March 25, 2011

Catalina Casaru
Department of Kinesiology
College of Education
The University of Alabama

Re: IRB Protocol # 10-029-ME
“Effects of Looser and Regular Fit of Firefighter Clothing on Heat Storage in Hot (35 C) and Temperate (21 C) Environments, Cognitive Performance”

Ms. Casaru:

The University of Alabama Medical IRB has received the revisions requested by the full board on 1/21/11. The board has reviewed the revisions and your protocol is now approved for a one year period. Please be advised that your protocol will expire one year from the date of approval, January 13, 2011.

Should you need to submit any further correspondence regarding this proposal, please include the assigned IRB application number. Please use reproductions of the IRB approved informed consent form to obtain consent from your participants.

Good luck with your research.

Sincerely,

John C. Higginbotham, Ph.D., MPH
Medical IRB Chair
The University of Alabama
I. Identifying information

<table>
<thead>
<tr>
<th>Principal Investigator</th>
<th>Second Investigator</th>
<th>Third Investigator</th>
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</thead>
<tbody>
<tr>
<td>Name: Catalina Casaru</td>
<td>Phillip A. Bishop, EdD</td>
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<tr>
<td>Department: Kinesiology</td>
<td>Kinesiology</td>
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<tr>
<td>College: Education</td>
<td>Education</td>
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<tr>
<td>University: University of Alabama</td>
<td>University of Alabama</td>
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<tr>
<td>Address: Box 870312, Moore Hall</td>
<td>Box 870312, Moore Hall</td>
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</tr>
<tr>
<td>Telephone: 205 348 1335</td>
<td>205 348 8370</td>
<td>205 348 0867</td>
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<td>FAX:</td>
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<td>E-mail: <a href="mailto:casar001@bama.ua.edu">casar001@bama.ua.edu</a></td>
<td><a href="mailto:pbishop@bamaed.ua.edu">pbishop@bamaed.ua.edu</a></td>
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</tbody>
</table>

Title of Research Project: Effects of looser and regular fit of firefighter clothing on heat storage in hot (35°C) and temperate (21°C) environments, Cognitive Performance.

Date Printed: 08/18/2010  
Funding Source: None

Type of Proposal: ___New  X Revision  ___Renewal  ___Completed  ___Exempt

Attach a renewal application

Attach a continuing review of studies form

Please enter the original IRB # at the top of the page

UA faculty or staff member signature: __________________________

II. NOTIFICATION OF IRB ACTION (to be completed by IRB):

Type of Review: ___Full board  ___Expedited

IRB Action:

___Rejected Date:__________

___Tabled Pending Revisions Date:__________

___Approved Pending Revisions Date:__________

✔ Approved—this proposal complies with University and federal regulations for the protection of human participants.

Approval is effective until the following date: 1/13/12

Items approved:

___Research protocol: dated

___Informed consent: dated

___Recruitment materials: dated

___Other: dated
### IRB Application Study Personnel List

**Page 1 (Insert after Face Sheet)**

#### Study Personnel and Study Responsibility

<table>
<thead>
<tr>
<th>Name and Degree(s) or student status (e.g., master's student)</th>
<th>Study Position Title (PI, Interviewer, Data Analyst, etc.)</th>
<th>Study Responsibilities</th>
<th>Date of Certificate of Investigator Human Subjects Training</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phil Bishop, Faculty</td>
<td>Primary Investigator</td>
<td>PI</td>
<td>5/29/2009</td>
</tr>
<tr>
<td>Catalina Casaru, PhD. Student</td>
<td>Primary Investigator</td>
<td>PI</td>
<td>07/25/2010</td>
</tr>
<tr>
<td>Yang Zhang, PhD. Student</td>
<td>Investigator</td>
<td>Administer protocol</td>
<td>10/14/2009</td>
</tr>
<tr>
<td>Charles Katica, PhD. Student</td>
<td>Investigator</td>
<td>Administer protocol</td>
<td>8/29/2009</td>
</tr>
</tbody>
</table>

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Approval signature: [Signature]

Date: 3/25/11
UNIVERSITY OF ALABAMA
HUMAN RESEARCH PROTECTION PROGRAM

UNIVERSITY OF ALABAMA INSTITUTIONAL REVIEW BOARD

INFORMED CONSENT

Study Title: Effects of loose and regular fit of firefighter clothing on heat storage in hot (35°C) and temperate (21°C) environments, cognitive performance.

