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BOSTON UNIVERSITY
MEDICAL CENTER
The University Hospital

Division of Surgery
88 East Newton Street
Boston, Massachusetts 02118-2393

Richard C. Dennis, M.D., F.A.C.S.
Associate Professor of Surgery
and Anesthesiology
Chief, Section on
Critical Care Medicine
617 638-6406

December 2, 1992

Michael Sawka, Ph.D.
Military Ergonomics Division
U.S.A.R.I.E.M.
Kansas Street
Natick, MA 01760-5007

Dear ~~Mr.~~ ^{*Mike*} Sawka:

Enclosed is the application for renewal and the approval for the research project entitled "Interaction of Aerobic Fitness and the Hypohydration Response During Exercise Heat Stress". Also included is the informed consent form for 1992-1993. It is under this protocol that the amendment "Interaction of Hydration and Metabolic Intensity on Thermal Regulatory Responses During Exercise Heat Stress" had been placed.

I hope things are going well with you and that your work continues to be productive.

Sincerely,

A handwritten signature in cursive script that reads 'Dick'.

Richard C. Dennis, M.D.

Enclosure

RCD/smc



The
University
Hospital

75 East Newton Street
Boston, Massachusetts
02118-2393
617 638-

Richard Dennis, M.D.
Critical Care Medicine
A 2

NOV 14 1992

November 12, 1992

RE: Protocol 2147/92

Dear Doctor Dennis:

The Status Report for your research project, entitled Interaction of Aerobic Fitness and the Hypohydration Response During Exercise Heat Stress, referenced above, was reviewed by the Institutional Review Board for Human Research at the meeting on November 12, 1992.

I am pleased to inform you that the continuation of this project has been approved. Approval is valid for a period of one year.

Enclosed you will find a validated consent form which shows the date through which it will be in effect. It is mandatory that you remove from your files any and all non-valid forms and use the enclosed as an original for the purpose of reproduction.

If you have any questions regarding this, please do not hesitate to contact me at extension 7207.

Sincerely,

A handwritten signature in cursive script, appearing to read "Linda L. Frattura".

Linda L. Frattura
Administrative Coordinator
I.R.B.

IRB-2147
1991

STATEMENT OF INFORMED CONSENT

INTERACTION OF HYDRATION AND METABOLIC
INTENSITY ON THERMAL REGULATORY RESPONSES
DURING EXERCISE-HEAT STRESS

SUMMARY: You are being asked to participate in a research project to examine your ability to work in the heat when you have less than normal body water (dehydrated). We wish to determine if dehydration has the same effect during light intensity work as it does during moderate and high intensity work (treadmill, walking and running). This study will be conducted at USARIEM facilities located in Natick, Massachusetts, and at the Naval Blood Research Laboratory in Boston, Massachusetts. Details of the heat exercise testing have been explained to you in a separate informed consent. The volume of plasma and red cells contained in your body will be measured a small amount of radioactive chromium and radioactive iodine. These measurements will help determine your level of hydration.

PROCEDURE: We will collect about 1 ounce of your blood which will be anticoagulated using a standard solution and labeled by adding a small amount of radioactive chromium to the blood. About 2 teaspoons of this sample and a small amount of radioactive iodine will be injected into your vein. You will receive 0.5 microcuries of radioactive ¹²⁵Iodine-labeled albumin, and 5 microcuries of radioactive ⁵¹Cr disodium chromate. Blood samples will be collected prior to the injection and up to 60 minutes after the injection. The total amount of blood collected will be less than about 2 ounces. The procedure described above is performed routinely in our laboratory. These measurements will take less than 2 hours and will be done at the Naval Blood Research Laboratory.

POTENTIAL RISKS AND HAZARDS: There is a remote chance that you might mistakenly be injected with another donor's blood and that this might possibly cause a reaction or disease (such as hepatitis), but a strict identification system virtually excludes this possibility. You could get a black and blue mark at the site of the IV, or an infection. There is also a slight risk that the radioactive iodine might cause a reaction. There are no risks known to be associated with the amounts of radioactivity that you will be exposed to in this study. The thyroid, the single organ subjected to the largest amount of ¹²⁵Iodine radiation during this study, receives less than 1/5 of the permissible exposure for a single study as outlined by the Food and Drug Administration. The radiation dose to the body is less than that of one chest x-ray.

BENEFITS: Personal satisfaction aside, you will derive no health or other benefits from your participation in this study. If you have any questions regarding the research or your participation in it, either now or at any time in the future, please feel free to ask the research team, particularly Dr. Dennis, who may be reached at 638-4950. You may obtain further information about your rights as a research subject by calling the Institutional Review Board for Human Research at Boston University Medical Center at 638-7266. If any problems arise as a result of your participation in this study, including research related injuries, please call Dr. Dennis, or Dr. Valeri at 638-4950 immediately.

