

Appendix F



ROC

Resuscitation Outcomes Consortium


**THE UNIVERSITY OF
ALABAMA AT BIRMINGHAM**
Institutional Review Board for Human Use
MEMORANDUM

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

FAX: 5-4662

FROM: Denise Ball *Denise*
On behalf of IRB 02

DATE: August 16, 2007

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

The IRB 02 met on August 15, 2007 and discussed the "opt-out" options available for individuals who do not want to participate in the ROC studies. The IRB noted that the current opt-out option in the Birmingham community is the use of an EPI card that is carried in a purse or wallet. The IRB confirmed that this an appropriate option for those individuals who prefer to be more inconspicuous about their decision not to participate and those who don't want to wear a bracelet at all times. However, to be consistent with the opt-out options at other ROC sites, the IRB determined that the bracelets should also be available to Alabama residents.

In a memorandum, please address whether it will be feasible to give individuals the option of obtaining either the EPI card or the bracelet. If the bracelets can be made available to the public, address your plans for educating the EMS staff and others involved with this study regarding this new opt-out option. Also address your plans for notifying the public about this new option.

The IRB also requested that you address the concern regarding whether EMS responders can find the EPI card and access the information on the card quickly enough in an emergency situation.

Please call me if you have any questions about the Board's decision.

itb

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The University of
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Mailing Address:
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Seattle-King County
Opt-out Bracelet
IRB-Approved Modification



ROC

Resuscitation Outcomes Consortium

University of Washington
Human Subjects Division

REC'D
Human Subjects Division

Modification Form

SEP 20 2007

UW

This box is for Human Subjects Review Committee Use Only		Master
HSRC signature: <u>[Signature]</u>	Date <u>approved/noted/denied: 9-20-07</u>	Committee
Contingencies: _____		Investigator
		AE/Safety Report

PLEASE READ THIS FORM CAREFULLY, ADDRESS EACH APPLICABLE ITEM OF INFORMATION REQUESTED IN NUMBERS

1-8, AND SEND THE REQUESTED NUMBER OF COPIES.

PLEASE DO NOT submit double-sided forms or attached materials!

Unless otherwise stated, submit three (3) copies of this form collated with three (3) copies of revised or additional materials. We will not accept handwritten forms, incomplete forms, or forms printed on both sides of the paper. Use 10 point type or larger throughout modification form.

Modifications may not be implemented until you have received approval. The approval of this modification does not change the original period of approval of your Human Subjects Review Committee application.

If an adverse event occurs at a site covered in your approval for this study, submit a UW "Adverse Event Report Form." This form is available on the Human Subjects Division web site at <http://depts.washington.edu/hsd/formin.htm/>

If you have any questions, please call our office at (206) 543-0098.

TITLE OF APPLICATION: Resuscitation Outcomes Consortium Prehospital Resuscitation using an Impedance threshold device and Early versus Delayed rhythm analysis (ROC-PRIMED)

Principal Investigator: Peter J. Kudenchuk, MD Current HSRC approval no.: 06-1314-A01

Dept./Div.: Medicine/Cardiology Box/Mailstop: 356422 Phone: 206 685 4176 Fax: 206 616 1022 Email: kudenchu@u.washington.edu

Contact person if not the PI: _____ Phone: _____ Email: _____

1. ADDING A NEW FUNDING SOURCE. Complete the information in the box below. Briefly summarize the procedures involving Human Subjects in this new funding proposal and describe any differences between the approved application and the new proposal. If there are multiple aims in this grant, please specify which aim(s) pertain to this specific Human Subjects Application, and flag or indicate the page. If this grant will modify the population, purpose or procedures, outline these changes under the appropriate heading below. Submit 3 copies of this form and 1 copy of the grant proposal.

