CITY OF EL PASO, TEXAS
AGENDA ITEM DEPARTMENT HEAD'S SUMMARY FORM

DEPARTMENT: Fire

AGENDA DATE: December 16, 2008

CONTACT PERSON/PHONE: Roberto Rivera 771-1000

DISTRICT(S) AFFECTED: All

SUBJECT:
APPROVE a resolution / ordinance / lease to do what? OR AUTHORIZE the City Manager to do what? Be descriptive of what we want Council to approve. Include $ amount if applicable.

Approve a resolution that the Fire Department EMS may participate in the Immediate Myocardial Metabolic Enhancement During Initial Assessment and Treatment in Emergency Care Trial

BACKGROUND / DISCUSSION:
Discussion of the what, why, where, when, and how to enable Council to have reasonably complete description of the contemplated action. This should include attachment of bid tabulation, or ordinance or resolution if appropriate. What are the benefits to the City of this action? What are the citizen concerns?

Allow the El Paso Fire Department to participate in a clinical study with Texas Tech Medical Center being conducted by Tufts Medical Center in Boston Massachusetts to provide treatment of patients suffering acute myocardial infarction.(heart attack). Will allow the City of El Paso to participate in medical research with a local school of medicine.

PRIOR COUNCIL ACTION:
Has the Council previously considered this item or a closely related one?

NO

AMOUNT AND SOURCE OF FUNDING:
How will this item be funded? Has the item been budgeted? If so, identify funding source by account numbers and description of account. Does it require a budget transfer?

All materials and training for the study will be provided by Texas Tech Health Sciences Center

BOARD / COMMISSION ACTION:
Enter appropriate comments or N/A

**********REQUIRED AUTHORIZATION**********

LEGAL: (if required) _____ **FINANCE:** (if required) _____

DEPARTMENT HEAD: Roberto Rivera

(Example: if RCA is initiated by Purchasing, client department should sign also)
Information copy to appropriate Deputy City Manager

APPROVED FOR AGENDA:

CITY MANAGER: _____ **DATE:** _____

RESOLUTION

BE IT RESOLVED BY THE CITY COUNCIL OF THE CITY OF EL PASO:

That the City Manager be authorized to sign the following agreements, all of which are necessary in order that the Fire Department EMS may participate in the Immediate Myocardial Metabolic Enhancement During Initial Assessment and Treatment In Emergency Care Trial:

(1) Memorandum of Understanding between the CITY OF EL PASO AND TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER, EL PASO PAUL L. FOSTER SCHOOL OF MEDICINE;

(2) Institutional Review Board (IRB) Authorization Agreement; and

(3) That the Fire Department be authorized to sign and submit the "Federalwide Assurance for the Protection of Human Subjects for Institutions Within the United States" application form.

ADOPTED THIS _____ DAY OF _____ 200__.

APPROVED AS TO CONTENT:

_____
John F. Cook, Mayor

ATTEST:

_____
Richarda Duffy Momsen, City Clerk

APPROVED AS TO FORM:

Mark Shoesmith
Assistant City Attorney

APPROVED AS TO CONTENT

Roberto Rivera, Fire Chief
Fire Department

44172 Immediate Trial 11/08: MSHO

MEMORANDUM OF UNDERSTANDING
BETWEEN
TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER –El Paso Paul L. Foster School of Medicine
AND
THE CITY OF EL PASO

This Memorandum of Understanding ("MOU") is effective as of the date of the last signature below ("Effective Date") by and between Texas Tech University Health Sciences Center –El Paso Paul L. Foster School of Medicine ("TTUHSC"), having an address at 5001 El Paso Drive, El Paso, Texas, and the City of El Paso ("the City"), having an address at 2 Civic Center Plaza, 10th Floor, El Paso, Texas (collectively "The Parties").

