Information Letter and Participant Consent Form

Title of Study: *Management of Persistent Epistaxis Using Floseal Hemostatic Matrix*

Principle Investigator:
Dr. David Côté
1E4.07 WMC, 8440 112 Street
University of Alberta Hospital
Edmonton, AB, T6G 2B7
780-407-4491

Study Coordinators:
Alexander Hopkins BSc.
1E4.07 WMC, 8440 112 Street
University of Alberta Hospital
Edmonton, AB, T6G 2B7
780-660-1059
arhopkin@ualberta.ca

Dr. Scott Murray
1E4.07 WMC, 8440 112 Street
University of Alberta Hospital
Edmonton, AB, T6G 2B7
587-891-6240
sipmurray@gmail.com

Why am I being asked to take part in this research study?

You are being asked to be in this study because you have a nosebleed that has not stopped even after a first try at treatment in the Emergency Department. There are a number of treatment options for people in your situation and we are interested in studying which treatment has the best result at stopping bleeding quickly and is the most comfortable.

The most standard treatment for severe nosebleeds is a re-packing of the nose using gauze by a trained Ear, Nose and Throat (ENT) specialist; this is what half of the participants in this study will receive. The other half of participants will be treated again by a trained ENT specialist using a less common (but still used) treatment called Floseal Hemostatic Matrix. We hope to have approximately 60 people participating in this study by the end of data collection.

Before you make a decision one of the researchers will go over this form with you. You are encouraged to ask questions if you feel anything needs to be made clearer. You will be given a copy of this form for your records.

What is the reason for doing the study?

Floseal Hemostatic Matrix is a treatment that is already approved by Health Canada, and is currently in use in a number of hospital settings. **In this study we want to know whether *Floseal* is more or less effective than simply packing the nose alone and whether it is more comfortable.**

What will I be asked to do?

The amount of time required for the actual treatment in this study will be no longer than if you were not participating in the study. There will also be a comfort questionnaire that will be completed over the telephone and should take no more than 10 minutes to complete.

The treatment you will receive (either Floseal or traditional gauze packing) will be determined using randomization. Meaning you will have a 50/50 chance for which group you

will be placed in. Neither you nor the doctor treating you will have no control over which group you are assigned to. In this study we will also need to access your medical records to observe the effectiveness of the treatment and whether additional steps (such as hospital admission) were taken.

Process

- Upon completion of reading this letter you will have the opportunity to ask questions about the study and decide whether you would like to participate or not.
- If you choose to participate you will sign the informed consent form.
- You will receive a random treatment assignment and the physician will perform the assigned treatment (either Floseal or traditional packing).
- Your care will continue as it normally would without participation in this study.
- You will be contacted by telephone or in person if you are still in the hospital 48 hours following treatment and asked a few short questions about how you felt with the treatment. You will be asked to keep this information package and answer based on the diagram on page 3.

What are the risks and discomforts?

As previously mentioned, Floseal is already an approved treatment for use in Canada. Should the Floseal not work in stopping the nosebleed, you may need to be re-packed and go to the operating theatre for surgical clipping of the nose vessels.

As some of the components of the Floseal Matrix come from human plasma, there is a very rare theoretical risk of transmitting an infectious agent to someone using it although this has never previously been reported. Similarly, a component of the matrix is derived from bovine (cow) sources and if you have a history of allergy to cow products please let us know.

If we find out anything new during the course of this research, which may change your willingness to be in the study, we will tell you about these findings.

What happens if I am injured because of this research?

If you become ill or injured as a result of being in this study, you will receive necessary medical treatment, at no additional cost to you. By signing this consent form you are not releasing the investigator(s) and/or institution(s) from their legal and professional responsibilities.

What are the benefits to me?

There may be no health benefit to you for being in the study. We hope that the information from this study may help inform doctors how to best treat other people with severe nosebleeds in the future.

Do I have to take part in the study?

Being in this study is your choice. If you decide to be in the study, you can change your mind and stop being in the study at any time, and it will in no way affect the medical care that you are entitled to.

