



Reperfusion of Acute Myocardial Infarction in Carolina Emergency Departments-
Emergency-Response

May 22, 2008

Dear State RACE Team,

On behalf of RACE Central, we would like to express our great appreciation for your participation in the RACE-ER Preliminary Launch Meeting and dedication to heart attack care. This landmark meeting brought together key healthcare personnel from across the state of North Carolina representing, for the first time ever, all 21 centers performing primary percutaneous intervention (PCI). Your unprecedented commitment to rapid and systematic coronary reperfusion will lead to the highest quality of cardiac care ever achieved on a statewide basis. More importantly, your efforts will save lives and prevent disability among the thousands of North Carolinians suffering heart attacks each year. The collaboration of virtually every major organization in the field including the North Carolina Office of Emergency Medical Services, the American Heart Association, the American College of Cardiology, the Society of Academic Emergency Medicine, the American College of Emergency Physicians, the North Carolina Hospital Association, critical care transport systems, all four medical schools, the North Carolina Division of Public Health, and front-line emergency physicians like Dr. Jonathan Kelly sends a powerful message and will assure our success.

We have attached for your review, and for those working with us who were unable to attend the meeting, the key discussion points of the meeting. Also, we are very pleased to announce that Jenny Underwood, RN, BSN has accepted the position of East State RACE Leader, joining our West State RACE Leader, Lisa Monk, RN, MSN. Please feel free to contact any of us at RACE Central for your suggestions, question, or concerns.

Sincerely,

RACE Central

Christopher B Granger, MD
Professor of Medicine
Director, Cardiac Care Unit

James G. Jollis, MD
Associate Professor of Medicine
Medical Director, RACE

Mayme Lou Roettig, RN, MSN
Executive Director, RACE



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RACE-Emergency Response Preliminary Launch Meeting

Sheraton Imperial Hotel and Conference Center

Durham, NC

May 15, 2008

Meeting Objectives

- Relay detailed information regarding RACE-ER Launch activities.
- Establish the necessary infrastructure among all primary PCI hospitals in the state to provide regional support to coronary reperfusion.
- Describe and implement a statewide STEMI network data system that includes blinded system reports, the ACTION-GWTG database, integration of NEMSIS data, ability to characterize “false” catheterization laboratory activations and deaths in transfer, a limited data set according to HIPAA privacy regulations, and Data Use Agreements from every participating hospital.
- Provide updates regarding pertinent developments in the field including national organizations, the Center for Medicare and Medicaid Services, quality initiatives, and recent clinical research development.
- Describe expansion and developments in the RACE organization regarding participation, leadership, and funding.
- Gain insight into regional STEMI system implementation from the perspective of experienced and successful colleagues.



Reperfusion of Acute Myocardial Infarction in Carolina Emergency Departments- Emergency-Response **RACE Recap**

The initial RACE project was a collaborative quality assurance effort to increase the rate and speed of reperfusion through systematic changes in emergency care. The original project was based upon the mutual effort of EMS personnel, physicians, nurses, administrators, and payers from five regions and 68 hospitals across North Carolina. The goals and recommendations of this project were based upon evidence from clinical trials and national clinical practice guidelines. The results of the initial RACE intervention were published in the Journal of the American Medical Association [JAMA 2007; 298: 2371-2380]. Comparing treatment times preceding and one year following the RACE project, coronary reperfusion significantly improved by almost every measure. For patients involved in a rapid hospital transfer strategy, door-in door-out times fell from 97 to 45 minutes, and first hospital door to device times fell from 149 to 106 minutes ($P < 0.001$). For patients presenting directly to angioplasty hospitals, the proportion of patients treated within 90 minutes increased from 57 to 72% ($p = 0.02$). The improved STEMI system at angioplasty hospitals also resulted in a substantial decrease in the “eligible for reperfusion but untreated” patients, falling from 23% to 11% by the end of the project ($P < 0.01$).

