EMORY UNIVERSITY

Institutional Review Board

Bryan McNally, MD
Med Sch: Emergency Medicine
EUH- Dept of Emergency Medicine
1364 Clifton Rd Box 80
Atlanta, GA 30322

RE: **NOTIFICATION OF PROTOCOL APPROVAL - EXEMPT**
PI: Bryan McNally, MD
IRB ID: **1377-2004**
TITLE: Project RESTART (Regional Enhancement of Cardiac Arrest Survival Through Applied Research and Treatment
DATE: January 03, 2005

The research proposal cited above has been reviewed and is exempt from further review. The proposal meets the criteria for exemption under 45 CFR 46.101(b) and thus is exempt from further review. The IRB will be apprised of this decision at its next meeting.

A waiver of authorization has been granted by the Emory University IRB for the purpose of determining eligibility and conducting this study. This waiver was reviewed and approved under the review procedure note above. The approval is granted based on this board's determination that all criteria for waiver of authorization have been met. The PHI that may be used or disclosed for this use is limited to: physician records and hospital records.

Any serious adverse events or issues resulting from this study should be reported immediately to the IRB and to any sponsoring agency (if any). Amendments to protocols and/or revisions to informed consent forms/process must have approval of the IRB before implemented.

All inquires and correspondence concerning this protocol must include the IRB number and the name of the Principal Investigator.

If you have any questions or concerns, please contact the IRB office at 404-727-5646 or at email address irb@emory.edu. Our web address is http://www.emory.edu/IRB. Thank you.

Sincerely,

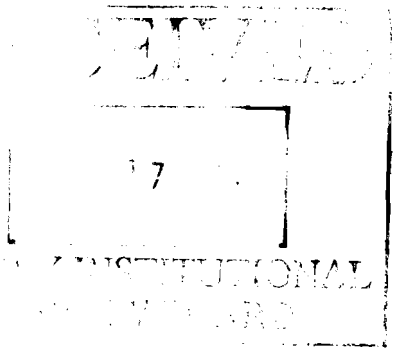
Golde Dudell, MD
Vice Chair, Institutional Review Board

cc: Arthur Kellermann, MD
Lorie Click

to VIC 12/17/04

EMORY UNIVERSITY
INSTITUTIONAL REVIEW BOARD
INITIAL SUBMISSION FORM

1256 Briarcliff Rd., Room 426-S, Atlanta, GA 30306
phone: (404) 727-5646 fax:(404) 727-1358
http://www.emory.edu/IRB



OFFICE USE ONLY
IRB #: 1377-04
Review Type: EX
Committee: Dudell
Specialist: Patti

Please Print Or Type. Complete form in its entirety. INCOMPLETE FORMS WILL NOT BE PROCESSED.

A. BASIC INFORMATION	
1. Title of Proposal	Project RESTART (Regional Enhancement of Cardiac Arrest Survival Through Applied Research and Treatment
2. Keywords	82-Emergency Medicine, 48-Cardiology, 187-Public Health, 88-Epidemiology

B1 . STUDY PERSONNEL (add rows by hitting the TAB key from the bottom right cell)

Name	Degree	Dept/Div	Address	Phone Number	Fax Number
1. Bryan F. McNally	MD, MPH	Emergency Medicine	Emory University Hospital, Department of Emergency Medicine 1364 Clifton Road, Box 80, Atlanta, GA 30322	404-712-0445	404-712-2001
2. Arthur Kellermann	MD, MPH	Emergency Medicine	Suite B6200, 1365 Clifton Road, Atlanta, GA 30322	404-778-2602	404-712-1872
3. Lorie A. Click	MN, MPH	Emergency Medicine	49 Jesse Hill Jr. Drive, S.E. Atlanta, GA 30303	404-616-6022	404-616-6182
4. Research assistant, tba	EMT				
5. Graduate student, tba					

B2. LINK TO ROW NUMBERS ABOVE

Role (e.g., PI, co-PI, coordinator, etc.)	Emory Affiliation (e.g., faculty, staff, student, etc.)	Receive Correspondence (Yes/No)	E-mail Address
1. Principal Investigator	Faculty	Yes	bryan_mcnally@emoryhealthcare.org
2. Co-principal Investigator	Faculty	Yes	akell01@emory.edu
3. Epidemiologist	Faculty	Yes	lclick@sph.emory.edu
4. Data collection	Staff	No	
5. Clerical	Work-study student	No	