In the event of opting out of the study your data will be withdrawn and discarded in a confidential manner.

Will my information be kept private?

Any personal information or data we record about you will be kept confidential. No data relating to this study that includes your name will be released outside of the researcher's office or published by the researchers. We will make every legal effort to make sure that your information is kept private.

The investigator or their study staff will need to look at your personal health records throughout the study. Any personal health information that we get from these records will be only what is needed for the study.

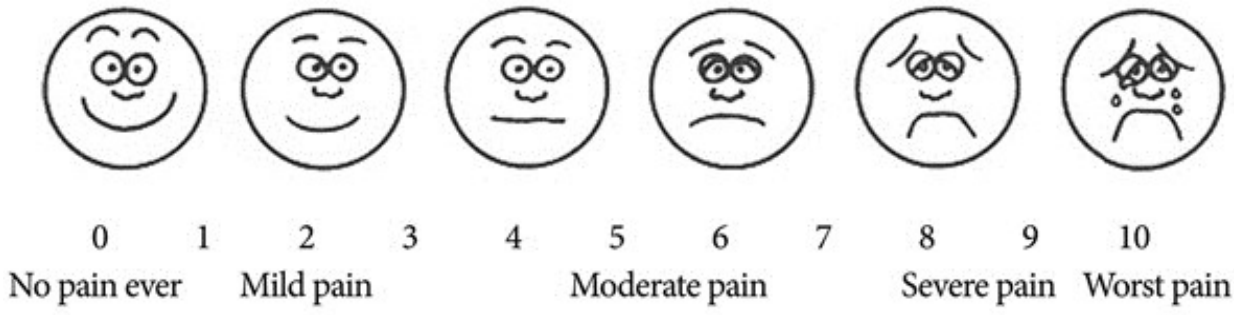
During research studies it is important that the data we get is accurate. For this reason your health data, including your name, may be looked at by people from the University of Alberta auditors and members of the Research Ethics Board.

By signing this consent form you are saying it is okay for the study team to collect, use and disclose information about you from your personal health records as described above. After the study is done, we will still need to securely store your health data that was collected as part of the study. At the University of Alberta, we keep data stored for a minimum of 5 years after the end of the study.

If you leave the study, we will not collect new health information about you, but we may need to keep the data that we have already collected. Data withdrawal is also possible with a request made to the research team, with the limitation for with drawl being the publication of the research.

What if I have questions?

If you have any questions about the research now or later, please contact **Alexander Hopkins [780-660-1059]**. If you have any questions regarding your rights as a research participant, you may contact the Health Research Ethics Board at 780-492-2615. This office has no affiliation with the study.



Envelope Number: Treatment Type:	Patient ID Sticker

CONSENT

Title of Study: Management of Persistent Epistaxis Using Floseal Hemostatic Matrix

Principal Investigator: Dr. David Côté **Phone Number:** 780-407-4491
Study Coordinator(s): Alexander Hopkins **Phone Number:** 780-660-1059
Dr. Scott Murray **Phone Number:** 587-891-6240

	Yes	No
Do you understand that you have been asked to be in a research study?	☐	☐
Have you read and received a copy of the attached Information Sheet?	☐	☐
Do you understand the benefits and risks involved in taking part in this research study?	☐	☐
Have you had an opportunity to ask questions and discuss this study?	☐	☐
Do you understand that you are free to leave the study at any time, without having to give a reason and without affecting your future medical care or without penalty?	☐	☐
Has the issue of confidentiality been explained to you?	☐	☐
Do you understand who will have access to your study records, including personally identifiable health information?	☐	☐

Who explained this study to you? _____

Best telephone number we can contact you at for follow-up: _____

I agree to take part in this study (Circle One): Yes No

Signature of Research Participant _____

(Printed Name) _____

Date:_____

I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate.

Signature of Investigator or Designee _____ Date _____

THE INFORMATION SHEET MUST BE ATTACHED TO THIS CONSENT FORM AND A COPY GIVEN TO THE RESEARCH PARTICIPANT