Communication Requirements

- RACE-ER Phone Book
 - Directory with name, credentials, titles, key contact information
 - This will be sent to CV Administrator/RACE System Coordinator at each institution
 - Once received by us, email distribution lists will be set up for RACE-ER PCI Teams
 - Your RACE System Coordinator will then do the same with our EMS and non-PCI center RACE Teams
- Register your referral base
 - List only non-PCI centers that refer “STEMI” urgently to your centers (not interested in your ACS referral pattern or chest pain capture)
 - This is critical to our non-PCI approach for maintaining existing appropriate referral patterns (2 centers share-both approach)
 - This will be sent to CV Admin/RACE System Coordinator at each institution
 - Tip- contact your Cardiac Cath Lab team> they know where the STEMI patients come from

RACE at its Best--Patient Vignettes was presented by William Hathaway, MD from the Mission Health System. Dr Hathaway emphasized that the system response was



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key to success in improving clinical and process outcomes for STEMI. It is not one person that makes timely incredible life sustaining reperfusion possible, but team work analogous to a pit crew in NASCAR. Each healthcare professional touching the patient during their chain of survival is critical to the success of the system of care.

A STEMI Update was provided by Christopher Granger, MD, co-medical director of RACE. Dr Granger reviewed the recent updates to the ACC/AHA guidelines for STEMI released in December, 2007. The emphasis on moving care forward with the first medical contact language in the process timeline goals was discussed. In addition, a society update was offered. Dr. Granger reminded the group that RACE is now endorsed by the American College of Cardiology, its original professional society sponsor, and the American Heart Association, through Mission: Lifeline. RACE continues to be the state quality improvement program of the NC Chapter of the American College of Cardiology (ACC). A number of NC ACC Councilors participated in the meeting (including Drs. David Bohle, Bill Hathaway, Chris Barber, Lee Jobe, Chris Granger, and James Jollis, MD). The highly successful ACC Door-to-Balloon program was reviewed as the foundation for RACE at PCI centers. The need to move the focus of care of the STEMI patient from the PCI hospital alone to the entire system (non-PCI and EMS point of entry) was emphasized. The AHA initiative, Mission: Lifeline, was discussed in detail, as well as a “thank you” to the NC RACE Team for being a model and important demonstration project for STEMI regionalization for the national effort.

What is Mission: Lifeline?

- Mission: Lifeline is a national community- based multidisciplinary initiative.
- The Overarching Goal→ Improve the mortality and morbidity and quality of care for the US AMI population, specifically through the development of STEMI systems of care.
- The Guiding principle: Patient centric, addressing the continuum of care for STEMI patients from symptom onset into the point of entry into the healthcare system, touching each aspect of the system, and return the patient back to the local community and physician,

Dr. Granger urged the STEMI systems represented to identify a system champion and to register their system on the AHA website (www.americanheart.org/missionlifeline). He informed the group that an official AHA comprehensive survey is going out to all EMS in the state to capture STEMI systems readiness (processes, equipment, staffing, etc). More information is available on the AHA website.

A brief STEMI research discussion followed. Dr Granger discussed the preliminary results of the TRANSFER-AMI trial presented at the national ACC Sessions in March. This trial evaluated patients treated with fibrinolytic therapy at community hospitals, and



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compared immediate transfer for PCI (time from tenecteplase to balloon 4 hours, interquartile range 3 to 5 hours) to rescue PCI (for patients with <50% ST resolution 60-90 minutes after TNK) and otherwise elective cath. +/- PCI > 24 hours after lytics. Clopidogrel, and GPIIb/IIIa inhibitors at the time of PCI, were generally used in both groups. The trial showed that for patients who receive lytics in a community hospital, routine transfer and early PCI resulted in better clinical outcome with acceptable bleeding risk.

While we await the final results and publication before this should impact practice, it suggests that early cath. and PCI, in the 3 to 5 hour range, is an excellent strategy following lytics. Of course, the preferred strategy, for patients who can get PCI within about 90 minutes of first door or first medical contact, is simply primary PCI.

A second trial, HORIZONS, which was just published in New England Journal of Medicine, was also discussed. This trial showed that bivalirudin is a reasonable alternative to heparin plus GPIIb/IIIa inhibitor for primary PCI. Bivalirudin resulted in less bleeding, at the cost of more stent thrombosis on the first day, and the suggestion of lower mortality.

RACE-ER – Overview

The next phase of RACE (RACE-Emergency Response, or *RACE-ER*) will aim to enroll all 100 NC hospitals and all EMS agencies (approximately 900). The goal of RACE-ER will be to improve the quality of care provided to the STEMI population at all stages of presentation and flow through the system (EMS, self-transport, PCI center, non-PCI center). This unique state-wide program will establish a network of all EMS systems and hospitals to share best practices and improve implementation of the American College of Cardiology / American Heart Association expert consensus document on the management of acute ST-Elevation Myocardial Infarction. This next phase will place particular focus on emergency medical services and impoverished communities in North Carolina.

