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August 15, 2007

Docket Number 95S-1058
Division of Dockets Management
Food and Drug Administration
5640 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

RE: Investigational New Drug Application #100681

Dear Sir

In accordance with 21 CFR 56.109 and 312.54 concerning our Investigational New Drug Application #100681, we are submitting copies of information that has been publicly disclosed by the Baylor IRB to document the community consultation/community notification activities for the emergency consent exception with our study.

Sincerely,

Claudia Robertson, M.D.

1995S-0158

RPT22

**Documentation of Community Notification/Consultation for
Use of the Emergency Consent Exception in the Study**

**Effects of Erythropoietin on Cerebral Vascular Dysfunction and
Anemia in Traumatic Brain Injury**

**Program Director: Claudia Robertson, M.D.
Professor, Department of Neurosurgery
Baylor College of Medicine
Houston, Texas 77030**

Supported by:

**The National Institute of Neurological
Disorders and Stroke (NINDS)**

#P01-NS38660

Study Intervention Provided by: N/A

**Sponsor of IND (IDE): Claudia Robertson, M.D.
BB-IND 12014**

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Factors Considered in Planning the Consultation Meetings

Major racial and ethnic groups in the Ben Taub General Hospital trauma population

From Harris County 2000 census:

<u>Group</u>	<u>% of Population</u>
White, non-Hispanic	42%
Hispanic (white race, other or multiple races)	33%
African American	18%
Asian	5%
Other	1%

TBI patients cared for at Ben Taub:

White, non-Hispanic	32%
Hispanic	45%
African American	18%
Asian	5%

Significant Healthcare Issues that will influence the choice of groups for consultation.
none

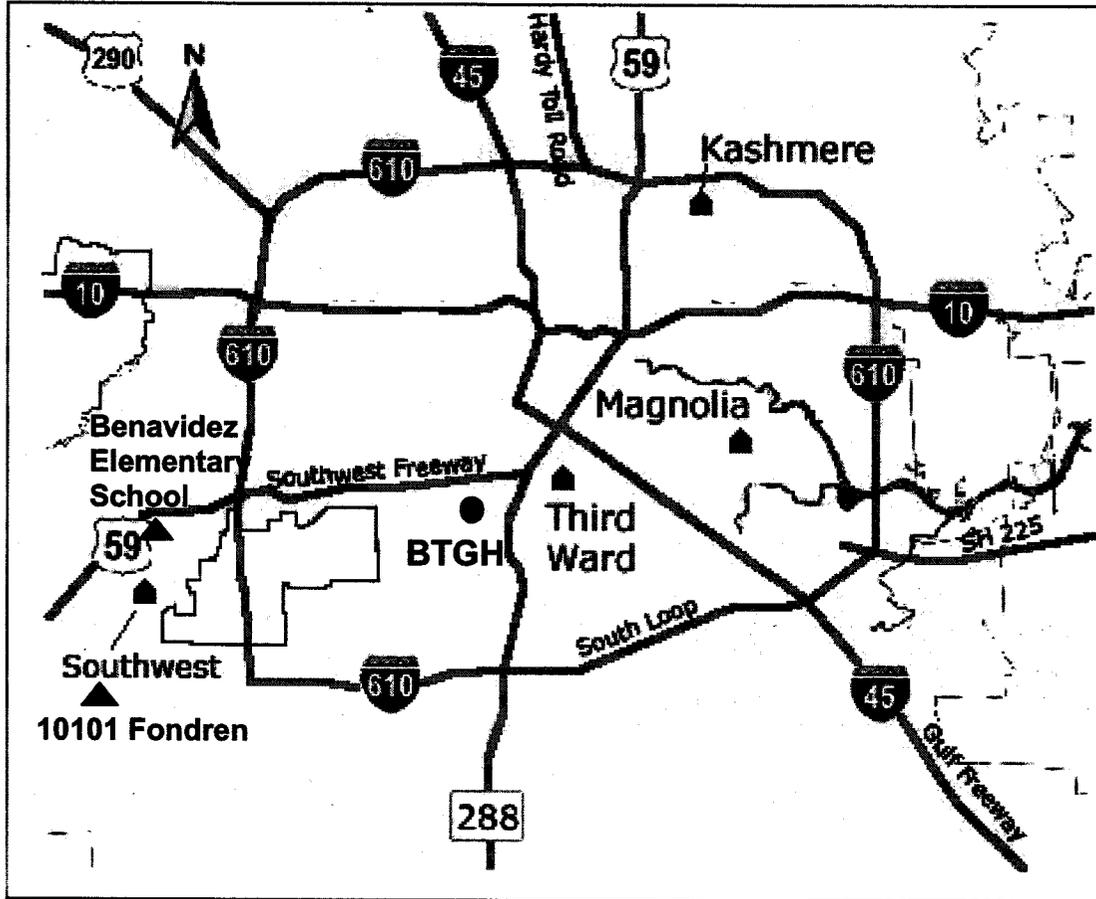
Major Social Issues that may influence the choice of groups for consultation.

1. Hispanics and African Americans are the major minority groups cared for at BTGH
2. Young adults and senior citizens have the highest incidence of TBI
3. TBI patients who do not have families immediately available are commonly minority, underinsured, and/or illegal immigrants

Any other pertinent or unique factors in your community that will influence the choice of groups for consultation?
none

Location of Community Meetings

The map below shows location of the community meetings that were held, as well as the location of Ben Taub General Hospital (BTGH). The communities chosen are those that are highly represented in the BTGH patient population, although for trauma cases anyone injured in Harris County could be brought to BTGH.



2 0 2 4 Miles

Summary of Community Notification Activities

Note: *These are the notification activities that were done to involve people in the community meetings. Additional notification activities will be done when the use of the emergency consent exception is approved.*

Strategy: webpage (<http://www.bcm.edu/neurosurgery/?pmid=5809>)

Target group: Houston community at large

Dates run: 3/28/07 to present

Strategy: announcement in Harris County Hospital District Newsletter

Target group: employees at the hospital district

Dates run: 5/2/07

Strategy: press release about use of emergency consent exception for the Epo study

Target group: Houston community at large

Dates run: 3/15/07

Strategy: advertisements in Houston Chronicle and Houston Press

Target group: Houston community at large

Dates run: ad in Chronicle ran on Thursday 4/26/07, and Sunday 4/29/07

Strategy: press release about community meetings giving date/times and locations

Target group: Houston community at large

Dates run: 4/18/07

Results: printed in Houston Chronicle on 4-19-07

Strategy: fliers advertising the meetings were distributed at each of the community centers for several days prior to each of the community meetings

Target group: local communities near the community centers

Dates run: a few days before each of the meetings

Summary of Community Consultation Activities

Strategy: meeting at Ben Taub NICU with slide presentation about study and about the emergency consent exception

Target group: leaders of Houston Fire Department EMS

Date: 1/26/07 at 11:30AM

of participants: 6

of evaluation forms returned: 6

% favorable to use exception:

- 5/6 (83%) agreed with enrolling patients initially without their consent
- 4/6 (67%) were willing to have the study done in their community

% unfavorable to use exception:

- 1/6 (17%) did not agree with enrolling patients initially without their consent
- 2/6 (33%) marked "n/a" for question asking if they were willing to have the study done in their community

other comments: Dr. Persse and the EMS chiefs were supportive of the plans, and will discuss with their respective paramedics

Strategy: meeting at TIRR Foundation headquarters with slide presentation about study and about the emergency consent exception

Target group: local (Gulf coast) CNS injury basic scientists (targeted because at least one important issue is the scientific need to give the drug early after injury)

Date: 2/9/07 at 2:00PM

of participants: 18

of evaluation forms returned: 12

% favorable to use exception:

- 12/12 (100%) agreed with enrolling patients initially without their consent
- 12/12 (100%) were willing to have study done in their community

% unfavorable to use exception: 0

other comments:

- interestingly 2/12 of these scientists who should understand the need for a randomized trial, were unwilling personally to participate in the study (the objection seemed to be the possible randomization to placebo), but were willing to have it done in their community
- there was agreement that the earlier a neuroprotective drug treatment is given, the better the chances for benefit
- the director of Mission Connect provided a letter of support in addition to the surveys completed at the meeting

Strategy: meeting at Ben Taub NICU with slide presentation about study

Target group: MADD (Mothers Against Drunk Drivers) leadership, a support group for patients with TBI

Date: 3/15/07

of participants: 4

of evaluation forms returned: 4

% favorable to use exception:

- 4/4 (100%) agreed with enrolling patients initially without their consent
- 4/4 (100%) were willing to have study done in their community

% unfavorable to use exception: 0

other comments:

Strategy: regular monthly Gateway to Care meeting at Third Ward Multi-service Center with handout and short verbal description of study followed by questions/discussion

Target group: Gateway to Care leaders (organization involved in increasing access of medical care to indigent/underinsured of Houston)

Date: 3/20/07 at 12 noon

of participants: ~60

of evaluation forms returned: 23

% favorable to use exception:

- 23/23 (100%) agreed with enrolling patients initially without their consent
- 20/23 (87%) were willing to have study done in their community

% unfavorable to use exception:

- 3/23 (13%) were not willing to have the study done in their community
 - 1/23 (4%) disagreed with use of the exception
 - 1/23 (4%) answered not sure
 - 1/23 (4%) did not answer the question but instead commented that we needed to widely publicize the study within the community

other comments: The board of directors authorized the director of Gateway to Care to write a letter of support in addition to the surveys that were filled out at the meeting.