Funding Type:	<input type="checkbox"/> Research Grant	<input type="checkbox"/> Fellowship	<input type="checkbox"/> Training Grant	<input type="checkbox"/> Contract	<input type="checkbox"/> Other, specify: _____
Principal Investigator (on grant proposal): _____					
Proposal Title: _____					
Funding Agency:	Agency Number (if known): _____				
Status:	<input type="checkbox"/> New <input type="checkbox"/> Competing Renewal <input type="checkbox"/> Non-competing Renewal				
Start Date:	End Date:	Submitted through OSP? <input type="checkbox"/> Yes <input type="checkbox"/> No. If No, explain _____			

University of Washington, Human Subjects Division, Box 355752, 3935 University Way NE, Seattle, WA 98105-6613
Phone: (206) 543-0098 Fax: (206) 543-9218 Email: hsd@u.washington.edu web page: <http://depts.washington.edu/hsd/>

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Human Subjects Division

Modification Form

- 2. CHANGE IN STUDY PURPOSE:** Describe the change/revision to the purpose of the study, and explain the reason for this change.
- 3. CHANGE IN PROCEDURES:** Briefly summarize proposed changes below. Explain why the changes are being made. Describe any changes in risks, and an assessment of whether or not any changes should be made to the consent form(s). If you believe no changes are necessary, please state. **Send 3 copies of this form along with 3 copies of the revised consent form(s).** (See 4, below.)

4. CHANGE IN POPULATION and/or RECRUITMENT: Briefly describe proposed changes in subject population or recruitment, including the reasons for this change. Include the following for each new population, if relevant: inclusion criteria, exclusion criteria, age range, number of subjects (cases and controls), approach and recruitment methods. **Submit 3 copies of this form and 3 copies of all revised or new recruitment materials.**

5. SITE: Submit three copies of this form and one copy of a letter of cooperation from each non-UW site. The letter should acknowledge that the agency is familiar with the study purpose and procedures, and with the investigator and their affiliation with the University of Washington.

6. REVISIONS TO CONSENT DOCUMENTS: Submit 3 copies of this form and 3 copies of each revised consent/assent form or oral consent script, incorporating changes in purpose, procedures, population, investigators and risks as described elsewhere on this form. **Highlight changes on one copy.** Please check the sample consent form and the consent form checklist on the HSD web site at <http://depts.washington.edu/hsd/FORMS> for current requirements. Please also refer to the Clinical Trials Handbook, at <http://www.hscer.washington.edu/clinicaltrialshandbook/4Consent.html>, for other sample consent form language.

State the total number of approved consent forms in current use for this study. State if this consent form replaces a current version (and specify the approval date), or is an additional consent form.

7. CHANGE IN INVESTIGATORS: Provide information requested below for each new investigator; also indicate if an investigator is no longer associated with this research. **If the Principal Investigator is appointing a new PI, both the current PI and new PI should sign this form.**

Name and Title	University Position	Dept./Div.	Phone	Box

8. OFF SITE ADVERSE EVENTS and SAFETY REPORTS: If an event occurs at a site covered in your approval for this study that is unexpected or more severe than anticipated, submit the UW "Adverse Event Report Form" available at <http://depts.washington.edu/hsd/FORMS/areport.doc>. If an adverse event occurs that is anticipated or no more severe than expected, it must be reported on the Status Report at annual renewal or when closing the study. Otherwise, state how many events are being reported here. List the dates of occurrence and provide a brief description of each event. Also, inform us whether these adverse events are new or follow-ups of events that were already reported to us, then include the date the event was originally reported. Assess whether or not changes are required to the consent form. If you believe no changes are required, please state. Also state whether enrollment is still open for this study and whether subjects are still undergoing study procedures. **Submit 2 copies of this form and 1 copy of each adverse event/safety report.**

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9. **PROTOCOL AMENDMENTS and INVESTIGATOR DRUG BROCHURES (for FDA regulated studies only):** Describe what changes are being made if not described above, and assess any changes in risks to subjects. If you believe there are no changes in risks, please state. If submitting a protocol amendment, submit 3 copies of this form, 3 copies of the amendment and 1 copy of the revised protocol. If submitting an updated Investigator Drug Brochure, submit 3 copies of this memo and 1 copy of the brochure.

10. **CONFLICT OF INTEREST:** If there has been a change in the financial interest for any members of the research team, provide a copy of the letter you received from the Office of Research about how this conflict of interest should be managed.

