September 15, 2005

Battelle
The Business of Innovation

Centers for Public Health Research and Evaluation
100 Capitola Drive, Suite 301
Durham, North Carolina 27713-4411
(919) 544-3717 Fax (919) 544-0830

Talmage Holmes, PhD
Battelle CPHRE
2971 Flowers Road South
Suite 233
Atlanta, GA 30341-5404

Dear Dr. Holmes:

The Battelle/CPHRE Institutional Review Board (IRB) has reviewed your responses to it's August 18th review of the study entitled "Human Behavior in Fire Study" (FG487102-10) and grants approval to proceed with this study. Because the study will obtain a Certificate of Confidentiality that reduces the risk of breach of confidentiality, the Board has declared the study minimal risk. In addition, the requirement for signed written consent is being waived for the telephone screener.

The Board has the following requirements and recommendations:

(1) Forward a copy of the revised flow chart to the Board.
(2) Forward a copy of the revised consent form to the Board after CDC's changes have been incorporated.
(3) Check Battelle's subcontract with Dr. Milke to see if it includes wording about human subject protection training for Dr. Milke and his assistants. If it does not the subcontract should be modified to add provisions for training. If it is not possible to revise the subcontract at this point in time, the Board suggests that Battelle provide training to Dr. Milke and his assistants.

As with all Battelle/CPHRE studies, this study will be subject to continuing review next year. We will notify you at the appropriate time. In the meantime, should any changes occur in your protocol or questionnaire, please inform the Board and submit the changes for review. Similarly, the IRB needs to be notified in case of any injury or unexpected outcome arising form this study.

Sincerely,

Margaret Pennybacker

Margaret Pennybacker, PhD, CIP
IRB Chair

cc: Brigette Brevard
Kevin Heaton
Jan Jaeger

Battelle/Centers for Public Health Research and Evaluation

100 Capitola Drive, Suite 301
Durham, NC 27713
Federal-wide Assurance No. FWA00004696

INSTITUTIONAL REVIEW BOARD NOTICE OF APPROVAL

PROJECT DIRECTOR: Talmage Holmes, PhD

PROJECT TITLE: Human Behavior in Fire Study

CLIENT: CDC PROTOCOL DATE: **8/4/05**

BATTELLE PROJECT CODE: FG487102-10 or PROPOSAL NUMBER: _ *(if preaward)*

NATURE OF REVIEW: *(check one)*

- [X] FULL MEETING DATE: **8/18/2005 (tabled pending revision); final approval 9/15/2005**
- [ ] EXPEDITED *(specify reason)*: _____
- [ ] EXEMPT *(specify reason)*: _____

TYPE OF APPROVAL: *(check one)*

- [ ] PRELIMINARY. SCHEDULE NEXT REVIEW PRIOR TO INVOLVEMENT OF HUMAN SUBJECTS.
- [ ] PRETEST/PILOT TEST. SCHEDULE NEXT REVIEW PRIOR TO FULL IMPLEMENTATION.
- [X] FULL IMPLEMENTATION.
- [ ] RENEWAL.
- [ ] AMENDMENT DATED

Please note the following requirements:

PROBLEMS OR ADVERSE REACTIONS: If any problems in treatment of human subjects or unexpected adverse reactions occur as a result of this study, you must notify the IRB Chairperson immediately, then complete an Adverse Event/Incident Report and forward it to the CPHRE IRB Administrator.

CHANGES IN PROTOCOL: If there are significant changes in procedures or study protocol, you must notify the IRB Chairperson and submit the revisions for review before they are implemented.

RENEWAL: You are required to apply for renewal of approval at least annually for as long as the study is active. Your next continuing review date should be on or before **9/15/06**.

M R Pennybacker 9/15/05

IRB Chairperson Date

Margaret R. Pennybacker, PhD, CIP
Print or Type Name

X Copy of approved Informed Consent on file.

cc: Project Director
IRB Administrator

UNIVERSITY OF MARYLAND
INSTITUTIONAL REVIEW BOARD

2100 Lee Building
College Park, Maryland 20742-5121
301.405.4212 TEL 301.314.1475 FAX
irb@deans.umd.edu
www.umresearch.umd.edu/IRB

To: James A. Milke
Department of Fire Protection Engineering

From: Roslyn Edson, M.S., CIP
IRB Manager
University of Maryland, College Park

Re: IRB Application # 01672
Title: Identification of Residential Fire-Injury Behavioral Risk Factors

Approval Date: August 18, 2005

Expiration Date: August 18, 2006

Type of Application: Initial

Type of Research: Nonexempt

Type of Review: Expedited

The University of Maryland, College Park Institutional Review Board (IRB) approved your IRB application. The research was approved in accordance with the University's IRB policies and procedures and 45 CFR 46, the Federal Policy for the Protection of Human Subjects. Please reference the above-cited IRB application number in any future communications with our office regarding this research.

Recruitment/Consent: For research requiring written informed consent, the IRB-approved and stamped informed consent document is enclosed. The IRB approval expiration date has been stamped on the informed consent document. Please keep copies of the consent forms used for this research for three years after the completion of the research.

Continuing Review: If you want to continue to collect data from human subjects or analyze data from human subjects after the expiration date for this approval, you must submit a renewal application to the IRB Office at least 30 days before the approval expiration date.

Modifications: Any changes to the approved protocol must be approved by the IRB before the change is implemented except when a change is necessary to eliminate apparent immediate hazards to the subjects. If you want to modify the approved protocol, please submit an IRB addendum application to the IRB Office.

Unanticipated Problems Involving Risks: You must promptly report any unanticipated problems involving risks to subjects or others to the IRB Manager at 301-405-0678 or redson@umresearch.umd.edu.

Student Researchers: Unless otherwise requested, this IRB approval document was sent to the Principal Investigator (PI). The PI should pass on the approval document or a copy to the student researchers. This IRB approval document may be a requirement for student researchers applying for graduation. The IRB may not be able to provide copies of the approval documents if several years have passed since the date of the original approval.

Additional Information: Please contact the IRB Office at 301-405-4212 if you have any IRB-related questions or concerns.