Strategy: email of one page description of study with references to web page and to press release about study, as well as copy of survey to be returned

Target group: leaders of organizations of the Gulfcoast United Way

Date: 3/21/07

of participants: 1400

of evaluation forms returned: 7

% favorable to use exception: 7/7 (100%)

% unfavorable to use exception: 0

other comments: One additional comment agreeing with the study was returned without the survey.

Strategy: booth at Health Fair at Kashmere Multi-service Center (4802 Lockwood Street, 10AM to 3PM)

Target group: local community, primarily African American

Date: 4/14/07

of participants: 56

of evaluation forms returned: 56

% favorable to use exception:

- 50/56 (89%) agreed with enrolling patients initially without their consent
- 54/56 (96%) agreed with the study being conducted in their community

% unfavorable to use exception:

- 6/56 (11%) disagreed with enrolling patients initially without their consent
 - 5 of these were willing to have the study done in their community
 - 3 of these would be willing to participate in the study personally
- 2/56 (4%) disagree with the study being conducted in their community

other comments: One participant was Asian, the remainder were primarily African American.

Strategy: short verbal presentation at Houston PIP (Positive Interaction Program) meeting (10101 Fondren)

Target group: local community, mixed ethnicity

Date: 4/17/07 at 6:30PM

of participants: ~30

of evaluation forms returned: 26

% favorable to use exception:

- 26/26 (100%) agreed with enrolling patients without their consent
- 26/26 (100%) were willing to have the study done in their community

% unfavorable to use exception: 0

other comments: Most of the community participants were white, the police participants were African American and Hispanic

Strategy: short verbal presentation at Houston PIP (Positive Interaction Program) meeting at Southwest Multi-service Center (6400 High Star)-participants were all invited to community meeting that evening

Target group: local community-primarily Hispanic, but also multi-national (Asian, Indian, African)

Date: 4/24/07 at 12PM

of participants: 35

of evaluation forms returned: 35

% favorable to use exception:

- 33/35 (94%) agreed with enrolling patients without their consent
- 33/35 (94%) were willing to have the study done in their community

% unfavorable to use exception: 2/35 (6%)

other comments: 1 additional person indicated that he would not be willing to participate in the study personally because he would want to get Epo definitively, 1 other person indicated that although he would be willing to participate in the study personally, he would unhappy if he received placebo

Strategy: community meeting at Southwest Multi-service Center (6400 High Star)

Target group: local community-primarily Hispanic, but also multi-national (Asian, Indian, African)

Date: 4/24/07 at 6:00PM

of participants: ~20

of evaluation forms returned: 13

% favorable to use exception:

- 13/13 (100%) agreed with enrolling patients without their consent
- 13/13 (100%) were willing to have the study done in their community

% unfavorable to use exception: 0

other comments:

- presentation and questions were in Spanish and English
- 3 participants were African American, the remainder were Hispanic

Strategy: short verbal presentation at Houston PIP (Positive Interaction Program) meeting (10101 Fondren)-participants invited to town hall meeting the following day

Target group: local community, mixed ethnicity

Date: 4/26/07 at 11:30AM

of participants: 15

of evaluation forms returned: 15

% favorable to use exception:

- 14/15 (93%) agreed with enrolling patients without their consent
- 11/15 (73%) were willing to have the study done in their community

% unfavorable to use exception:

- 4/15 (27%) were not willing to have the study done in their community
 - one person commented that “I do not feel that anybody has the right to vote as a whole to force a study on someone else”
 - one person indicated that they would like to have the real drug

other comments:

- One person commented “If this medication will save a life, it sounds great”
- Participants were mixture of white, African American, and Hispanic

Strategy: community meeting at Kashmere Multi-service Center (4802 Lockwood St)

Target group: local community-African American, and senior citizens

Date: 4/27/07 at 11AM

of participants: 37

of evaluation forms returned: 37

% favorable to use exception:

- 30/37 (81%) agreed with enrolling patients without their consent
- 33/37 (89%) were willing to have the study done in their community

% unfavorable to use exception:

- 7/37 (19%) did not agree with enrolling patients without their consent
 - 4/7 question was left blank or commented “unsure”
- 4/37 (11%) were not willing to have the study done in their community

- 2/7 answered "strongly disagree"
- 2/7 question was left blank or "unsure"

other comments: Several of the questionnaires had answers to one or more questions left blank. We're not sure if everyone understood all of the questions.

Strategy: community meeting at Magnolia Multi-service Center (7037 Capitol St.)

Target group: local community, primarily Hispanic

Date: 4/30/07 at 9AM

of participants: 37

of evaluation forms returned: 37

% favorable to use exception:

- 35/37 (95%) agreed with enrolling patients without their consent
- 34/37 (92%) were willing to have the study done in their community

% unfavorable to use exception:

- 2/37 (5%) disagreed with enrolling patients without their consent
- 3/37 (8%) were not willing to have the study done in their community

other comments:

- The presentations were in Spanish and English.
 - Most participants were Hispanic.
-

Strategy: both at Health Fair at Benavidez Elementary School (6262 Gulfon St)

Target group: local community, primarily Hispanic

Date: 5/2/07 at 1:00-4:00 PM

of participants: 24

of evaluation forms returned: 24

% favorable to use exception:

- 22/24 (92%) agreed with enrolling patients without their consent
- 22/24 (92%) were willing to have the study done in their community

% unfavorable to use exception:

- 2/24 (8%) disagreed with enrolling patients without their consent
- 2/24 (8%) were not willing to have the study done in their community
 - 1 of these was willing to participate in the study personally

other comments:

Summary of Survey Results – All Meetings
(295 surveys were returned)

Question 1 Results: Do you understand the study?

Strongly agree	= 124 (42%)	
Agree	= 161 (55%)	Total agree = 285 (97%)
Disagree	= 5 (2%)	
Strongly disagree	= 1 (0.3%)	
No answer	= 3 (1%)	
“unsure”	= 1 (0.3%)	

Question 2 Results: Do you understand that most of the patients will be enrolled in the study initially without their consent?

Strongly agree	= 108 (37%)	
Agree	= 166 (56%)	Total agree = 274 (93%)
Disagree	= 13 (4%)	
Strongly disagree	= 4 (1%)	
No answer	= 2 (0.7%)	
“unsure”	= 2 (0.7%)	

Question 3 Results: Do you understand that patients will be randomly assigned to receive erythropoietin or placebo?

Strongly agree	= 109 (37%)	
Agree	= 162 (55%)	Total agree = 271 (92%)
Disagree	= 16 (5%)	
Strongly disagree	= 6 (2%)	
No answer	= 2 (0.7%)	

Question 4 Results: Do you understand that all patients will receive standard care for head injury, regardless of whether or not they receive erythropoietin?

Strongly agree	= 149 (51%)	
Agree	= 131 (44%)	Total agree = 280 (95%)
Disagree	= 10 (3%)	
Strongly disagree	= 2 (0.7%)	
No answer	= 3 (1%)	

Question 5 Results: Are you willing for this study to be done in your community?

Strongly agree	= 129 (44%)	
Agree	= 147 (50%)	Total agree = 276 (94%)
Disagree	= 5 (2%)	
Strongly disagree	= 8 (3%)	
“not sure”	= 2 (0.7%)	
“n/a”	= 2 (0.7%)	
No answer	= 1 (0.3%)	
“you need to widely publicize the study”	= 1 (0.3%)	

Question 6 Results: Would you be willing to participate in the study if you were to have a head injury?

