

Appendix B



ROC

Resuscitation Outcomes Consortium

MEMORANDUM

TO: Jeffrey D. Kerby, MD, PhD, FACS
Principal Investigator

FROM: Denise Ball, CIP
Associate Director, Office of the IRB

DATE: March 30, 2007

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

Dr. Oberman, Sheila, and I would like to thank you, Shannon, and Carolyn for taking time away from your busy schedules to meet with us this morning. The regulatory spreadsheet you provided has been helpful in determining the status of each site. I believe it would be beneficial for you to provide an updated spreadsheet each time you submit the protocol for continuing IRB review. As you're aware, on March 28, 2007, the IRB 02 reviewed your response to the IRB's letters dated February 14, 2007 and March 21, 2007. The IRB determined your responses to the Board's previous concerns have been adequately addressed. The following is a summary of the items that are ongoing:

1. The following is a list of community consultation activities that are planned. I am working to have IRB representative at these meetings. Please verify that these dates are correct and if there are any omissions.
 - a. The Clay City Council Meeting - Monday, April 2 at 7:00 p.m.
 - b. The Jasper City Council Meeting - Tuesday, April 3 at 10:00 a.m.
 - c. The Bessemer Meeting - Wednesday, April 4 (Need time, location and type of meeting)
 - d. The Center Point Council Meeting - Thursday, April 4 at 6:30 p.m.
 - e. Jefferson County Community Meeting - Wednesday, April 25 at 2:00 p.m.
2. We have discussed a couple of options for community consultation in the areas covered by Omniflight (Lifesaver) services. One of the options involved telephone surveys and the other involved attending City Council Meetings in the larger communities, i.e., Tuscaloosa, Anniston, and Gadsden. Once you've decided the best approach for the broadest representative, please submit this plan as a formal request via an amendment to the IRB for review and approval.
3. Please continue to keep us posted on the activities concerning the Hispanic population. The PSA that you provided for the Spanish language radio is approved and we are aware that you are working to have a plan in place for having a translator available to receive these calls.

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4. As discussed at our meeting today, we are asking that you submit a memorandum to the IRB each time you are ready to start with an EMS Agency. The memorandum should include information regarding the MOA status, FWA #, GCP Training, and disclosure/community consultation activities. Once the IRB and/or the IRB Chairman has reviewed the information provided, we will stamp the memorandum "approved" and will notify you that you may begin the study with that agency.
5. I would again like to remind you that public disclosure and community consultation should be an ongoing effort. With each IRB renewal submission, you will need to address your plans for ongoing disclosure and community consultation.

I hope that I've covered everything in this memorandum. If I've forgotten something or if you have any questions, please call or email me. I look forward to working with you and your research team as we ensure this emergency research study is conducted in a safe and appropriate manner.

cc: Ms. Sheila Moore
Dr. Al Oberman

dhb