Objectives:

Establish regional STEMI systems

Increase reperfusion rate for All eligible patients

Increase speed of reperfusion

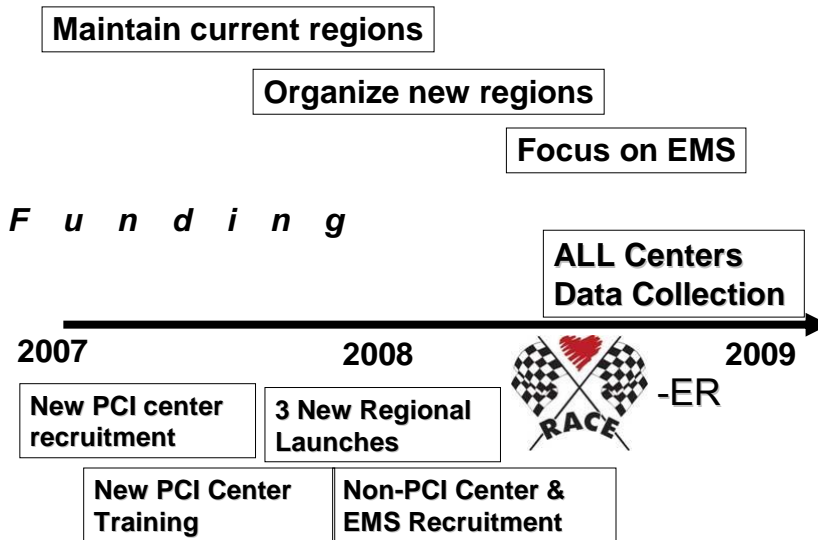
<30 minutes – fibrinolysis

<90 minutes - PCI



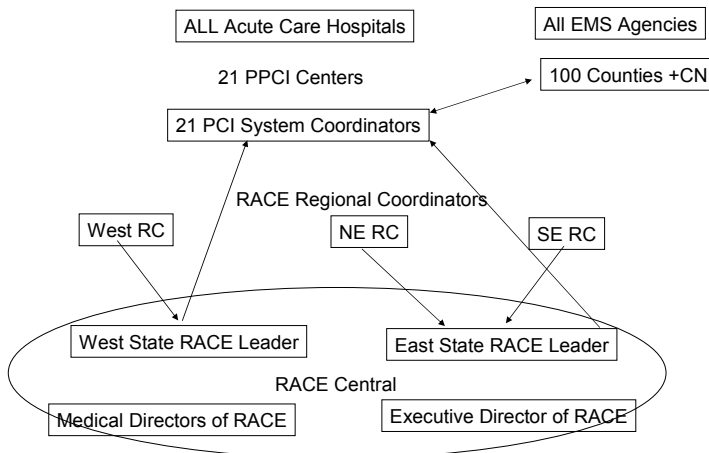
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RACE ER Timeline

RACE Phase 3 RACE-ER
 (Emergency Response)



Mayme Lou Roettig reviewed the new RACE-ER Structure and staffing needs.

RACE Structure



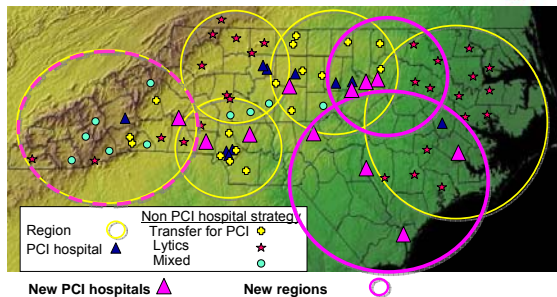


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James Jollis, MD provided an overview of RACE-ER

RACE – Emergency Response

- 1) Maintain and continue to improve at existing sites
 - 1) How can we accelerate transfer processes?
 - 2) Reach current (90 minute) or faster (60 minute) benchmarks.
 - 3) Improve current plans
 - 4) EMS bypass in spoke non-PCI counties
- 2) Expand to entire state (100 hospitals / 900 EMS agencies)