C. FUNDING	
1. Is Project Funded?	☐ No ☒ Yes ☐ Pending
2. Type:	☐ Corp. ☒ Fed. ***(If federally funded, provide a copy of your grant)*** ☐ State ☐ Other
3. Sponsor:	Centers for Disease Control and Prevention
4. OSP Status:	☐ N/A ☒ To be submitted ☐ Submitted on

D. BIOSAFETY	
1. Does this study involve:	recombinant DNA Yes ☐ No ☒ biological toxins Yes ☐ No ☒ infectious agents Yes ☐ No ☒
2. If yes, do you have biosafety approval?	☐ No ☐ Yes (Authorization #)

E. RADIATION	
1. Is radiation used in this project?	☒ No ☐ Yes
2. If yes, what forms of radiation?	☐ X-rays ☐ Radiation therapy ☐ Radioisotopes
3. Is it beyond standard of care?	☐ No ☐ Yes
4. Radiation Safety Committee (RSC) approval:	Authorization #
5. Name of person who holds the RSC approval?	

F. INVESTIGATIONAL DRUGS		
1. Will drugs be used in this study?	☒ No ☐ Yes	
2. If yes, are they FDA-approved for the indication described in this protocol ?	☐ No ☐ Yes	
3. If not FDA-approved, is there an IND? The clinical investigation of a marketed drug or biologic does not require submission of an IND if certain conditions are met. Go to http://www.emory.edu/IRB/drugsdevices.htm for more information.	☐ No (meets criteria for IND waiver) ☐ Yes (IND #: _____) ☐ Pending	
4. Name of investigational drug	generic	trade
5. Manufacturer		
6. Who holds the IND #?	☐ Sponsor ☐ Investigator	
7. Investigator's Drug Brochure submitted?	☐ No ☐ Yes	If no, explain why
8. Will the investigational drugs be managed by the Emory University Investigational Drug Service (IDS) @ Emory Hospital?	☐ No ☐ Yes	
9. If you do not use the IDS, please describe your procedures for the management and control of the investigational drugs(attach additional sheet if necessary):		

G. INVESTIGATIONAL DEVICES			
1. Will devices be used in this study?		☒ No ☐ Yes	
2. If devices will be used, are they FDA-approved for the use described in this protocol?		☐ No ☐ Yes	
3. If not FDA-approved, is there an IDE?		☐ No ☐ Yes (IDE #: ____)	
4. If yes, indicate category:	Experimental/Investigational; Innovative device, not previously approved	☐ Category A	
	Non-experimental / Investigational; Proven technology, new application	☐ Category B	
5. Name of investigational device		Generic	trade
6. Manufacturer			
7. Who holds the IDE #?		☐ Sponsor ☐ Investigator	
8. Risk of Device (*written justification is required*)		☐ Significant Risk ☐ Non-significant Risk	
9. Has device been submitted to medical engineering?		☐ No ☐ Yes	
10. Investigator's Brochure submitted?		☐ No ☐ Yes	If no, explain why

H. DATA MONITORING AND SECURITY	
1. Will data be reviewed by a Data Safety Monitoring Board (DSMB)?	☒ No ☐ Yes
2. If yes, describe composition, frequency of meetings, etc.	
3. If no DSMB, describe what plan is in place to minimize risks and ensure the safety of subjects (include any stopping rules).	This project will only involve record review so it poses no physical risk for the subjects. Please see attached documentation of data security procedures.
4. How will any electronic data be secured?	☒ secure network ☒ password protection ☐ Other (explain) Please see attached data safety plan.
5. How will hard copy data be secured?	☒ locked office ☒ locked filing cabinet ☒ Data De-identified (see http://www.emory.edu/IRB/HIPAA_exceptions.htm for list of identifiers that must be stripped) ☐ Data coded by PI with re-identification link secured in separate location ☒ Other (explain) Please see attached documentation of data security procedures.
6. Will the research data and information be part of the medical chart?	☒ No ☐ Yes
7. Describe any additional procedures to be used to provide/maintain confidentiality of data (attach additional sheet if necessary)	Please see attached documentation of data security procedures.

I. HIPAA APPLICABILITY	
Will you be using, receiving or disclosing any health information concerning any subject that has any of the following identifiers? If yes, what identifiers will be included? Mark all that apply. ☒ Names ☒ Geographic identifiers ☒ Elements of dates ☐ Ages over 89 years ☐ Telephone or fax numbers ☐ E-mail, URL or IP addresses ☐ Social Security Numbers ☒ Medical records numbers ☐ Health plan beneficiary numbers ☐ Account numbers ☐ Certificate or license numbers ☐ Vehicle identification, serial or license plate numbers ☐ Biometric identifiers ☐ Full face photographic images ☐ Any other unique identifying number, characteristic or code	☐ No ☒ Yes
If Yes, you must complete sections J and K. If No, skip to section L.	