Investigator(s): Faculty advisor Dr. Phillip A. Bishop, Catalina Casaru

Funding Source: None.

You are being asked to take part in a research study.

This study is called “Effects of loose and regular fit of firefighter clothing on heat storage in hot (35°C) and temperate (21°C) environments, cognitive performance. The study is being done by Catalina Casaru and Dr. Phillip Bishop. Mrs. Casaru is being supervised by Dr. Phillip Bishop, who is a full professor of Department of Kinesiology.

This study is not being paid for by a grant from external funder.

Is the researcher being paid for this study?

The investigators are not receiving additional salary to do this study.

Is this research developing a product that will be sold, and if so, will the researcher profit from it?

The present researcher is not developing a new product. The principle investigators Dr. Phillip Bishop and Catalina Casaru will evaluate the efficacy of bigger size firefighter gear versus regular size firefighter gear and make suggestions to the industry. The changes in the firefighter gear MAY eventually be adopted by the industry if and marketed in the future. However, the researchers will NOT profit ANY from future sales of the modified firefighter gear.

Does the researcher have any conflict of interest in this study?

The researchers have no conflict of interest in this study.

What is this study about?

This study is being done to find out the effects of a loose fit of the firefighter gear compared to regular fit firefighter gear on thermoregulation and on cognitive performance after performing rescues in hot environments.

This knowledge is important/useful because work related heat injuries are still common in USA. The goal of this study is to reduce overall risk of firefighters who work in hot environments and assess the cognitive performance of the firefighters after a rescue.

Why have I been asked to take part in this study?

You have been asked to be in this study because you are physically active and your age meets the typical age ranges of firefighters.

How many people will be in this study?

About nine (9) other people will be in this study.
In general, you will complete six exercise trials (described below). The two exercise trials will be identical (the same exercise protocol throughout) except that in two trial you will wear your normal fit firefighter gear, for two other trials you will wear one size bigger firefighter gear and for next two trials you will wear your own t-shirt and shorts.

**YOU SHOULD NOT PARTICIPATE IF YOU:**
1. YOU ARE YOUNGER THAN 19 OR OLDER THAN 40
2. ONLY MALE PARTICIPANTS ARE ELIGIBLE FOR THIS STUDY
3. IF YOU ARE A FEMALE (hormonal variation may have unintended consequences that are not being measured in this study. Females comprise a very low percentage of incumbent firefighters and this is the first study of these variables.)
4. YOU HAVE PREVIOUSLY EXPERIENCED HEAT INJURY
5. YOU ARE TAKING DRUGS (PRESCRIPTION OR ANY OTHER)
6. YOUR MEDICAL HISTORY INDICATES ANY PREVIOUS HEART, BLOOD VESSEL, OR KIDNEY DISEASE OR IF YOU HAVE HIGH BLOOD PRESSURE
7. YOU HAVE A HISTORY OF HEAT STROKE OR HEAT ILLNESS

If you meet the criteria and you agree to take part in this study you will be asked to do these things:

**Procedures:** This research project will involve 7 separate testing sessions which are described in detail below. Each session will last approximately 1 hour. Each lab session will be separated by at least 48 hours but no more than 7 days. Data collection for this study will take place over a minimum period of time of 4 weeks. The order for completing session 2, 3, 4, 5, 6 and 7 will be different for different participants. The total time required of you should be 7 hours including 3 hours and 15 minutes of moderate exercise. You will provide informed consent (see attachment) and will be screened for safety (see below) prior to participation and will complete the following.

