A PROPOSAL TO STUDENT ENHANCEMENT AWARD REVIEW COMMITTEE

TITLE OF PROJECT: Evaluation of a novel respiratory intervention for use with whole blood donors to attenuate syncopal symptoms.

NAME OF APPLICANT: Jennifer M. Kowalsky, MS

STATUS: Undergraduate Graduate (MA/MS) Graduate (PhD) Medical

CAMPUS/LOCAL ADDRESS: 455 Richland Ave, Athens, OH, 45701

E-MAIL ADDRESS: jmkowalsky@gmail.com

DEPARTMENT: Psychology

EXPECTED GRADUATION DATE: May 2014

RE-SUBMISSION: YES (Original Submission Date ____ )

PROPOSAL CATEGORY (select one): Life/Biomedical Sciences Social/Behavioral Sciences Arts/Humanities Physical Sciences/Engineering

BUDGET: Total Request $5,627.50

(May not exceed $6,000)

FACULTY MENTOR INFORMATION:

NAME: Christopher R. France, PhD

E-MAIL ADDRESS: france@ohio.edu

CAMPUS ADDRESS: 251 Porter Hall, Ohio University

DEPARTMENT: Psychology

IRB AND IACUC APPROVAL:

To ensure that the University is in compliance with all federal regulations, complete the checklist below. Note: your proposal can be approved prior to IRB or IACUC approval, but funding will be withheld until notification of approval or exemption.

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<th>Policy #</th>
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<td>Human Subjects in Research (including surveys, interviews, educational interventions): Institutional Review Board (IRB) Approval #: Expiration Date:</td>
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<td>Animal Species: Institutional Animal Care &amp; Use Committee (IACUC) Approval #: Expiration Date:</td>
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SIGNATURES

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<th>Faculty Mentor's Signature</th>
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<tr>
<td>Name</td>
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<tr>
<td>Jennifer M Kowalsky, MS</td>
<td>Christopher R France, PhD</td>
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<tr>
<td>Dept/School Psychology</td>
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☐ Optional:

If selected for funding, I give permission to the Office of the Vice President for Research and Creative Activity to use my proposal as an example during training and workshop exercises.

Signature: Date: 1/24/2013
STUDENT ENHANCEMENT AWARD
APPLICATION CHECKLIST

Applicants must complete and sign the checklist. The checklist should be included as the second page of the application (following the cover page).

- [ ] Cover page
- [ ] Checklist
- [ ] Abstract*
- [ ] Resubmission Summary (For Re-submissions Only)*
- [ ] Project Narrative
- [ ] Glossary/Definition of Terms* (Not required)
- [ ] Bibliography (Not required)
- [ ] Presentation of Results
- [ ] Mentor's Endorsement
- [ ] Biographical information (Applicant(s) and key personnel)
- [ ] Budget and Justification
- [ ] Appended Materials/Multimedia Files
- [ ] Electronic copy of proposal

Sections marked with a bullet (*) identify text sections that should be written in language understandable by an informed layperson to assist the Committee in its review.

**Please Note: Proposals that do not conform to these format and section requirements will be returned without review by the committee.**

Applicant signature: 

[Signature]
Abstract

Used to save and improve lives, the demand for blood products is constant and critical shortages often occur. When a blood donor experiences syncopal symptoms (e.g., fainting, dizziness) during the donation process, they are significantly less likely to donate again. Intervention research to attenuate syncopal symptoms has focused primarily on the use of applied muscle tension (tensing the abdomen, buttocks and legs); however, this technique is not effective for all donors. A novel respiratory intervention (shallow, slower breathing) is emerging as effective for use with blood phobia patients to reduce syncopal symptoms, and has exciting potential for use with blood donors. The purpose of this study is to systematically evaluate the effectiveness of the respiratory intervention to attenuate or avert syncopal symptoms in blood donors, with the goal of improving their experience and ultimately increase donor retention, a concern for blood collection agencies globally. For this study, whole blood donors will be recruited at American Red Cross blood drives. The respiratory intervention will be compared against an applied muscle tension intervention and a no treatment control group to evaluate (1) differences in the frequency and severity of syncopal symptoms, and (2) changes during the donation process in cerebral oxygenation and respiration. This is the first study to evaluate the application of this respiratory intervention with blood donors, and will inform future research examining interventions designed to improve blood donors’ experience and retention.