The parties desire to participate in a clinical study for the purpose of testing the impact of pharmacological myocardial metabolic support, in the form of intravenous glucose, insulin and potassium ("GIK"), for the treatment of patients with threatened or established acute myocardial infarction, entitled "IMMEDIATE (Immediate Myocardial Metabolic Enhancement During Initial Assessment and Treatment in Emergency Care) Trial" ("Study"). The Study is being conducted by Tufts Medical Center in Boston, Massachusetts, with funding from the National Heart, Lung, and Blood Institute of the National Institutes of Health. The Study is of mutual interest and benefit to the parties because it furthers research objectives and may benefit patient care. The parties agree that the Study will be conducted under the terms and conditions set forth below:

1. THE STUDY

1.1 Description. Patients with symptoms consistent with acute coronary syndromes (ACS), considered to be having a threatened or established acute myocardial infarction (AMI) will be identified by emergency medical system (EMS) paramedics in the field prior to transport to the receiving hospital. If patients meet inclusion criteria and agree to participate, they will be randomized to receive a 12-hour intravenous infusion of either GIK or placebo (a 5% dextrose solution). Data will be collected for a 30 day, 6 month and 1 year post-treatment follow-up.

1.2 Personnel. TTUHSC has designated Robert Woolard, M.D. to be the Principal Investigator ("PI") of the Study, to be responsible for the conduct and direct supervision of all employees and agents of TTUHSC assigned to participate in the performance of the Study. Dr. James Loflin, EMS medical director for the City pursuant to an Interlocal Agreement dated August 28, 2007 between the City and TTUHSC, shall be the subinvestigator designated to oversee the ambulance/EMS site for the IMMEDIATE Trial. He (or his successor) will serve in this capacity at no cost to the City, and his duties shall include oversight of EMS

personnel of the City involved in the IMMEDIATE Trial. Other investigators include: Susan Watts, Ph.D., David Gough, M.D., and Ken Berumen, M.D

1.3 IRB Approval. TTUHSC's IRB has reviewed and approved the IMMEDIATE Trial protocol. This approval extends to the EMS paramedics who will be responsible for screening patients for inclusion in the Study. The City will obtain a "Federalwide Assurance ('FWA') for the Protection of Human Subjects for Institutions Within the United States", designating the TTUHSC IRB as the IRB reviewing the research performed under the Study. TTUHSC will provide the IRB approval letter and continuing review approval letters to the City.

2. RESPONSIBILITIES OF THE PARTIES

2.1 TTUHSC shall be responsible for the following:

2.1.1 Managing the Study. This includes implementation of the Protocol and oversight of the Study at all phases of the Study.

2.1.2 Providing training to the Emergency Medical Services (" EMS") paramedics of the City, including training specific to the Study, such as training in the protection of human subjects, the consent process and conduct of a clinical trial, and providing access to resources required by the EMS paramedics, being available to answer questions, and providing feedback and updates.

2.1.3 Providing training to hospital personnel including, but not limited to, the Emergency Department, Cath Lab, and Coronary Care Unit regarding the Study and their respective roles in the Study.

2.1.4 Obtaining written informed consent, for all patients as soon as is feasible.

2.1.5 Performing all data extraction, provide reports to the IRB and Tufts Medical Center, and provide feedback to the City and hospitals as needed.

2.1.6 Providing relevant minutes of IRB meetings to the City.

2.1.7 Follow up with patients periodically for one year.

2.2 The City of El Paso shall be responsible for the following:

2.2.1 Requiring that the EMS paramedics are available for training.

2.2.2 Requiring that EMS paramedics submit appropriate conflict of interest forms. The TTUHSC IRB requires that all research personnel sign the TTUHSC "Financial Disclosure For Research Personnel" form, which is attached to this MOU as Attachment A and incorporated herein by reference. A copy of the TTUHSC Conflict of Interest in Research policy (HSC 73.09) referenced in that form is provided separately.

2.2.3 Requiring that the EMS paramedics incorporate Study-related activities into their usual paramedic activities when appropriate, based on the clinical judgment of the paramedic.

2.2.4 EMS paramedics shall screen patients and administer the Study drug in accordance with the Study Protocol.

2.2.5 Before departing from the hospital, EMS paramedics shall leave the patient's study folder, the screening form, a copy of the EKG, and the study drug at the hospital Emergency Department in accordance with the Study Protocol.

3. CONDUCT OF THE STUDY

TTUHSC and Principal Investigator will exercise their best efforts to carry out the Study in a competent manner with strict adherence to the Study protocol (as it may be amended from time to time by Tufts Medical Center). TTUHSC and Principal Investigator will comply with all applicable federal, state and local government laws, regulations and guidelines including, but not limited to, the Code of Federal Regulations, the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use ("ICH/GCP"), the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and all other applicable medical privacy laws and regulations. TTUHSC has obtained and will maintain all authorizations and permits required by applicable law or regulation for TTUHSC and Investigator to conduct the Study under this MOU.