**Lab Session 1 (Consent, Screening, Test for maximal oxygen consumption)**
1) At the beginning of the first lab visit you will be measured for descriptive data (age, height, weight, and percent body fat). Percent body fat will be estimated by measuring skinfold thickness at your chest, abdomen, and thigh. This process requires testers to pinch your skin and use a small device to measure the thickness of the pinched skin. This measurement will be performed in a non-public setting, locker room located at Human Performance Lab at Moore Hall 201.

2) Report to the lab and complete surveys regarding your current health status (You will do this immediately after this consent form, if you agree to participate). These surveys will be used to evaluate your safety.* The information will be kept confidential. It is important that you answer these questions accurately and completely. If you have any questions, please ask. Any questions you may have about your participation and the forms you complete will be answered to your satisfaction. If these forms indicate it may not be safe for you to participate, you will not be allowed to continue.

**Health surveys*: If you do not meet the criteria, you cannot take part in the study and will be removed from it by the investigator.

3) Next, you will participate in a familiarization trial for each of the cognitive tests:
   i) Short-term memory test (MEM) - you are given 90 seconds to memorize as many words as possible from a list. The list consists of 40, five-letter words that include nouns, verbs, adjectives, adverbs and prepositions. After the 90 s, you will have 60 s to write down as many words as you could remember.

   ii) MATH test- Right after the MEM test, a simple arithmetic test (MATH) will be administered. The MATH test consists of columns of addition, subtraction and multiplication problems (one of each in the abovementioned order). The difficulty of the problems progresses uniformly.

   iii) Reaction time/tracking time- The final test is computerized reaction time/tracking test (RTT) http://faculty.washington.edu/chudler/java/dottime.html For this test you will have 30 s to use a mouse to click a dot that randomly appears in a 6 x 10 grid of circles. The dot will remain in the same circle until it will be clicked on and will then appear in another circle. For every correct click, one point will be added and for every incorrect click one point will be subtracted. These methods are similar to those previously used in our lab (Oneal, et al., in press).
Firefighter clothing

If there are any misunderstandings the primary investigator (Catalina Casaru) will further explain the cognitive performance testing protocol.

4). Prior to enter the study, you will perform a graded maximal treadmill test to determine maximal oxygen consumption (VO2 max). The test consists of 3-minute stages with an initial speed of 6 or 7 mph/h⁻¹ and initial incline of 0%. Treadmill speed and incline will increase every 3 minutes until test termination. Test duration depends on your fitness level, and it can last between 10 and 25 minutes. Due to high energy expenditure that the firefighters encounter while performing rescues the maximal oxygen consumption has to exceed 42 ml/kg⁻¹/min⁻¹. Therefore, in order to achieve a representative population sample, your maximal oxygen consumption has to exceed 42 ml/kg⁻¹/min⁻¹ in order to participate in this study. If you fall below this, you cannot participate. During this test, you will wear a breathing mask (connected to a metabolic cart) and a heart monitor. The following criteria for terminating an exercise test will be:
   a) You request the test to be stopped for any reason.
   b) You reach volitional exhaustion
   c) You shows signs or symptoms which indicate the exercise test should be stopped (poor perfusion, ataxia, pallor, etc.)
   d) You can no longer maintain the required speed and grade level or testers feel for any reason it is unsafe for the participant to continue.

5). Next, your firefighter turn-out clothing size will be determined. A tape measure will be used to determine the following measurements: chest, waist, hip, and crotch height. Each measurement will be taken three times and the average of the three will be recorded. While measures are taken, you will be standing erect without shoes and with feet approximately 15 cm apart.

Total estimation of time required for Session I is approximately one hour with approximately 15 min of total exercise.

Order of Lab Session II, III, IV, V, VI and VII (following) can be in any order.

Procedures for Lab Session II, III, IV, V, VI AND VII
As a participant in this research project you will be asked to do the following:
   You will participate in 6 separate lab sessions. Each session will last approximately 60 minutes with ~30 min of total exercise. Each session you will undergo the following procedures:

1. First, you will participate in a series of three cognitive performance tests, lasting approximately ten minutes. The procedures are the same as in the familiarization trial explained above.

