letter of information and consent form, and have had sufficient time to consider the information provided and to ask questions. I have had satisfactory responses to my questions.

My participation in this study is voluntary. I can refuse to participate in this study without any consequences. I can withdraw from this study without any consequences up until one week from the date of interview; if I withdraw thereafter I understand the data I contribute will be used in the research study.

I have been told that I will receive a copy of this signed and dated consent form.

Signature of Subject	Date/Time	Printed Name
Signature of Person obtaining consent	Date/Time	Printed Name

I hereby certify that the study staff/myself explained the study information to the participant on the date stated on the consent form.

Signature of Investigator **Date / Time**

Printed Name of Investigator