

IRB/Public Disclosure and Community Consultation/Notification Log: ROC & Hypertonic Saline

Site: ALABAMA

Date	Event Description	Attendance		Expenditures (describe)	Cost	Advertised days	Advertising media (billboard, print, radio, TV)	Activity (IRB, etc.)	Hours Spent
		Expected	Actual						
08/18/05	City of Birmingham City Council Meeting	~25	27	Staff time.	Staff time.	None	No advertising for this meeting	Public Disclosure (PD)	2 hrs.
09/8/05	Trauma Grand Rounds-UAB Hospital	~75	61	Staff time.	Staff time.	Unknown	Trauma Grand Rounds flyers posted at Hospital	PD	2 hrs.
10/25/05	9 <sup>th</sup> Annual UAB Trauma Symposium		~150	Staff time.	Staff time.	~3 months	Flyers posted	PD	6 hrs.
02/15/06	In Service/UAB ED Staff	30	27	Staff time.	Hospital Catering & Staff Time	7 days	Flyers posted	PD	2.5 hrs
02/20/06	In Service/UAB ED Staff	30	28	Staff time.	Hosp. Catering & Staff Time	7 days	Flyers posted	PD	2.5 hrs
3/30/06	ROC Advisory Committee Meeting	30	19	Staff time.	Staff Time.	e-mails two weeks in advance	E-mail and phone calls	PD and community consultation (CC)	3.5 hrs
4/11/06	NBC News Story	N/A	N/A	Staff time.	Staff time.	No advertising;	Local news story	PD	30 minutes



				Staff Time	Time		Staff	Time		Time	Contacted via	PD/CC	1 hour
7/27/2006	Radio Station Interview										telephone	PD/CC	
7/27/2006	FOX News at 10		91,691 (Nielsen Audience)									PD/CC	
7/27/2006	FOX News at 5		107,044 (Nielsen Audience)									PD/CC	
7/27/2006	WCFT-ABC News at 5		69,687 (Nielsen Audience)									PD/CC	
7/27/2006	WIAAT-CBS News at 10		59,667 (Nielsen Audience)									PD/CC	
7/27/2006	WIAAT-CBS News at 5		36,292 (Nielsen Audience)									PD/CC	
7/27/2006	WTTQ-WB News at 9		18,217 (Nielsen Audience)									PD/CC	
7/28/2006	WBRC-FOX News at Noon		65,674 (Nielsen Audience)									PD/CC	
7/28/2006	WBRC-FOX News Daybreak		79,712 (Nielsen Audience)									PD/CC	
7/27/2006	Birmingham News/Post Herald											PD/CC	
	Abbeville Herald											PD/CC	
	Alabama Messenger											PD/CC	
	Alexander City Outlook											PD/CC	
	Andalusia Star News											PD/CC	
	Arab Tribune											PD/CC	
	Atmore Advanced											PD/CC	
	Birmingham Business Journal											PD/CC	





3/7/2006	SEMCC	~75		Staff Time	Staff Time		E-mails sent requesting attendance	PD/CC	
3/30/2006	Injury Control Research Center Grand Rounds			Staff Time	Staff Time		Flyers posted 14 days in advance	PD/CC	
8/31/2006	In-Service Meeting			Staff Time	Staff Time		E-mails sent requesting attendance	PD	
9/14/2006	In-Service Meeting			Staff Time	Staff Time		E-mails sent requesting attendance	PD	
8/10/2006	Current Therapies for Acutely Decompensated Heart Failure			Staff Time	Staff Time		Flyers/E-mails	PD	
8/14/2006	Meeting with the Mayor			Staff Time	Staff Time		E-mails	PD/CC	
9/19/2006	Resuscitation Interest Meeting	~25		Staff Time	Staff Time		E-mails/Flyers	PD/CC	
8/31/2006	In-Service Meeting			Staff Time	Staff Time		E-mails sent requesting attendance	PD	
9/14/2006	In-Service Meeting			Staff Time	Staff Time		E-mails sent requesting attendance	PD	
3/22/2007	Vestavia Hills United Methodist Church	~25	~25	Staff Time	Staff Time	7 days	describing the ARC and the HS trial	CC	3 hours
4/2/2007	Clay City Council Meeting	~40		Staff Time	Staff Time	3 days	describing the ARC and the HS trial	CC	30 minutes.
4/2/2007	Centerpoint City Council Meeting	~50		Staff Time	Staff Time	7 days	describing the ARC and the HS trial	CC	30 minutes.
4/5/2007	Birmingham Community Advisory Board	99 community members	99	Print flyers			describing the ARC and the HS trial	PD/CC	

The UAB Institutional Review Board (IRB) is seeking public opinion and feedback on a proposed study by the UAB Departments of Emergency Medicine and Surgery, to improve the current treatment for trauma patients by local Emergency Medical Service (EMS) responders. The IRB's mission is to ensure that research involving human participants is conducted in an ethical manner. This includes ensuring that risks to participants are minimized, the selection of participants is made without regard to ethnicity, race or gender, and participants are informed fully of what their participation will entail and of the potential risks and benefits. The IRB strongly encourages community input into the process of conducting this type of research.