Strongly agree	= 138 (47%)
Agree	= 126 (43%)
Disagree	= 15 (5%)
Strongly disagree	= 11 (4%)
No answer	= 3 (1%)
“unsure”	= 2 (0.7%)

Total agree = 264 (89%)

Detailed Documentation of Community Notification Activities



Research: Center for Neurosurgical Intensive Care

Claudia Robertson, M.D., Professor and Medical Director

Current Research Projects

1. **Effects of Erythropoietin on Cerebral Vascular Dysfunction and Anemia in Traumatic Brain Injury (funded by NIH grant #P01-NS38660).** This project is a randomized clinical trial of erythropoietin in patients with severe traumatic brain injury.

Trial is registered in www.clinicaltrials.gov - Identifier = NCT00313716

Proposal for use of emergency consent exception in trial ([link to next page](#))

2. **The Role of NOS3 in the Cerebrovascular Response to TBI (funded by NIH grant #R01-NS048428).** This clinical study is examining the effect of common single nucleotide polymorphisms of the NOS3 gene on cerebrovascular function (cerebral blood flow, pressure autoregulation, CO₂ reactivity) in patients with severe traumatic brain injury.
3. **Biomarkers of Traumatic Brain Injury (funded by NIH grant #R01-NS052831)**
This clinical study is trying to develop a panel of biomarkers that would indicate the presence and severity of brain injury after trauma. Eventually this panel might be used as a simple blood test.

Investigators Seek Approval to Use Emergency Consent Exception for Brain Injury Study

Name of Study: Effects of Erythropoietin on Cerebral Vascular Dysfunction and Anemia in Traumatic Brain Injury (Trial is registered in www.clinicaltrials.gov - Identifier = NCT00313716)

Erythropoietin for TBI Patients:

Erythropoietin is growth factor normally produced by the kidneys that stimulates production of red blood cells. It is FDA approved to treat chronic anemia associated with chronic renal failure, cancer, and AIDS. This trial will study whether erythropoietin will reduce the incidence and severity of anemia, and therefore the need for blood transfusion, and if erythropoietin will improve neurological recovery after traumatic brain injury.

Summary of Erythropoietin Study Protocol:

This study is being conducted at Ben Taub General Hospital in Houston, Texas. Patients age 15 and above, who are admitted to the hospital with a severe closed head injury, are eligible for the study. Currently, only those patients who have relatives available at the hospital and who give written informed consent within 6 hr of injury can be enrolled.

All patients enrolled in the study receive standard treatment of their brain injury, that is, the same standard treatment they would receive if they did not participate in the study.

In addition to this standard treatment, the patients are randomly assigned to receive erythropoietin or placebo. Also, the patients are randomly assigned to keep their hemoglobin concentration at least 7gm/dl or 10gm/dl. Patients participating in the study are followed for six months after injury to assess their neurological recovery.

The potential benefits of erythropoietin treatment are that hemoglobin concentration may be higher and fewer blood transfusions may be required, and that neurological outcome may be improved. Potential risks of erythropoietin treatment are hypertension and thrombotic events such as deep venous thrombosis or pulmonary embolus.

Need for Rapid Enrollment and Administration of Study Drug:

Although enrollment in this clinical trial is ongoing, it has been very difficult to enroll patients rapidly enough to give the study drug at the most optimal time for neuroprotection. A total of 22 of the planned 200 subjects have been enrolled in the study to date. The average

Study Webpage, pg. 2

Research: Center for Neurosurgical Intensive Care - Department of Neurosurgery - Baylor College of Medi... Page 2 of 2

time of administration of the study drug in these initial subjects was 5.5 hr post-injury. No patient has yet received the study drug within 3 hr of injury, when the treatment is likely to be most effective. Because of this, the investigators are seeking to use the emergency consent exception under 21 CFR 50.24 for this trial.

Emergency Consent Exception (21CFR 50.24):

A fundamental principle of clinical research is that individual subjects are able to decide whether or not they wish to participate based on knowledge of the risks and the potential benefits of the study. In addition, research subjects can withdraw from a research study at anytime.

In 21 CFR 50.24, federal law defines the very special circumstance of emergency research where patients are unable because of their illness or injury to give informed consent and where relatives are not likely to be available in time to give informed consent because of the urgency to start treatment. In place of individual informed consent, additional assurances are required, including disclosure to the community that the study will be conducted and that most of the patients will be initially enrolled in the study without individual informed consent. When families are subsequently located or if the patient regains consciousness, they are informed about the study and allowed to decide to continue to participate or to withdraw from the study.

Comments:

To comment on or to ask questions about the proposed use of the emergency consent exception for this study, click on the link: <mailto:tbl@bcm.tmc.edu>

E-mail this page to a friend

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<http://www.bcm.edu/neurosurgery/?pmid=5809>

4/2/2007

Announcement in Harris County Hospital District Newsletter

From: HCHD Communications
Sent: Wednesday, May 02, 2007 10:12 AM
Subject: Beat Briefs

Beat Briefs



A weekly bulletin from Corporate Communications offering timely information to HCHD employees.

Volume 1, Issue 43
May 2, 2007

Recognizing Service and Achievements

The Harris County Hospital District will mark National Hospitals Week and National Nurses Week May 6-12 with several special events to thank employees for their service. In addition, colorful banners announcing the annual weeklong celebration will be displayed at Ben Taub, LBJ, and Quentin Mease hospitals.

New BT Parking Garage Guidelines

Please note, there are important new guidelines in place for the parking garage at Ben Taub, including: HCHD staff not assigned to Ben Taub may access the fifth through ninth levels of the parking garage with a new ID badge and the appropriate parking decal; employees assigned to the Leeland and Brown lots may access the fifth through ninth levels of the Ben Taub parking garage from 6 p.m. to 7:30 a.m. Monday through Friday, and all day on weekends and holidays; and all employees are asked to use their ID badges when exiting the garage.

Ben Taub Study Needs Feedback

Local trauma care specialists are soliciting input from the public for a new emergency treatment being studied at Ben Taub and Baylor College of Medicine. The study is looking at the effects of an emergency treatment for head injury using a medication that increases the production and lifespan of red blood cells. The treatment requires a response so immediate that it is difficult to get families' permission to allow patients to take part. Because of this, researchers at Baylor College of Medicine and Ben Taub are seeking a "waiver of consent" under federal rules for emergency research. For more information and to make a comment, click [here](#).

E-Presentations Schedule Change

E-Presentations online learning modules will be unavailable to new registrants from May 1-31 for a system update. Registrations will resume June 1 and participants will receive access to the modules on June 15. Current E-Presentation users have until May 15 to complete their modules. Failure to complete modules by this date will require June registration.

Calendar

Book Signing and Inspirational Words
Nationally known author J.L. King
Wednesday, May 2
11 a.m.-1 p.m.
Thomas Street-3rd floor conference room

Nationwide Representative
Thursday, May 3
8 a.m.-4 p.m.
LBJ cafeteria

National Day of Prayer Observance
Thursday, May 3
1 p.m.
LBJ chapel

Blessing of the Hands Services
Thursday, May 3
noon-1 p.m.
Ben Taub, LBJ, Quentin Mease, Thomas Street chapels

Blessing of the Hands Service
Thursday, May 3
10 a.m.
Strawberry Health Center

Nursing Discovery Day for Girl Scouts
Saturday, May 5
10 a.m.-1 p.m.
Northwest Health Center
1100 W. 34th St.



- Ross Tomlin 713-798-7973 htomlin@bcm.tmc.edu
- E-mail this article to a friend

Treatment for head injury requires emergency waiver

HOUSTON -- (March 15, 2007) -- A study of the effects of an emergency treatment for head injury using erythropoietin, a medication that increases the production and lifespan of red blood cells, requires a response so immediate that it is difficult to get families' permission to allow patients to take part.

Because of this, researchers led by Dr. Claudia Robertson, professor of neurosurgery at Baylor College of Medicine and medical director of the neurosurgical intensive care unit at Ben Taub General Hospital, are seeking a "waiver of consent" under federal rules for emergency research.

This would allow them to treat the patient within the six-hour time frame required to determine if the drug will actually save precious brain tissue. For the past few months, Robertson and her colleagues have tried to get consent from families of patients who might take part in the study, but notifying them of the accident takes time. Many arrive at the hospital too late to give consent.

As a result, the researchers have not been able to enroll enough patients to determine if the medication can improve the lives of those who have had severe injuries to their brains. They had hoped to enroll 40 patients per year.

Under the U.S. Food and Drug Administration's emergency research rules, it is possible to enroll patients in a study of an emergency procedure without informed consent as long as certain criteria are met. One of these criteria is to obtain community approval of the study. Robertson and her colleagues must meet with community representatives and discuss their plans with them and get their input. They must also make their plans known to the community at large through the media and other means.

