Variation in Cerebral Oxygenation during Whole Blood Donation: The Impact of Applied Muscle Tension

A thesis presented to
the faculty of
the College of Arts and Sciences of Ohio University

In partial fulfillment
of the requirements for the degree
Master of Science

Jennifer M. Kowalsky
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This thesis titled
Variation in Cerebral Oxygenation during Whole Blood Donation: The Impact of
Applied Muscle Tension

by

JENNIFER M. KOWALSKY

has been approved for
the Department of Psychology
and the College of Arts and Sciences by

Christopher R. France
Professor of Psychology

Benjamin M. Ogles
Dean, College of Arts and Sciences
Abstract

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Variation in Cerebral Oxygenation during Whole Blood Donation: The Impact of
Applied Muscle Tension

Director of Thesis: Christopher R. France

Background: Rhythmic tensing of the muscles of the core and lower extremities (applied muscle tension, or AMT) has been associated with decreased rates and severity of whole blood donor reactions. A possible mechanism by which this occurs is via increased availability of oxygen in the brain. The purpose of this study was to examine the effects of applied muscle tensing on changes in cerebral oxygenation during blood donation.

Methods: Seventy-two female blood donors were recruited at mobile blood drives in the American Red Cross Blood Services – Central Ohio Region. Participants were randomly assigned to engage in either AMT during donation, or a distraction-control condition in which donors engaged in a repeated, gentle foot flexion movement. Cerebral oxygenation was monitored throughout the donation process using near infrared spectroscopy.

Results: Participants who engaged in applied muscle tensing were shown to have attenuated decreases in cerebral oxygenation across the three intervals of the blood draw relative to the distraction manipulation, $F(1, 70) = 8.144, p = 0.006$. Whereas cerebral oxygenation decreased 1.42% (SD = 2.09) for those in the distraction-control group, oxygenation levels increased 0.13% (SD = 2.56) in the applied muscle tension group.
**Conclusion:** Applied muscle tension is associated with an attenuated decrease in cerebral oxygenation compared to a distraction-control group. This suggests that the salutary effect of AMT may be in part due to an increase in oxygen available to the brain.

Approved: _____________________________________________________________

Christopher R. France

Professor of Psychology
Acknowledgements

I am very grateful to all those who were involved with this thesis: Drs. France and France for their support throughout the data collection process and during drafts of the following document; my family for remaining excited about this project throughout all stages of its development; and my friends for helping me maintain perspective. I greatly appreciate the cooperation and collaboration of the donor recruitment representatives and phlebotomists of the American Red Cross Blood Services, Central Ohio Region. Finally, a special note of appreciation is due to the donors who participated in this project.
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Introduction

Whether or not a blood donor returns to donate again, is influenced in part by their experience while donating blood. For example, mild donor complications as benign as presyncopal symptoms (e.g., feeling faint, dizzy, or lightheaded) have been shown to decrease the likelihood of donor return for both novice and experienced donors (Eder et al. 2008; France, Rader and Carlson, 2005; Notari et al. 2009; Rader, France and Carlson, 2009). The frequency of occurrence of presyncopal reactions varies depending on a variety of donor characteristics, including pre-donation anxiety (Ditto and France, 2006a; Labus, France and Taylor, 2000; Ruetz et al. 1967; Meade, France and Peterson, 1996), prior donation history (Eder et al. 2008; Wiltbank et al. 2008; Kamel et al. 2010; France et al. 2004), and total blood volume (Wiltbank et al. 2008; Kamel et al. 2010); however, in young, novice donors presyncopal symptoms may occur in up to 12% of all donations (Eder et al. 2008; France, Rader and Carlson, 2005; Wiltbank et al. 2008; Trouern-Trend et al. 1999; Newman, 2003). Despite the relatively common occurrence of presyncopal symptoms, a clear understanding of the physiological changes that accompany such reactions has not yet been attained.