UAB is 1 of 10 centers in the United States and Canada which is tasked with conducting clinical trials for cardiac arrest and life threatening trauma. Traumatic injury is the leading cause of death in the United States between the ages of 1 and 44 years, resulting in nearly 175,000 deaths per year. Alabama has one of the highest traumatic injury death rates per capita in the nation. Half of these deaths occur before the patient reaches an emergency department, mostly because of severe blood loss or swelling of the brain. In this study, patients with injuries and either a low blood pressure or with an altered mental state, will receive, through an IV, either a small amount of normal saline (water with the saltiness of the blood which is currently the standard of care), hypertonic saline (more concentrated salt water), or hypertonic saline with dextran (more concentrated salt water with a sugar molecule added). Potential benefits of hypertonic resuscitation include: compensating for blood loss more effectively with more rapid improvement of blood pressure, improved blood flow to the brain while at the same time decreasing pressure in the injured brain and lessening the inflammatory response, which may decrease the risk of infection and organ injury. As with all medical treatments involved with giving medications, there might be some adverse effects. Hypertonic saline has been studied extensively in Europe and has been tested in the US in over 500 patients in 8 clinical trials without reports of life threatening adverse effects. Possible adverse effects that our study will monitor includes: increased sodium (salt) levels that could contribute to seizures requiring medical treatment, the potential for the blood not to clot as well as usual which might cause increased bleeding, skin irritation at the site of the infusion or a rash due to a minor allergic reaction.

It is expected that the majority of patients who meet the enrollment criteria will either be unconscious or have an altered mental status and unable to properly consent to be enrolled in this study. This study will be conducted under strict Food and Drug Administration guidelines that allow for patients in life threatening situations to participate in research without standard informed consent. Patients and/or family will be notified of their participation as soon as feasible and consent will be sought for ongoing study participation.

If you have any questions or concerns about this research study, Dr. Jeffrey Kerby, or one of the other UAB researchers involved with these studies, will be glad to answer them. Their number is 205-934-9532. You may also find more information regarding this and other emergency research studies at UAB by visiting their web site at [www.uab.edu/arc](http://www.uab.edu/arc). If you have questions about your rights as a potential research participant, you may contact Ms. Sheila Moore, Director of the Office of the Institutional Review Board for Human Use (IRB). Ms. Moore may be reached at (205) 934-3789 between the hours of 8:00 a.m. and 5:00 p.m. CT, Monday through Friday or via email at [irb@uab.edu](mailto:irb@uab.edu). Regardless, UAB would appreciate any feedback the public has about these studies. Please feel free to contact us at any of the numbers listed above.

*As part of a UAB study to determine the safest, most effective way to save the lives, emergency medical responders will begin testing a new treatment on patients suffering from life-threatening illnesses and injuries. We want your feedback! To learn more about the study and offer your opinions, please call Sheila Moore at 934-3789 or Jeffrey Kerby at 934-9532. An interpreter will be provided.*

## Shortened Version of the PSA

The UAB Institutional Review Board seeks public feedback on a proposed UAB study to improve emergency medical responders' treatment methods for trauma patients. Alabama has one of the highest traumatic-injury death rates in the country. By administering a solution that contains a varying concentration of saline (salt), EMS workers hope to determine the safest, most effective method to save the lives of trauma patients. Side effects are rare. However, because of their condition, most of the patients who meet enrollment criteria will be unable to give proper consent. To offer your feedback on this proposed study, contact Jeffrey Kerby at 934-9532 or Sheila Moore at 934-3789.

April 10, 2007

Media Contact: Kristen Ruggeri  
205-934-8935 or kmr0901@uab.edu

## **MEDIA ADVISORY** **FOR WEDNESDAY, APRIL 11**

### **UAB KICKS OFF EMERGENCY RESCUE RESEARCH PROJECT**

- What:** UAB, the only level 1 trauma center in the state, introduces a new study to find the most effective treatment methods for trauma patients by local emergency medical service (EMS) responders.
- Who:** Jeffrey Kerby, M.D., associate professor of surgery and trauma at UAB, and Bob Vanhooser, EMS chief for Center Point Fire and Rescue will speak about the objectives of this study, and the importance of providing EMS responders with the necessary tools to treat those suffering from severe trauma.
- When:** Wednesday, April 11 at 11:00 a.m.
- Where:** Center Point Fire and Rescue  
2233 Center Point Pkwy.  
Birmingham, AL 35215
- Background:** UAB, along with 10 other centers across the United States and Canada, will conduct clinical trials for cardiac arrest and life-threatening trauma. Alabama has one of the highest traumatic-injury death rates per capita in the nation, and this research could help emergency medical workers determine the safest and most effective way to compensate for blood loss, improve blood flow, decrease pressure to the injured brain, lessen inflammatory response, and decrease the risk of infection and organ injury.