Another criterion is to inform patients and their families about their participation in the study. "As soon as we can locate the families, we can ask permission," Robertson said. "If they do not want their family member to be part of the study, we can stop then." If the patient regains consciousness and does not want to take part, he or she can ask that the treatment be stopped.

Their study, planned to involve 200 patients in the neurosurgical intensive care unit at Ben Taub, is the centerpiece of a five-year, \$6 million grant from the National Institute of Neurological Disease and Stroke. Robertson hopes that it will help her determine if erythropoietin can actually help prevent the cascade of events that lead to severe brain damage in patients who have had head injuries.

Patients enrolled in the study will receive either placebo or one of two different dosages of erythropoietin. They will, of course, receive all other standard treatments for patients with severe brain injury.

Damage to a brain continues after the initial injury as tissue dies, giving off chemicals and other factors that can continue to kill brain cells. Protecting brain tissue from this secondary damage is a major goal of Robertson's work.

In studies with animals with brain injury, giving erythropoietin protects the brain and improves their outcome, she said. Erythropoietin is approved for other purposes and causes few side effects. The most common side-effects that have occurred in other studies is hypertension and an increased risk of blood clotting.

She and her colleagues see two possible advantages to giving the medication.

Patients with brain injury often have lost a lot of blood and need blood transfusions. Giving them erythropoietin will reduce the need for transfusions and the risks that they carry.

Study Press Release, pg. 2:

Treatment for head injury requires emergency waiver - Baylor College of Medicine

Page 2 of 2

"We also think it may protect the brain," said Robertson.

Others taking parting the work under the grant include Drs. Shankar Gopinath, Robert Bryan, Leela Cherian and J. Clay Goodman, all of BCM as well as H. Julia Hannay, professor of psychology at University of Houston, and Paul R. Swank, professor of developmental pediatrics at University of Texas Health Science Center at Houston.

Those interested in more information or those who have comments on the plan can call 713-798-4696 or e-mail neurosurgery@bcm.edu.

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Last modified: February 9, 2006

<http://www.bcm.edu/news/item.cfm?newsID=830>

4/2/2007

Advertisement of Community Meetings, pg. 1

Houston Chronicle ad (ran on Thursday 4/26/07, and Sunday 4/29/07):

**BCM** Baylor College of Medicine

Traumatic Brain Injury

Baylor Neurosurgery at Ben Taub General Hospital is considering emergency waiver of consent for brain injured patients. Please come to a community meeting to share your opinion:

- April 27, 11-12 PM at Kashmere Multi-Service Center (4802 Lockwood St)
- April 30, 9-10 AM at Magnolia Multi-Service Center (7037 Capitol St)

See our webpage for more information:
<http://www.bcm.edu/neurosurgery/?pmid=5809>

713-873-2794

www.bcm.edu/clinicalstudies

Houston Press ad (ran 4/26/07 through 5/2/07)



El departamento de Neurocirugía en el Hospital General de Ben Taub esta considerando no utilizar autorización escrita en caso de una situación de emergencia para el tratamiento de pacientes con lesión cerebral.

Por favor venga a la junta de comunidad y comparta su opinión:

- + Abril 24, 6-7 PM en el Southwest Multi-Service Center (6400 High Star)
- + Abril 27, 11-12 PM en el Kashmere Multi-Service Center (4802 Lockwood St)
- + Abril 30, 9-10 A, en el Magnolia Multi-Service Center (7307 Capitol St)

Para mayor información por favor visite nuestra página web
<http://www.bcm.edu/neurosurgery/?pmid=5809>



Baylor College of Neurosurgery at Ben Taub General Hospital is considering emergency waiver of consent for brain injured patients.

Please come to a community meeting to share your opinion:

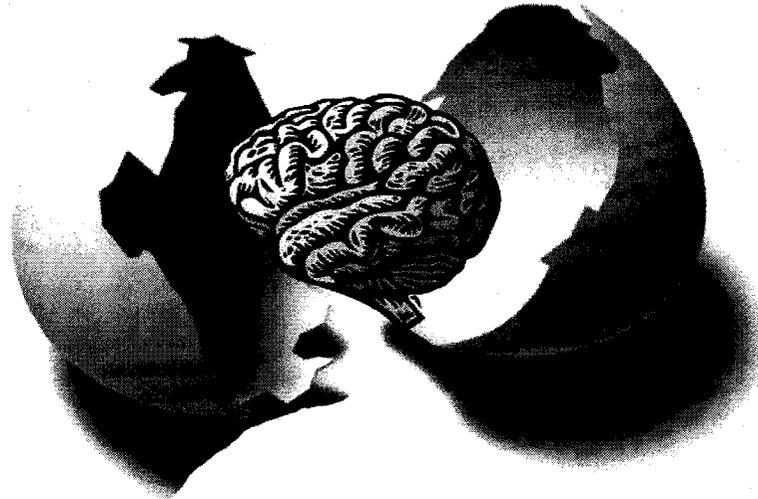
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See our webpage for more information about the study
<http://www.bcm.edu/neurosurgery/?pmid=5809>

Advertisements of Community Meetings, pg. 2

Fliers passed out at community centers (English version):

What can you do for a brain injury?



Baylor Neurosurgery at Ben Taub General Hospital is recruiting patients with severe traumatic brain injury for a research study of erythropoietin.

Erythropoietin inhibits neuronal cell death, has anti-inflammatory activities, and may improve cerebral blood flow. In experimental studies it improves neurological recovery from brain and spinal cord injury, and from stroke. In addition, erythropoietin stimulates red cell production and is expected to reduce the number of blood transfusions required.

Eligible patients for the study are:

- in coma due to closed head injury
- at least 15 years old
- have no life-threatening systemic injuries

The drug must be given within 6 hours of the brain injury.

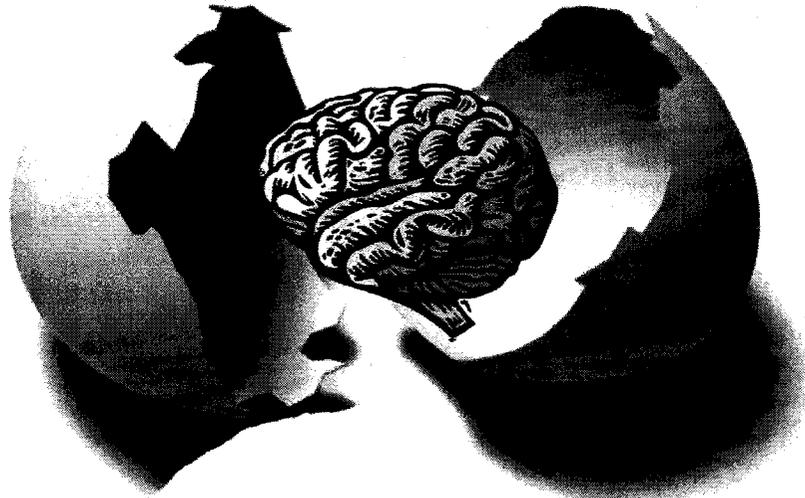
To send comments, e-mail us at tbi@bcm.tmc.edu

You are invited to a community meeting to discuss the use of emergency waiver of consent for this study. The meetings will be held:

- **April 24, 6-7PM at Southwest Multi-Service Center (6400 High Star)**
- **April 27, 11-12PM at Kashmere Multi-Service Center (4802 Lockwood St)**
- **April 30, 9-10AM at Magnolia Multi-Service Center (7037 Capitol St)**

Please come to a meeting and give your opinion.

¿Que puede hacer usted por una lesión cerebral?



**El departamento de Neurocirugia en el Hospital General de Ben Taub
esta considerando no utilizar autorización escrita en caso de una
situación de emergencia para el tratamiento de pacientes con lesión
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Press Release about Community Meetings (4/18/07)

Public consent needed for emergency treatment - Baylor College of Medicine

Page 1 of 1



- Ross Tomlin 713-798-7973 htomlin@bcm.tmc.edu
- E-mail this article to a friend

Public consent needed for emergency treatment

HOUSTON – (April 18, 2007) – Local trauma care specialists are soliciting input this month from the public for a new emergency treatment being studied at Ben Taub General Hospital and Baylor College of Medicine.

The study is looking at the effects of an emergency treatment for head injury using erythropoietin, a medication that increases the production and lifespan of red blood cells. The treatment requires a response so immediate that it is difficult to get families' permission to allow patients to take part.