J. COLLECTION AND USE OF PROTECTED HEALTH INFORMATION

1. What are your sources of health information? (check all that apply)

- ☒ Physician records
- ☒ Hospital records
- ☐ Billing records
- ☐ Data previously collected for research purposes:
- ☐ Clinic records
- ☐ Mental health records
- ☐ Laboratory results
- ☐ Biological or tissue samples
- ☐ Pathology results
- ☐ Radiology results
- ☐ Interviews/surveys/questionnaires

If so, last date collected Please see attached documentation of data sources.

Was it collected pursuant to an IRB approved protocol?	☐ Yes	☐ No
Was there informed consent?	☐ Yes	☐ No
Was there a waiver of informed consent?	☐ Yes	☐ No

2a. Will you require access to PHI for:	☒ identification of eligible subjects for recruitment. ☒ conduct of protocol.
2b. Do you need access to the entire medical record for recruitment? Do you need access to the entire medical record for conduct of protocol?	☐ Yes ☒ No ☐ Yes ☒ No
2c. If NO, describe the portions of the PHI for which you require access:	The PHI needed for recruitment: Please see attached documentation describing the collection and use of PHI. The PHI needed for conduct of protocol: Please see attached documentation describing the collection and use of PHI.

3. It is assumed that all study personnel listed in section B will be requesting and collecting the PHI. If you plan to use any other persons to request/collect the PHI that are not listed in that section, please identify them here:	☐ N/A	Names: Hospital Infection control Nurse

4. PHI will be shared with the IRB. In addition, please identify any other person or group with whom the PHI will be shared/disclosed during the study. If known, provide specific name or description.	☒ Other investigators ☐ Registries ☒ Study sponsor ☐ CRO ☐ Study monitor ☒ Statisticians ☐ Labs ☒ Gov't oversight agencies ☒ IRB (other than Emory) ☐ Other	1. Centers for Disease Control and Prevention, National Center for Chronic Disease and Public Health Prevention, Division of Adult and Community Health. a. Zhi-jie Zheng, epidemiologist b. Akaki Lekiachvile, health scientist c. Michael Matters, Public Health Informatics Fellow d. Other CDC personnel as needed to complete the project e. Participating hospitals in Fulton County

5. List the date on which, or event by which, you will no longer need to use the collected PHI.	Ongoing registry, no stop date forseen

K. WAIVER OF HIPAA AUTHORIZATION

1. Are you seeking a:	☒ COMPLETE HIPAA waiver for the entire study? ☐ PARTIAL HIPAA waiver for identifying potential subjects and determining eligibility? ☐ Neither (skip to section L)

2. If waiver sought, describe why the research cannot be practicably conducted without **authorized** access to the PHI:	Please see the attached documentation describing the need for waiver of HIPPA authorization.
3. How privacy will be accomplished?	Please see the attached document describing privacy.

4. The use or disclosure of the PHI for this study represents no more than a minimal risk to the privacy of the subject because:

☒ Identifiers are protected against improper use or disclosure by the following means (check all that apply)	☒ Research team members will sign Confidentiality agreements ☒ Information will not be disclosed unless it is scrubbed of all identifiers ☒ Only coded data will be disclosed, and agreement is in place per only Covered Entity will have coding list.
☒ Identifiers will be destroyed upon completion of:	☐ Subject participation and end of any record-keeping requirements ☐ Data Analysis ☐ FDA Approval/end of any record-keeping requirements ☐ Specimen processing ☒ Other (explain): Please see the attached documentation about destroying identifiers.
5. If identifiers will not be destroyed, then please explain below why they must be retained (e.g., longitudinal study; specific federal requirements, etc.)	

L. SUBJECTS

1.Gender	☐ Male Only ☐ Female Only ☒ Both	
2.Will enrollment be limited to specific ethnic or social group(s)?	☒ No ☐ Yes	If yes, describe:
3. Will specific populations be excluded from the research?	☒ No ☐ Yes	If yes, justify:
4a.Total number of subjects to be enrolled at Emory sites:	Please see attached documentation that describes the subjects and source population.	
4b.This number represents:	☒ target enrollment ☐ minimum needed for statistical significance	
5. Age Groups	☒ <6 years ☒ 6-10 years ☒ 11-17 years ☒ >18 years ☒ >65 years	