The maintenance of appropriate blood pressure is regulated by a complex, dynamic system; however, once mean perfusion pressure drops below 60mmHg the brain is no longer receiving sufficient oxygen and presyncopal symptoms are experienced (Madsen et al. 1998; Szufladowicz et al. 2004). Threats to blood pressure occur at multiple points in the donation process, including: 1) elevated anxiety for some donors in anticipation of the phlebotomy leading to autonomic nervous system dysregulation (Ditto
and France, 2006a; Labus, France and Taylor, 2000; Ruetz et al. 1967); 2) reduced vascular pressure related to decreases in total blood volume; and 3) orthostatic stress associated with standing following an extended period in a semi-reclined or supine position in the donation cot (Grasser et al. 2009; Goswami et al. 2009). The earliest studies evaluating changes in blood pressure prior to and following blood donation noted a significant decrease in arterial blood pressure (Brown and McCormack, 1942; Poles and Boycott, 1942; Graham, Kabler and Lunsford, 1961). However, more recent evaluations of blood pressure changes experienced by donors have highlighted that blood pressure may remain stable, or in some cases, increase from pre-donation values following blood donation (Riddez et al. 1997; Zollei et al. 2004). Most recently, Ditto and colleagues (2009) used ambulatory monitoring procedures to observe cardiovascular changes during actual donation. Results indicated that, on average, heart rate gradually decreased throughout the donation process while total peripheral resistance initially decreased and then recovered in the latter half of the donation (Ditto, Byrne and Holly, 2009). It should be noted, however, that cardiovascular responses are likely to show significantly inter-donor variability, hence average patterns of responsivity may not adequately capture individual donor changes.

Despite the varied physiological and psychological challenges that may be present during the donation process, most donors appear to effectively adapt to the demands and do not report adverse reactions during or after donation. However, because some donors may be less effective than others at preventing reactions, strategies such as applied muscle tension (AMT) have been applied in the donation context in an attempt to reduce
symptoms and ultimately improve the donation experience and likelihood of donor return. Applied muscle tension (AMT) consists of rhythmic, isometric contractions of the muscles of the core and lower extremities (Ost, Fellenius and Sterner, 1991; Bodycoat et al. 2000). It has been suggested that the rhythmic tensing employed in AMT may help to avert reactions by increasing venous return (Groothuis et al. 2007) and subsequently increase cerebral blood flow and oxygenation (Krediet et al. 2005; France, France and Patterson, 2006; Foulds et al. 1990). First developed as an intervention for use with blood, injection, injury phobia patients (Ost, Fellenius and Sterner, 1991), AMT has since been used with patients diagnosed with orthostatic hypotension (Krediet et al. 2005; Krediet et al. 2002; Krediet et al. 2007) and within the blood donation context (Ditto and France, 2006a; Ditto et al. 2003a; Ditto et al. 2003b; Ditto and France, 2006b; Ditto et al. 2007; Ditto et al. 2009; France et al. 2010). In general, studies that have evaluated the use of AMT as an intervention for blood donors have reported fewer adverse reactions, as indicated by phlebotomist donor code ratings and cot-reclining behavior as well as donor self-report. Further, individuals who engage in AMT during blood donation have been reported to be more likely to provide a subsequent donation (Ditto et al. 2007). Although it has been suggested that AMT may help to offset the risk of presyncopal and syncopal reactions in blood donors by enhancing venous return, and thereby maintaining adequate blood pressure and cerebral oxygenation, no studies to date have directly examined this hypothesis.

