

DISPOSITION FORM

For use of this form, see AR 340-15; the proponent agency is TAGO.

REFERENCE OR OFFICE SYMBOL SGRD-UE-MEP	SUBJECT Addendum to Protocol, "Blood Volume Expansion and Exercise Performance in the Heat"
TO THRU Dir, Mil Erg Div <i>lwa</i> Commander, USARIEM	FROM C, Physiol Br Mil Erg Div DATE 29 November 1985 CMT1 Dr. Sawka/phd/5141

1. Reference letter, SGRD-HR, dtd 19 Nov 85, subject: Protocol Entitled "Blood Volume Expansion and Exercise Performance in the Heat", HURC #155, Michael Sawka, Ph.D., Responsible Investigator (Log No. A-3527), (copy enclosed).
2. The consent form of the addendum to the subject protocol has been modified to indicate:
 - a. The blood drawn for reinfusion will be tested for HTLV III antibody and that individuals with positive results will be referred to an appropriate medical screening facility.
 - b. That all subjects will be reinfused with blood. Therefore, the question if the non-reinfused blood will be used for other research is no longer pertinent.
3. If any other changes are required, I will be happy to comply.

Michael N. Sawka for MNS

MICHAEL N. SAWKA, Ph.D.
Chief, Physiology Branch

2 Encl

1. Ltr dtd 19 Nov 85
2. Revised Consent Form



DEPARTMENT OF THE ARMY
U S ARMY RESEARCH INSTITUTE OF ENVIRONMENTAL MEDICINE
NATICK, MASSACHUSETTS 01760

SGRD-UEZ

³¹/₁₅ October 1985

SUBJECT: Protocol Entitled "Blood Volume Expansion and Exercise Performance in the Heat," HURC #155, Michael Sawka, Ph.D., Responsible Investigator

Commander
U.S. Army Medical Research & Development Command
ATTN: SGRD-HR/LTC Clyde
Fort Detrick
Frederick, MD 21701-5012

1. The local Human Use Review Committee has reviewed and approved this addendum to subject protocol. Their Decisions and Recommendations are enclosed.
2. This study, which falls within the limits of the Type Protocol for Thermal Stress, appears reasonable and safe with proper protection of the subjects' rights in compliance with AR and USAMRDC Regulation 70-25. A Privacy Act statement is included in the Volunteer Participation Agreement to be signed by each test subject.

2 Encl
1. D&R 30 Oct 85
2. Protocol #155

BRENDAN E. JOYCE
Colonel, MSC
Commanding

HUMAN TEST VOLUNTEER AGREEMENT - DA PERSONNEL
(NRDC-M 70-4)

NOTICE REQUIRED BY THE PRIVACY ACT OF 1974 (5 U.S.C. 552a)

1. **Authority:** Section 301 of Title 5, U.S. Code; Sections 1071-1087 and 3012 of Title 44, U.S. Code; and Executive Order 9397.
2. **Principal Purposes:** To satisfy the scientific objectives of the study, to provide minimum information necessary to contact you later should it be in your best interests to do so, or should you require medical treatment for a condition resulting from your participation in this study.
3. **Routine Uses:** This information will be used as a record of your participation in this study, in analyzing the results of the study, and in reporting or publishing results of the study without identifying the individual participants. The information also may be used to implement health and communicable disease control programs including reporting of medical conditions as required by law to other federal, state, and local agencies, and to adjudicate claims and determine benefits.
4. **Mandatory or Voluntary Disclosure and Effect on Individual not Providing Information:** Disclosure of requested information is voluntary. If requested information is not furnished, your participation in this study may be prevented or terminated.

A. VOLUNTEER AGREEMENT
(Please Print)

I, _____, having full capacity to consent, do hereby volunteer to participate in a research study entitled: Blood Volume Expansion and Exercise Performance in the Heat under the direction of Dr. Michael N. Sawka.