2. You will be weighed with shorts on.

3. You will then self insert a rectal thermocouple. The rectal thermocouple is a small wire about the size of a pipe cleaner. It is not painful at any time to any degree. The thermocouple will be inside a sterile cover. You will be required to insert your own rectal thermocouple, which is no problem for most people.

4. Skin thermocouples will then be placed on your chest, thigh, and calf. The skin thermocouples are a wire with a small disk (half the size of a dime) attached using elastic Velcro

5. Next, a heart rate monitor "chest strap will be placed on you. Heart rate monitor"- a two piece strap, half inch wide that goes around your body, right under chest area.

6. Then, one industrial external temperature/humidity sensor (Davis instruments*) will be placed on your shorts, under trousers, and the second Davis instrument will be placed on the heart rate monitor strap under coat. Davis instruments* - a 2 inch x 2 inch plastic device that measures humidity and temperature inside clothing. The device will be attached to your short with the help of a built in clip.

7. You will be weighed with the firefighter gear on.

8. Next, you will be dressed in the trial appropriate clothing:
   a. Two of the six trials are considered baseline trials; you will wear shorts and t-shirt and your own running shoes and socks. One trial will take place in a 21°C (70°F) environment and another in a 35°C (95°F) environment.
b. For the next two trials you will wear a normal size full firefighter gear, which includes: pants, coat, hood, helmet, gloves, self contained breathing apparatus (SCBA) and your own running shoes and socks.

c. For the last two trials you will wear a bigger size full firefighter gear, which includes: pants, coat, hood, helmet, gloves, self contained breathing apparatus (SCBA) and their own running shoes and socks.

1. All trials will be tested in a partially counterbalanced order with at least two days (48 hours) between the trials with each “Hot” exposure separated by a “Temperate” trial to avoid acclimatization.

9. Exercise- You will exercise for three sessions in a heat chamber* heated to 95°F with moderate humidity 50 %, and three sessions in 70°F with moderate humidity 50%. You will walk on a treadmill at a work load* of 55% of the VO2max (about 3.5mph) for 30 minutes. At 4 min the treadmill will be stopped and physiological variables (rectal and skin temperatures, heart rate, and internal environment and temperature) will be recorded. You will not be allowed to drink water during the trial. You will then perform 10 bicep curls within one minute with a bar weighing 13.9 kg. One minute after stopping the treadmill you will begin walking again. This cycle will continue for approximately 30 minutes. Throughout the trials, rating of perceived exertion (RPE) and thermal sensation (TS), clothing humidity (CH), and clothing comfort (CC) will be recorded every five minutes.

Heat chamber*: The environmental chamber is located in Moore Hall, room 201 in the main lab area of the Human Performance Laboratory of Dept. of Kinesiology. This is a small closed area (volume ~ 29.5 m³). During the heat exposure trials, the room inside will be heated via several heaters on the ground and heat bulbs on the roof. The temperature within the environmental chamber will be continuously monitored via one computerized system (Iso-Thermex Model 256, Columbus Instruments, Columbus, Ohio). And the relative humidity will also be continuously monitored via Davis Weather Monitor II (Davis Instruments Corp., Hayward, CA). The current environmental setting will be dry bulb temperature 35 °C (95 °F) and 50% relative humidity (RH) or 21 °C (70 °F) and 50% relative humidity (RH) which is hot and humid or temperate environment simulating summer conditions in the southeastern USA. This environmental chamber temperature and humidity setting has been followed in our lab numerous times without any adverse events.

Work load*: This is moderately high but sustainable work rate comparable to digging ditches or pushing a lawnmower rapidly. It will be performed in a warm humid environment similar to Tuscaloosa in mid-morning to mid-afternoon in August. The hottest temperature will be about 100 °F (38 °C), with a high relative humidity. You will be uncomfortable and you will sweat profusely.

10. Weigh you with firefighter gear on.

11. Weigh you with shorts on.

12. Ergonomics questionnaire - You will be asked to circle the word/phrase that most closely corresponds to the fit of the firefighter gear. A few questions ask for your opinion on the fit of the firefighter gear.