- [www.uab.edu/news](http://www.uab.edu/news) -

## **Hospital ICU Staff Education for the Hypertonic Saline Trial**

- Start Date.....Wednesday, April 11, 2007 at Noon.
- Patient should arrive to the unit with a yellow arm band with the contact information and the study fluid ID number listed...do not remove.
- If the patient arrives to the unit with the study bag attached, call the ROC Research Coordinator on call to retrieve it... do not discard.
- The patient should have an **“Information for Care Providers”** sheet in their permanent record. The study fluid ID number is located in the upper right hand corner. Should the need arise; please provide this number to the ROC Research Coordinator on call if you have any questions or concerns during the patient’s length of stay.
- Soon after the patient is admitted to the ICU, please change the Attending Physician from Dr. Rue to Dr. Kerby and order a new arm band.
- There is a set of **“ROC HS PROTOCOL”** orders in PIN. Upon patient arrival to the unit please initiate these orders. Follow the steps listed below:
  - Locate the Patient in PIN
  - Click on Ordering Guide
  - Click on Enter Orders for MD
  - Click on Protocol/Standing Order
  - Type in Kerby’s name and press F10
  - Click on “Kerby, Jeffrey D.”
  - Under Miscellaneous, click on Order Set
  - Click on Personal
  - Click on Continue
  - Click on “ROC HS TRIAL”
  - Click on “ALL OF THE ABOVE”
  - Click Review then Enter

- The patient's serum sodium levels have to be monitored q8hrs or q6hrs if they receive Mannitol and/or any other type of hypertonic saline. It is currently standard of care to draw FBP's q4hours on severely injured patients; we will use the serum sodium level from these labs. In the event that a FBP is not drawn at least q8hr then follow the HS Order Set.
- During the course of their hospital stay, these patients should not be enrolled into any other hospital based clinical trial. If you have any question please contact the ROC Research Coordinator on call.
- Please report any of the following **Adverse Events** to the ROC Research Coordinator:
  - Serum Sodium level greater than 170 mEq/L and requires therapeutic interventions
  - Evidence of increased intracranial hemorrhage on the Head CT scan.
  - Unexplained coagulopathy.
  - Irritation or infiltration at the site of infusion.
  - Minor allergic reaction including skin rash (with or without hemodynamic effects).
  - Any evidence of increased bleeding.
  - Death that is not explained by the injury severity.
- If the physician caring for the patient feels it is imperative to learn which type of study fluid that the patient received in order to safely continue treatment. Please page the ROC Research Coordinator on call.
- Notify the ROC Research Coordinator before discharging the patient.
- EPI Card....method to opt-out of the study. [www.myepi.com](http://www.myepi.com)

## Hospital Nursing Unit Staff Education for the Hypertonic Saline Trial

- Start Date.....Wednesday, April 11, 2007 at Noon.
- Patient should arrive to the unit with a yellow arm band with the contact information and the study fluid ID number listed...do not remove.
- If the patient arrives to the unit with the study bag attached, call the ROC Research Coordinator on call to retrieve it... do not discard.
- The patient should have an **“Information for Care Providers”** sheet in their permanent record. The study fluid ID number is located in the upper right hand corner. Should the need arise; please provide this number to the ROC Research Coordinator on call if you have any questions or concerns during the patient’s length of stay.
- Soon after the patient is admitted to the Unit, please change the Attending Physician from Dr. Rue to Dr. Kerby and order a new arm band.
- There is a set of **“ROC HS PROTOCOL”** orders in PIN. If these patients are admitted directly to TBNU or ATCU from the ED, no sodium monitoring is required. Therefore, you do not have to follow the ICU set of orders. Upon patient arrival to the unit please initiate these orders. Follow the steps listed below:
  - Locate the Patient in PIN
  - Click on Ordering Guide
  - Click on Enter Orders for MD
  - Click on Protocol/Standing Order
  - Type in Kerby’s name and press F10
  - Click on “Kerby, Jeffrey D.”
  - Under Miscellaneous, click on Order Set
  - Click on Personal
  - Click on Continue
  - Click on “ROC HS TRIAL”
  - Click on “ALL OF THE ABOVE”
  - Click Review then Enter