4. LIMITATION OF COSTS

Participation in the IMMEDIATE Trial shall be at no direct cost (out-of-pocket) to the City of El Paso. Medication, computer programming, equipment or other direct costs shall be at the expense of TTUHSC.

5. TERMINATION

Either party may terminate this MOU by giving the other party sixty (60) days written notice, provide that in no event shall this MOU continue beyond the time period for which the IMMEDIATE Trial is approved by the Institutional Review Board.

6. LIABILITY

NEITHER PARTY WAIVES SOVEREIGN IMMUNITY BY ITS EXECUTION OF OR BY ANY CONDUCT OF ITS REPRESENTATIVES UNDER THIS MOU.

7. NOTICES

Any notices under this MOU shall be in writing and delivered to the parties at the postal addresses set forth below, or to the postal address subsequently provided by a party in accordance with this section, by a nationally-recognized overnight courier service, with notice deemed given on the date of receipt as indicated on the courier's receipt:

If to TTUHSC:

Managing Director for Research
Office of the Associate Dean for Research
Texas Tech University Health Sciences Center
Paul L. Foster School of Medicine
5001 El Paso Drive
El Paso, TX 79905
Telephone: 915-783-5227
Fax: 915-783-5222

If to Principal Investigator:

Dr. Robert Woolard
Department of Emergency Medicine
Texas Tech University Health Sciences Center
Paul L. Foster School of Medicine
4800 Alberta Avenue
El Paso, TX 79905
Telephone: 915-545-7333
Fax: 915-545-7338

If to the City of El Paso:

City Manager
City of El Paso
2 Civic Center Plaza -10th Floor
El Paso, TX 79901-1153

And:

El Paso Fire Department
8600 Montana Avenue
El Paso, TX 79925

8. MISCELLANEOUS

Independent Contractor. TTUHSC and the City of El Paso will be deemed to be and will be independent contractors. No party is authorized or empowered to act as agent for any other party for any purpose and will not, on behalf of another party, enter into any contract, warranty or representation as to any matter. No party will be bound by the acts or conduct of any other party.

Use of Name. No party will use any other party's name without the prior written approval of such other party, provided, however, that the foregoing will not preclude any legally required disclosure, reports generated in the normal course of business, or acknowledgement of sponsorship as required by the guidelines of a scientific or academic organization.

Headings. This Agreement contains headings only for convenience and the headings do not constitute or form a part of this Agreement, and should not be used in the construction of this Agreement.

Waiver. No waiver of any term, provision or condition of this Agreement (whether by conduct or otherwise) in any one or more instances will be deemed to be or construed as a further or continuing waiver of any such term, provision or condition of this Agreement.

Amendments. This MOU may be amended in writing to include such provision(s) as the Parties may agree upon.

Counterparts. This Agreement may be executed in any number of counterparts, each of which will be deemed to be an original and all of which together will constitute one and the same instrument.

Governing Law. All matters affecting the interpretation, validity and performance of this Agreement shall be governed by the laws of the State of Texas, without regard or giving effect to its conflict of laws principles.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives:

TEXAS TECH UNIVERSITY
HEALTH SCIENCES CENTER-El Paso
Paul L. Foster School of Medicine

By:_____
J. Manuel de la Rosa, M.D.
Founding Dean

Date: _____

CITY OF EL PASO

By: _____
Joyce Wilson
City Manager

Date: _____

Approved as to form:

Mark Shoesmith
Assistant City Attorney
El Paso Fire Department

Date:_____

Approved as to content:

Roberto Rivera
Fire Chief
El Paso Fire Department

Date:_____

Institutional Review Board (IRB) Authorization Agreement

Name of Institution or Organization Providing IRB Review:
Texas Tech University Health Sciences Center (TTUHSC)

IRB Registration #: 00000098 Federalwide Assurance (FWA) #: 00006767

Name of Institution Relying on the Designated IRB:
City of El Paso Fire Department Federalwide Assurance (FWA) #: 00013593

The Officials signing below agree that City of El Paso Fire Department may rely on the TTUHSC IRB for review and continuing oversight of its human subjects research described below: (*check one*)

(___) This agreement applies to all human subjects research covered by Institution B's FWA.