A few studies have examined changes in cerebral oxygenation during blood loss. Not surprisingly, regional cerebral oxygenation has been shown to decrease in direct
proportion to amount of blood withdrawn (Menke, Stocker and Sibrowski, 2004; Torella et al. 2002a; Torella et al. 2002b; Colier et al. 1997; Torella, Haynes and McCollum, 2002) with a 6% reduction in total blood volume being associated with a 1% decrease in cerebral oxygenation (Torella et al. 2002a). Interestingly, AMT has been shown to produce an 1% increase in regional cerebral oxygenation when practiced outside of the donation context (France, France and Patterson, 2006). Therefore it is reasonable to hypothesize that engaging in AMT during blood donation may help to compensate for the decreases in cerebral oxygenation that naturally accompany blood loss. Accordingly, the present study was designed to examine changes in cerebral oxygenation during blood donation among donors who were randomly assigned to engage in either AMT or a distraction control procedure (i.e., gentle toe pointing).
Materials and Methods

Participants

Seventy-five female, whole-blood donors were recruited at mobile drives in Athens, OH and Columbus, OH between December 2009 and March 2010. Recruitment was restricted to female donors who, on average, have lower blood volumes and therefore may show the largest changes in cerebral oxygenation in response to blood draw and AMT. Data from 3 donors were excluded due to incomplete oxygenation data (n=2) or being unable to provide a full donation (n=1). The final sample consisted of 72 participants between 18 and 70 years of age (mean = 38.9; SD = 16.0), and was primarily Caucasian (93%). The number of prior donations ranged from 0-51 (median = 6).

NIRS Monitor – INVOS 5100

The INVOS-5100 (Somanetics Corp., Troy, MI) uses in vivo optical spectroscopy (INVOS) technology to measure changes in regional cerebral oxygen saturation (cerebral oxygenation). Non-invasive measurement is provided by a “SomaSensor” containing an LED light source and two return signal detectors, which is placed on the forehead. The amount of light reflected by oxygenated and deoxygenated hemoglobin is measured at two sites, 3 and 4cm from the LED, allowing for the mathematical subtraction of the influence of the external layers of the cranium, i.e. skull, skin, and meninges (Wahr et al. 1996). This technology has been demonstrated as valid for monitoring changes in cerebral oxygenation during blood loss (Menke, Stocker and Sibrowski, 2004; Torella et al. 2002a; Torella et al. 2002b; Colier et al. 1997; Torella, Haynes and McCollum, 2002), and has been shown to be sensitive to changes in cerebral oxygenation elicited by AMT.
PocketPC – iPAQ 111

The iPAQ 111 PocketPC (Hewlett-Packard Development Company, L.P., Palo Alto, CA) is a touch screen handheld device that can be used to deliver questionnaire items at pre-determined intervals. In the present study this device was set to administer a brief questionnaire, at 3-min intervals, regarding donor presyncopal symptoms, anxiety, and location in the donation process (i.e., following health screening, donor cot, post-donation canteen). Pendragon Forms 5.1 software (Pendragon Software Corporation, Libertyville, IL) was used to develop the questionnaire.

Demographic and Pre-Donation Information

A brief questionnaire was used to assess donor demographic characteristics (i.e. age, sex, height, weight, race, ethnicity, and education) and number of prior donations of blood or plasma.

Study Protocol

After signing in and reviewing the American Red Cross consent form to donate blood, female donors were approached and asked to participate in the study. Those who expressed an interest were provided details about the study and invited to meet with the researcher after their donation health screen. For those who completed the health screen and were cleared to donate, the primary investigator reviewed the study consent form and answered any questions. Those who agreed to participate were randomly assigned to one of two study groups using an online random number generator. Next, the INVOS SomaSensor was placed on the left quadrant of their forehead. NIRS monitoring began at
this point and continued until the end of the study.

Following placement of the sensor, participants were provided with the PocketPC and went through a practice questionnaire to acquaint them with the device. They were then informed of their group assignment and asked to briefly practice the assigned movement while the researcher supervised and provided feedback as needed. Participants assigned to the AMT group were instructed to cross their legs and tense their thighs, buttocks, and stomach muscles for 5s, then rest for 5s, beginning when the needle was inserted and continuing until just before they left the donation chair. The distraction-control group was instructed to gently point one foot for 5s, then switch and point the other foot for 5s. As with the AMT group, they were instructed to begin this movement when the needle was inserted, and then continue until they were cleared to leave the donation chair. Following the instructions, all participants were provided a small box that contained a light that flashed every 5s and instructed to use this as a cue to time their exercise.