- During the course of their hospital stay, these patients should not be enrolled into any other hospital based clinical trial. If you have any question please contact the ROC Research Coordinator on call.
- Please report any of the following **Adverse Events** to the ROC Research Coordinator:
  - Serum Sodium level greater than 170 mEq/L and requires therapeutic interventions
  - Evidence of increased intracranial hemorrhage on the Head CT scan.
  - Unexplained coagulopathy.
  - Irritation or infiltration at the site of infusion.
  - Minor allergic reaction including skin rash (with or without hemodynamic effects).
  - Any evidence of increased bleeding.
  - Death that is not explained by the injury severity.
- If the physician caring for the patient feels it is imperative to learn which type of study fluid that the patient received in order to safely continue treatment. Please page the ROC Research Coordinator on call.
- Notify the ROC Research Coordinator before discharging the patient.
- EPI card....information on how to opt-out. [www.myepi.com](http://www.myepi.com)

## Research Participant's Bill of Rights

If you are asked to participate in a research study, you have the right to

1. Be told what kind of study it is and why it is being done.
2. Be given an explanation of the procedures to be used, as well as a description of any drug or device to be used.
3. Be given a description of any discomforts and risks to be expected, as well as whether there will be any financial costs to you or your insurance company.
4. Be given an explanation of benefits to be expected, if any.
5. Be told of procedures, drugs, or devices that might help you if you do *not* participate in the study, as well as how the risks and benefits of such options compare with those of participating.
6. Be told of any treatment or alternative treatment, if any, available to you during and after the study.
7. Be given an opportunity to ask any questions about the study or the procedures involved.
8. Be told of new findings that could change your willingness to consent and be informed that you may withdraw your consent to participate at any time, without penalty to you.
9. Be given a copy of any consent form used in relation to the study.
10. Be given the time and opportunity to decide freely whether to consent or not consent to participate in the study.

## ¿ If you have questions, please ask!

You will be given a person's name and telephone number as a contact for the study. If not, ask anyone working on the study! Wondering about benefits and risks of the study? Ask. Wondering whether you'll be paid? Ask.

For more information about the rights of research participants, please contact Ms. Sheila Moore in the Office of the IRB. Her phone number is listed at the bottom of this page.

You can also use the web to learn about research with humans at any of these sites:

**Office for Human Research Protections**  
<http://ohrp.osophs.dhhs.gov>

**National Center for Bioethics**  
<http://www.tuskegee.edu/bioethics>

**NIH Bioethics Resources on the Web**  
<http://www.nih.gov/signs/bioethics>

### Institutional Review Board for Human Use



Phone: 205-934-3789 or 800-822-8816

If no one answers, use the menu options to reach Ms. Sheila Moore. Help in Spanish upon request.

Email: [irb@uab.edu](mailto:irb@uab.edu)

Web: <http://www.uab.edu/irb>

# Participating in Research Studies

University of  
Alabama at Birmingham

Institutional Review Board  
for Human Use



# UAB — Medicine that Touches the World



**UAB** provides medical care through University Hospital and clinics. UAB is also a major center for education and medical research. Both care and education are necessary for medicine to succeed and advance.

Many of the men and women who provide medical care at UAB, or provide support for that care, are conducting research studies to improve the quality of medical care—to develop new medications or procedures, for example. As a patient at UAB, you may be asked to participate in such a research study.

## Informed Consent

For some studies, if you agree to participate, someone from the study will ask for your "informed consent." To give that consent, you may be asked to sign a form, but remember:

***Informed Consent Is a Process,  
Not a Form.***

If you have a question or concern about your participation at any time during the study, ask about it. After all, you need to be informed before you can give your consent.

## Your Rights & Responsibilities

The ultimate goal of research at the UAB Medical Center is to improve health care. However, to study possible improvements, our researchers need to compare different treatments, drugs, or procedures to see how they work.

Regardless of the nature of the study or the participant group you might be placed in, you have the same rights.

Your general rights are outlined on the back of this brochure. The researchers may give you more information on these rights during the informed consent process. They will also tell you what is expected of you (your responsibilities) while you are in the study.

## Children in Research

You may be asked if you are willing to allow your child to participate in a research study. Special efforts are made to protect children who participate in research.

Most studies involve no more than minimal risk to children, or they offer some possibility of direct benefit. No undue risks are taken with children who participate in research.



As a parent, you play an important role in this process. Make sure you understand the risks as well as any possible benefits of your child participating in the study.

Ask questions of anyone involved in the study, and feel free to discuss the study with your child's regular pediatrician as well. Children also have the right to an age-appropriate explanation of the research.

***We want both you and your  
child to be comfortable.***

## Adverse Events

For the research to be complete, you may be asked to tell the study staff about any unusual symptoms or problems with your health while you are on the study. The researchers will explain this to you during the informed consent process.