YOU WILL BE PERMITTED TO STOP ANY TRIAL AT ANY TIME YOU WANT FOR ANY REASON WITHOUT PENALTY OR PREJUDICE!

NOTE: YOU WILL BE VERBALLY ENCOURAGED TO PROVIDE YOUR BEST EFFORT FOR EACH SESSION BUT WILL BE PERMITTED TO STOP ANY TRIAL AT ANY TIME YOU WANT FOR ANY REASON WITHOUT PENALTY OR PREJUDICE!

How much time will I spend being in this study?

The first screening visit will take you about one hour to complete. And the following six experimental trials should take about one hour each to complete. In all, being in this study will take about seven (7) hours of your time over the next month.

Will being in this study cost me anything?

There is no cost for participating in this study.
Can the researcher take me out of this study?

The researcher may take you out of this study for any of the following to ensure your safety:
1. Your core body temperature = 38.9 °C
2. Your Heart Rate = 90% of age-predicted maximum
3. Your volition
4. Any symptoms of heat or other injury or illness
5. Any fear the investigators have for your health and safety
6. Completion of time requirements

What are the benefits (good things) that may happen to me if I am in this study?

There are no direct benefits to you from being in this study. Although benefits cannot be promised in research, for participating in this research you will receive information regarding your fitness (percent body fat). You may or may not regard information about your physical fitness as a benefit. Although you will not benefit from being in this study, you may feel good about knowing that you have helped future soldiers, law enforcement officers etc. manage/reduce their job related risks.

Compensation

You will not receive monetary compensation for your time and effort.

What are the benefits to scientists or society?

This study will help firefighters stay cooler during rescues and ultimately take better decisions while performing rescues. Society will benefit if we can reduce the number of injuries and accidents for those people who perform high-risk jobs.

What are the risks (dangers or harm) to me if I am in this study?

Potential risks to your health and well-being because of your participation include: 1) heart attack, stroke, and death, 2) severe acute fatigue, 3) lightheadedness, dizziness, nausea, 4) heat illness or heat stroke, 5) all other possible risks associated with intense exercise and exposure to heat. Precautions are taken to reduce the risk of these occurrences, and the risk of serious injury is small; however, there is risk involved. Acute fatigue and local muscular pain associated with intense exercise is likely.

In case of a research-related injury, the principle investigators Catalina Casar (205-886-0709) and the faculty advisor Dr. Phillip Bishop UA Box 870312, University of Alabama, Tuscaloosa, AL 35487-0312, (205-348-4699), will be the contact personnel.

If you are injured because of being in this study, we will take you to the hospital immediately. In the event of an injury we will supply first aid. Neither the investigators nor The University of Alabama can assume responsibility for additional medical costs you may incur as a result of your participation in this research.

You will be closely monitored during and after testing by trained CPR individuals, and testing will be terminated if you exhibit adverse signs/symptoms such as irritation, pain, the onset of angina or angina-like symptoms, signs of poor perfusion such as lightheadedness, confusion, ataxia, pallor, cyanosis, nausea, or cold, clammy skin, or if the participant feels for any other reason they need/want to stop. Water will be provided for you, and you will be encouraged to drink water after the completion of each session to ensure adequate hydration prior to departure of the Human Performance lab. In case of accident or illness, proper care will be given by a CPR certified individual until emergency medical services personnel arrive. AED is present in the Human Performance Lab, Moore Hall room 201, where the study will take place. Also, first responders within the building will be principal investigators and study supervisor that will be present at all times during the study. Emergency medical treatment by experienced technicians is immediately available from a fire station within approximately three blocks of our laboratory. A full hospital emergency room with extensive support is available less than one mile from the laboratory. You will be made aware of these risks and given the opportunity to ask questions or withdraw from the study at any time.

UNIVERSITY OF ALABAMA IRB
CONSENT FORM APPROVED: 3-25-11
EXPIRATION DATE: 1-15-12
What do I need to do prior to arriving at the lab for each session?