When the phlebotomist was ready for them, participants proceeded to the donation chair and donated blood according to standard American Red Cross procedures. The researcher unobtrusively observed participants during the donation process and noted whether they engaged in their assigned exercise, including if the correct timing (i.e., 5s intervals) was used, if the intensity of the exercise was sufficient (e.g., not too vigorous if in the distraction-control condition), and whether the exercise was consistent throughout the expected time (i.e., from insertion of the needle until cleared to leave the donation chair). If a participant appeared to stop the exercise, the researcher prompted them to
continue. Following the blood draw, participants proceeded to a post-donation canteen where data collection continued for 5 minutes. Finally, the recording sensor was removed and participants were thanked for their participation and provided a written description of the study and its purpose.

The American Red Cross Blood Services and Ohio University IRB Committees approved the study protocol.

**Statistical Analyses**

All statistical analyses were conducted using computer software (PASW Version 18.0, SPSS, Inc., Chicago, IL). Because blood donation draw times vary across individuals, cerebral oxygenation data were averaged into three equal periods for all participants (i.e., first, second, and third interval of their donation). Results of all analyses were considered significant when p<0.05, and effect sizes are reported as partial eta-squared ($\eta_p^2$) for ANOVAs and Cohen’s d for t-tests.
Results

Demographic Characteristics

Demographic characteristics of the two groups are provided in Table 1. Independent samples t-tests revealed no significant differences between the two groups with regard to age, body mass index, number of previous blood donations, and total pre-donation liquid consumed (all $p > 0.10$). Adherence to group condition instructions was monitored through observation, and all participants were noted to have engaged in the appropriate exercise for an acceptable minimum amount of time (i.e., at least 75% of the time).

Cerebral Oxygenation

As can be seen in Figure 1, results of a 2 Group (AMT, distraction-control) x 3 Interval (first, second, third) mixed model ANOVA conducted on baseline to donation interval change scores revealed a significant difference in regional cerebral oxygenation between the AMT and distraction-control conditions during blood donation, $F(1, 70) = 8.144, p = .006, \eta^2_p = .104$. Similar results were obtained when an equivalent ANCOVA was conducted controlling for body mass index and number of prior donations, $F(1, 68) = 5.889, p=.018, \eta^2_p = .080$. Follow-up analyses revealed that the observed group differences in regional cerebral oxygenation were significant during each interval of the donation process [i.e., first third $t(70) = 2.44, p = 0.01, d = 0.57$; second third $t(70) = 3.00, p = 0.004, d = 0.70$; and last third $t(70) = 2.82, p = 0.006, d = 0.66$]. Overall, relative to pre-donation, during the final interval of the blood draw donors in the control
Table 1. Characteristics of donors in the applied muscle tension and distraction control groups.

<table>
<thead>
<tr>
<th>Variable</th>
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<th>Applied Muscle Tension (n=34)</th>
<th>Distraction Control (n=38)</th>
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<tr>
<td>Age</td>
<td>years</td>
<td>37.2 (15.5)</td>
<td>40.5 (16.4)</td>
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<tr>
<td>Body Mass Index</td>
<td>kg/m$^2$</td>
<td>26.1 (5.5)</td>
<td>28.5 (6.8)</td>
</tr>
<tr>
<td>Prior whole blood donations</td>
<td>count</td>
<td>9 (12)</td>
<td>9 (8)</td>
</tr>
<tr>
<td>Pre-donation hydration</td>
<td>ml</td>
<td>718 (390)</td>
<td>638 (409)</td>
</tr>
</tbody>
</table>
Figure 1. Average (+/- SEM) change in cerebral oxygenation during whole blood donation for donors engaging in lower body applied muscle tension (AMT) or a distraction-control involving gentle foot-flexion.
condition showed a mean cerebral oxygenation decrease of 1.42% (SD = 2.09) whereas donors in the AMT condition showed a mean increase of 0.13% (SD = 2.56).

