

4. The IRB noted emergency medical services in two communities have completed the required training programs and are ready to begin the research. Therefore, the IRB is ready to consult with these communities regarding their opinions about the study. The IRB will be setting up community meetings in these two areas, Vestavia Hills and Centerpoint. The IRB will secure the location for the forum and may ask that you advertise the meetings in local newspapers, church bulletins, school newsletters and post flyers in those communities to advertise the forum. Please use the same sort of PSA information as that used in the Spanish PSA.
5. Please note that any public forum for community consultation you are planning in the future must be attended by an IRB member. Please contact the IRB in advance so that arrangements may be made for one or more IRB members to attend.
6. You informed the IRB of a meeting held with the Birmingham City Council to discuss this study. Please provide documentation regarding this meeting including the date of the meeting, a general description of the information provided at the meeting, attendees of the meeting and an approximate number of community members (the public) that attended the meeting. Also, provide any feedback from the meeting.

Please note that this protocol was approved with limited modifications and the IRB has requested additional information. The IRB Office must review this information before formal approval of the protocol is issued. Enrollment may begin after formal approval of the protocol and approval of waiver of informed consent has been issued by the IRB Office.

Please submit a memorandum addressing the issues above.

Shock Enrollment Breakdown as of 4/30/2007					
EMS Agencies/Hospitals	Children's Hosp	Univ Hosp	Died in the Field	Total	
Alabama Lifesaver	0	0	0	0	
Bessemer Fire and Rescue	0	0	0	0	
Birmingham Fire and Rescue	0	0	0	0	
Centerpoint Fire and Rescue	0	0	0	0	
Homewood	0	0	0	0	
Pelham Fire	0	0	0	0	
Trussville Fire	0	0	0	0	
Vestavia Hills Fire	0	0	0	0	
Total for Hospital	0	0	0	0	

Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption (Common Rule)

Policy: Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (58FR28003, June 18, 1991) unless the activities are exempt from or approved in accordance with the Common Rule. See section 101(b) of the Common Rule for exemptions. Institutions submitting applications or proposals for support must submit certification of appropriate Institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the Common Rule. Institutions must have an assurance of compliance that applies to the research to be conducted and should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency.

1. Request Type <input checked="" type="checkbox"/> ORIGINAL <input type="checkbox"/> CONTINUATION <input type="checkbox"/> EXEMPTION	2. Type of Mechanism <input type="checkbox"/> GRANT <input type="checkbox"/> CONTRACT <input type="checkbox"/> FELLOWSHIP <input type="checkbox"/> COOPERATIVE AGREEMENT <input type="checkbox"/> OTHER: _____	3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No.
4. Title of Application or Activity Hypertonic Resuscitation Following Traumatic Injury (Southeastern Resuscitation Research Center)		5. Name of Principal Investigator, Program Director, Fellow, or Other KERBY, JEFFREY D

6. Assurance Status of this Project (Respond to one of the following)

This Assurance, on file with Department of Health and Human Services, covers this activity:
 Assurance Identification No. FWA00005960, the expiration date 2/14/09 IRB Registration No. IRB00000726

This Assurance, on file with (agency/dept) _____, Assurance No. _____, the expiration date _____ IRB Registration/Identification No. _____ (if applicable) covers this activity.

No assurance has been filed for this institution. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon request.

Exemption Status: Human subjects are involved, but this activity qualifies for exemption under Section 101(b), paragraph _____.

7. Certification of IRB Review (Respond to one of the following IF you have an Assurance on file)

This activity has been reviewed and approved by the IRB in accordance with the Common Rule and any other governing regulations.
 by: Full IRB Review on (date of IRB meeting) 3/28/2007 or Expedited Review on (date) _____
 if less than one year approval, provide expiration date 09-28-07

This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the Common Rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments

Protocol subject to BI-annual continuing review.

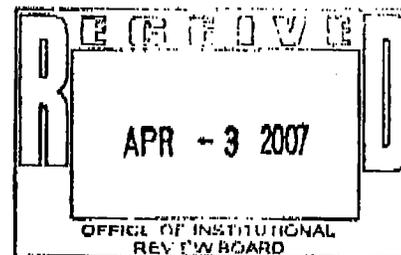
Title F060328008
 Hypertonic Resuscitation Following Traumatic Injury (Southeastern Resuscitation Research Center)

IRB Approval Issued: 04-05-07

9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed until study closure and certification will be provided.	10. Name and Address of Institution University of Alabama at Birmingham 701 20th Street South Birmingham, AL 35294
11. Phone No. (with area code) (205) 934-3789 12. Fax No. (with area code) (205) 934-1301 13. Email: <u>smoore@uab.edu</u>	15. Title Vice Chair, IRB
14. Name of Official Albert Oberman, M.D., MPH	17. Date <u>04-05-07</u>
16. Signature <u>Albert Oberman, MD, MPH / db</u> Authorized for local reproduction	

UAB SCHOOL OF
MEDICINE

Department of Emergency Medicine

**MEMORANDUM**

TO: Sheila Moore, CIP
Office of the IRB

FROM: Jeffrey D. Kerby, MD, PhD. *JK*
Principal Investigator

DATE: April 3, 2007

RE: **F060328008 - Hypertonic Resuscitation following Traumatic Injury (Southeastern Resuscitation Research Center)**

This memorandum is a written request to begin enrollment in the above protocol for Vestavia Hills Fire Department (VHFD).