6. Indicate which of the following populations are the focus of the research:

☐ Intellectually or emotionally impaired	☒ Patients	☐ Pregnant subjects or fetuses
☐ Prisoners, parolees, incarcerated subjects	☐ Students or trainees	☐ Employees of study sites
☐ Subjects whose 1st language is not English	☐ Normal Volunteers	☐ Employees or subordinates of investigators
☐ No subjects – existing data or specimens		

M. RECRUITMENT

1. Describe how subjects will be identified and recruited.	Please see attached documentation of subject recruitment.
2. Describe who will make initial contact and how.	Please see attached documentation of subject recruitment.
3. Will physicians or staff refer subjects?	☒ No ☐ Yes
4. Will referring physicians or staff receive any incentives to recommend subjects for study participation?	☐ No ☐ Yes ☒ N/A
5. If yes, describe the incentive:	

N. INFORMED CONSENT/ASSENT	
1. How many consents/assents are contained in your submission? (Do not include HIPAA authorization)	**Consent(s): none Assent(s): none**
2. Type of consent to be obtained	☐ written ☐ oral ☒ Waiver requested
3. Type of assent to be obtained	☐ written (ages 11-17) ☐ oral (6-10) ☒ Waiver requested
4. HIPAA Authorization	☐ N/A ☐ Stand-alone document ☐ incorporated in consent
5. How and where will permission be recorded?	
6. Will all adult subjects have the capacity to give informed consent?	☒ No ☐ Yes
7. How will subjects' understanding be assessed?	
8. If subjects are unable to give consent (e.g., minors or mentally incompetent), describe how consent of the legally authorized representative and assent from the subject will be obtained and documented.	**EMS personnel arriving on the scene of a 911 call obtain information from bystanders about the victim and the circumstances of the event. This data collection is part of routine EMS practice and patient care and is documented on the trip sheet. The trip sheet is the legal medical record of the patient and the treatment protocol followed at the scene.**
9. In relation to the actual data gathering, when and where will consent be discussed and documentation be obtained (e.g., pre-operatively, or several days before)? Be specific.	

O. BLOOD AND/OR OTHER TISSUE BANKING/STORAGE	
1. Does this research involve blood/tissue storage or banking?	☐ Yes ☒ No **(If No, skip to section P)**
2. Describe the nature and number of samples to be collected.	
3. For what period of time will these samples remain stored?	
4. Identify the primary custodian of the samples.	
5. Are the use of the samples for both current and/or future research activities clearly described in the informed consent form and process?	☐ Yes ☐ No
6a. Describe any identifiers that will be linked to the samples.	
6b. If linked, are subjects able to request destruction of samples at a later date? (If so, this should be described in consent form).	☐ Yes ☐ No
7. If the samples have direct or indirect links to the subject, describe the measures in place to maintain the confidentiality of information relating to the samples.	
8a. Are there current plans to make the samples available to researchers outside of the institution?	☐ No ☐ Yes
8b. If yes, provide a list of recipients and a description of how decisions are made to release samples to researchers outside of Emory.	
9. Are there plans to re-contact the subjects to request additional samples?	☐ No ☐ Yes
10. Will cells be immortalized?	☐ No ☐ Yes
11. Do the subjects and/or their families receive information regarding the interpretation of research or other incidental findings?	☐ No ☐ Yes
12. Are any genetic findings recorded in the subject's medical record?	☐ No ☐ Yes
13a. Are any genetic findings made known to third parties (e.g., subject's physician, family members, other researchers, insurance company)?	☐ No ☐ Yes

13b. If yes describe the conditions under which such disclosures are made.	
14. Will genetic counseling be offered to subjects and/or their families?	☐ Yes ☐ No If no, please justify:

P. FACILITIES WHERE STUDY WILL BE CONDUCTED (mark all that apply):

☒ Emory University Hospital	☐ The Atlanta Veterans Affairs Medical Center (VA R&D Committee approval is required)
☐ The Emory Clinic, Inc.	☒ Crawford W. Long Hospital
☐ Emory West	☒ Grady Memorial Hospital (Grady Research Oversight Committee approval is required)
☒ Children's Healthcare of Atlanta	☐ Wesley Woods Geriatric Center and Hospital
☐ Emory General Clinical Research Center	☐ Grady General Clinical Research Center
☐ Emory Children's Center	☒ Other: All hospitals in Fulton County that receive cardiac arrest patients from Grady EMS and Rural Metro EMS will be contacted by study staff for patient information. Refer to list in appendix.