(_X_) This agreement is limited to the following specific protocol(s):

Name of Research Project: Immediate Myocardial Metabolic Enhancement During Initial Assessment and Treatment via Emergency care.

Name of Principal Investigator: Robert Woolard, MD; other investigators Susan Watts PhD, James R. Loflin, MD, David Gough MD, Ken Berumen MD

Sponsor or Funding Agency: National Heart Lung and Blood Institute (NHLBI) of the National Institutes of Health (NIH) Award Number: U01 HL077821

(___) Other: _____

The review performed by the TTUHSC IRB will meet the human subject protection requirements of City of El Paso Fire Department's FWA approved by the Office for Human Research Protection (OHRP). The IRB at TTUHSC will follow written procedures for reporting its findings and actions to appropriate officials at City of El Paso Fire Department. Relevant minutes of IRB meetings will be sent to the City of El Paso Fire Department. The City of El Paso Fire Department remains responsible for ensuring compliance with the IRB's determinations **(see Appendix A for details)** and with the Terms of its OHRP-approved FWA. This document must be kept on file by both parties and provided to OHRP upon request.

Signature of Signatory Official Texas Tech University Health Sciences Center:

_____ Date: _____
Print Full Name: Douglas Stocco, PhD Institutional Title:
Executive Vice President for Research

Signature of Signatory Official City of El Paso:

Print Full Name: Joyce Wilson

Date: _____
Institutional Title: City Manager

Approved as to form:

Mark Shoesmith
Assistant City Attorney

Approved as to content:

Roberto Rivera, Chief
El Paso Fire Department

APPENDIX A

1. The Emergency Medical Services (EMS) paramedics [EMS paramedics] employed by the El Paso Fire Department will undergo training specific to the IMMEDIATE Trial. It will include training in the protection of human subjects, the consent process and the related-conduct of participation in a research study.

2. The Texas Tech University Health Sciences Center (TTUHSC) has agreed that their Institutional Review Board (IRB) will act in the capacity of an IRB for the El Paso Fire Department. They will be granted to do so under the Federalwide Assurance process.

3. The TTUHSC's IRB is an approved IRB under the Office of Human Research Protection (OHRP) and follows their (OHRP) rules and regulations accordingly.

4. The TTUHSC's IRB has reviewed and approved the IMMEDIATE Trial Protocol. This approval extends to the EMS paramedics who will be responsible for the screening and enrolling patients into the Trial.

5. The El Paso Fire Department EMS paramedics' compliance with the Trial's Protocol will not interfere with their standard current practice and is in addition to the standard of care that they currently provide. Compliance with the Trial's Protocol includes screening and enrolling patients into the study based on the inclusion and exclusion criteria.

6. Patients who call 911 and are evaluated by the paramedics for a likely heart attack will typically have an electrocardiogram (EKG) done. For every patient who has an EKG, the paramedic will complete a screening form to determine if the patient is eligible for the study, if the patient is eligible then he/she will be given the option (by the paramedic) to participate in the study. If the patient agrees then the study drug will be started in the ambulance. These standards and processes are part of the Protocol approved by the TTUHSC's IRB.

7. The TTUHSC's IRB will receive a report of enrollment on an annual basis for their review and approval of the Trial's continuation. The TTUHSC's IRB will provide a copy of the annual approval to the El Paso Fire Department. If there are any other determinations made (for example to not approve or stop the study early) they will notify the El Paso Fire Department accordingly.

OMB No. 0990-0278
Approved for use through May 31, 2011

Federalwide Assurance (FWA) for the Protection of Human Subjects for Institutions Within the United States

[ ] New Filing **[ ] Update or Renewal for FWA Number:** _____

1. Institution Filing Assurance

Legal Name:

City: State:

HHS Institution Profile File (IPF) code, if known:

Federal Entity Identification Number (EIN), if known:

If this Assurance replaces an MPA or CPA, please provide the "M" or "T" number:

2. Institutional Components

List below all components over which the Institution has legal authority that operate under a different name. Also list with an asterisk (*) any alternate names under which the Institution operates. The Institution should have available for review by the Office for Human Research Protections (OHRP) upon request a brief description and line diagram explaining the interrelationships among the Assurance Signatory Official, the Institutional Review Board(s) (IRB), IRB support staff, and investigators in these various components.