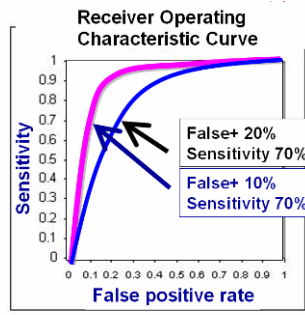
Hospitals
 100 (35 new)



3) Focus on EMS

- 1) Claire Meyer NREMT-P, new Southeast RACE Coordinator and the first paramedic Coordinator. Charged to build RACE EMS organization.
- 2) ECG training – Regional courses, Online course available to all NC EMT's

IMPROVE ECG
 PERFORMANCE
*Fewer false activations
 without missing
 more STEMI's*



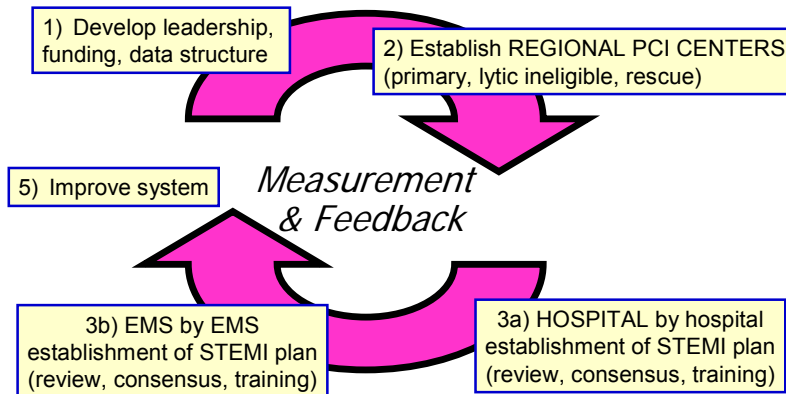
4) Additional resources for impoverished counties – Kate B. Reynolds Foundation





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RACE Process



RACE PRIMARY PCI Center*



1. 24/7 PCI capability within 30 minutes
 - Interventional cardiologist is present and directs the entire procedure from cath. lab arrival
2. Single number activation
 - Immediate, cardiologist accepts patient, cath. lab called in
 - Establish a daily primary PCI operator schedule that is coordinated between all cardiologists, and involves a single rotating physician
3. Accept patients regardless of bed availability
4. Ongoing data monitoring and feedback
 - ACTION-GWTG, cath. lab activation registry
5. STEMI Team with strong administrative support and dedicated STEMI coordinator
6. Improve STEMI care for all hospitals in region regardless of affiliation

* *Must be fully operating by September 1, 2008 to be a RACE regional PCI center*

The Primary PCI requirements will be reviewed by RACE Central staff and the final list of RACE PPCI centers meeting these requirements and letter will be sent to all hospitals across the state.



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Keys to Success for STEMI System Implementation Reperfusion in Wilkes County Jonathan Kelly, MD Wilkes Regional Medical Center Emergency Medicine

Dr. Kelly described the STEMI reperfusion system in Wilkes County, birthplace of NASCAR icon Junior Johnson and home of the North Wilkesboro Speedway. Wilkes County EMS has one of the most advanced systems in the country, administering fibrinolysis “in the field.” This system requires strong medical leadership and oversight, and a highly trained EMT staff. Shifts are adjusted to allow for more experienced EMT-P’s to work with those less experienced on every shift. When he initially started at Wilkes Memorial, Stephanie Starling-Edwards, RN, BSN, the RACE coordinator, oriented Dr. Kelly to the Wilkes reperfusion system. Before approving fibrinolysis, Dr. Kelly feels that he must personally review the ECG. In cases when ECG transmission is not possible, he meets the EMS in the truck at the hospital door to review the ECG. All patients treated by EMS are transported to regional PCI hospitals. Regarding patients who present directly to the Wilkes Regional Medical Center Emergency Department, Dr. Kelly indicated that the RACE “hotline” transfer system is very helpful. The knowledge that all patients have an accepting cardiologist and bed overcomes many of the challenges and delays in obtaining acute care at tertiary hospitals. He refers patients to Wake Forest University Baptist Medical Center and Forsyth Medical Center, the choice of which depends upon patient and family preference.