Q. CONFLICT OF INTEREST STATEMENT:

1. Does any participating member, staff, students (or his/her spouse or dependent children) have any financial interest such as royalty, equity or any other payments (e.g., consulting, salary, etc...) in the sponsor?	☒No ☐Yes If yes, who:
2. Does any participating member, staff, students (or his/her spouse or dependent children) have any intellectual property interests (patent or copyright) in the drug, device or technology being studied?	☒No ☐Yes If yes, who:
3. Does/will any equity interest exceed $10,000 in current value or exceed 1% of ownership interest?	☒No ☐Yes
4. Does/will aggregate annual payments for royalty and other payments exceed $10,000?	☒No ☐Yes
5. Was the drug, device or technology involved in this study developed at Emory?	☒No ☐Yes
6. Is the sponsor of this study an Emory start-up company?	☒No ☐Yes

SIGNATURES ***[Note: All Studies must have approval of the Department Chairperson]***

As Principal Investigator, I acknowledge responsibility for this project and assure that [illegible] participate in the study are qualified (or will be adequately trained) to conduct it. I also hereby agree that I will ensure [illegible] and my research team are in accordance with HIPAA's Minimum Necessary Rule, will collect only the minimum amount of protected health information necessary to conduct the study described herein; (b) that access to protected health information will be limited to the greatest extent reasonably practicable possible within the research team; and (c) that neither I, nor any other member of my research team will re-use or disclose protected health information to any other person or entity except for those uses and disclosures outlined above and specifically approved by the IRB (or by subject authorization), required by law, or required by research oversight.

Principal Investigator:	Bryan McNally MD, MPH	Date:	12/16/04
I have reviewed this proposal and concur with its submission.			
Departmental chair:	Arthur L Kellermann MD	Date:	12/17/04
Typed Name of Chairman:	Arthur L. Kellermann, MD, MPH		
Signature of Faculty advisor/Sponsor (if applicable)		Date:	

13b. If yes describe the conditions under which such disclosures are made.	
14. Will genetic counseling be offered to subjects and/or their families?	☐ Yes ☐ No If no, please justify:

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☒ Emory University Hospital	☐ The Atlanta Veterans Affairs Medical Center (VA R&D Committee approval is required)
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2. Does any participating member, staff, students (or his/her spouse or dependent children) have any intellectual property interests (patent or copyright) in the drug, device or technology being studied?	☒No ☐Yes If yes, who:
3. Does/will any equity interest exceed $10,000 in current value or exceed 1% of ownership interest?	☒No ☐Yes
4. Does/will aggregate annual payments for royalty and other payments exceed $10,000?	☒No ☐Yes
5. Was the drug, device or technology involved in this study developed at Emory?	☒No ☐Yes
6. Is the sponsor of this study an Emory start-up company?	☒No ☐Yes

SIGNATURES ***{Note: All Studies must have approval of the Department Chairperson}***

As Principal Investigator, I acknowledge responsibility for this project and assure that the faculty and staff who participate in it are qualified (or will be adequately trained) to conduct it. I also hereby agree that I will ensure (a) that myself and my research team, in accordance with HIPAA's Minimum Necessary Rule, will collect only the minimum amount of protected health information necessary to conduct the study described herein; (b) that access to protected health information will be limited to the greatest extent reasonably possible within the research team; and (c) that neither I, nor any other member of my research team, will re-use or disclose protected health information to any other person or entity except for those uses and disclosures outlined above and specifically approved by the IRB (or by subject authorization), required by law, or required by research oversight.

Principal Investigator:		Date:	
I have reviewed this proposal and concur with its submission.			
Departmental chair:		Date:	
Typed Name of Chairman:	**Arthur L. Kellermann, MD, MPH**		
Signature of Faculty advisor/Sponsor (if applicable)		Date:	

IRB Submission Checklist

☒ Non-technical Lay summary included. (Lay summary MUST be written in simple non-scientific terms)
☐ Informed consent/assent form(s) included. Number of *different* forms: _____
☐ Clinical Investigator's Brochure included. 5 copies are required.
☒ Conflict of Interest section completed
☐ Advertisements included? ☒No ☐Yes
☐ correct number of packets submitted*
☒ Initial submission form signed by department chairman
☐ Does the protocol include any amendments? ☒No ☐Yes Amendment number/date:____

For Clinical Trials: SiteMinder software system will be required for the management of all new and renewal clinical trials routed on or after June 1, 2004. It has been recommended that PI's begin the transition to SiteMinder as soon as possible. Please contact the Clinical Trials Office to help determine if your study is a clinical trial or if you have questions about SiteMinder (404-728-6940 or cto@emory.edu).