NOTE: The Signatory Official signing this Assurance must be legally authorized to represent the Institution providing this Assurance and all components listed below. Entities that the Signatory Official is not legally authorized to represent may not be listed here without the prior approval of OHRP.

[ ] Please check here if there are no such components or alternate names.

Name of Component or Alternate Names Used	City	State (or Country if Outside U.S.)

3. Statement of Principles

This Institution assures that all of its activities related to human subjects research, regardless of the source of support, will be guided by the ethical principles in the following document(s): (*indicate below*)

[ ] ***The Belmont Report***
[ ] ***Other:*** *(Please submit copy to OHRP with this Assurance)*

4. Applicability

(a) This Institution assures that whenever it engages in human subjects research conducted or supported by any federal department or agency that has adopted the Federal Policy for the Protection of Human Subjects, known as the Common Rule, the Institution will comply with the **Terms of the Federalwide Assurance for Institutions Within the United States (contained in a separate document on the OHRP website)**, unless the research is otherwise exempt from the requirements of the Common Rule or a department or agency conducting or supporting the research has determined that the research shall be covered by a separate assurance.

(b) *Optional:* This Institution elects to apply the following to all of its human subjects research regardless of the source of support, except for research that is covered by a separate assurance:

[ ] ***The Common Rule (see section 3 of the Terms of the FWA for Institutions Within the United States for a list of departments and agencies that have adopted the Common Rule and the applicable citations to the Code of Federal Regulations)***
[ ] ***The Common Rule and subparts B, C, and D of the HHS regulations at 45 CFR part 46***

5. Designation of Institutional Review Boards (IRBs)

This Institution designates the following IRB(s) for review of research under this Assurance *(if the IRB has not previously registered with HHS or has not provided a membership roster to HHS, please submit to OHRP the appropriate IRB registration materials which are available on the OHRP website)*.

NOTE: Reliance on the IRB of another institution or organization or an independent IRB must be documented by a written agreement that is available for review by OHRP upon request. OHRP's sample IRB Authorization Agreement may be used for this purpose, or the parties involved may develop their own agreement. Future designation of other IRBs requires an update of the FWA.

HHS IRB Registration Number	Name of IRB as Registered with HHS

6. Human Protections Administrator (e.g., Human Subjects Administrator or Human Subjects

Contact Person)

First Name: Middle Initial: Last Name:

Degrees or Suffix: Institutional Title:

Institution:

Telephone: FAX: E-Mail:

Address:

City: State: Zip Code:

7. Signatory Official (i.e., Official Legally Authorized to Represent the Institution)

I understand that the Assurance Training Modules on the OHRP website describe the responsibilities of the Signatory Official, the IRB Chair(s), and the Human Protections Administrator under this Assurance. Additionally, I recognize that providing research investigators, IRB members and staff, and other relevant personnel with appropriate initial and continuing education about human subject protections will help ensure that the requirements of this Assurance are satisfied.

Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure protections for human subjects as specified above. The IRB(s) designated above are to provide review for all research to which this Assurance applies. The designated IRB(s) will comply with the **Terms of the Federalwide Assurance for Institutions Within the United States** and possess appropriate knowledge of the local context in which this Institution's research will be conducted.

All information provided with this Assurance is up-to-date and accurate. *I am aware that false statements could be cause for invalidating this Assurance and may lead to other administrative or legal action.*

Signature _____ Date: _____

First Name: Middle Initial: Last Name:

Degrees or Suffix: Institutional Title:

Institution:

Telephone: FAX: E-Mail:

Address:

City: State: Zip Code:

NOTE: Institutions operated by the U.S. Government may need to obtain department or agency clearance prior to submission of the FWA to OHRP. Please contact the relevant department or agency Human Subject Protections Officer before forwarding this Assurance to OHRP.

8. FWA Approval

The Federalwide Assurance for the Protection of Human Subjects for Institutions Within the United States submitted to HHS by the above Institution is hereby approved.

Assurance Number: Expiration Date:

Signature of HHS Approving Official: _____ Date:_____

Public burden for this collection of information is estimated to average two hours for a new FWA filing and less than an hour for an FWA renewal or update. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: OS Reports Clearance Officer, Room 537H, 200 Independence Avenue, SW., Washington, DC 20201. *Do not return the completed form to this address.*