An expert in the area of blood donor research, the PI’s mentor, Dr. Christopher France, has provided guidance regarding research design, understanding the changes that occur during blood donation, and use of the monitoring equipment for this study. Dr. France also facilitated the PI’s prior work with the American Red Cross, supporting the successful completion of two previous studies, and setting the foundation for success of the current study.
Project Narrative

BACKGROUND: Blood products are needed on a daily basis to respond to traumatic injury, treat patients with cancer, and maintain quality of life for individuals with certain chronic conditions such as sickle cell anemia. Ensuring sufficient availability of blood is a global health concern because the blood supply depends upon voluntary donors. As the demographic of the U.S. changes over the coming years, the “baby boom” generation will transition from being the most active blood donors to the most common recipients of blood products (Zou et al. 2008; Crawford et al. 2008). In order to effectively cope with this shift, research addressing donor recruitment and retention efforts is critical. This dissertation study will focus on improving blood donor retention by systematically evaluating a novel intervention designed to attenuate or avert the experience of syncopal symptoms, ultimately improving the donor’s experience.

Syncopal symptoms, such as fainting, dizziness or lightheadedness, are experienced when a healthy person’s mean arterial pressure (MAP) decreases below 60mmHg and cerebral oxygenation is no longer sufficient (Madsen et al. 1998; Szufladowicz et al. 2004). These symptoms have been noted in response a number of stimuli present in the blood donation context, including exposure to blood and needles, blood loss, and orthostatic stress (Ditto & France, 2006; Ruetz et al. 1967; Wieling et al. 2011). Syncopal symptoms occur in up to 12% of high risk donors (i.e., female first time donors; Eder et al. 2008). Although syncopal symptoms are transient and considered medically benign, they exhibit a robust adverse effect on donor retention for both first time and experienced donors (France et al. 2005).

Given the negative impact that syncopal symptoms have on donor return, interventions have been developed to attempt to mitigate these symptoms and ameliorate return. The intervention with the strongest research base is applied muscle tension (AMT). First developed
for use with patients with blood and injection phobia, AMT involves repeated isometric contraction of the large muscles in the abdomen, buttocks and legs, where tension is sustained for 5s followed by a 5s rest. This technique increases the return rate of blood from the lower extremities where it would otherwise pool (Groothuis et al. 2007). Continuous use of AMT has been demonstrated to have a significant salutary effect on cerebral oxygenation in female donors (Kowalsky et al. 2011), and more recently, AMT was demonstrated as effective when used on an as needed basis, in response to biofeedback, with novice blood donors (Kowalsky et al. in prep). Further, AMT has been shown to significantly decrease the frequency of subjective and phlebotomist-reported syncopal symptoms for female donors (Ditto et al. 2003). In general, however, the effectiveness of AMT on symptom reduction and donor retention appears to be limited to female donors (France et al. 2010; Ditto & France, 2006). Recently, persuasive evidence from the blood phobia literature suggests that a respiratory intervention may be an ideal alternative to AMT to mitigate or avert syncopal symptoms.

The primary role of respiration in mammals is to regulate oxygen and carbon dioxide within the blood and tissue (Feldman, in press). In humans, hyperventilation (an increase in respiration rate or depth; Meuret & Ritz, 2010) leads to hypocapnia (a significant decrease in carbon dioxide levels), causing cerebral blood vessels to constrict. This decreases oxygen availability in the brain (Cipolla, 2009). Although hyperventilation alone is insufficient to cause a complete faint, it is certainly a contributor, with healthy individuals experiencing a decrease of up to 50% of cerebral blood flow (Ritz et al. 2010). Respiratory interventions to return carbon dioxide levels to normal, involve modifying the timing and depth of the inhalations and exhalations through biofeedback. Previous research has used a structured respiratory intervention implementing shallow, slower inhalations resulting in amelioration of carbon dioxide levels from
a hypocapnic state to normal levels (Ritz et al. 2010). The novel application of this respiratory intervention to the blood donation context has exciting potential for improving blood donors’ experience, and is the basis of the following project aims: 1) Evaluate the effect of the respiratory intervention on syncopal symptoms among whole blood donors; and 2) Evaluate the effects of the respiratory intervention on changes over time in cerebral oxygenation, respiration rate and carbon dioxide levels among whole blood donors.