If this protocol is a clinical trial, has it been entered into SiteMinder? ☐ Yes ☐ No (explain: Not a clinical trial)

***** INCOMPLETE SUBMISSIONS WILL NOT BE PROCESSED. *****

_____ _____
Signature of Person Preparing Paperwork Date

* Submit 5 packets for full committee review, 2 packets for exemptand expedited
The following elements constitute a protocol packet:
A. Initial Submission Form (must be signed by your Dept. Chair)
B. lay summary
C. A protocol
D. Consent and Assent Forms (if applicable)
E. Investigator's Brochure (if available)
F. Recruiting materials (if available)

Institutional Review Board
1256 Briarcliff Road, 307-N
Atlanta, GA 30306

Phone (404) 712-0720
Fax (404) 727-1358
http://www.emory.edu/IRB

REQUEST FOR MODIFICATION

Modification #: _ _____

Section I. Investigator Information

IRB Number 1377-2004	Title Cardiac Arrest Registry to Enhance Survival (CARES); formerly Regional Enhancement of Cardiac Arrest Survival Through Applied Research and Treatment (RESTART)	
Principal Investigator Bryan McNally, MD, MPH	Interoffice Address (Include Department, Bldg, Room or mail stop number) 531 Asbury Cir - Annex Suite N340 Atlanta, Georgia 30322	
Contact Name Paula Bokros		
Phone 404-778-2602	Fax 404-778-2630	Email pbokros@emory.edu

Section II. Type of Modification (Select ALL that apply)

☐	Amendment	(Attach a Narrative and Supporting documentation) Amendment # _____ Date of Amendment _____
☒	New Procedures	Describe how the change affects the risk/benefit: (Attach a description of the procedures) The program name has changed from Regional Enhancement of Cardiac Arrest Survival Through Applied Research and Treatment (RESTART) to Cardiac Arrest Registry to Enhance Survival (CARES). Please see attached updated lay summary.
☐	Change in Study Personnel	☐ add ☐ delete ☐ change Include role of personnel, address, phone, fax, email for additions – REMEMBER, all persons on a study must have current CITI certification.
☐	Change of Site	☒ add ☐ delete ☐ modify (Attach a narrative that lists the resulting sites) See updated attached list
☐	Change in Enrollment	(Attach narrative justifying the change) increase #_____ decrease #_____ resulting total _____ to be enrolled
☐ ☐	Consent Change New Consent	Version Date:_____ **Highlighted changes** and **A clean copy must be attached** Date: _____ Targeted Population: _____
☐	Advertisement	Select All that apply and attach copies of ad or announcement ☐ Newspaper Ad – Name of Paper _____ ☐ Radio Announcement – Station _____ ☐ Internet Posting - Web-site _____ ☐ Post on Clinical Trials Web site (www.emoryhealthcare.org/clinicaltrials) ☐ Television Announcement – Station _____ ☐ Flyer – Distributed where _____ ☐ Information Brochure - Distributed how _____ ☐ Other - Describe:_____ Has this ad been approved by the sponsor? ☐ Yes ☐ No ☐ N/A
☐	Clinical Investigator's Brochure	Select one: ☐ Addendum Date: ☐ Updated Date: ☐ New Date: Should consent be changed based upon this revision? ☐ Yes ☐ No
☒	Funding	☒ Add Agency Name: The Center for Disease Control and Prevention (CDC) is continuing to fund CARES for years 3, 4, and 5 at $300,000 per year. ☐ Delete Agency Name:

☒	Site	List all sites this amendment applies to: See Attached List of Hospital Expansion
☐	Other	(e.g., Annual Report, Package Insert, General Correspondence) Describe and attach a narrative.

☒ Supporting documentation is attached. (e.g., Narrative, **highlighted consent**, form 1572, etc.) MANDATORY

PI Signature Bryan McNeely, MD, MPH Date 1/25/07

Faculty Advisor (if PI is student) _____ Date _____

NARRATIVE:

Section III. IRB USE ONLY

*** Protocol expiration is not changed by the approval of this modification***

✓ The Modification has been approved.

✓ The Correspondence has been acknowledged.

___ Consent(s) and/or HIPAA Authorization dated_____ has been approved.

___ Subjects currently enrolled must sign the new consent.

_____ Approval Date: 2/5/07 Approval Type: ___ Full ✓ Expedited

IRB Committee Member

Section below for Research Studies Performed at the Atlanta VA

Section IV. RESEARCH & DEVELOPMENT COMMITTEE USE ONLY

___ Modification has been approved by the R&D Committee

_____

R&D Committee Chair Approval Date

Institutional Review Board
1256 Briarcliff Road, 307-N
Atlanta, GA 30306

Phone (404) 712-0720
Fax (404) 727-1358
http://www.emory.edu/IRB

REQUEST FOR MODIFICATION

Modification #: _ _____

Section I. Investigator Information

IRB Number 1377-2004	Title Cardiac Arrest Registry to Enhance Survival (CARES); formerly Regional Enhancement of Cardiac Arrest Survival Through Applied Research and Treatment (RESTART)	
Principal Investigator Bryan McNally, MD, MPH	Interoffice Address (Include Department, Bldg, Room or mail stop number) 531 Asbury Cir - Annex Suite N340 Atlanta, Georgia 30322	
Contact Name Paula Bokros		
Phone 404-778-2602	Fax 404-778-2630	Email pbokros@emory.edu