Diagnosis to Reperfusion Hadley Wilson, MD Carolinas Medical Center

Dr. Hadley Wilson, an interventional cardiologist and founding RACE physician at Carolinas Medical Center, provided a detailed description of the reperfusion system in the Charlotte Region. Despite having been up until 6 AM the morning of the meeting performing primary PCI (a victim of his own success), Dr. Wilson felt that his support of the RACE-ER meeting was critical. He credited much of the success of RACE to the collaboration of physicians and hospitals in the Charlotte region (Presbyterian, CMC-Main, CMC-Mercy) who were able to overcome traditional competitive issues. A highlight of his presentation involved the newer concept of “E2B” (emergency contact-to-balloon). Among 99 patients treated in the first three quarters of 2007 who had pre-hospital ECG’s, 93% achieved door-to-balloon times (D2B) of under 90 minutes (median 64 minutes), and 74% achieved E2B times of under 90 minutes. 8 of 99 patients were “catheterization only,” not requiring angioplasty. These treatment times are among the best ever reported in the U.S. He concluded that 1) E2B times under 90



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minutes are achievable with EMS pre-hospital ECG's, 2) door-to-balloon times under 60 minutes are achievable at PCI hospitals, 3) EMS bypass of non PCI hospitals accelerates time to reperfusion, 4) enhanced efficiencies in transfers can be achieved by "leaving patients on the stretcher" for transfer, eliminating IV pump drugs, and single number for cath. lab activation, 5) there remains room for improvement in more distant non-PCI hospitals, and 6) the best system was developed through coordinated efforts of the healthcare community with all hospitals and EMS involved in STEMI care.

*Regional Discussion: steering meeting and planning next steps
This needs our direction in next steps

Regional Approaches-RACE Coordinator / State Leader View

Keys to Success for New STEMI Regions Jenny Underwood, RN, BSN Duke University Medical Center

- Clarify your team's goals (patient-focused care)
- Internal process development ("get your ducks in a row") – ensure that your own center has implemented all RACE concepts
- External process development:
 - Initial Outreach/Assessment (include all key stakeholders: ED, EMS, Cardiology, Administration, Quality)
 - Reperfusion Plan
 - Transport Strategy
 - Feedback Strategy
 - Ongoing Training/Education

Keys to Success for Maintaining RACE Regions Lisa Monk, RN, MSN RACE

Lisa reviewed the 5 concepts for success:

Passion, Commitment, Education, Data and Feedback

Challenges:

Maintaining or improving the gains made with:

- EKG Times- using EMS EKGs, data collectors finding EMS EKG or documentation that ED used EKG for clinical decisions, atypical presentation of STEMI-EKG protocols for EMS and ED's
- Scene Times –scoop and run, EKG done asap, transmission if possible, notification of ED MD
- ED Turnaround Times-goal < 60 or faster-streamline processes to move in and out rapidly
- Door to Lytic Times -< 30 mins
- Door to Balloon Times-< 90 (EMS EKG to balloon times < 90)



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Bypassing ED:

- Direct Admit to Cath Lab
- Lytic Ineligible Patients bypass outlying ED if stable
- Lytics in the field bypass ED if stable to get to PCI center sooner if no reperfusion.

**“WANT TO BE KNOWN AS THE SAFEST PLACE IN THE WORLD
TO HAVE A HEART ATTACK”**

The RACE-ER Data plan was reviewed by James Jollis, MD Medical Director, RACE.

Data collection and feedback are essential drivers of any quality improvement process and STEMI system, and much of our success in the first phase of RACE was based upon review of data by participating hospitals and emergency medical systems. Our objectives will be to measure the processes and outcomes involved with improving the rate and speed of coronary reperfusion. As before, findings will be reported at the system level, with the specific exclusion of hospital identified data.

RACE will collect data from 3 sources: 1) ACTION-GWTG for PCI hospitals (supplemented with matching EMS data) 2) Catheterization Lab Activation Registry, and 3) a supplemental data collection from fibrinolytic / non-PCI hospitals.

Hospital / ACTION data will be supplemented by additional data pertinent to STEMI reperfusion systems including transferring hospital identification and matching EMS data from the NC DHHS. The Catheterization Lab Activation Registry will be collected to characterize false positive activations and to identify deaths in transfer that may not be otherwise identified by ACTION data. Cath. lab activation calls will be identified according to call time, decision time, cancelled procedures and reason (death, not indicated, other), the lack of a culprit (infarct related) artery, and negative cardiac enzymes. Data sources will include communications centers, cath. lab logs, and EMS run data.