Because of this, researchers at Baylor College of Medicine and Ben Taub General Hospital, part of the Harris County Hospital District, are seeking a "waiver of consent" under federal rules for emergency research. Community meetings designed to do just that are scheduled at the following times and locations:

- April 24 (Tuesday), 6-7 p.m., at the Southwest Multi-service Center, 6400 High Star
- April 27 (Friday), 11 a.m.-12 noon, at the Kashmere Multi-service Center, 4802 Lockwood St.
- April 30 (Monday), 9-10 a.m., at the Magnolia Multi-service Center, 7037 Capital St.

The meetings are free and open to the public.

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Last modified: February 9, 2006



Alief/Southwest News

April 19, 2007, 5:36PM

Hospital officials seek public comment on emergency medical treatment

Local trauma care specialists are soliciting input this month from the public for a new emergency treatment being studied at Ben Taub General Hospital and Baylor College of Medicine.

The study is looking at the effects of an emergency treatment for head injury using erythropoietin, a medication that increases the production and lifespan of red blood cells. The treatment requires a response so immediate that it is difficult to get families' permission to allow patients to take part.

Because of this, researchers at Baylor College of Medicine and Ben Taub General Hospital, part of the Harris County Hospital District, are seeking a "waiver of consent" under federal rules for emergency research, according to a press release from Baylor College of Medicine.

Community meetings designed to do just that are scheduled at the following times and locations:

- 6-7 p.m. Tuesday, at the Southwest Multi-service Center, 6400 High Star
 - 11 a.m.-noon, April 27, at the Kashmere Multi-service Center, 4802 Lockwood St.
 - 9-10 a.m., April 30, at the Magnolia Multi-service Center, 7037 Capital St.
- The meetings are free and open to the public.

VOICES OF HOUSTON

POWERED BY Pluck

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Detailed Documentation of Community Consultation Activities

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Summary of Meeting with EMS Leadership on 1/26/07 11:30AM in Ben Taub NICU Classroom:

Present were representatives from the study (Claudia Robertson, MD, Shankar Gopinath, MD, Emmy Miller, RN), representatives from the Ben Taub trauma service (Brad Scott, MD, Matthew Carrick, MD, and Michael Norman, MD), the HFD EMS Director (David Persse, MD), three EMS chiefs, and two EMS techs. Dr. Robertson gave a presentation describing the emergency consent exception, and explaining why the Epo study is proposing to now use this procedure for enrolling patients. After the presentation, a discussion ensued. Some of the points discussed included:

Dr. Persse emphasized that the emergency consent exception was very important for the field of emergency research to be able to make progress. It was reviewed that a number of clinical trials in Houston have used the emergency consent exception, including the hypothermia and polyheme trial. In addition, Matthew Carrick and Mike Norman as well as David Persse have studies in the planning stage which will use the emergency consent exception. None of these planned studies will be possible to conduct using usual informed consent since the time to enroll patients will be very short.

One of the EMS chiefs asked why we were planning to look for family for 3 hrs before enrolling patients. That is, why not enroll patients even earlier? We looked again at the time course data in experimental studies, and showed that that good neuroprotection occurred at 3 hrs post-injury, but was significantly less at 6 hrs post-injury. We explained that we want to enroll patients using informed consent from the family whenever possible, and felt that this was the best balance between this desire to obtain informed consent when possible and the need to give the drug as early as possible.

Emmy Miller further explained that it might not be necessary to search for families for the full 3 hrs in all cases, for example if it were discovered that family were not local and could not be contacted. No objections to the plans were expressed. The 6 EMS participants all completed the survey at the end of the meeting.

Slide Presentation for Meeting with EMS Leadership, pg. 1:

Epo Clinical Trial

- Federal regulations for research consent
- Epo trial-background and enrollment to date
- Our proposal for using the emergency consent exception
 - Feasibility of the study without the emergency consent exception
- Recommendation-timing of the Epo administration is crucial to the success of the trial

Informed Consent

- Fundamental principle of research
- Difficult to achieve in emergency research

Who can give consent for research?

- Legally authorized representative (LAR)
- Family (in order)
 - Spouse
 - Parent
 - Adult Child
 - Sibling



How is Informed Consent Documented for Research?

- Written informed consent document must be signed
- No phone consents, but can be faxed
- Innovative ways to do this for emergency projects

Exception from Informed Consent in Emergency Research

- 21 CFR 50.24
- Designed for implementation of research in emergency settings when exception from informed consent is not possible



http://www.fda.gov/oc/compliance_of_hmo/lar_guide.htm

Criteria

- The exception applies when:
 - Human subjects cannot give informed consent because of emerging, life-threatening medical condition
 - Available treatments for the condition are unproven or unsatisfactory
 - The intervention must be administered before informed consent from LAR is feasible



Slide Presentation for Meeting with EMS Leadership, pg. 2:

Benefits and Risks

- Participation must hold out prospect of **direct benefit** to the subject
 - If placebo design is used, standard care must be given to all subjects
- Risks of the study are **reasonable** in relation to:
 - What is known about the medical condition of the potential subjects
 - The risks and benefits of standard therapy
 - Any benefits of the proposed treatment

Study Design

- Design should be adequate to the task of evaluating whether the treatment provides the hypothesized effect
- The therapeutic window must be defined
- The amount of time spent in locating family members must be defined



Contact of Family Members

- Attempts to contact a legally authorized representative (LAR) or family member need not exhaust the entire therapeutic window
- The effect of delaying study treatment must be taken into account when determining the portion of the therapeutic window to be spent trying to locate family



Public Disclosure and Community Consultation

- Prior to start of the study -- public disclosure of sufficient information to describe:
 - the nature and purpose of the study
 - the fact that informed consent will not be obtained for most study subjects
- Following completion of the study information about the study results must be disclosed
 - to the community where the research was done
 - the research community should have access to comprehensive summary data

FDA Position on Our Trial

- Study meets all of the requirements for the emergency consent exception except
 - it is not practicable without the exception
- They argued that adding another site would allow us to complete the study
- We want to argue that early administration of Epo is crucial to the success of the trial

Erythropoietin (Epo)

- A hematopoietic growth factor, produced in the kidney
- Stimulates production of RBCs
- Clinical use -- chronic anemia associated with kidney disease, cancer, HIV

Slide Presentation for Meeting with EMS Leadership, pg. 3:

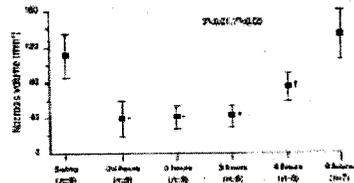
Anemia in TBI Patients

- Anemia in severe trauma is the result of a complex interaction of factors:
 - bleeding
 - blunted Epo response to low hemoglobin concentrations
 - inflammatory mediators
 - decreased iron stores
- An estimated 40-50% of all critically ill trauma patients receive a transfusion of blood products.

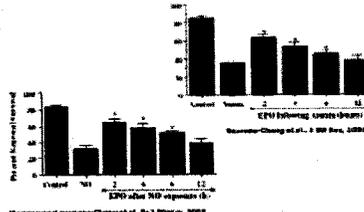
Epo Also Has Neuroprotective Actions

- *Experimental cerebral ischemia* (Kumral 2006, Junk 2002, Catania 2002, Siren 2001, Bernardin 1998, Brines 2000, Sakanska 1998)
- *Experimental traumatic brain injury* (Brines 2000)
- *Glutamate neurotoxicity* (Morishita 1997)
- *Spinal cord ischemia* (Celik 2002)
- *Spinal cord trauma* (Goto 2002)
- *Subarachnoid hemorrhage* (Grasso 2001, Alafaci 2000, Springborg 2002, Iwasaki 2002)

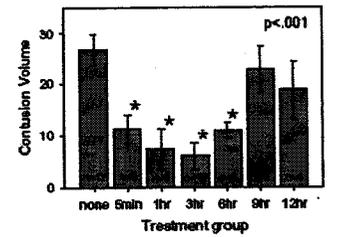
Time Window for Epo Neuroprotection
mca stroke model in rats, Brines et al. 2002



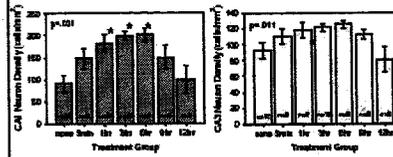
Time Window for Epo Neuroprotection
cell culture injury models



Epo Reduces Contusion Volume



Epo Reduces Neuronal Loss in Hippocampus



Slide Presentation for Meeting with EMS Leadership, pg. 4:

Risk/Benefit for Epo

- Potential benefit
 - Increased hematocrit, reduced need for blood transfusion
 - Improved neurological outcome
- Potential Risk
 - Hypertension
 - Thrombotic events (DVT, PE, AMI-have mostly occurred when a normal hematocrit is targeted)

Pilot Clinical Trial in Stroke Patients
(Ehrenreich et al., Molecular Medicine 8:495-505,2002)

- 40 patients randomly assigned to Epo 33,000 IU q24h x 3
- No safety concerns
- CSF Epo levels 60-100 x times greater in treated group
- Trend for improved neurological outcome

**Epo Clinical Trial:
Primary Objective**

- To determine the effect of early administration of Epo on long-term neurological outcome after severe TBI.
- Hypothesis, early administration of Epo improves global neurological outcome at 6 months post-injury.