VHFD has a signed and fully executed contract on file with the UAB Office of Grants and Contracts Administration. VHFD has also secured a Federal Wide Assurance number from the Office for Human Research Protections (FWA00010924). This agency has completed the training in Good Clinical Practices. As a component of our IRB approved Community Consultation / Public Disclosure plan, we have presented an overview of the above protocol at the Vestavia Hills United Methodist Church Meeting on 3/22/2007 at 7:00 PM. We solicited feedback from the community. UAB IRB board members attended this meeting.

Thank you in advance for your consideration of this request to begin enrollment and for your support of emergency research. If you have any questions or need any additional information, please do not hesitate to contact me.

Approved*Sheila Moore, CIP for*

IRB Chairman

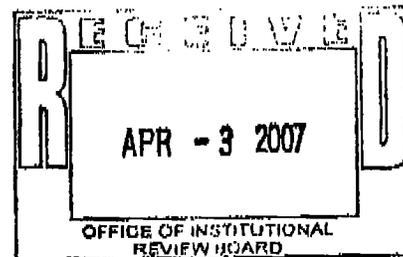
Albert Oberman, MD

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SCHOOL OF
MEDICINE

Department of Emergency Medicine



MEMORANDUM

TO: Sheila Moore, CIP
Office of the IRB

FROM: Jeffrey D. Kerby, MD, PhD. *JK*
Principal Investigator

DATE: April 3, 2007

RE: **F060328008 - Hypertonic Resuscitation following Traumatic Injury (Southeastern Resuscitation Research Center)**

This memorandum is a written request to begin enrollment in the above protocol for Centerpoint Fire Department (CPFD).

CPFD has a signed and fully executed contract on file with the UAB Office of Grants and Contracts Administration. CPFD has also secured a Federal Wide Assurance number from the Office for Human Research Protections (FWA00010918). This agency has completed the training in Good Clinical Practices. As a component of our IRB approved Community Consultation / Public Disclosure plan, we have presented an overview of the above protocol at the Clay City Council Meeting on 4/2/2007 at 7:00 PM. We solicited feedback from the community. UAB IRB board members attended this meeting.

Thank you in advance for your consideration of this request to begin enrollment and for your support of emergency research. If you have any questions or need any additional information, please do not hesitate to contact me.

Approved

Sheila Moore, CIP for
IRB Chairman *Albert Okerman MD*

IRB Vice Chair

266N Jefferson Tower
625 19th Street South

The University of
Alabama at Birmingham
ID:UW CTC

MEMORANDUM

TO: Jeffrey Kerby, MD
Principal Investigator **FAX: 6-5019**

FROM: Amanda Murphy, RN, CIP *AM*
On behalf of IRB 02

DATE: February 14, 2007

RE: F060328008
Hypertonic Resuscitation Following Traumatic Injury (Southeastern Resuscitation Research Center)

The IRB 02 met on February 14, 2007 and approved with limited modifications the protocol referenced above. The modifications requested are listed by number below. Please respond by memorandum to the Board, addressing each item by number.

1. The IRB thanks you, Todd Brown, Shannon Stephens, and Carolyn Williams for attending the IRB-02 meeting on February 14, 2007 to discuss the above referenced protocol and answer the Board's questions.
2. The IRB noted your considerable efforts to notify the community about the study.
3. The IRB discussed that both nationally and locally, opinions regarding the optimal way to obtain community consultation for research of this nature, varies widely. The IRB agreed that community notification and consultation for this research is an ongoing process; therefore, the IRB makes the following recommendations.
 - a. You informed the IRB that you will be mailing flyers to every address in Jefferson County. The IRB recommends that the flyer contain three options for providing feedback about the study. Please provide a telephone number, e-mail addresses (one you may have set up for this purpose and the IRB's address, irb@uab.edu), and a mailing address on the flyer so that persons may not only opt out, but provide comment about the study. You may need to revise the flyer so that persons are aware you are soliciting feedback about the study as well as providing a way to opt out. Please keep a record of all communication received.
 - b. The IRB noted your efforts to inform the Spanish speaking population through a local Spanish language newspaper; however, the IRB recommends that you submit a public service announcement (PSA) to local Spanish language radio stations. The PSA should include ways for the Spanish community to provide feedback and/or an opportunity to opt out of the study. The IRB suggested that you work with Media Relations regarding the PSA. The IRB asks that the PSA not appear to be an advertisement nor a press release touting only the benefits of the research that is being conducted at UAB, but a sharing of information and a sincere solicitation of the public's opinion regarding the research.