VOLUNTEER SUBJECT CONSENT

I have read and understand the above explanation and the risks of participating in this study. Details of this procedure and potential risks and hazards have been verbally explained to me and I have had a chance to ask questions which have been answered to my satisfaction. I understand that any new information developed during the course of the research that may

IRB 11/12/92



The University Hospital

Division of Surgery
88 East Newton Street
Boston, Massachusetts
02118-2393

Richard C. Dennis, M.D. F.A.C.S.
Associate Professor of Surgery
and Anesthesiology
Chief, Section on
Critical Care Medicine
617 638-6406

October 23, 1992

Ms. Linda Frattura, Coordinator
Institutional Review Board for Human Research
Boston University Medical Center
88 East Newton Street
Boston, MA 02118

Dear Ms. Frattura:

Re: Protocol 2147/92

Enclosed is the report on Status of Approved Research for the research protocol entitled "Interaction of Aerobic Fitness and the Hypohydration Response During Exercise - Heat Stress" (Protocol 2147/92). There were nineteen subjects entered into the first phase of this protocol, and in the past year an additional eleven subjects have been entered into the second phase. There have been no complications, problems, or changes in the protocol. We wish to renew this project.

Sincerely,

Richard C. Dennis, M.D.
Principal Investigator

RCD:mi

REPORT ON STATUS OF APPROVED RESEARCH

INSTRUCTIONS: submit 30 copies of this completed application, collated with 30 copies of the current Informed Consent Form, and 30 copies of a revised Informed Consent Form if changes are being requested; use numbered continuation sheets as necessary, identifying responses with appropriate roman numerals and/or letters; THIS REPORT MUST BE TYPED

- I RESEARCH PROJECT TITLE: Interaction of Aerobic Fitness and the Hypohydration Response During Exercise- Heat Stress
- II PRINCIPAL INVESTIGATOR: Richard C. Dennis, M.D.
- III DATE OF ORIGINAL APPROVAL BY IRB: 9/87
DATE OF LAST APPROVAL BY IRB: 11/91
- IV PRESENT STATUS OF PROJECT: ACTIVE INACTIVE NOT BEGUN
 COMPLETED TERMINATED (INCOMPLETE BUT TERMINATED)
- V RENEWAL OF APPROVAL:
 RENEWAL IS REQUESTED RENEWAL IS NOT REQUESTED
If the project is not active please state reasons for requesting renewal:
- VI RESEARCH PROJECT HAS NOT CHANGED FROM THAT DESCRIBED IN THE ORIGINAL APPROVED APPLICATION, OR THE LAST REPORT ON STATUS OF APPROVED RESEARCH
 RESEARCH PROJECT HAS CHANGED (SEE ITEM VIII E)
 CHANGE(S) IN RESEARCH PROJECT ARE CONTEMPLATED. IRB APPROVAL IS BEING REQUESTED (SEE ITEM VIII F)
- VII TOTAL NUMBER OF SUBJECTS ORIGINALLY PROPOSED: 60
NUMBER OF SUBJECTS ENROLLED TO DATE: 30
NUMBER OF SUBJECTS ENROLLED THIS YEAR: 11

VII. Narrative Progress Report Protocol 2147/92

A. A total of nineteen subjects were entered into the original protocol. A total of eleven subjects were entered into the modification approved by the IRB on July 6, 1990 and approved at the annual review on October 11, 1990.

B. A manuscript entitled "Role of Thermofactors on Aerobic Capacity Improvements with Endurance Training" has been submitted to the Journal of Applied Physiology based on the original protocol. The eleven subjects in the modification are still being studied.

C. There have been no untoward effects or adverse reactions or injuries.

D. There have been no unanticipated events.

E. No new changes in the research project since the last IRB approval.

SIGNATURE: Richard C Dennis (PRINCIPAL INVESTIGATOR)

TELEPHONE: 617-638-6406

SIGNATURE: Richard C Dennis (SECTION/DEPT/DIV CHIEF)

DATE: 10-23-92

IRB-2147
1991

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BENEFITS: Personal satisfaction aside, you will derive no health or other benefits from your participation in this study. If you have any questions regarding the research or your participation in it, either now or at any time in the future, please feel free to ask the research team, particularly Dr. Dennis, who may be reached at 638-4950. You may obtain further information about your rights as a research subject by calling the Institutional Review Board for Human Research at Boston University Medical Center at 638-7266. If any problems arise as a result of your participation in this study, including research related injuries, please call Dr. Dennis, or Dr. Valeri at 638-4950 immediately.

VOLUNTEER SUBJECT CONSENT

I have read and understand the above explanation and the risks of participating in this study. Details of this procedure and potential risks and hazards have been verbally explained to me and I have had a chance to ask questions which have been answered to my satisfaction. I understand that any new information developed during the course of the research that may

IRB 11/14/91

relate to my willingness to continue participation will be provided to me. I understand that my blood will be injected back to me after it has been manipulated in the laboratory and that I am asked to provide blood samples after the injection. However, I may discontinue participation at any time without penalty or loss of benefits to which I am otherwise entitled. I further understand that my identity will be known only to the investigators and I will not be identified by name in any publication resulting from this study. However, the Food and Drug Administration may inspect my record. I authorize the attending physician, his assistants or designees to perform such therapies or procedures which in his professional judgement may become necessary to safeguard my health during this study.

I understand that in the event injury occurs resulting from this research procedure, medical treatment will be available at University Hospital. However, no special arrangement will be made for compensation or for payment for treatment solely because of my participation in this experiment. I understand that this paragraph is a statement of University Hospital's policy and does not waive any of my legal rights.

I understand that I will receive a copy of this form.

SIGNATURE OF WITNESS

SIGNATURE OF VOLUNTEER

SIGNATURE OF INVESTIGATOR

DATE

Valid for use through: 11/30/92
Per IRB: LF 11/14/91