Inclusion Criteria

- Age \geq 15 yrs
- Motor GCS \leq 5 (not following commands)
- Enrolled within 6hrs of injury

Interventions

- Patients will be randomly assigned to one of four treatment groups:

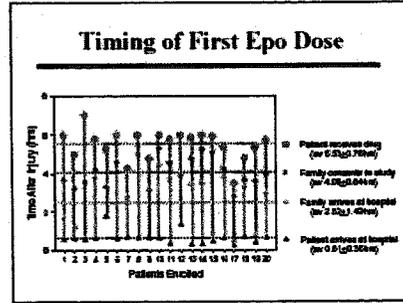
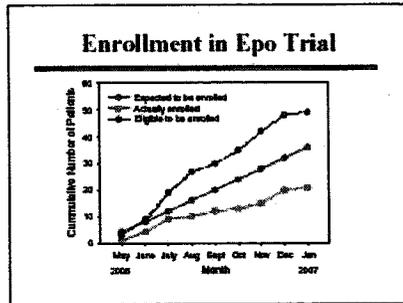
Treatment with Epo Transfusion trigger of < 10 g/dl	Treatment with Placebo Transfusion trigger of < 10 g/dl
Treatment with Epo Transfusion trigger of < 7 g/dl	Treatment with Placebo Transfusion trigger of < 7 g/dl

- Epo 500 IU/kg IV q24h x 3 doses, then qwk x 2 additional doses
- All patients will also receive standard management of TBI

Enrollment in Study

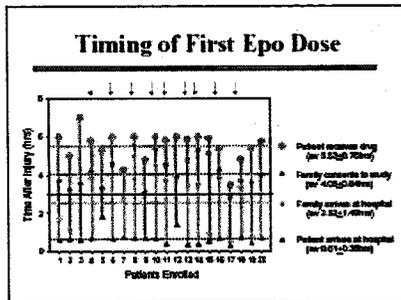
- Plan to enroll 200 patients over 5 years
- 40 patients per year
- Enrollment started in May 2006
- 20 patients have been enrolled so far (9 months)
- Average time of first dose of drug 5.5 hr post-injury

Slide Presentation for Meeting with EMS Leadership, pg. 5:



- ### Proposed Plan
- Look for family for up to 3hr post-injury
 - If family is available, only enroll patient if consent is obtained
 - If family is not available
 - Enroll patient under the emergency consent exception
 - When family arrives, inform them about the study and obtain consent for the patient to continue to participate in the study

- ### Proposed Plan
- More patients (2.5 X more) will be eligible for the study
 - The study drug will be given earlier when it has the best chance to be effective
 - But most patients will be enrolled in the study under the emergency consent exception



Surveys Returned for Meeting with EMS Leadership, pg. 1:

Community Consultation Survey for
Erythropoietin Clinical Trial

Date of meeting: 26 JAN 07

	Circle one answer:			
	Strongly Agree	Agree	Disagree	Strongly Disagree
1. Do you understand the study?	4	3	2	1
2. Do you understand that most of the patients will be enrolled initially without their consent?	4	3	2	1
3. Do you understand that patients will be randomly assigned to receive erythropoietin or placebo?	4	3	2	1
4. Do you understand that all patients will receive standard care for TBI, regardless of whether or not they receive erythropoietin?	4	3	2	1
5. Are you willing for the study to be done in your community?	N/A	3	2	1
6. Would you be willing to participate in the study if you were to have a head injury?	4	3	2	1

Surveys Returned for Meeting with EMS Leadership, pg. 2:

**Community Consultation Survey for
Erythropoietin Clinical Trial**

Date of meeting: 1-26-07

	Circle one answer:			
	Strongly Agree	Agree	Disagree	Strongly Disagree
1. Do you understand the study?	(4)	3	2	1
2. Do you understand that most of the patients will be enrolled initially without their consent?	4	(3)	2	1
3. Do you understand that patients will be randomly assigned to receive erythropoietin or placebo?	(4)	3	2	1
4. Do you understand that all patients will receive standard care for TBI, regardless of whether or not they receive erythropoietin?	(4)	3	2	1
5. Are you willing for the study to be done in your community?	(3)	3	2	1
6. Would you be willing to participate in the study if you were to have a head injury?	(3)	3	2	1

Surveys Returned for Meeting with EMS Leadership, pg. 3

Community Consultation Survey for
Erythropoietin Clinical Trial

Date of meeting: 26 Oct 2007

Circle one answer:

	Strongly Agree	Agree	Disagree	Strongly Disagree	
1. Do you understand the study?	4	3	2	1	
2. Do you understand that most of the patients will be enrolled initially without their consent?	4	3	2	1	
3. Do you understand that patients will be randomly assigned to receive erythropoietin or placebo?	4	3	2	1	
4. Do you understand that all patients will receive standard care for TBI, regardless of whether or not they receive erythropoietin?	4	3	2	1	
5. Are you willing for the study to be done in your community?	N/A	4	3	2	1
6. Would you be willing to participate in the study if you were to have a head injury?	4	3	2	1	

Surveys Returned for Meeting with EMS Leadership, pg. 4:

Community Consultation Survey for
Erythropoietin Clinical Trial

Date of meeting: 1/26/07

Circle one answer:

	Strongly Agree	Agree	Disagree	Strongly Disagree
1. Do you understand the study?	4	3	2	1
2. Do you understand that most of the patients will be enrolled initially without their consent?	4	3	2	1
3. Do you understand that patients will be randomly assigned to receive erythropoietin or placebo?	4	3	2	1
4. Do you understand that all patients will receive standard care for TBI, regardless of whether or not they receive erythropoietin?	4	3	2	1
5. Are you willing for the study to be done in your community?	4	3	2	1
6. Would you be willing to participate in the study if you were to have a head injury?	4	3	2	1

Surveys Returned for Meeting with EMS Leadership, pg. 5:

Community Consultation Survey for
Erythropoietin Clinical Trial

Date of meeting: 1-26-07

Circle one answer:

	Strongly Agree	Agree	Disagree	Strongly Disagree
1. Do you understand the study?	4	3	2	1
2. Do you understand that most of the patients will be enrolled initially without their consent?	4	3	2	1
3. Do you understand that patients will be randomly assigned to receive erythropoietin or placebo?	4	3	2	1
4. Do you understand that all patients will receive standard care for TBI, regardless of whether or not they receive erythropoietin?	4	3	2	1
5. Are you willing for the study to be done in your community?	4	3	2	1
6. Would you be willing to participate in the study if you were to have a head injury?	4	3	2	1

Surveys Returned for Meeting with EMS Leadership, pg. 6:

Community Consultation Survey for
Erythropoietin Clinical Trial

Date of meeting: 1-26-07

Circle one answer:

	Strongly Agree	Agree	Disagree	Strongly Disagree
1. Do you understand the study?	4	5	2	1
2. Do you understand that most of the patients will be enrolled initially without their consent?	4	3	2	1
3. Do you understand that patients will be randomly assigned to receive erythropoietin or placebo?	4	3	2	1
4. Do you understand that all patients will receive standard care for TBI, regardless of whether or not they receive erythropoietin?	4	6	2	1
5. Are you willing for the study to be done in your community?	4	6	2	1
6. Would you be willing to participate in the study if you were to have a head injury?	4	3	2	1

Summary for Mission Connect Meeting, pg. 1:

This presentation was given at a regular monthly meeting of the Mission Connect scientists, which are a group of primarily basic research scientists involved in brain injury and spinal cord injury research from Baylor College of Medicine, UT Health Sciences Center-Houston, UT Medical Branch, and Texas A&M University. The administrative functions of the group are provided by the TIRR Foundation. The website for the organization is at:

<http://www.missionconnect.org/index2.html>

Dr. Robertson presented a slide show describing the issues of obtaining written informed consent for research in the emergency setting, information about the emergency consent exception, and details about the Epo study. Many comments were expressed supporting the study and the use of the emergency consent exception and several questions were asked during the discussion that followed.