The implications of my voluntary participation; the nature, duration, and purpose; the methods and means by which it is to be conducted; and the inconveniences and hazards which may reasonably be expected have been explained to me by: Dr. Michael N. Sawka, and are set forth on the reverse and any additional pages of this Agreement, which I have initialed. I have been given an opportunity to read and to keep a copy of this Agreement and to ask questions concerning this study. Any such questions have been answered to my full and complete satisfaction. Should any further questions arise, I will be able to contact: Dr. Michael N. Sawka at 617-651-5141, USARIEM, Natick, MA 01760-5007

I understand that I may revoke my consent and withdraw from the study at any time without prejudice. I may be required to undergo certain further examinations if, in the opinion of the attending physician, such examinations are necessary for my health or well-being.

I understand that medical treatment is available for any injury or illness which results from my participation in this study and that there are no provisions for payment or compensation specifically for such illness or injury. Further information on the rights of human subjects may be obtained from the Office of Chief Counsel, US Army Natick Research and Development Center (Natick R&D Center), ext. 4322.

Signature, Test Subject

Permanent Address

I was present during the explanation and question period referred to and have witnessed the signature above.

Witness' Signature

Date

(Continued, over)

B. DESCRIPTION OF STUDY

(by Responsible Investigator)

This study will examine the effect of increasing your red blood cell volume on your ability to exercise in the heat. This technique is known as "blood doping" and supposedly helps some athletes perform better. If increasing red blood cell volume helps you perform better in the heat, this could be of use to the military for some operations in the heat.

This study will be conducted at USARIEM (Natick, MA) and the Naval Blood Research Laboratory (Boston, MA). It requires about 16 test days over the course of about 4 months. Prior to testing you will receive a medical examination.

During the first week of testing, you will have one unit (about one pint) of blood withdrawn and about six weeks later you will have another unit of blood withdrawn. Five to eight weeks after that, you will have your body fat determined, and perform submaximal and maximal exercise tests; and then perform two Heat Stress Tests, one when you are normally hydrated, and one when you are dehydrated by 5% of your body weight. After these tests, your blood volume will be measured. A week later you will receive a transfusion of your red blood cells in a water, salt, sugar solution. Your blood volume will be measured again the next day; and during the subsequent week you will repeat the maximal exercise test and the two Heat Stress Tests. The tests and procedures are described below.

% Body Fat. To estimate your body fat, you will be weighed on a scale underwater while you hold your breath. The gas in your lungs will be measured by having you breathe oxygen. This procedure takes about 45 minutes.

Maximal Effort Exercise. You will first practice walking and running on a treadmill. For the maximal effort exercise test, you will run on the treadmill and the treadmill incline will be increased at 2-minute intervals (by 2-1/2% grade). This test will continue until you are physically exhausted. For the submaximal effort exercise test, you will pedal a cycle ergometer at different workloads in order to determine a workload that elicits an energy expenditure that is 60% of your maximal level.

Blood Withdrawal. This will be done at the Naval Blood Research Laboratory in Boston. Your blood will be frozen and stored so that you may later be reinfused with it. Your blood will be tested for AIDS antibody (HTLV III) as would any donated blood. If the HTLV III test were positive you would be referred to the appropriate medical treatment facility.

Heat Stress Tests. You will be asked to limit your food and fluid intake for about two days before the dehydration Heat Stress Tests. The day before the Heat Stress Test, you will report at 1200 h and be weighed. You will enter a Climatic Chamber, which will be 100°F (20% humidity). In the chamber, you will rest and exercise so that you sweat. If this is the day before the normal hydration Heat Stress Test, you will be given water to replace your sweat. If this is the day before the dehydration Heat Stress Test, you will not be given water. Once you have lost 5% of your body weight, you will go to a comfortable room. In the morning, you will enter the chamber for the Heat Stress Test. It will be 113°F (20% humidity). You will try to pedal the cycle ergometer for two hours at 60% of your maximal effort. You will be wearing shorts and tennis shoes, and will be given water every 20 minutes.