The group difference in mean cerebral oxygenation change from baseline to post-donation canteen (AMT Mean = -3.87%, SD = 2.34; distraction-control Mean = -4.27%, SD = 3.59) was not significant, t(70) = 0.55, p = 0.58, d = 0.13.
Discussion

The results of this study confirm that engaging in applied muscle tension of the lower body significantly attenuates the decrease in cerebral oxygen associated with blood donation. Further, this salutary effect of AMT remained after controlling for individuals differences in donor size and prior donation experience. It is worth noting that the beneficial effect of AMT was present from the first interval and was maintained throughout the donation. This is important as it has been reported that decreases in cerebral oxygenation, as measured using near infrared spectroscopy, precede the experience of presyncopal symptoms by 1.3 minutes and syncope by 3.3 minutes (Szufladowicz et al. 2004). This temporal lag indicates that AMT is likely to be viable as an intervention that blood donors can use to avert syncope should they begin to experience presyncopal symptoms.

A second important finding in the present study is that the oxygenation benefits of AMT appear to be short-lived and dependent upon ongoing muscle tensing. Specifically, when donors from both groups were seated in the post-donation canteen, and no longer engaging in their prescribed exercise, they exhibited a notable decrease in cerebral oxygenation of approximately 4% relative to pre-donation baseline. Although this change is slightly larger than the 1-3% decreases noted in prior blood loss studies (Menke, Stocker and Sibrowski, 2004; Torella et al. 2002a; Torella et al. 2002b; Torella, Haynes, and McCollum, 2002), there are several methodological differences between the present study and previous studies that likely account for the larger changes observed in the present sample. First, the present study was restricted to female donors who typically
experience a greater percentage of total blood volume loss during donation than men due to differences in body size. Second, unlike previous studies which measured post-donation cerebral oxygenation for ten minutes, we restricted our readings to the first five minutes because this is the period of greatest vulnerability to presyncopal reactions (Kamel et al. 2010). Accordingly, previous studies may have observed smaller cerebral oxygenation changes due to a greater opportunity for physiological adjustments to the recent blood loss. Finally, because different studies use different monitoring equipment the computed estimates of cerebral oxygenation may not be directly comparable.

Regardless of the absolute change in cerebral oxygenation, the present findings indicate that future studies should evaluate the potential benefit of instructing blood donors to either continue AMT into the post-donation interval, or, perhaps more realistically, to encourage them to apply AMT if they begin to experience presyncopal symptoms.

It should be noted that because the current sample was limited to female and largely Caucasian participants the observed findings may not generalize to all donors. For example, it has been suggested that, relative to men, women may have more difficulty adapting to acute blood loss due to the physiological differences such as smaller, less distensible hearts and lower resting blood pressures (Ludwig et al. 2001; Fu et al. 2005; Fu and Levine, 2010). Thus men and women may show differential responses to AMT both in terms of cerebral oxygenation responses and prevention of presyncopal and syncopal reactions. Similarly, there is significant evidence of racial differences in risk for blood donation syncope and this may differ as a function of immediate versus delayed reactions (Wiltbank et al. 2008; Kamel et al. 2010).
In sum, AMT attenuates blood donation-related decreases in cerebral oxygenation in women with a range of prior donation experience and this effect is dependent upon active engagement in muscle tensing to obtain maximal benefit. Future research should evaluate changes in cerebral oxygenation in diverse samples of donors who are encouraged to engage in AMT at the first signs of presyncopal symptoms.
References


Appendix A: Supplemental Text

Although the original hypotheses included that the relationship between applied muscle tensing and reduced presyncopal symptoms as measured by the BDRI was mediated by an attenuated decrease in cerebral oxygenation, the meditational analysis for this hypothesis was unable to be conducted. As illustrated in Figure 2, the distribution of BDRI ratings were positively skewed (skewness = 2.64), and lacked the necessary variability to be included in the analyses. Because of the floor effect that was present in this variable, with 63% of the sample reporting not having experienced any presyncopal symptoms during donation (i.e., range of possible scores was 4-20; mean was 4.60), analyses controlling for distributions which violate the assumption of normality could not be used. Similarly, measures of anxiety could not be incorporated into the analyses due to lack of variability. As can be seen in Figure 3, predonation anxiety was positively skewed (skewness = 1.87), with 82% of the sample reporting an anxiety level of 2 or less (range = 0 “not at all” to 10 “to an extreme degree”; mean = 1.53).