“What’s latency of effect on RBC’s - how long does it take to increase RBC’s?”

Dr. Robertson answered that it would take 1-2 weeks to see an effect on RBC’s.

“In your experience with the time-limited effect on ischemia, how well does it apply to humans?”

Dr. Robertson replied that time windows determined in experimental models of cerebral ischemia have fairly closely predicted the effective time window of such treatments in humans. There have not been any successful treatments of TBI in humans, but it is assumed that the time window for most neuroprotective agents would certainly not be longer in humans than it is in animal models.

“When was Epo applied in Stroke?”

Dr. Robertson replied that in the pilot clinical trial of Epo in stroke, a time window of 8 hrs was used.

“Is there known mechanism of action for protection?”

Dr. Robertson answered that it is likely that there are multiple beneficial effects of Epo, including inhibition of apoptosis, suppression of inflammatory response, and possibly even an improvement in cerebral blood flow.

“The cell culture effects were in the absence of other cell types?”

Dr. Robertson answered that the cell culture studies showing neuroprotection with NO exposure and with anoxia were both neuronal cultures.

“Is enrollment equal to time of treatment?”

Dr. Robertson answered that no, after enrollment there is some time required for the pharmacy to prepare the drug. The average time between enrollment and drug administration is about 1 hour in the patients that have been enrolled so far. We are working on ways to reduce this time, but it is difficult with a busy hospital pharmacy.

Summary for Mission Connect Meeting, pg. 2:

“How many families reject enrollment?”

Dr. Robertson answered that out of the 140 patients that have been screened for the study so far, only 3 have declined to participate in the study.

“Can we give them placebo?”

Dr. Robertson answered that the rules for the emergency consent exception allows the use of a placebo arm if that is the design that is required to demonstrate effectiveness of the treatment. All patients, however, receive standard treatment of their brain injury, which would be provided even if they did not participate in the study. So no one in the study is receiving no treatment.

“What if you find family in 3 hrs, do you have to wait?”

Dr. Robertson answered that if we locate family within 3 hrs, we will only enroll patients if their relatives agree and sign the informed consent form.

“Is there possibility to significantly reduce the number of patients receiving dose < 3 hrs by having drug already prepared?”

Dr. Robertson answered that it would not be possible to prepare the drug ahead of time, because at enrollment the drug treatment is randomly assigned for each patient.

“Do you find HIPPA regulations a problem with collecting data?”

Dr. Robertson answered that to use the emergency consent exception, we would require a waiver of HIPPA requirements as well.



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Our Vision

Reverse the consequences of spinal cord injuries, traumatic brain injuries, and central nervous system disorders by conducting groundbreaking research through collaborative efforts.

Our History

Established in 1997 by TIRR Foundation, Mission Connect unites Baylor College of Medicine, The University of Texas Health Science Center at Houston, The University of Texas Medical Branch at Galveston, and Texas A&M University System Health Science Center Institute for Bioscience and Technology. Eleven scientific initiatives have been funded by Mission Connect.

Unique

The collaborative effort among the partners is very unique in the field of medical research. Typically, research institutions compete with one another for funding, and seldom share their research findings. From the beginning, Mission Connect was set up to foster cooperation. This is an important tool in fundraising efforts that support and sustain research. One hundred percent of the money provided to Mission Connect scientist is dedicated to research.

Our Future

Mission Connect is dedicated to medical research that will make a difference in the lives of people who have catastrophic injuries and illnesses. Toward accomplishing that goal, TIRR Foundation is committed raising at least \$20 million for Mission Connect research.



SCIENTISTS AND THEIR RESEARCH

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[Mingyao Liu, Ph.D.](#)



[David J. McAdoo, Ph.D.](#)



[Olivera Nesic-Taylor](#)



[Kenneth Parsons, M.D.](#)

[H. David Shine, Ph.D.](#)

Information About Mission Connect Organization, pg. 3:

Mission Connect: Scientists and their Research



Robert Tsai, M.D., Ph.D.



Kishore K. Wary, Ph.D.



Rong Yu, Ph.D.



Fen Wang, Ph.D.



Ping Wu, M.D., Ph.D.





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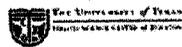
Baylor College of Medicine (BCM)

The only private medical school in the Greater Southwest, Baylor College of Medicine was founded in 1900 and is today an internationally respected medical and research institution known for excellence in education, research, and patient care.



Texas A&M University System Health Science Center, Institute of Biosciences and Technology

A part of the Texas A&M University System Health Science Center, the Institute of Biosciences and Technology (IBT) is located in Houston's Texas Medical Center. IBT encourages collaborative and interdisciplinary ventures that bring about synergies in biomedical science.



The University of Texas Health Science Center at Houston

Located in the world renowned Texas Medical Center, The University of Texas Health Science Center brings together the Dental Branch, the Graduate School of Biomedical Sciences, the Medical School, the School of Public Health, the School of Nursing, the School of Health Information Sciences, the UT Harris County Psychiatric Center, and the Brown Foundation Institute of Molecular Medicine for the Prevention of Human Disease.



The University of Texas Medical Branch (UTMB) at Galveston
UTMB provides scholarly teaching, innovative scientific investigation, and state-of-the-art patient care in a learning environment to better the health of society. UTMB's education programs enable the state's talented individuals to become outstanding practitioners, teachers, and investigators in the health care sciences.

Slide Presentation for Mission Connect Meeting, pg. 1:

Epo Clinical Trial

- Federal regulations for research consent
- Epo trial background and enrollment to date
- Our proposal for using the emergency consent exception
 - Practicability of the study without the emergency consent exception
- Recommendation-timing of the Epo administration is crucial to the success of the trial

Informed Consent

- Fundamental principle of research
- Difficult to achieve in emergency research

Who can give consent for research?

- Legally authorized representative (LAR)
- Family (in order)
 - Spouse
 - Parent
 - Adult Child
 - Sibling



How is Informed Consent Documented for Research?

- Written informed consent document must be signed
- No phone consents, but can be faxed
- Innovative ways to do this for emergency projects

Exception from Informed Consent in Emergency Research

- 21 CFR 50.24
- Designed for implementation of research in emergency settings when exception from informed consent is not possible



http://www.fda.gov/cber/compliance_of_hmo/ur_guid.htm

Criteria

- The exception applies when:
 - Human subjects cannot give informed consent because of emerging, life-threatening medical condition
 - Available treatments for the condition are unproven or unsatisfactory
 - The intervention must be administered before informed consent from LAR is feasible



Slides for Mission Connect Meeting, pg. 2:

Benefits and Risks

- Participation must hold out prospect of direct benefit to the subject
 - If placebo design is used, standard care must be given to all subjects
- Risks of the study are reasonable in relation to:
 - What is known about the medical condition of the potential subjects
 - The risks and benefits of standard therapy
 - Any benefits of the proposed treatment

Study Design

- Design should be adequate to the task of evaluating whether the treatment provides the hypothesized effect
- The therapeutic window must be defined
- The amount of time spent in locating family members must be defined



Contact of Family Members

- Attempts to contact a legally authorized representative (LAR) or family member need not exhaust the entire therapeutic window
- The effect of delaying study treatment must be taken into account when determining the portion of the therapeutic window to be spent trying to locate family



Public Disclosure and Community Consultation

- Prior to start of the study -- public disclosure of sufficient information to describe :
 - the nature and purpose of the study
 - the fact that informed consent will not be obtained for most study subjects
- Following completion of the study information about the study results must be disclosed
 - to the community where the research was done
 - the research community should have access to comprehensive summary data

FDA Position on Our Trial

- Study meets all of the requirements for the emergency consent exception except
 - it is not practicable without the exception
- They argued that adding another site would allow us to complete the study
- We want to argue that early administration of Epo is crucial to the success of the trial

Erythropoietin (Epo)

- A hematopoietic growth factor, produced in the kidney
- Stimulates production of RBCs
- Clinical use -- chronic anemia associated with kidney disease, cancer, HIV

Slides for Mission Connect Meeting, pg. 3:

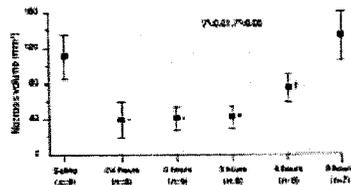
Anemia in TBI Patients

- Anemia in severe trauma is the result of a complex interaction of factors:
 - bleeding
 - blunted Epo response to low hemoglobin concentrations
 - inflammatory mediators
 - decreased iron stores
- An estimated 40-50% of all critically ill trauma patients receive a transfusion of blood products.