**METHODS:** Participation in this study will be limited to whole blood donors, 18 years of age or older, who have successfully passed the American Red Cross (ARC) health screen. Donors will be recruited on site at blood drives taking place in Athens, OH and Columbus, OH. The use of multiple sites allows for increased diversity of blood donors within the sample. The number of donors needed for this study was determined by conducting a power analysis, with G*Power v3.1.5., using cut offs standard to psychology (alpha = 0.05, and power = 0.80), and the effect size for the weaker intervention (AMT; $f = 0.30$; Kowalsky et al. in prep). This indicated that 40 donors per group will be required for all planned statistical analyses.

When donors first arrive to the blood drive, the ARC staff will conduct the donor registration and health screening, following their standard procedures. Donors who are interested in participating will receive both oral and written descriptions of the study, and written documentation of informed consent will be obtained. Donors who are not interested in participating in the study will continue the donation process with the ARC alone. Following receipt of informed consent to participate in the study, donors will complete a brief questionnaire assessing demographic information (see Appendix A1 for questionnaire). Next, donors will have a **SomaSensor** placed on their forehead, a **nasal canula** placed in their nose, and 3 minutes of baseline monitoring will occur. The SomaSensor allows for non-invasive monitoring of cerebral
oxygenation using a light emitting diode (LED) that produces light in the near-infrared spectrum (i.e., 730nm and 805nm) and two signal receivers that measure changes in the amount of light reflected by the red blood cells (INVOS-5100, Somanetics Corp., Troy, MI). The nasal canula (Capnostream 20, Oridion Capnography, Inc., Bedford, MA) is a small tube that monitors carbon dioxide and respiration rate continuously. Both the INVOS-5100 and Capnostream 20 are ambulatory monitors, and the stand upon which they will be attached has previously been used successfully for data collection at blood drives. Data will be acquired from the INVOS-5100 and Capnostream 20 to a portable laptop computer using a specifically designed Labview (National Instruments Corporation, Austin, TX) computer program.

Following acquisition of the 3 minutes of baseline data, donors will be randomly assigned to one of three groups: respiratory intervention based on biofeedback, AMT based on biofeedback, or no treatment control. The laptop computer that acquires the data also provides biofeedback consisting of cues to engage in the assigned intervention. These cues occur following decreases greater than 1% from baseline in carbon dioxide for the respiratory intervention, or cerebral oxygenation for the AMT intervention. Consistent with previous research, the respiratory intervention will consist of shallow, slower breathing, and the AMT intervention will consist of repeated, isometric tensing of the abdominals, buttocks and legs. Both the respiratory and AMT interventions are easy for donors to use at any point in the donation process. Following the group assignment, instructions specific to each group, will be provided (see Appendix B). Donors in the intervention groups will be oriented to the biofeedback program, and will have the opportunity to practice the intervention with the PI to ensure understanding, and proper implementation. Next, with the biofeedback program displayed on the laptop, in comfortable view for the donors, donors will donate blood according to ARC
procedures. Once each donor’s donation is complete, they will proceed to the post-donation canteen and the final 5 minutes of monitoring will occur. Upon completion, the monitoring equipment will be removed from the donor, and they will complete the Blood Donation Reactions Inventory (BDRI; France et al. 2008; Appendix A2). Finally, the donation duration and rating of presence or absence of syncopal symptoms will be obtained from the phlebotomist.

To address the primary aim of the study, first, it is hypothesized that donors using the respiratory intervention will be significantly less likely to experience syncopal symptoms as measured by phlebotomist ratings and donor’s self-report (BDRI), compared to the AMT and no treatment control groups. This will be evaluated using chi square tests and independent samples t-tests to identify group differences, and binary logistic regression to predict the likelihood of donors experiencing syncopal symptoms. For Aim 2, it is hypothesized that the use of the respiratory intervention will be associated with a significantly lower respiration rate and increased carbon dioxide levels compared to the AMT and no-treatment control groups. Cerebral oxygenation is hypothesized to be significantly higher for the respiratory intervention and AMT groups compared to the no treatment control group. This will be evaluated using a series of mixed model ANOVAs. All statistical analyses will be conducted using IBM SPSS v19 (IBM Corporation, Armonk, NY).