Transfusion. This will be done at the Naval Laboratory. You will be given two units of either your own red blood cells, or a saline solution (water, sugar, salt). During the transfusion you will be blindfolded so you cannot see if you are getting blood or saline. This procedure takes about 1-2 hours.

Signature of Responsible Investigator Organization

Initialed by test subject: _____

B. DESCRIPTION OF STUDY
(by Responsible Investigator)

Blood Volume. At the Naval Laboratory, a small sample of blood (less than an ounce) will be taken from your arm vein. Radioactive chromium and iodine will be added to this blood and then it will be reinjected into your arm. Small blood samples will be then taken at time intervals.

During all exercise tests, you will wear shorts and tennis shoes. You will have several electrodes taped to your chest so that we can monitor your heart rate and determine sweat rate. During the Heat Stress Tests, we will measure your skin, rectal, and/or esophageal temperature. The rectal and esophageal thermometers are flexible probes which may be somewhat unpleasant to insert the first time, but are not harmful or uncomfortable. The esophageal thermometer is inserted through your nose into your esophagus. During the Heat Stress Tests, you will have a sterile plastic catheter in your arm vein so that we can take blood samples every half hour.

Potential Risks and Hazards. Muscle soreness, cramps and general fatigue may result from exercise. This is temporary and not harmful. The stress of exercise, especially maximal effort, increases the potential for uncovering and/or aggravating pre-existing heart problems. Therefore, the EKG will be continuously monitored throughout all work periods during the maximal tests. During submaximal testing, the EKG will be monitored periodically. Performing exercise in the heat can lead to exhaustion, injury or even heat stroke. Therefore, your skin temperature and rectal temperature will be closely monitored and kept within a safe limit. Testing will be stopped and you will be removed to a cool room if your rectal temperature exceeds 103 F. Even if the above limits have not been reached the exercise and heat exposure will be discontinued if you show any symptoms or signs of impending heat illness. The heat exposure will also be stopped if you so request.

There are minor risks associated with having blood withdrawn. Occasionally following a needle puncture, the puncture site may be temporarily sore or develop a bruise. Also, there is a small risk of infection whenever a needle or catheter is placed in a blood vessel. Potential risks are associated with all blood transfusions. There is a remote chance that you might mistakenly be injected with another donor's blood and this could possibly cause an allergic reaction or disease (especially hepatitis), but a strict identification system virtually excludes this possibility. Another possibility is that your own blood might become contaminated during the procedure, but your blood will be checked for this before it is injected into your veins. There is a potential risk of fluid overload. This is minimized because the total volume of 23 ounces will be given slowly and under the direct supervision of a physician. There is also a slight risk that the radioactive iodine might cause a reaction when injected. There are no risks known to be associated with the amounts of radioactivity that you will be exposed to in this study. Transfusions and blood volume tests are done routinely and safely at the Naval Laboratory.

During the Heat Stress Tests, especially when you are dehydrated, you may feel very hot, faint, nauseous, and/or thirsty. Even though you feel uncomfortable, we may ask you to continue as long as you are within the safety limits.

At any time during this study, you are at liberty to withdraw, permanently or temporarily for any reason without fear of retaliation or prejudicial action. Because of our belief in the scientific and military importance of this study, we have tried to identify and minimize the risks and maximize given the scientific framework of the study, your comfort.

Signature of Responsible Investigator Organization

Initialed by test subject: _____

B. DESCRIPTION OF STUDY

(by Responsible Investigator)

All data and medical information obtained about you as an individual will be considered privileged and held in confidence; you will not be identified in any presentation of the results. Complete confidentiality cannot be promised, particularly to subjects who are military personnel because information bearing on your health may be required to be reported to appropriate medical or command authorities, and applicable regulation "notes the possibility that the Food and Drug Administration and U.S. Army Medical Research and Development Command officials may inspect the records".

The time commitment and effort required by this study will be demanding for you. Please consider this carefully before you volunteer for this study.

