Appendix 1. Recruitment email and attached participant information sheet

Dear Colleague:

You are being asked to consider participating in the research study entitled ***"****Development of a Canadian prehospital blood product transfusion protocol - a modified RAND Delphi study".*

The study is led by Drs. Brodie Nolan (Principal Investigator), Johannes von Vopelius-Feldt, and Joel Lockwood.

The primary outcome of our proposed study is to create a consensus document to guide and standardize the use of blood products in prehospital care in Canada. We hope to achieve this using a modified-Delphi approach among national experts in prehospital care, trauma and blood transfusion sciences.

You are asked to consider participating in this Delphi because you have been identified as an expert in prehospital care, trauma and/or blood transfusion sciences. As such, we are asking you to provide your knowledge in developing a list of statements to guide best practice in prehospital transfusion of blood products.

A primary literature search of relevant studies was undertaken to establish a preliminary list of statements supporting the following seven domains: 1. General oversight and clinical governance; 2.Storage and transport of prehospital blood products; 3. Initiation of prehospital blood transfusion; 4.Types and order of blood products to be given; 5. Delivery and monitoring of blood product transfusion; 6. Indications for and use of transfusion adjuncts; 7.Resuscitation targets to halt ongoing transfusion.

As an expert participant, you will be asked to independently rate each statement on a 7-point scale (1=lowest and 7=highest score), representing "definitely should not include" to "definitely should include". You will also be able to suggest additional statements as needed, propose wording changes to existing statements, and add free text comments if required. We will analyze the responses from all participating experts. Statements with high levels of agreement (median score 6-7) and no comments will be included in the final consensus statement. Statements with very low (median score 1-2) will be removed from further rounds. Statements with intermediate levels of agreement (median score 3-5) and/or relevant comments or edits will be discussed at a panel meeting via video conference. These statements as well as additionally suggested once will then undergo a further round of independent ranking by each participant. This process will be repeated if required. This final iteration of the Delphi-validated statements will be use to generate best practice recommendations on the use of prehospital blood products in Canada.

Attached is a letter of information about the study. **By completing the survey via JotForm or by emailing your response form to the Study Coordinator, you are consenting to participate in this study.**

If you have any additional questions or would like to receive further information, please contact either Emma or Melissa.

Emma O'Neil, Emergency Medicine Research Assistant
Tel: 416.864.6060 ext. 49597 | Email: [redacted]

Melissa McGowan, Emergency Medicine Research Education Coordinator
Tel: 416.864.6060 ext. 49091 I Email: [redacted]

If you know of other experts in relevant areas who may be interested in participating in this Delphi, please feel free to forward on this email.

Sincerely,

Brodie Nolan, Principal Investigator, on behalf of the study team

ST. MICHAEL'S
UNITY HEALTH TORONTO

LETTER OF INFORMATION TO PARTICIPATE IN A RESEARCH STUDY

You are being asked to participate in a research study to develop a Canadian prehospital blood product transfusion protocol using a Delphi survey method. If you have any questions, please ask a staff study member.

In order to decide whether you wish to participate in this research study, you should understand enough about its risks and benefits to be able to make an informed decision.

TITLE: *Development of a Canadian prehospital blood product transfusion protocol - a modified RAND Delphi study*

INVESTIGATORS:

Brodie Nolan, MD MSc Principal Investigator, Emergency Medicine	Johannes von Vopelius-Feldt, MSc PhD DipIMC FRCEM Co-Investigator
Joel Lockwood, MD Co-Investigator	Melissa McGowan, MHK Study Coordinator, Emergency Medicine [redacted]
Emma O'Neil, BA Research Assistant, Emergency Medicine [redacted]	

All St. Michael's study team is available Monday to Friday 8:00am – 4:00 pm.

INTRODUCTION
You are invited to take part in a study aimed at creating consensus on prehospital transfusion of blood products in the Canadian setting.

PURPOSE OF THE RESEARCH
To guide and standardize the use of blood products in prehospital care in Canada.

DESCRIPTION OF THE RESEARCH
You are being asked to participate in a modified Delphi process to establish a core set of statements outlining best practice in the use of prehospital blood products in Canada.

A primary literature search of relevant studies was undertaken to establish a preliminary list of statements supporting the following seven domains:

1. General oversight and clinical governance
2. Storage and transport of prehospital blood products
3. Initiation of prehospital blood transfusion
4. Types and order of blood products to be given
5. Delivery and monitoring of blood product transfusion
6. Indications for and use of transfusion adjuncts
7. Resuscitation targets to halt ongoing transfusion.