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JAN 26 2007
EMORY INSTITUTIONAL REVIEW BOARD

Section II. Type of Modification (Select ALL that apply)

☐	Amendment	(Attach a Narrative and Supporting documentation) Amendment # _____ Date of Amendment _____
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☐	Change in Enrollment	(Attach narrative justifying the change) increase #_____ decrease #_____ resulting total _____ to be enrolled
☐ ☐	Consent Change New Consent	Version Date:_____ **Highlighted changes** and **A clean copy must be attached** Date: _____ Targeted Population: _____
☐	Advertisement	Select All that apply and attach copies of ad or announcement ☐ Newspaper Ad – Name of Paper _____ ☐ Radio Announcement – Station _____ ☐ Internet Posting - Web-site _____ ☐ Post on Clinical Trials Web site (www.emoryhealthcare.org/clinicaltrials) ☐ Television Announcement – Station _____ ☐ Flyer – Distributed where _____ ☐ Information Brochure - Distributed how _____ ☐ Other - Describe:_____ Has this ad been approved by the sponsor? ☐ Yes ☐ No ☐ N/A
☐	Clinical Investigator's Brochure	Select one: ☐ Addendum Date: ☐ Updated Date: ☐ New Date: Should consent be changed based upon this revision? ☐ Yes ☐ No
☒	Funding	☒ Add Agency Name: The Center for Disease Control and Prevention (CDC) is continuing to fund CARES for years 3, 4, and 5 at $300,000 per year. ☐ Delete Agency Name:

☒	Site	List all sites this amendment applies to: See Attached List of Hospital Expansion
☐	Other	(e.g., Annual Report, Package Insert, General Correspondence) Describe and attach a narrative.

☒ Supporting documentation is attached. (e.g., Narrative, **highlighted consent**, form 1572, etc.) MANDATORY

PI Signature Bryan McNally, MD, MPH Date 1/25/07

Faculty Advisor (if PI is student) _____ Date _____

NARRATIVE:

Section III. IRB USE ONLY

*** Protocol expiration is not changed by the approval of this modification***

✓ The Modification has been approved.

✓ The Correspondence has been acknowledged.

___ Consent(s) and/or HIPAA Authorization dated_____ has been approved.

___ Subjects currently enrolled must sign the new consent.

_____ Approval Date: 2/5/07 Approval Type: ___ Full ✓ Expedited

IRB Committee Member

Section below for Research Studies Performed at the Atlanta VA

Section IV. RESEARCH & DEVELOPMENT COMMITTEE USE ONLY

___ Modification has been approved by the R&D Committee

R&D Committee Chair Approval Date

EMORY
UNIVERSITY
SCHOOL OF
MEDICINE

Department of Emergency Medicine
531 Asbury Circle - Annex
Suite N340
Atlanta, GA 30322
(404) 778-5975
(404) 778-2630 (fax)

January 25, 2007

James W. Keller, MD, Chair
Emory University Institutional Review Board
1256 Briarcliff Road, N.E.
Building A, 4th Floor, South Wing
Atlanta, GA 30306-2556

RE: IRB # 1377-2004 CARES – Cardiac Arrest Registry to Enhance Survival, formerly know as RESTART

Dear Dr. Keller,

I am writing to you to give an update about the CARES Program which was formerly known as the RESTART Program and previously approved under exempt status. The CDC has provided additional grant funding to extend the program for an additional three years through 2009 with the future goal of expanding the program nationally. The expansion phase of the program will focus on using the CARES program as a template model for an eventual national cardiac arrest registry and we plan to begin working with the following cities: Boston, Massachusetts; Nashville, Tennessee, Louisville, Kentucky; Raleigh, North Carolina; Austin, Texas; Houston, Texas; Omaha, Nebraska; Kansas City, Missouri; Oklahoma City, Oklahoma; Tulsa, Oklahoma; Tucson, Arizona; San Francisco, California; Anchorage, Alaska. Likely in 12 months CARES staff will reassess the need to expand to additional sites based on the progress made to date with above communities. The respective 911 receiving hospitals in each community will be identified and asked to participate in the CARES program. I have attached a current list of all the known hospitals to date that will be participating in the CARES Program and will continue to update the list annually to keep it current.
I am also attaching copies of the data use agreements that were developed with the assistance of legal staff at the Georgia Hospital Association and reviewed by Emory University legal staff to recognize the data being held confidential by CARES program staff and the respective EMS agencies, Hospital Staff and EMS dispatch centers. Each of these agencies have been encouraged to review the data use agreements and complete them to acknowledge the confidentiality of the data collection and storage process for the CARES Registry. Please do not hesitate to contact me if you have any questions about the expansion phase of the CARES program. Thank you.