You will be given a separate Volunteer Participation Agreement to sign for the transfusion and blood volume measurements performed at the Naval Laboratory.

Signature of Responsible Investigator Organization

Initialed by test subject: _____

BLOOD REINFUSION STUDY OUTLINE (Dr. Sawka)

I. Volunteers: Ten healthy male volunteers, less than 35 years old.

II. Phlebotomy (at NBRL):

- a. Collect and freeze 1 unit of red cells.
- b. Wait 6 weeks.
- c. Collect and freeze 1 unit of red cells.
- d. Wait 5-8 weeks.

III. Pre-Transfusion Exercise Tests (at USARIEM):

- a. Maximal Test (Treadmill)
- b. Body Composition (Underwater Weighing)
- c. Submaximal Test (Cycle).

IV. Pre-Transfusion Blood Volume (at NBRL)

- a. ^{125}I Albumin Plasma Volume (0.25 u Ci).
- b. ^{51}Cr Red Blood Cell Volume (2 u Ci).

V. Pre-Transfusion Heat Stress Tests (at USARIEM):

- a. Euhydration.
- b. Dehydration (5% body weight loss).

VI. Transfusion (at NBRL)

VII. Post-Transfusion Blood Volume (at NBRL):

- a. ^{125}I Albumin Plasma Volume (0.5 u Ci).
- b. ^{51}Cr Red Blood Cell Volume (15 u Ci).

VIII. Post-Transfusion Exercise Test (at USARIEM):

(Maximal test only)

IX. Post-Transfusion Heat Stress Tests (at USARIEM):

(Same as V. above)

DISPOSITION FORM

For use of this form, see AR 340-15; the proponent agency is TAGO.

REFERENCE OR OFFICE SYMBOL SGRD-UEZ	SUBJECT Report of the USARIEM Human Use Review Committee
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79 THRU C, Mil Erg Div FROM Commander DATE 31 Oct 85 CMT 1

TO Dr. Michael Sawka

1. The USARIEM Human Use Review Committee has reviewed and approved your addendum to protocol #155 entitled "Blood Volume Expansion and Exercise Performance in the Heat." The Committee's Decisions and Recommendations are attached.
2. I will forward your addendum to USAMRDC for final approval.

Encl



BRENDAN E. JOYCE
Colonel, MSC
Commanding

USARIEM HUMAN USE REVIEW COMMITTEE

30 October 1985

Decisions and Recommendations

HURC #155A - "Blood Volume Expansion and Exercise Performance in the Heat,"
Dr. Michael Sawka, Responsible Investigator

1. The USARIEM Human Use Review Committee reviewed your addendum to protocol #155 at its meeting of 30 October 1985 and unanimously recommended its approval.



Howard G. Knuttgen, Ph.D.
Chairman
USARIEM Human Use Review Committee

DISPOSITION FORM

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REFERENCE OR OFFICE SYMBOL

SGRD-UE-MEP

SUBJECT

Addendum to Protocol, "Blood Volume Expansion and Exercise Performance in the Heat:

70 THRU Dir, Mil Erg Div ~~CS~~ FROM C, Physiol Br DATE 16 October 1985 CMT 1
TO Commander, USARIEM Mil Erg Div Dr. Sawka/phd/5141

1. We recently completed experiments studying the effects of autologous blood reinfusion on thermoregulation during exercise-heat stress (ME-4-83). For these experiments, soldiers were reinfused with erythrocytes (from two previously obtained units), which significantly increased hemoglobin, hematocrit and red cell volume, but did not alter blood volume (see Table 1).

2. Preliminary analysis of our data indicates that after reinfusion a euhydrated soldier incurs reduced heat storage during exercise-heat stress (see Figure 1). This suggests that acute erythrocythemia provides a way to artificially improve man's ability to work in the heat. During our experiments, the subjects did not encounter any adverse effects from autologous blood reinfusion or the subsequent acute erythrocythemia.