**SIGNIFICANCE & BROADER IMPACTS:** In light of the limitations of current interventions to improve the blood donor’s experience, this novel respiratory intervention is anticipated to positively impact the experience of a broader set of donors by decreasing syncopal symptoms. This research study contributes to the broader goal of improving blood donor retention, which is a concern for blood collection agencies globally and critical to the maintenance health of the U.S. population.
**Glossary**

**Biofeedback:** A computer-based program that increases awareness of physical changes (in this study, providing real time feedback regarding carbon dioxide to cue use of the respiratory intervention, and cerebral oxygenation to cue use of AMT) with the goal of returning to a normal state.

**Hyperventilation:** An increase in the rate or depth of the inhalation.

**Hypocapnia:** A decrease in levels of carbon dioxide in the blood.

**Nasal Canula:** A 1/8\(^{th}\) inch diameter tube placed comfortably in the outer half inch of the nose. This connects to the Capnostream 20 to collect carbon dioxide and respiration rate data.

**Orthostatic Stress:** The physiological challenge that the human body experiences when moving from a seated, with legs elevated, position to standing. This causes blood to shift from the core of the body down to the legs.

**Phlebotomist:** A staff member of the American Red Cross specifically responsible for conducting the blood draw.

**SomaSensor:** A 3 inch by 1.5 inch sensor with an LED and 2 signal receivers that is placed on the forehead. This connects to the INVOS-5100 to collect cerebral oxygenation data.
Bibliography


**Presentation of Results**

The results of this study will be presented at the American Psychosomatic Society’s Annual Meeting, taking place March 12-15, 2014, in San Francisco, CA. This society attracts researchers globally, providing an excellent opportunity to network and represent Ohio University. The focus of the American Psychosomatic Society on interdisciplinary research including biological, psychological, social and behavioral factors provides an ideal milieu for presenting this study with its focus on biological (i.e., carbon dioxide, respiration rate and cerebral oxygenation) and behavioral (i.e., the respiratory intervention and AMT) factors associated with the blood donation process. This research will also be presented at the American Association for Blood Banks’ Annual Meeting, taking place October 25-28, 2014, in Philadelphia, PA. Presenting the research findings at this conference allows for the dissemination of this research directly to the community (blood collection agencies) most invested in further evaluation and implementation of interventions to reduce syncopal symptoms in blood donors. This conference will also allow for a dialogue directly with blood collection agencies, further informing future research directions. Additionally, this research will be presented at the Annual Student Research and Creative Activity Expo hosted at Ohio University.

This study is expected to result in at least one publication, with a targeted submission to the peer-reviewed journal “Transfusion.” Transfusion is the premiere journal in the field of blood donation research, with an Impact Factor of 3.217.
Mentor's Letter Dedacted
Biographical Information
Jennifer M. Kowalsky
455 Richland Ave, Athens, OH, 45701
Electronic Mail: jmkowalsky@gmail.com
Phone Number: (740) 591-9197

EDUCATION
Ph.D. in Experimental Psychology, Ohio University (Athens, Ohio), expected May 2014
Dissertation: Evaluation of a novel respiratory intervention for use with whole blood donors to attenuate syncopal symptoms.
Advisor: Dr. Christopher France
Current GPA: 3.84

M.P.H. Ohio University (Athens, Ohio), expected May 2014
Advisor: Dr. Tania Basta

M.S. in Clinical Psychology, Ohio University (Athens, Ohio), 2011
Thesis: Variation in Cerebral Oxygenation during Whole Blood Donation: The Impact of Applied Muscle Tension
Advisor: Dr. Christopher France

B.A. (First Class Honors) in Psychology, University of Calgary (Calgary, Canada), 2007
Thesis: The Demise of Comparative Psychology
Advisor: Dr. Henderikus Stam

B.Sc. (with Distinction) in Primatology, University of Calgary (Calgary, Canada), 2007

PEER-REVIEWED PUBLICATIONS


**SELECTED PEER-REVIEWED PRESENTATIONS**  (Total = 21, 9 first author)


**RELEVANT GRADUATE LEVEL COURSE WORK**
- PSY6120: Advanced Experimental Psychology
- PSY6210: Psychophysiology
- PSY7111 & 7130: Multivariate Statistics I & II
- PSY7150: Causal Modeling
- PSY7210: Neuropsychology
- PSY7250: Health Psychology
- PSY8946: Social Endocrinology