The unanticipated lack of variability in anxiety and presyncopal symptoms can be accounted for by demographic characteristics of this sample. Given that the sample was comprised of primarily older, experienced donors, with an average of nine self-reported previous donations (see Table 1), the likelihood of them experiencing an adverse reaction is decreased compared to younger, novice donors.

Because the data were collected at two separate locations (i.e., Athens and Columbus, Ohio), a mixed model ANCOVA was conducted to evaluate the effect of drive location on the results. As detailed in Table 2, no significant changes to the model
were detected with the addition of drive location and its interaction with the condition to which participants were assigned.
Figure 2. Distribution of mean Blood Donation Reactions Inventory (BDRI) ratings for all participants during blood donation.
Figure 3. Distribution of pre-donation anxiety ratings for all participants.
Table 2. Mixed model ANCOVA predicting changes in cerebral oxygenation.

<table>
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<tr>
<th></th>
<th>df</th>
<th>F</th>
<th>p</th>
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<td>5.99</td>
<td>0.02</td>
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<tr>
<td>Group</td>
<td>1, 64</td>
<td>4.59</td>
<td>0.04</td>
</tr>
<tr>
<td>Drive location</td>
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<td>1.69</td>
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<td>Group*Drive location</td>
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<td>0.04</td>
<td>0.85</td>
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<tr>
<td>Body Mass Index</td>
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<td>9.12</td>
<td>0.00</td>
</tr>
<tr>
<td>Pre-donation hydration</td>
<td>1, 64</td>
<td>0.12</td>
<td>0.73</td>
</tr>
<tr>
<td>Prior blood donations</td>
<td>1, 64</td>
<td>6.03</td>
<td>0.02</td>
</tr>
</tbody>
</table>
Appendix B: Study Forms and Measures

B.1. Voluntary Informed Consent Form

The Effect of Applied Muscle Tension on Cerebral Oxygenation during Blood Donation.

Mary Ellen Wissel, M.D.                      Christopher France, Ph.D.
American Red Cross Blood Services            Department of Psychology
Central Ohio Region                           Ohio University
995 East Broad Street                         245 Porter Hall
Columbus OH 43205                            Athens OH 45701
wisselm@usa.redcross.org                      france@ohio.edu
(614) 253-2740 ext. 2236                   (740) 593-1079

You are being asked to participate in research. For you to be able to decide whether you want to participate in this project, you should understand what the project is about, as well as the possible risks and benefits in order to make an informed decision. This process is known as informed consent. This form describes the purpose, procedures, possible benefits, and risks. It also explains how your personal information will be used and protected. Once you have read this form and your questions about the study are answered, you will be asked to sign it. This will allow your participation in this study. You should receive a copy of this document to take with you.

EXPLANATION OF STUDY

PURPOSE
This study will evaluate the effect of lower body muscle tensing on changes in blood-oxygen levels in the brain (i.e., cerebral oxygenation) during blood donation. Participation in this study is limited to females who are at least 18 years old, and have passed the health screen of the American Red Cross.

PROCEDURE
1. Before you donate blood today, a researcher will place a small sensor on your forehead to monitor changes in blood-oxygen levels in your brain. The sensor has two small light-emitting diodes (LEDs) and a detector that records the amount of light reflected back by your red blood cells. The sensor will be attached to your forehead much like a large Band-aid.
2. We will assign an ID code to keep your study information confidential, and ask you to complete a short series of questions about yourself and what you ate and drank prior to coming to the donation site, how you are currently feeling, and ratings of fears that you may have in medical settings. These questions will take no more than 10 minutes to complete.
3. You will then be randomly assigned to one of two exercise techniques.
4. You will also receive a handheld device (i.e., a Palm Pilot) to answer some brief questions every three minutes about how you are feeling during the donation.
5. Five minutes after you complete your donation the sensor on your forehead will be removed.
6. Finally, the researcher will collect information concerning your donation reactions (if any) and the amount of time that it took for your donation from the American Red Cross staff who obtained your donation.