3. We desire to expand the described (ME-4-83) experiments to examine the effects of recent blood reinfusion on performance of subjects during exercise-heat stress when hypohydrated (5% decrease in body weight). Hypohydration results in an augmented heat storage and reduced exercise performance in the heat relative to euhydration. We believe that acute erythrocythemia will reduce the physiological strain and improve exercise performance of hypohydrated soldiers in the heat. These experiments are necessary to better determine the ergogenic and military value of acute erythrocythemia on exercise-heat performance. During military operations, soldiers frequently incur moderate (4-6%) levels of hypohydration (Adolph and Associates, Man in the Desert).

4. Within the past three years, we have conducted 104 exercise-heat experiments on subjects hypohydrated by a 5% reduction in body weight. With the exception of heat syncope, we have not encountered any adverse physiological effects of 5% hypohydration. A possible medical concern of acute erythrocythemia combined with hypohydration might be an excessively high hematocrit. We do not expect hematocrit to exceed the normal range limit (~52%) for healthy adults in the proposed experiments. Blood reinfusion (~700 ml of sodium chloride-glucose phosphate solution at 60% hematocrit) will increase venous hematocrit by ~5 units (see Table 1). Likewise, the largest increase in hematocrit that we have observed from 5% hypohydration has been ~3 units (see enclosed reprint, p. 92).

5. We desire to essentially reconduct ME-4-83 as approved, but to add a hypohydration heat stress test both before and after blood reinfusion. Since the initial experiments provided great military promise, we wish to follow-up these experiments as expeditiously as possible. After acquiring subjects, it takes approximately three to five months to remove two units of blood and initiate testing in normocythemic subjects.

6. Approval is hereby requested for this addendum to a previously approved protocol (ME-4-83), "Blood Volume Expansion and Exercise Performance in the Heat". Request is made for the following additions:

a. That a hypohydration (-5% body weight) heat stress test be conducted both before and after blood reinfusion. All hypohydration procedures will be identical to those previously described (ME-9-83) in enclosed reprint.

b. That for the heat stress tests relative exercise intensity be changed from 50% to 60%.

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16 October 198

SUBJECT: Addendum to Protocol, "Blood Volume Expansion and Exercise Performance in the Heat"

c. That the heat stress test protocol be changed from three bouts of 45-min exercise preceded by 15 min of rest, to one continuous 120-min exercise bout.

d. That the hot/wet condition of $T_{db} = 35^{\circ}\text{C}$, $rh = 70\%$ (WBGT = 32°C) be changed to the hot/dry conditions of $T_{db} = 45^{\circ}\text{C}$, $rh = 20\%$ (WBGT = 33°C).

7. It is the responsible investigator's belief that these changes do not significantly alter the risks associated with this protocol.

3 Encl

Michael N. Sawka
MICHAEL N. SAWKA, Ph.D.
Chief, Physiology Branch

TABLE I. Influence of red cell or sham (control) infusion on hematological parameters at rest.

	Blood Volume (l)	Plasma Volume (l)	Red Cell Volume (l)	Hemoglobin (g·dl ⁻¹)	Hematocrit, H _v (%)	F - Cell (H ₀ ·H _v ⁻¹)
Reinfusion (n = 6)						
Pre	\bar{X} 5.753	3.674	2.079	13.9	42	0.89
	SD 0.425	0.285	0.258	1.1	3	0.06
Post	\bar{X} 5.710	3.409	2.301	15.3	47	0.87
	SD 0.451	0.238	0.234	1.1	2	0.03
	%Δ -	-7	11	10	12	-
Control (n = 3)						
Pre	\bar{X} 5.621	3.463	2.158	14.9	44	0.88
	SD 1.015	0.661	0.358	0.6	2	0.01
Post	\bar{X} 5.403	3.311	2.093	14.9	44	0.89
	SD 0.954	0.625	0.335	0.8	2	0.02
	%Δ -4	-	-	-	-	-