The Duke IRB has reviewed and approved the RACE-ER project to assemble a Limited Data Set as defined by HIPAA privacy rules (HHS regulations for the protection of human research subjects 45 CFR part 46). Each participating hospital must sign a Data Use Agreement with RACE according to the format established by the HIPAA privacy rules. This agreement assures that the data will be used solely to for the purposes of RACE and requires data system security. A major objective of this meeting is to expedite the signing of Data Use Agreements between participating hospitals and RACE as soon as possible.



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The complete and comprehensive RACE-ER data plan will soon be available to RACE participants so that, if required, an expedited IRB review may be completed at each Primary PCI Center.

Data Plan



Limited Data Set

- Data Use Agreement (HIPAA template)
- Between hospital and RACE Central
- Standard data pertaining to STEMI reperfusion
- Matching EMS run data from DHHS
- Hospital specific data will not be released

Data Use Agreement for RACE - DURE Data

This Data Use Agreement for a Limited Data Set (LDDS) is effective on the 1st day of July, 2008.

CORONARY REPERFUSION IN CAROLINA (CORONARY REPERFUSION IN CAROLINA) is a research project of the University of North Carolina at Chapel Hill, and the University of North Carolina at Chapel Hill, a non-profit organization located at Chapel Hill, North Carolina, is hereby referred to as "Researcher".

The Covered Entity is a COVERED ENTITY as defined in the Health Insurance Portability and Accountability Act of 1996, as amended ("HIPAA"), and the Covered Entity is providing information to Researcher in a Limited Data Set (LDDS) as defined in 45 CFR 162.102(a)(1) for the purpose of conducting research on the topic of "CORONARY REPERFUSION IN CAROLINA" as defined in HIPAA.

The Parties agree to the provisions of this LDDS in order to address the requirements of HIPAA and to permit the research project herein.

- DEFINITIONS:** Except as otherwise defined herein, any and all capitalized terms in this LDDS shall have the definitions set forth in HIPAA. In the event of any discrepancy between the provisions of this LDDS and any applicable provisions of HIPAA, as amended, the HIPAA provisions shall control. Where provisions of this LDDS are different from those provided in HIPAA, but are permitted by HIPAA, the provisions of this LDDS shall control.
- USE OF LDDS BY RESEARCHER:** Researcher shall have the right to use or disclose all PII provided to it by the Covered Entity for the Research and Public Health Purposes, as defined below.

Researcher shall not disclose, publish, transmit, disseminate, or otherwise use the LDDS for any purpose other than the Research and Public Health Purposes.
- RESTRICTIONS ON USE:** Researcher agrees that it, and any employees, agents and subcontractors to whom it discloses the LDDS, will not use or disclose the PII other than as permitted by this LDDS, or as otherwise required by law or regulation. Researcher shall use appropriate safeguards to protect the PII from misuse or unauthorized access, and to prevent any use or disclosure of the PII other than as permitted in this LDDS, or as otherwise required by law or regulation. Researcher shall not attempt to identify the individuals to whom the PII pertains, or attempt to contact such individuals.
- RESPONSE:** Researcher shall report to Covered Entity any use or disclosure of the PII not permitted by this LDDS, or which Researcher becomes aware. Researcher will take reasonable steps to block any further use or disclosure.
- TERMINATION:** This LDDS shall be effective on the 1st day of July, 2008. This LDDS shall terminate as long as Researcher retains the LDDS, unless otherwise terminated by applicable law or regulation. Researcher may terminate this Agreement by notifying or disclosing the PII and providing written notice to the Covered Entity. Should Researcher terminate or cease use of the LDDS, which is not used within thirty (30) days after Researcher receives notice of termination from the Covered Entity, then the Covered Entity will immediately destroy all PII and will report the breach to the Secretary, Department of Health and Human Services.

For CORONARY REPERFUSION IN CAROLINA	For the Covered Entity
Signature	Signature
Printed Name: James G. Sallis, MD	Printed Name
Title: Co-Medical Director, RACE Project	Title
Date: May 15, 2008	Date

Please attach the original signatures to this document. You should keep a copy of this document for your records.

James G. Sallis, MD
 May 15, 2008
 Date: May 15, 2008

<http://www.hhs.gov/ocr/hipaa/guidelines/research.pdf>

RACE-ER Call to Action Granger/Roettig

Questions / answers / additional recommendations RACE Central/ State Teams