



Dallas Area Designated as a Federal Resuscitation Research Center

July 10, 2006

OFFICIAL NOTICE:

In a first of its kind initiative, the *U.S. National Institutes of Health* (NIH) -- working with the *Canadian Institutes of Health Research* (CIHR), *Defence Research and Development Canada*, and the *Heart and Stroke Foundation of Canada* -- announces the creation and multi-year funding of a national *Resuscitation Outcomes Consortium* (ROC), an ambitious federal program to conduct multiple clinical trials that will formally test interventions to improve survival chances from sudden cardiac arrest and trauma – see ROC.UWCTC.org.

The **DALLAS CENTER FOR RESUSCITATION RESEARCH**, comprised of the Dallas area BioTel System and its respective municipalities and receiving hospitals, under the stewardship of the *University of Texas Southwestern Medical Center at Dallas*, has been designated officially as one of only 7 metropolitan U.S. sites named to enter the ROC along with one rural U.S. site, and two Canadian teams (involving 3 major Canadian cities). The initial funding for this project is \$50,000,000 with the inaugural phase being conducted for approximately 5 years. The first clinical trials are expected to be launched this Summer.

Dr. Tracey Hoke, the NIH Medical Officer who provided oversight for the development of this major new research venture, calls the NIH initiative both “necessary and timely”. Says Dr. Hoke, “It is estimated that tens of thousands of Americans die needlessly each year because promising new interventions for sudden death and trauma have not yet been formally tested. We now have a mechanism to get this life-saving job done”.

Cardiac Arrest: There are nearly 1,000 persons who experience sudden cardiac arrest each day in the U.S. alone and most die. It is now believed that a very large number of these persons have the potential to be saved, especially with some of the new interventions now being developed.

Severe Trauma: Severe injury claims tens of thousands of lives annually and it is the number one killer of children and young adults (those under 45 years of age). New resuscitation methods are now believed to improve the chances of survival, thus restoring many years of productive life for thousands of Americans annually.

* The BioTel System is the coalition of more than a dozen Dallas area cities' EMS (9-1-1 system) programs that receive medical oversight from the *UT Southwestern Medical Center* working in conjunction with the majority of receiving hospitals within the Dallas County area.



The first interventions to be studied:

- A unique airway valve called the “**inspiratory threshold device**” (ITD)* will be tested in **cardiac arrest** patients. This simple airway attachment is designed to significantly enhance return blood flow back to the chest during CPR and, in turn, blood flow to the heart and brain.
- A customized intravenous (“I.V.”) fluid that can be given to **severely injured** persons called “**hypertonic saline in dextran**” (HSD)*, a highly concentrated salt solution that helps to rapidly restore fluid back into the bloodstream of bleeding patients.

*Both techniques have already been studied in hundreds of patients in preliminary, single center studies that have not only demonstrated safety, but also have indicated a life-saving effect, at least in the short term. The ROC will now have the ability to provide definitive proof of effectiveness to support their widespread adoption and use.

Says Dr. Ahamed H. Idris, Professor of Surgery (Emergency Medicine) at *UT Southwestern*, Principal Investigator and Director for the Dallas Center for Resuscitation Research, “This NIH designation not only is a great honor that recognizes and places the Dallas area on the cutting edge of life-saving research, but it will also immediately benefit our patients because of the additional support, training, equipment and focus that this federal initiative will bring to the Dallas area”.

Dr. Idris also stresses that the ultimate success of the Dallas area ROC and its life-saving potential will depend on the interdependent participation of an array of Dallas area healthcare institutions and public safety agencies including more than 30 area hospitals and more than a dozen municipal EMS programs involving thousands of area healthcare workers focused on these life-saving projects.

Other sites / main communities participating along with the Dallas area ROC on this NIH initiative include:

- Birmingham, AL – University of Alabama
- Iowa – University of Iowa
- Milwaukee, WI – Medical College of Wisconsin
- Ottawa/Vancouver – University of Ottawa & University of British Columbia
- Pittsburgh, PA – University of Pittsburgh Medical Center
- Portland, OR – Oregon Health and Sciences University
- San Diego, CA – University of California, San Diego
- Seattle, WA – University of Washington
- Toronto – University of Toronto

Annual enrollment of patients in these studies could be as high as 10,000 for cardiac arrests and 5,000 for major trauma each year.



Additional information about the ROC can be found at the Websites:
ROC.UWCTC.ORG or WWW.BIOTEL.WS

SPECIAL PUBLIC NOTIFICATIONS:

Informed Consent

A special consideration about these projects is that they involve clinical trials that use an exception to the requirement to obtain informed consent from the patients who are eligible to be included. This is because persons being enrolled in these studies (cardiac arrest or severe trauma patients) will be incapable of providing informed consent and, also, they are patients very likely to quickly die and therefore requiring immediate therapy.

The ROC scientists will be following strict federal guidelines* that allow for exception to informed consent. In addition to close federal scrutiny, prior to implementing each project, the researchers must obtain final approval from local groups that oversee and monitor research (called Institutional Review Boards). This approval will come only after they have consulted with members of the communities in which the research will take place. They will also notify the public at large about this research.

* U.S. Department of Health and Human Services (US DHHS) Federal Drug Administration (FDA) has reviewed this matter in great depth through a series of hearings and it has now issued a ruling that permits exception to informed consent in such emergency circumstances (21 CFR 50.24).

Randomization

Patients enrolled into the studies (adult 9-1-1 patients presenting with highly-lethal cardiac arrest or severe trauma) will have a **50 – 50 chance of getting either the treatment being studied or the standard treatment**. The process does not allow for special considerations or exceptions. Every person will otherwise be treated in the same way. In some cases, there may be a third option making these odds one-third, one-third, one-third, or two-thirds chance of getting a study treatment.

Risk-Benefits

The initial tests will be conducted with “interventions” that have been previously tested in preliminary research that has demonstrated safety in hundreds of patients and short-term survival advantages. The ROC is tasked with providing definitive proof of long-term benefits, including improved survival chances. Therefore, the research poses little risk to the patients, particularly considering that patients to be enrolled are those whose chances of survival are very slim in the first place. Also, it has been shown in studies of this sort that survival chances and eventual outcomes are significantly improved for all patients enrolled, whether they receive the treatment under study or standard treatments. This is because the researchers update training, re-visit the best standards for treatment and, along with third party experts, they closely monitor how the study is being conducted, thus ensuring the quality of care delivered. In summary, there is **unlikely risk** and **significant potential benefit** of participating in these research projects. More importantly, despite their grim prognoses, the **chances of survival** and **overall outcomes** for patients **are likely to be improved just by being enrolled** into the research.

Additional advantages for the public at large come from all of the information that health officials can gather about the various causes and consequences of cardiac arrest and trauma. Although information about individual patients will be protected and kept in strict confidence, the collective information from thousands of these (unidentified) patients can be used to help us unravel many important mysteries about what might lead to sudden cardiac arrest and injury deaths, including

precipitating factors and predictors of survival (using age, sex, race, occupation, time of day, zip code, place of occurrence, heralding symptoms, and a host of other clues).

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