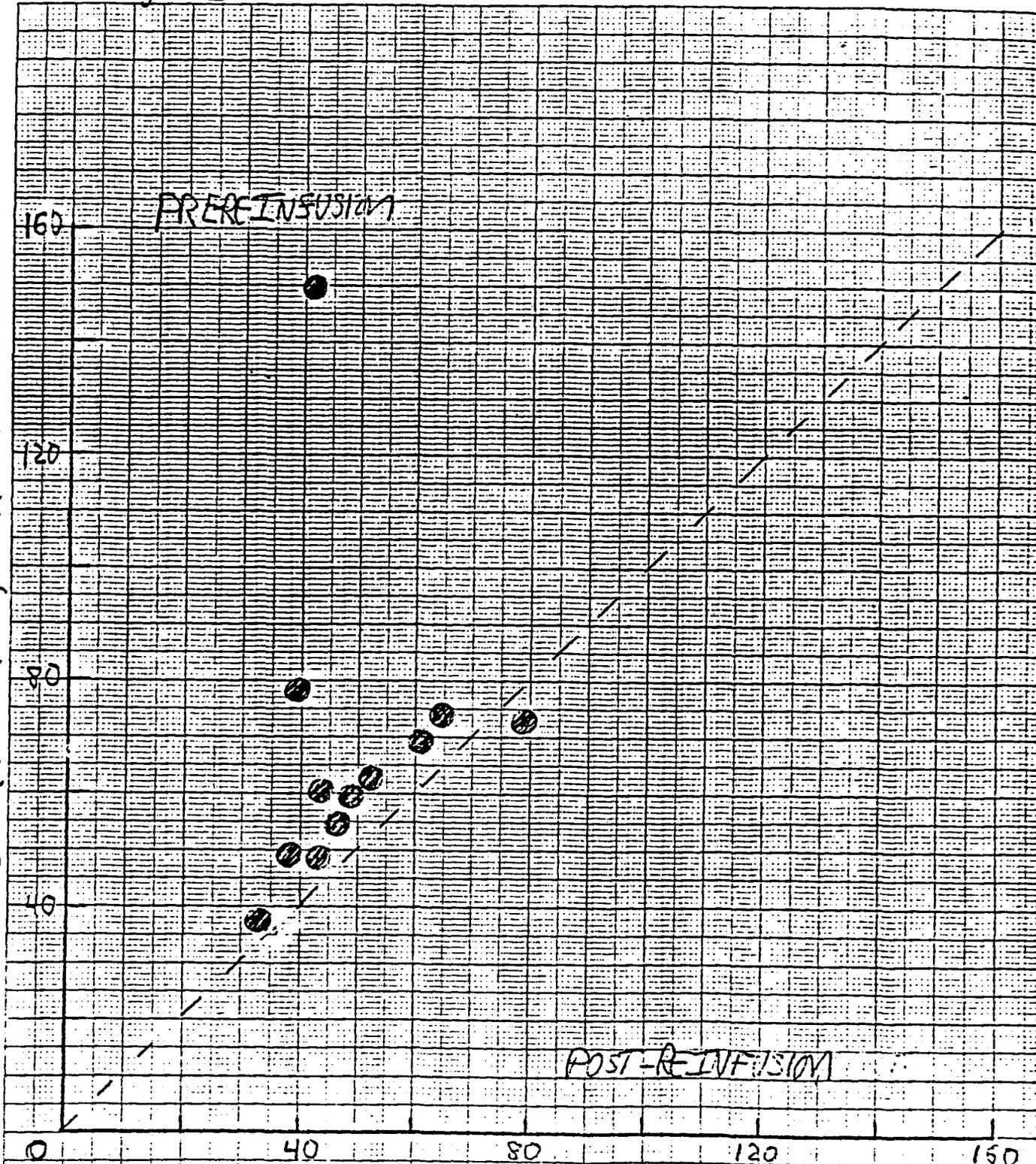
H_v is venous hematocrit, H₀ is overall hematocrit

Figure 1

461510

1 1/2 X 10 X 10 TO THE CENTIMETER 10 X 25 CM
KEUFEL & ESSER CO. MADE IN U.S.A.