Bryan McNally, MD, MPH
Assistant Professor of Emergency Medicine
Emory University School of Medicine

Bryan McNally MD MPH

Cardiac Arrest Registry to Enhance Survival (CARES)
LAY SUMMARY

Sudden cardiac death (SCD) is the leading cause of death among adults in the United States and Western countries. It is estimated that approximately 400,000 deaths occur every year. Most of these deaths are due to a fatal heart rhythm disturbance called ventricular fibrillation.

Nationally, only about 35 communities actively monitor and report their survival rates from out-of-hospital cardiac arrest. The range of survival in these communities for ventricular fibrillation is anywhere - from 2% to 35%, a striking difference, since the approach to the care of these patients is uniform and there is no evidence that patients in one part of the country are different biologically from another.

CARES will create a model SCD registry capable of identifying and tracking all cases of cardiac arrest in a defined geographic area. During the first year of development, the system has been confined to Fulton County, the most populous county in the state of Georgia. In year two, it expanded to a multi-county area of metropolitan Atlanta, GA. We will also work collaboratively with the CDC and the American Heart Association to share the templates and data elements with other metropolitan areas and regional or state EMS systems that wish to improve their performance in the treatment of out-of-hospital cardiac arrest. In years 3-5, CARES will expand nationally to several large metropolitan areas. Because the data system we are devising is intended to be universally applicable to EMS operations nationwide, it will be designed to be compatible with the National Electronic Disease Surveillance System (NEDSS) and use generally agreed upon standardized data elements and definitions.

The ultimate goals of this cardiac arrest registry will be to help local EMS administrators and medical directors identify who is affected, when and where cardiac arrest events occur, which elements of the system are functioning properly and which elements are not, and how changes can be made to improve cardiac arrest outcomes.

A uniform, simple and sustainable cardiac arrest registry is essential to help communities assess their provision of care to victims of SCD and measure the outcomes that are achieved. It is arguably the most important step in improving out of hospital care, and ultimately the community's rate of survival from this common and devastating event. Decades of research have established that the likelihood that a victim who sustains a witnessed cardiac arrest from ventricular fibrillation will survive with good neurological function largely depends on receiving bystander CPR and rapid defibrillation within 4-8 minutes of collapse. The longer these vital interventions are delayed, the more likely the cardiac arrest event will be irreversible and the victim will die. Presently, the odds of surviving an episode of out of hospital cardiac arrest in the United States vary by a factor of 10 to 20, depending on the community in which it occurs. Disparities in outcome this extreme are unacceptable and are what the CARES project will be able to identify and allow communities to improve upon.

EMORY
UNIVERSITY

Institutional Review Board

Bryan McNally MD
SOM: Emergency Medicine
EUH- Dept of Emergency Medicine
1364 Clifton Rd Box 80
Atlanta, GA 30322

RE: **NOTIFICATION OF PROTOCOL APPROVAL - EXEMPT**
PI: Bryan McNally MD
IRB ID: **1377-2004**
TITLE: Cardiac Arrest Registry to Enhance Survival (CARES)
DATE: October 02, 2007

The research proposal cited above remains exempt from further review in meeting the requirements of the criteria for exemption under 45 CFR 46.101(b). The IRB acknowledges hiring for positions approved under the original exemption effective today and records have been updated to include Ms. Allison "Allie" Parker as the research study contact and Dr. Comilla Sasson as the graduate fellow (other). CITI authorization has been verified.

If you have further questions or concerns, please contact the IRB office at 404-712-0720 or at email address, irb@emory.edu . Our web address is http://www.emory.edu/IRB . Thank you.

Sincerely,

Colleen DiIorio, PhD
Chair
Institutional Review Board

Emory University
1599 Clifton Road, 5th Floor, Room 213
Atlanta, Georgia 30322
Tel 404.712.0720
Fax 404.727.1358
IRB@emory.edu