**GRANTS and AWARDS**
- Department of Psychology, Competitive Research Grant (November 2012) $495.00
  - “Psychological and physiological changes in healthy adults to a novel, non-invasive blood and injection stimulus.”
- Graduate Student Senate Travel Award (March 2012) $500.00
- Thomas Creer Travel Award (May 2009 & 2010) $500.00

**TEACHING EXPERIENCE**
- **Instructor**, Spring 2013
  - Department of Psychology, Ohio University
  - Course: PSY2110: Statistics for the Behavioral Sciences
- **Instructor**, Fall 2012 (Overall Instructor Rating: 4.64/5.00)
  - Department of Psychology, Ohio University
  - Course: PSY2210: Physiological Psychology
- **Instructor**, Spring 2012 (Overall Instructor Rating: 4.22/5.00)
  - Department of Psychology, Ohio University
  - Course: PSY221: Statistics for the Behavioral Sciences

**SERVICE**
- Chair, 2012-2013
  - Graduate Student Senate Grant Review Committee, Ohio University
- Grant Reviewer, 2011-2012
  - Graduate Student Senate Grant Review Committee, Ohio University
- Annual Meeting Activities Coordinator, 2011-2012
  - Student Special Interest Group, Society of Behavioral Medicine
- Graduate Student Representative, 2010-2011
  - Clinical Health Psychology Graduate Student Admissions, Ohio University
- Graduate Student Representative, 2010-2011
  - Clinical Health Psychology Faculty Search, Ohio University
## Budget

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<td><strong>Section B: Travel</strong></td>
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<td><strong>Section D: Other</strong></td>
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**Conference Travel**

- American Psychosomatic Society Annual Meeting 2014, San Francisco, CA
  - Airfare (Round trip Columbus, OH to San Francisco, CA) | $500.00 |
  - Accommodation (3 nights) | $600.00 |
- **TOTAL** | $1,100.00 |

Requested from SEA | $5,627.50 |
Budget Justification

Nasal Canulae: The Capnostream 20 requires single use, disposal nasal canulae to measure carbon dioxide levels via non-dispersive infrared spectroscopy. Nasal canulae can be purchased at a discount in boxes of 100; as such, funds for 200 nasal canulae are being requested.

Photocopying: Costs for photocopying the questionnaires and consent forms, are based on the reduced, department rate available through the Psychology Department at Ohio University.

Mileage: Mileage is being requested to cover transportation costs of attending the blood drives for data collection. Based upon previous studies conducted by the PI, the average number of participants recruited per blood drive is 3, and with greater availability of blood drives, and diversity of donors, in Columbus, OH, it is anticipated that 2/3 of the data collection (80 donors) will take place in Columbus, OH and 1/3 (40 donors) in Athens, OH. As such, mileage (based on Ohio University’s standard of $0.55 per mile) for 27 round trips from Athens, OH to Columbus, OH is being requested.

Equipment not requiring funds: The remaining equipment for this study, including the capnometer (Capnostream 20, Oridion Capnography, Inc., Bedford, MA), cerebral oxygenation monitor and sensors (INVOS-5100 & SomaSensors, Somanetics Corp, Troy, MI), and portable laptop computer (Dell Latitude E6420) have already been purchased by Dr. France for use with previous studies conducted by the PI. Thus, funding is not being requested for these items. The biofeedback computer programs for carbon dioxide and cerebral oxygenation changes have already been created, therefore funds are not necessary to hire a computer programmer.
Appendix A1. Demographic Questionnaire.

1. Age: _________ years

2. Sex: □ Female   □ Male

3. Height: _____ feet ______ inches

4. Weight: _______________ pounds

5. Race: (check all that apply)
   □ African American or Black
   □ American Indian or Alaska Native
   □ Asian American
   □ European American or White or Caucasian
   □ Native Hawaiian or Other Pacific Islander
   □ Other _______________________________

6. Ethnicity:
   □ Hispanic/Latino(a)
   □ Nonhispanic

7. Please list anything you’ve had to drink in the past 2 hours, before you arrived at the blood drive.
   a) drink 1: ________ serving size of drink 1: ________
   b) drink 2: ________ serving size of drink 2: ________

8. Please list anything you’ve had to eat in the past 2 hours, before you arrived at the blood drive.
   a) food item 1: ________ serving size of item 1: ________
   b) food item 2: ________ serving size of item 2: ________

9. Have you consumed any nicotine in the past 2 hours, before you arrived at the blood drive?
   YES       NO

10. How many times have you donated whole blood before? ___________

11. How many times have you donated plasma before? _______________

12. How afraid are you of having blood drawn from your arm?
   □ Not at all afraid
   □ Somewhat afraid
   □ Moderately afraid
   □ Very afraid
   □ Extremely afraid
Appendix A2. Blood Donation Reactions Inventory.