HEAT STORAGE (Tes) $W \cdot m^{-2}$



HEAT STORAGE (Tes) $W \cdot m^{-2}$

Exposure Grid #1

Exposure Grid #2

Pre- \bar{x} 65.0
SD 11.3
Post- \bar{x} 54.3
SD 15.2

72.1
37.4
43.0
5.0

HUMAN TEST VOLUNTEER AGREEMENT - DA PERSONNEL
(NRDC-M 70-4)

NOTICE REQUIRED BY THE PRIVACY ACT OF 1974 (5 U.S.C. 552a)

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A. VOLUNTEER AGREEMENT
(Please Print)

I, _____, having full capacity to consent, do hereby volunteer to participate in a research study entitled: Blood Volume Expansion and Exercise Performance in the Heat under the direction of Dr. Michael N. Sawka.

The implications of my voluntary participation; the nature, duration, and purpose; the methods and means by which it is to be conducted; and the inconveniences and hazards which may reasonably be expected have been explained to me by: Dr. Michael N. Sawka, and are set forth on the reverse and any additional pages of this Agreement, which I have initialed. I have been given an opportunity to read and to keep a copy of this Agreement and to ask questions concerning this study. Any such questions have been answered to my full and complete satisfaction. Should any further questions arise, I will be able to contact: Dr. Michael N. Sawka at 617-651-5141, USARIEM, Natick, MA 01760-5

I understand that I may revoke my consent and withdraw from the study at any time without prejudice. I may be required to undergo certain further examinations if, in the opinion of the attending physician, such examinations are necessary for my health or well-being.

I understand that medical treatment is available for any injury or illness which results from my participation in this study and that there are no provisions for payment or compensation specifically for such illness or injury. Further information on the rights of human subjects may be obtained from the Office of Chief Counsel, US Army Natick Research and Development Center (Natick R&D Center), ext. 4322.

Signature, Test Subject

Permanent Address

I was present during the explanation and question period referred to and have witnessed the signature above.

Witness' Signature

Date

(Continued, over)

B. DESCRIPTION OF STUDY
(by Responsible Investigator)

This study will examine the effect of increasing your red blood cell volume on your ability exercise in the heat. This technique is known as "blood doping" and supposedly helps some athletes perform better. If increasing red blood cell volume helps you perform better in the heat, this could be of use to the military for some operations in the heat.

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% Body Fat. To estimate your body fat, you will be weighed on a scale underwater while you hold your breath. The gas in your lungs will be measured by having you breathe oxygen. This procedure takes about 45 minutes.

Maximal Effort Exercise. You will first practice walking and running on a treadmill. For the maximal effort exercise test, you will run on the treadmill and the treadmill incline will be increased at 1 minute intervals (by 2-1/2% grade). This test will continue until you are physically exhausted. For the submaximal effort exercise test, you will pedal a cycle ergometer at different workloads in order to determine a workload that elicits an energy expenditure that is 60% of your maximal level.

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Heat Stress Tests. You will be asked to limit your food and fluid intake for about two days before the dehydration Heat Stress Tests. The day before the Heat Stress Test, you will report at 1200 h and be weighed. You will enter a Climatic Chamber, which will be 100°F (20% humidity). In the chamber, you will rest and exercise so that you sweat. If this is the day before the normal hydration Heat Stress Test, you will be given water to replace your sweat. If this is the day before the dehydration Heat Stress Test, you will not be given water. Once you have lost 5% of your body weight, you will go to a comfortable room. In the morning, you will enter the chamber for the Heat Stress Test. It will be 113°F (20% humidity). You will try to pedal the cycle ergometer for two hours at 60% of your maximal effort. You will be wearing shorts and tennis shoes, and will be given water every 20 minutes.