National experts in the field of prehospital care, trauma care and blood transfusion sciences are recruited for the Delphi process. Using an established modified Delphi method, you will be asked to independently rate each statement on a 7-point scale (1=lowest and 7=highest score), representing “definitely should not include” to “definitely should include”. You will also be able to suggest additional statements as needed, propose wording changes to existing statements, and add free text comments if required. We will analyze the responses from all participating experts. Statements with high levels of agreement (median score 6-7) and no comments will be included in the final consensus statement. Statements with very low (median score 1-2) will be removed from further rounds. Statements with intermediate levels of agreement (median score 3-5) and/or relevant comments or edits will be discussed at a panel meeting via video conference. These statements as well as additionally suggested once will then undergo a further round of independent ranking by each participant. This process will be repeated if required.

This final iteration of the Delphi-validated statements will be use to generate best practice recommendations on the use of prehospital blood products in Canada.

EXPECTED TIME REQUIREMENT
We expect that participation will take 3-6 hours of your time over the course of 1-3 months.

POTENTIAL HARMS (INJURY, DISCOMFORT OR INCONVENIENCE)
There are no known harms from participating in this Delphi process, but taking part may present an inconvenience related to the time spent completing the survey(s). You may choose to stop at any time. You may also refuse to answer any questions on the form if you choose.

POTENTIAL BENEFITS
You may not derive any direct benefit from this study, however, this study will offer an opportunity to develop a consensus based best practice guide on the use of prehospital blood products. This may lead to changes that will positively impact patient care, safety and outcomes.

CONFIDENTIALITY AND PRIVACY
You will be given a unique identifier that will be used to label all data collected in the course of the study. The unique identifier will be linked to your identity by means of a master list. This master list will only be available to the Study Coordinator and kept securely on the hospital network.

You may either respond online via JotForm or you may email your response form to the Study Coordinator, who will de-identify the form from your email address, and will assign a study ID before your response is analyzed by the study team.

By completing this Delphi online you are agreeing to the following: As JotForm’s servers are located in the United States, they are subject to the conditions of the USA PATRIOT Act of 2001. As such, we cannot guarantee that these files will not be accessed by others. However, no information that personally identifies you will be collected in this survey.

The results of the Delphi study will include responses from many people grouped together. Responses will be aggregated so that no one person can be identified. The data provided by you may be used in a research publication. Direct quotes from your responses may be used in reports or publications, but the quotes will not be attributed to you or contain any information that could be used to identify you. Any responses, records or personal information that could be directly linked to you will not be reported or shared with anyone outside of the study team.

Data will be stored for a minimum of 5 years after the end of the study and destroyed 5 years follow publication. Any response forms emailed to the Study Coordinator will be kept in a locked cabinet in the Study Coordinator's office at St. Michael's Hospital. The St. Michael's Hospital Research Ethics Board will have access to the data provided by you in the future.

We would like to acknowledge the experts participating in this Delphi study in the resulting presentations or publications. You can consent to your name and professional role being used for acknowledgement by providing these details in the survey / or response form. This information will not be linked to any of your responses or comments during your participation.

PARTICIPATION AND WITHDRAWAL

Participation in research is voluntary. By entering information in the survey you will be consenting to participate in the research as outlined above. If you chose to participate in this study, you may withdraw at any time. You may withdraw by closing the webpage before finalizing the survey responses or by contacting a member of the study team at any time. You do not need to give any reasons for withdrawal. If you withdraw from the study after the collection of the data, all data collected online or from your form up to that point will be stored and used as described above. The research findings will be available upon the completion of the research project should you request it.

ALTERNATIVES TO PARTICIPATION

This study is not researching ways to provide you with medical treatment, so the alternative to taking part in this study is to not take part in the study.

Questions: If you have any questions about the study, please contact either Emma or Melissa during normal business hours

Emma O'Neil
Melissa McGowan [redacted]

Research Ethics Board Contact: If you have any questions regarding your rights as a research participant, you may contact the Unity Health Toronto Research Ethics Board Office at 416-864-6060 ext. 42557 during business hours (9:00am to 5:00pm).

Please keep a copy of this document for your records.

Sincerely,
Dr. Brodie Nolan, Dr. Johannes von Vopelius-Feldt, Dr. Joel Lockwood and Research Team