Directions: Indicate the degree to which you experienced the following sensations during or after the simulated blood draw by circling a number between 0 ("not at all") and 5 ("to an extreme degree").

0 = not at all  
1 = to a slight degree  
2 = to a moderate degree  
3 = to a strong degree  
4 = to a very strong degree  
5 = to an extreme degree

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<tr>
<th>1. Faintness (as if about to faint or become unconscious)</th>
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<td>2. Dizziness</td>
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<tr>
<td>3. Weakness</td>
<td>0 1 2 3 4 5</td>
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<tr>
<td>4. Facial flush</td>
<td>0 1 2 3 4 5</td>
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<td>5. Visual disturbance (such as blurred vision or tunnel vision)</td>
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<tr>
<td>6. Difficulty hearing</td>
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<td>7. Lightheadedness</td>
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<td>8. Rapid or pounding heartbeat</td>
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<td>9. Sweating</td>
<td>0 1 2 3 4 5</td>
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<tr>
<td>10. Rapid or difficult breathing</td>
<td>0 1 2 3 4 5</td>
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<tr>
<td>11. Nausea or upset stomach</td>
<td>0 1 2 3 4 5</td>
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Appendix B. Script for group instructions.

No treatment control:

“During blood donation, donors may feel slightly lightheaded or dizzy, which is very similar to any lightheadedness you feel if you were to stand up too quickly. The same thing is occurring physically in both situations, with less oxygen being available in your brain. In this study, we will simply be monitoring the changes that occur in respiration and carbon dioxide while you donate blood.”

Applied Muscle Tension intervention based on biofeedback:

“During blood donation, donors may feel slightly lightheaded or dizzy, which is very similar to any lightheadedness you feel if you were to get up too quickly. The same thing is occurring physically in both situations, with less oxygen being available in your brain. In this study, we are testing to see what effect a muscle tensing technique has on oxygen in your brain. Applied muscle tension has been designed to make the donation process more pleasant and increase the amount of oxygen available in the brain. We would like you to do one simple thing at today’s donation: You will use applied muscle tensing during the donation process. Applied muscle tensing involves crossing your legs, and focusing on tensing the muscles in your abdomen, buttocks and thighs for 5 second intervals. Really focus on pressing your legs together. During your blood donation, and when you stand up, the amount of oxygen in your brain changes. This happens for everybody. From the moment the needle goes in, you will watch this laptop screen. Once the oxygen decreases to a certain point, the message on the screen will change from “rest” to “tense” to cue you to begin the muscle tensing exercise. The message will alternate between “tense” and “rest” every 5 seconds to keep the correct timing for you. You will continue to watch
the screen and use the muscle tensing technique as needed during the donation period and until 5 minutes have gone by in the post-donation canteen.”

Respiratory intervention based on biofeedback:

“During blood donation, donors may feel slightly lightheaded or dizzy, which is very similar to any lightheadedness you feel if you were to stand up too quickly. The same thing is occurring physically in both situations, with less oxygen being available in your brain. In this study, we are testing the effect of a respiratory intervention. This intervention has been designed to make the donation process more pleasant. You will use the respiration intervention on an as needed basis. From the moment the needle goes in, you will watch the laptop screen. In order to keep the amount of carbon dioxide within your breath as close as possible to your baseline value that we just recorded, you will time your breathing using the bar on the laptop screen. When the line appears in the bar, you will start the breathing technique. As the line in the bar moves towards the top, you will inhale, and as the line moves down, you will exhale. When the line disappears, you will breathe in the way that feels most natural to you. You will continue to watch the laptop screen until the end of the monitoring period, 5 minutes after being seated in the post-donation canteen.”