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Signature of Responsible Investigator Organization

Initialed by test subject: _____

B. DESCRIPTION OF STUDY
(by Responsible Investigator)

Blood Volume. At the Naval Laboratory, a small sample of blood (less than an ounce) will be taken from your arm vein. Radioactive chromium and iodine will be added to this blood and then it will be reinjected into your arm. Small blood samples will be then taken at time intervals.

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Potential Risks and Hazards. Muscle soreness, cramps and general fatigue may result from exercise. This is temporary and not harmful. The stress of exercise, especially maximal effort, increases the potential for uncovering and/or aggravating pre-existing heart problems. Therefore, the EKG will be continuously monitored throughout all work periods during the maximal tests. During submaximal testing, the EKG will be monitored periodically. Performing exercise in the heat can lead to exhaustion, injury or even heat stroke. Therefore, your skin temperature and rectal temperature will be closely monitored and kept within a safe limit. Testing will be stopped and you will be removed to a cool room if your rectal temperature exceeds 103°F. Even if the above limits have not been reached, the exercise and heat exposure will be discontinued if you show any symptoms or signs of impending heat illness. The heat exposure will also be stopped if you so request.

There are minor risks associated with having blood withdrawn. Occasionally following a needle puncture, the puncture site may be temporarily sore or develop a bruise. Also, there is a small risk of infection whenever a needle or catheter is placed in a blood vessel. Potential risks are also associated with all blood transfusions. There is a remote chance that you might mistakenly be injected with another donor's blood and this could possibly cause an allergic reaction or disease (especially hepatitis), but a strict identification system virtually excludes this possibility. Another possibility is that your own blood might become contaminated during the procedure, but your blood will be checked for this before it is injected into your veins. There is a potential risk of fluid overload. This is minimized because the total volume of 23 ounces will be given slowly and under the direct supervision of a physician. There is also a slight risk that the radioactive iodine might cause a reaction when injected. There are no risks known to be associated with the amounts of radioactivity that you will be exposed to in this study. Transfusions and blood volume tests are done routinely and safely at the Naval Laboratory.

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At any time during this study, you are at liberty to withdraw, permanently or temporarily, for any reason without fear of retaliation or prejudicial action. Because of our belief in the scientific and military importance of this study, we have tried to identify and minimize the risks and maximize your comfort given the scientific framework of the study, your comfort.

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You will be given a separate Volunteer Participation Agreement to sign for the transfusion and blood volume measurements performed at the Naval Laboratory.

Signature of Responsible Investigator Organization

Initialed by test subject: _____

BLOOD REINFUSION STUDY OUTLINE (Dr. Sawka)

- I. Volunteers: Ten healthy male volunteers, less than 35 years old.
- II. Phlebotomy (at NBRL):
 - a. Collect and freeze 1 unit of red cells.
 - b. Wait 6 weeks.
 - c. Collect and freeze 1 unit of red cells.
 - d. Wait 5-8 weeks.
- III. Pre-Transfusion Exercise Tests (at USARIEM):
 - a. Maximal Test (Treadmill)
 - b. Body Composition (Underwater Weighing)
 - c. Submaximal Test (Cycle).
- IV. Pre-Transfusion Blood Volume (at NBRL)
 - a. ^{125}I Albumin Plasma Volume (0.25 u Ci).
 - b. ^{51}Cr Red Blood Cell Volume (2 u Ci).
- V. Pre-Transfusion Heat Stress Tests (at USARIEM):
 - a. Euhydration.
 - b. Dehydration (5% body weight loss).
- VI. Transfusion (at NBRL)
- VII. Post-Transfusion Blood Volume (at NBRL):
 - a. ^{125}I Albumin Plasma Volume (0.5 u Ci).
 - b. ^{51}Cr Red Blood Cell Volume (15 u Ci).
- VIII. Post-Transfusion Exercise Test (at USARIEM):

(Maximal test only)
- IX. Post-Transfusion Heat Stress Tests (at USARIEM):

(Same as V. above)