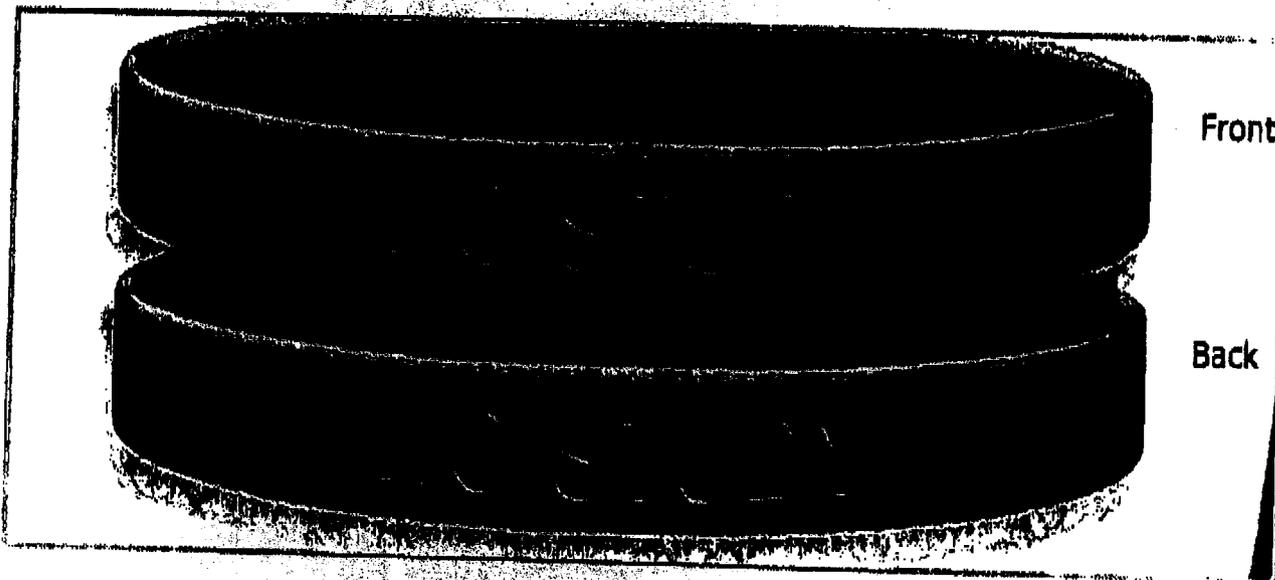
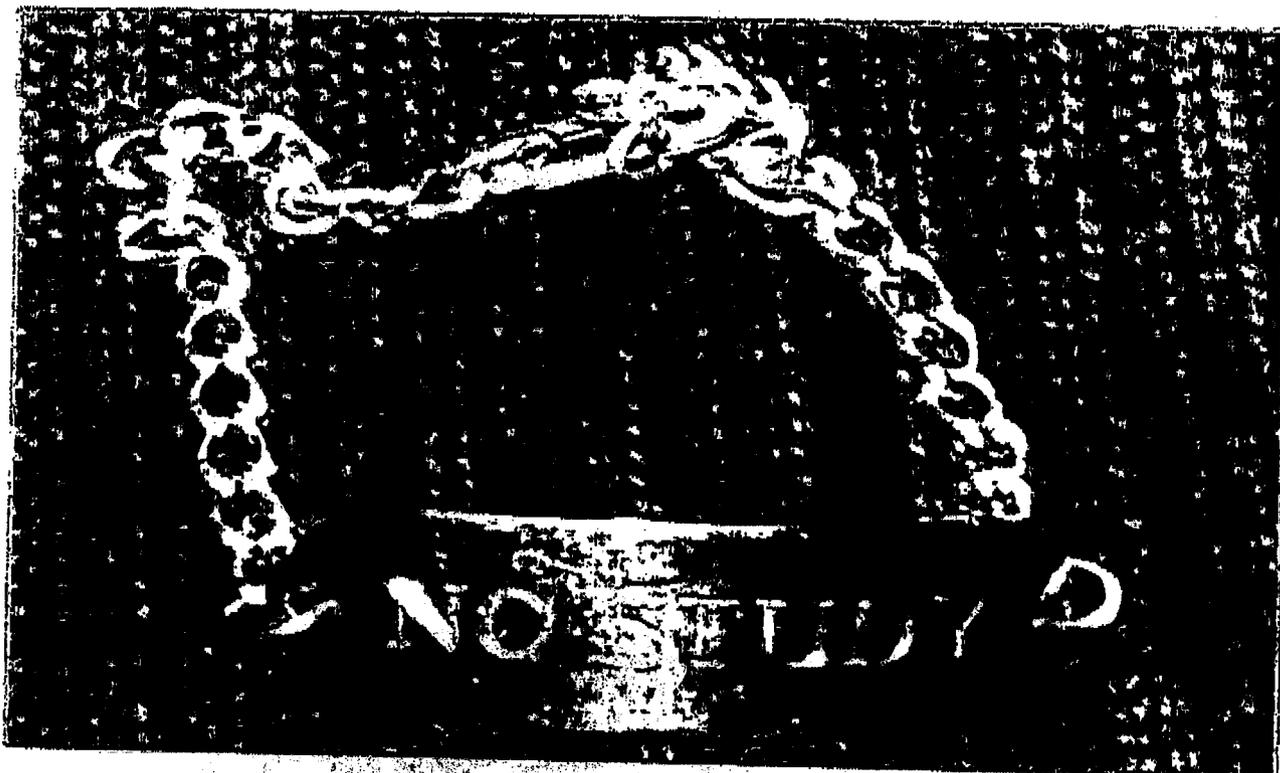
11. **OTHER (protocol violations, relevant compliance approvals, and data monitoring, etc.):**