We will take every precaution to ensure your safety. It is very important that you fully disclose anything that would increase your risk for exercise.

- **IT IS IMPORTANT THAT YOU DO NOT CONSUME HEAVY FOODS FOR APPROXIMATELY 3 HOURS PRIOR TO EACH LAB SESSION.**
- **DRINK PLENTY OF FLUIDS AND AVOID ALCOHOL FOR 24 HOURS BEFORE PARTICIPATING IN THE EXERCISE TRIALS.**
- **REPORT TO THE LAB EACH TIME WELL-RESTED (NO STRENUEUS EXERCISE FOR 48 HOURS PRIOR TO THE LAB SESSION).**
- **IT IS IMPORTANT THAT YOU INFORM THE PRINCIPAL INVESTIGATOR IF YOU PARTICIPATE IN OTHER STUDIES**
- **If you are sick, even slightly, inform the lab personnel BEFORE coming in.**
- **Please, do NOT CONSUME ANY CAFFEINE the days when you are participating.**

**How will my privacy be protected?**

We will not tell anyone you are in this study. You do not have to answer any questions or give us any information that you do not want to.

**How will my confidentiality be protected?**

Your name will not be associated with these data. No publication or other public material will carry your name as a participant. In order for you not to be identified or associated with any data collected, a master list will link your name with a consecutive number from 1 to 10. During the data collection your name will not appear on any of the data collection sheets. Only the informed consent will contain your name, which will be kept in a different folder from the data collection sheets in order to protect your confidentiality. The master list and all data will be kept secure and filed in the principle investigator Catalina Casaru’s personal filing cabinet and will be kept there until the conclusion of the trial. The filing cabinet is located in Moore Hall Room 201 and the filing cabinet will be locked all the time. Only two principle investigators, the faculty advisor Dr. Phillip Bishop and Catalina Casaru, would have access to the filing cabinet by using a secured key.

**What are the alternatives to being in this study? Do I have other choices?**

It is your right to NOT participant in the study at any point for any reason. Choosing NOT to participate in the study will NOT adversely affect you in any manner. You should also understand that the investigator might ask you to withdraw from the study based on other factors such as an increased risk to your health and well-being.

**What are my rights as a participant in this study?**

Taking part in this study is voluntary—it is your free choice. You can refuse to be in the study. If you start the study, you can stop at any time. There will be no effects on your care or your relations with the University of Alabama.

**Who do I call if I have questions or problems?**

If you have questions about the study right now, please ask them. If you have questions about the study later on, please call the investigator Catalina Casaru at 205-886-0709 or faculty advisor Dr. Phillip Bishop at 205-348-4699. If you have questions about your rights as a person taking part in a research study, you may call Ms. Tanta Myles, the Research Compliance Officer of the University at 205-348-8461 or toll-free at 1-877-820-3066.

You may also ask questions, make suggestions, or file complaints and concerns through the IRB Outreach Website at http://osp.ua.edu/site/PRCO_Welcome.html. You may email us at participantoutreach@bama.ua.edu.

After you participate, you are encouraged to complete the survey for research participants that is online at the outreach website or you may ask the investigator for a copy of it. Mail it back to the University of Alabama Office for Research Compliance, Box 870104, 152 Rose Administration Building, Tuscaloosa, AL 35487-0104.
I have read this consent form. I have had a chance to ask questions. I understand what I will be asked to do. I freely agree to take part in it. I will receive a copy of this consent form to keep.

Signature of Research Participant

__________________________________________

Date

Investigator

__________________________________________

Date

The consent form has been reviewed with me prior to session 1 __________ (Initial)

The consent form has been reviewed with me prior to session 2 __________ (Initial)

The consent form has been reviewed with me prior to session 3 __________ (Initial)

The consent form has been reviewed with me prior to session 4 __________ (Initial)

The consent form has been reviewed with me prior to session 5 __________ (Initial)

The consent form has been reviewed with me prior to session 6 __________ (Initial)

The consent form has been reviewed with me prior to session 7 __________ (Initial)