**RISKS AND DISCOMFORTS**

You will be exposed to minimal risks or discomforts as a result of participating in this study. The risks are no greater than the risks already associated with blood donation. You will be asked to provide some basic demographic information (but not any personal identifying information), and learn about some information designed to enhance the donation experience in blood donors. Participation in the study is completely voluntary, and you may discontinue the study at any time.

**BENEFITS**

You may benefit by receiving information that is intended to enhance the overall blood donation experience and that may lessen the occurrence of reactions. Your participation in this study may also benefit society by helping us to develop methods to encourage donors to give blood again in the future.

**ALTERNATIVES TO PARTICIPATION**

It is not necessary for you to participate in the study if you want to donate blood. You can donate at this blood drive even if you do not take part in the study.

**CONFIDENTIALITY AND RECORDS**

We will keep confidential any information that we obtain from this study. All study information will be recorded anonymously, using only a participant ID code, and will be kept in a locked filing cabinet and a computer in a secure laboratory at Ohio University. Information provided by the American Red Cross will be the phlebotomist’s rating of donor reaction, and duration of blood draw. This information will be obtained directly from the phlebotomist immediately following the blood draw, so no future access of your information will be needed from the American Red Cross. Further, in any publications resulting from this project, data will be reported as an aggregate and no individual participants will be identified. You will not be identified or identifiable in any public reports about the study. Information from the study will not be given to anyone except the research staff without your permission. Additionally, while every effort will be made
to keep your study-related information confidential, there may be circumstances where this information must be shared with: (1) Federal agencies (for example the Office of Human Research Protections, whose responsibility is to protect human subjects in research); and/or (2) representatives of Ohio University, including the Institutional Review Board (a committee that oversees the research at Ohio University).

**COMPENSATION/COSTS**

If you have volunteered to participate in this study as a member of Ohio University’s Psychology Department research pool, then you will already have received 3 credits for your appearance at the blood drive today.

**IN CASE OF INJURY**

In the event that you suffer physical injury as a direct result of your participation in this research activity, the American Red Cross will assume responsibility for making immediate medical care available to you. This care will be provided without charge if you notify Dr. Wissel at 614-253-2740 Ext. 2257 within fifteen days of the date of the injury or appearance of symptoms, and consent to the care offered. There is no provision for monetary compensation to you at the expense of American Red Cross for such things as lost wages, disability, injury or discomfort resulting to you from such physical injury. Further information concerning treatment and payment of medical expenses in the event of an injury may be obtained from Dr. Wissel at 614-253-2740 ext. 2257.

**PARTICIPANTS’ RIGHTS**

Your decision whether or not to take part in this study is voluntary. It will not change your future relationship with Ohio University or the American Red Cross in any way. You are free to end your participation at any time without harm to your rights or your future relationship with Ohio University or the American Red Cross.

**CONTACT INFORMATION**

If you have any questions regarding this study, please do not hesitate to ask the experimenter. You may also contact Dr. Christopher France either by telephone (740-593-1079) or email (france@ohio.edu). If you have any questions regarding your rights as a research participant, please contact Jo Ellen Sherow, Director of Research Compliance, Ohio University, (740) 593-0664, or Nicole Dungee, IRB Administrator, American Red Cross, 301-738-0630.

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**CONSENT AUTHORIZATION**

By signing below, you are agreeing that:

- you have read this consent form (or it has been read to you) and have been given the opportunity to ask questions
- known risks to you have been explained to your satisfaction
- you understand Ohio University has no policy or plan to pay for any injuries you might receive as a result of participating in this research protocol
- you are 18 years of age or older
- your participation in this research is given voluntarily
- you may change your mind and stop participation at any time without penalty or loss of any benefits to which you may otherwise be entitled.