The following information is provided as an interim summary to the Committee of our community notification activities pertaining to adoption of an opt out protocol modification, which applies specifically to persons who may indicate their wish to be excluded from ROC-PRIMED before sustaining a cardiac arrest that might result in their enrollment in the trial. As the Committee is aware, this is a separate issue from our pre-existing policy that subjects already enrolled in the trial will be notified of their participation as soon as feasible upon their admission to the hospital and offered the opportunity to opt out of further participation in the trial, which has always been and remains our standard operating procedure.

On May 30, 2007 a modification of the ROC-PRIMED protocol was requested and approved by the Committee for institution of an a priori opt out provision pertaining to persons who may indicate their wish to be excluded from the trial before their enrollment. Such persons would be mailed an "opt out bracelet" along with a letter, indicating the bracelet's purpose and instructions for its use. Subsequent modifications of this policy that were approved by the Committee included permission to issue temporary plastic bracelets to expeditiously accommodate incoming requests (because of unexpected logistical delays before engraved permanent stainless steel bracelets were initially available for mailing), permission to substitute the words "NO STUDY" for "NO RESEARCH STUDY" to allow these letters to be sufficiently large to be easily legible on the bracelets, and permission to issue permanent plastic opt out bracelets as an alternative to the permanent stainless steel bracelets for persons indicating an allergy to metals. As of this date, all requests for opt out bracelets have been accommodated and all temporary plastic bracelets have been replaced with permanent stainless steel bracelets or a permanent plastic bracelet (in the case of metal-allergic persons), each professionally engraved with the words "NO STUDY" in large letters as depicted below. Prehospital providers have been shown these bracelets and familiarized with their appearance and the need to exclude persons wearing them from enrollment in the prehospital trial.

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The community has been notified about this a priori opt out policy, the availability of, and means of obtaining opt out bracelets upon request. Such community notification has occurred through published articles in the Seattle Times between the dates of 6/3 - 6/11/2007, local radio spots on KIRO and KOMO radio on 6/6/2007, a variety of websites including Seattlest on 6/11/07, Fox Cable Television on 6/22/2007, and KOMO Television and KOMO radio on 8/16/2007. We will also be providing additional information in a scheduled radio presentation on KVI Radio on 9/30/07. In addition, this information is provided on our dedicated public information website www.uwheartroc.org.

To date, 216 individual requests for opt out bracelets (some requesting multiple bracelets) have been received and all have been accommodated. Some requests have come from other communities, including Portland, OR; Providence, RI; and as far away as Ottawa, Canada and Australia. All requests have expressed the desire to opt out of any study that does not require prior written informed consent, regardless of the nature of the intervention. For this reason, with the approval by the Committee of such an a priori opt out provision for each trial, we intend to continue to use a single bracelet inscribed with "NO STUDY" for all prehospital trials being conducted locally with exception to informed consent, in this case ROC-PRIMED as well as the ROC-hypertonic saline (HSD) trauma trial. Persons requesting an opt out bracelet, and the date when such bracelets were mailed have been and will continue to be documented. This information remains available upon request to the Committee.

Typed name and original inked signature of P.I.: Peter J. Kudenchuk, MD Date: 9/18/2007