

# Capturing physiological responses to blood donation using a portable sensor

<b>Submission date</b> 23/11/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 07/12/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 29/06/2022	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Vasovagal reactions consist of symptoms like dizziness, sweating, pallor, and anxiety. They are among the most common adverse events seen in blood donation. They can cause donors distress, potential injury from falling and are a strong disincentive for donors to return, which affects the stability and safety of the blood supply. Once early symptoms of vasovagal reactions are noticed by donors or staff, it is often too late to avoid a number of complications.

Vasovagal reactions are inherently a stress-related response associated with fear and a variety of changes in autonomic arousal (e.g., the activity of the autonomic nervous system of the body – not associated with any medical condition; this activity is responsible for the body's processes, including heart rate and perspiration). As such, the prediction of vasovagal reactions may be improved by assessing autonomic activity throughout donation, including the pre-donation period.

The aim of this study is to assess the effectiveness and feasibility of continuous physiological measures during the complete donation process of assisting in the early prediction of vasovagal and other adverse reactions.

### Who can participate?

Healthy adult volunteers who are giving their first whole blood or apheresis plasma donation at one of the participating donor centres.

### What does the study involve?

All participants will be given a monitor to place on their finger to measure their autonomic activity (e.g. heart rate, perspiration) after they register for their donation appointment until they completed their donation and are resting in the refreshments area. This monitor will be accompanied by a tablet on which the participants are asked to provide timestamps throughout their appointment (e.g., the needle was inserted, the needle was removed). They will also be asked to complete a short survey before their donation interview and a longer survey after their donation about their donation experience and any vasovagal symptoms they may have felt.

### What are the possible benefits and risks of participating?

There are minimal foreseeable risks associated with participating in the study, and the researchers don't expect the participant to experience any discomfort by taking part.

Participation in this study is completely voluntary, and there is no compensation for participating.

Where is the study run from?  
Macquarie University (Australia)

When is the study starting and how long is it expected to run for?  
February 2020 to May 2022

Who is funding the study?  
Australian Red Cross Lifeblood (Australia)

Who is the main contact?  
Dr Philippe Gilchrist  
philippe.gilchrist@mq.edu.au

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**ClinicalTrials.gov (NCT)**  
Nil known

**Protocol serial number**  
2020#09

## Study information

**Scientific Title**

Predicting vasovagal and other adverse events in Australian voluntary blood donors using a portable sensor that measures bio-signal data (PREVENT)

## **Acronym**

PREVENT

## **Study objectives**

Patterns of higher pre-donation skin conductance (SC) and sympathetic withdrawal (lower low frequency/high frequency [LF/HF] heart rate variability) will be associated with subsequent phlebotomist-recorded and self-reported symptoms of vasovagal reactions.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 08/07/2020, Australian Red Cross Lifeblood Ethics Committee (17 O'Riordan Street, Alexandria, NSW 2015, Australia; +61 (0)2 9234 2368; ethics@redcrossblood.org.au), ref: 2020#09

## **Study design**

Multicentre observational cross-sectional cohort study

## **Primary study design**

Observational

## **Study type(s)**

Diagnostic

## **Health condition(s) or problem(s) studied**

Vasovagal/pre faint symptoms in voluntary whole blood and apheresis plasma donors

## **Interventions**

Immediately after donor registration and providing consent, an ambulatory physiological monitor (e.g., the 'evu TPS' sensor; <https://evutps.com/en/>) will be attached to the participant's finger to monitor autonomic activity throughout donation, from the point of consent up until arrival at the refreshment area after donation, continuously measuring skin conductance response (and heart rate variability for exploratory analyses). The ambulatory monitor is a compact and lightweight portable sensor measuring bio-signal data from a small (i.e., ~3 cm x ~2 cm x ~2 cm) device attached to a finger. The bio-signal is sent in real time via Bluetooth to a tablet for later analysis. The device will be removed after completing the blood donation at the refreshment area.

## **Intervention Type**

Device

## **Phase**

Not Applicable

## **Primary outcome(s)**

1. Self-reported vasovagal symptoms measured using the Blood Donation Reactions Inventory (BDRI) at the haemoglobin test, needle insertion, first red cell return (plasma only), saline administration (plasma only), needle removal, and post-donation
2. Donation fear measured using a single fear question pre- and post-donation
3. Venipuncture pain measured using a self-report post-donation
4. Donor anxiety measured using the Blood Donor Anxiety Scale post-donation
5. Donor satisfaction with biometric sensor device measured using a self-report post-donation

### **Key secondary outcome(s)**

1. Staff-recorded vasovagal reactions measured using Australian Red Cross Lifeblood standard procedures at any point at the donation centre
2. Donor return measured using Australian Red Cross Lifeblood records at 6-month follow-up
3. Time taken to return measured using the donor's next attendance date as recorded by Australian Red Cross Lifeblood at 6-month follow up

### **Completion date**

16/05/2022

## **Eligibility**

### **Key inclusion criteria**

1. Eligible to donate as per the Australian Red Cross Lifeblood Guidelines for the Selection of Blood Donors
2. Donating whole blood or plasma for the first time
3. Willing and able to provide informed consent
4. Has a plasma or whole blood appointment at one of the participating donor centres (appointment made as a walk-in donor or scheduled appointment)

### **Participant type(s)**

Healthy volunteer

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **Total final enrolment**

522

### **Key exclusion criteria**

1. Unwilling or unable to provide informed consent
2. Lack of understanding of the English language necessary to complete questionnaires. This study will not use translation services or interpreters

3. Contacted for a research study in the last 6 months as per Lifeblood contact policy
4. Donors with therapeutic, autologous, sample or platelet donation appointments
5. Lifeblood employees

**Date of first enrolment**

23/11/2021

**Date of final enrolment**

16/05/2022

## **Locations**

**Countries of recruitment**

Australia

**Study participating centre**

**Australian Red Cross Lifeblood Brisbane Donor Centre**

288 Edward Street

Brisbane

Australia

4000

**Study participating centre**

**Australian Red Cross Lifeblood Chatswood Donor Centre**

Shop 62

Chatswood Interchange

436 Victoria Avenue

Chatswood

Australia

2067

**Study participating centre**

**Australian Red Cross Lifeblood Parramatta Donor Centre**

22-30 Oak Street

Rosehill

Australia

2142

## **Sponsor information**

**Organisation**

Australian Red Cross Lifeblood

**ROR**

<https://ror.org/00evjd729>

## **Funder(s)**

**Funder type**

Charity

**Funder Name**

Australian Red Cross Lifeblood

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

The data-sharing plans for the current study are unknown and will be made available at a later date

**IPD sharing plan summary**

Data sharing statement to be made available at a later date