____________________________________  __________________
Signature                  Date

____________________________________
Printed or Typed Name
B.2. Recruitment Materials: Study Information for the Research Participation

System at Ohio University.

Study Name: Donate Blood with the Red Cross!

Abstract: This study evaluates the effect of a simple muscle exercise on the proportion of oxygen in the blood flowing in your brain during blood donation.

Description: In this study you will go through the standard introduction, health screen and blood donation process with the American Red Cross. Following approval of the Red Cross to donate blood, you will review the consent form with the researcher to participate in the study. Next, you will have a sensor placed on your forehead to measure changes in cerebral oxygenation (i.e. the proportion of oxygen in the blood flowing in your brain). The sensor shines an LED light on your forehead to measure changes in blood flow – you don’t feel anything. All you have to do is place the sensor on your forehead (like putting a sticker or a bandaid on your forehead). You will then complete a brief set of questionnaires, and will be assigned to one of two exercises to do during blood donation.

Sign-Up Restrictions: None

Prescreen Restrictions: Yes: must be female and must be at least 18 years of age.

Duration: 180 minutes

Credits: 3 credits

Researchers: Christopher France, Jennifer Kowalsky

Participant Sign-Up Deadline: 24 hours before the study is to occur
B.3. Demographic and Pre-donation Information

Sex: male / female

Age (years):_____

Height (in feet and inches):__________  Weight (in pounds): ______

Race: Please choose a category (or categories) that best describes your racial background:

_____ American Indian or Alaskan native
_____ Asian
_____ Native Hawaiian or Other Pacific Islander
_____ Black or African American
_____ White
_____ Other (please describe:_________________)

Ethnicity: Please choose a category that best describes your ethnicity:

_____ Hispanic or Latino
_____ Not Hispanic or Latino

Highest Level of Education Completed:

_____ Professional or Graduate School
_____ College graduate
_____ 1-4 years of college
_____ High school graduate
_____ grades 10-11
_____ grades 7-10
_____ Less than 7 years of school

Please list anything you’ve had to drink in the past 4 hours, before you arrived at the donation clinic:

a) drink 1: ___________ serving size of drink 1: ___________

b) drink 2: ___________ serving size of drink 2: ___________

c) drink 3: ___________ serving size of drink 3: ___________

d) other drinks: __________________________________

Please list anything you’ve eaten in the past 4 hours, before you arrived at the donation clinic:

a) food item 1: ___________ serving size of food item 1: ___________

b) food item 2: ___________ serving size of food item 2: ___________

c) food item 3: ___________ serving size of food item 3: ___________

d) other food: __________________________________

Number of times you have previously donated blood (not including today): _______
Number of times you have previously donated double-red blood cells: ___________
Number of times you have donated plasma: ___________
B.4. Blood Donation Reactions Inventory

Indicate the degree to which you experienced the following sensations at the blood donation clinic today 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

<table>
<thead>
<tr>
<th>1. Faintness (as if about to faint or become unconscious)</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Dizziness</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>3. Weakness</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>4. Facial flush</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>5. Visual disturbance (such as blurred vision or tunnel vision)</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>6. Difficulty hearing</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>7. Lightheadedness</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>8. Rapid or pounding heartbeat</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>9. Sweating</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>10. Rapid or difficult breathing</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>11. Nausea or upset stomach</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>
B.5. iPAQ 111 Questionnaires

Indicate the degree to which you are experiencing the following sensations by tapping a number between 0 (not at all) and 4 (to an extreme degree).

1. Faintness
2. Dizziness
3. Weakness
4. Lightheadedness

Indicate how anxious you are feeling by moving the vertical bar between 0 (not at all) and 10 (to an extreme degree).

Indicate where you are in the donation process by selecting one of the options below
- Predonation
- Donation chair
- Postdonation