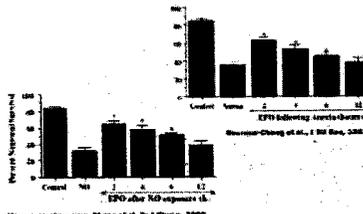
Epo Also Has Neuroprotective Actions

- *Experimental cerebral ischemia* (Kumral 2006, Junk 2002, Catania 2002, Siren 2001, Bernardin 1998, Brines 2000, Sakonaka 1998)
- *Experimental traumatic brain injury* (Brines 2000)
- *Glutamate neurotoxicity* (Morishita 1997)
- *Spinal cord ischemia* (Calik 2002)
- *Spinal cord trauma* (Goto 2002)
- *Subarachnoid hemorrhage* (Grasso 2001, Alafaci 2000, Springborg 2002, Iwasaki 2002)

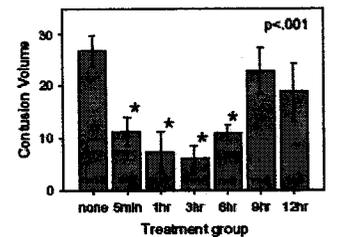
Time Window for Epo Neuroprotection
 mca stroke model in rats, Brines et al. 2002



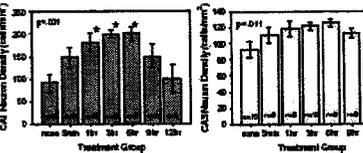
Time Window for Epo Neuroprotection
 cell culture injury models



Epo Reduces Contusion Volume



Epo Reduces Neuronal Loss in Hippocampus



Slides for Mission Connect Meeting, pg. 4:

Risk/Benefit for Epo

- Potential benefit
 - Increased hematocrit, reduced need for blood transfusion
 - Improved neurological outcome
- Potential Risk
 - Hypertension
 - Thrombotic events (DVT, PE, AMI-have mostly occurred when a normal hematocrit is targeted)

Pilot Clinical Trial in Stroke Patients (Ehrenreich et al., Molecular Medicine 8:495-505,2002)

- 40 patients randomly assigned to Epo 33,000 IU q24h x 3
- No safety concerns
- CSF Epo levels 60-100 x times greater in treated group
- Trend for improved neurological outcome

Epo Clinical Trial: Primary Objective

- To determine the effect of early administration of Epo on long-term neurological outcome after severe TBI
- Hypothesis: early administration of Epo improves global neurological outcome at 6 months post-injury.

Inclusion Criteria

- Age \geq 15 yrs
- Motor GCS \leq 5 (not following commands)
- Enrolled within 6hrs of injury

Interventions

- Patients will be randomly assigned to one of four treatment groups:

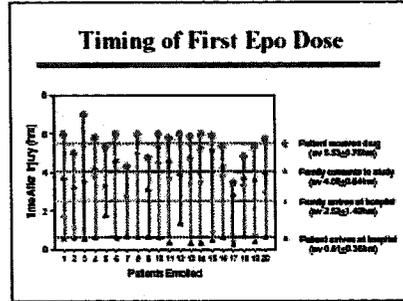
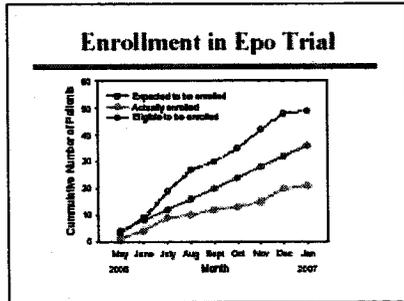
Treatment with Epo Transfusion trigger of < 10 g/dl	Treatment with Placebo Transfusion trigger of < 10 g/dl
Treatment with Epo Transfusion trigger of < 7 g/dl	Treatment with Placebo Transfusion trigger of < 7 g/dl

- Epo 500 IU/kg IV q24h x 3 doses, then qwk x 2 additional doses
- All patients will also receive standard management of TBI

Enrollment in Study

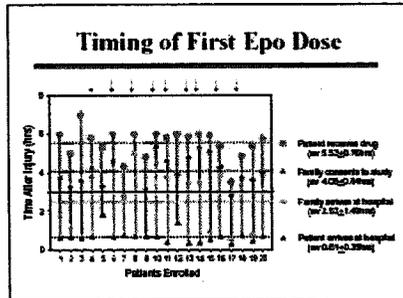
- Plan to enroll 200 patients over 5 years
- 40 patients per year
- Enrollment started in May 2006
- 20 patients have been enrolled so far (9 months)
- Average time of first dose of drug 5.5 hr post-injury

Slides for Mission Connect Meeting, pg. 5:



- ### Proposed Plan
- Look for family for up to 3hr post-injury
 - If family is available, only enroll patient if consent is obtained
 - If family is not available
 - Enroll patient under the emergency consent exception
 - When family arrives, inform them about the study and obtain consent for the patient to continue to participate in the study

- ### Proposed Plan
- More patients (2.5 X more) will be eligible for the study
 - The study drug will be given earlier when it has the best chance to be effective
 - But most patients will be enrolled in the study under the emergency consent exception



Surveys Returned for Mission Connect Meeting, pg. 1:

Community Consultation Survey for
Erythropoietin Clinical Trial

Date of Meeting: February 9, 2007

Please circle one answer for each question.

1. Do you understand the study?

Strongly agree Agree Disagree Strongly disagree

2. Do you understand that most of the patients will be enrolled in the study initially without their consent?

Strongly agree Agree Disagree Strongly disagree

3. Do you understand that patients will be randomly assigned to receive erythropoietin or placebo?

Strongly agree Agree Disagree Strongly disagree

4. Do you understand that all patients will receive standard care for head injury, regardless of whether or not they receive erythropoietin?

Strongly agree Agree Disagree Strongly disagree

5. Are you willing for this study to be done in your community?

Strongly agree Agree Disagree Strongly disagree

6. Would you be willing to participate in the study if you were to have a head injury?

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Surveys Returned for Mission Connect Meeting, pg. 2:

Community Consultation Survey for
Erythropoietin Clinical Trial

Date of Meeting: February 9, 2007

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Erythropoietin Clinical Trial

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Surveys Returned for Mission Connect Meeting, pg. 4:

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Date of Meeting: February 9, 2007

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Surveys Returned for Mission Connect Meeting, pg. 5:

Community Consultation Survey for
Erythropoietin Clinical Trial

Date of Meeting: February 9, 2007

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Surveys Returned for Mission Connect Meeting, pg. 6:

Community Consultation Survey for
Erythropoietin Clinical Trial

Date of Meeting: February 9, 2007

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Surveys Returned for Mission Connect Meeting, pg. 7:

Community Consultation Survey for
Erythropoietin Clinical Trial

Date of Meeting: February 9, 2007

Please circle one answer for each question.

1. Do you understand the study?

Strongly agree Agree Disagree Strongly disagree

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Strongly agree Agree Disagree Strongly disagree

Surveys Returned for Mission Connect Meeting, pg. 8:

Community Consultation Survey for
Erythropoietin Clinical Trial

Date of Meeting: February 9, 2007

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Strongly agree Agree Disagree Strongly disagree

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Strongly agree Agree Disagree Strongly disagree

Surveys Returned for Mission Connect Meeting, pg. 9:

Community Consultation Survey for
Erythropoietin Clinical Trial

Date of Meeting: February 9, 2007

Please circle one answer for each question.

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Surveys Returned for Mission Connect Meeting, pg. 10:

Community Consultation Survey for
Erythropoietin Clinical Trial

Date of Meeting: February 9, 2007

Please circle one answer for each question.

1. Do you understand the study?

Strongly agree

Agree

Disagree

Strongly disagree

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Strongly agree

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Disagree

Strongly disagree

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Strongly agree

Agree

Disagree

Strongly disagree

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Strongly agree

Agree

Disagree

Strongly disagree

6. Would you be willing to participate in the study if you were to have a head injury?

Strongly agree

Agree

Disagree

Strongly disagree

Surveys Returned for Mission Connect Meeting, pg. 11:

Community Consultation Survey for
Erythropoietin Clinical Trial

Date of Meeting: February 9, 2007

Please circle one answer for each question.

1. Do you understand the study?

Strongly agree Agree Disagree Strongly disagree

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Strongly agree Agree Disagree Strongly disagree

Surveys for Mission Connect Meeting, pg. 12:

Community Consultation Survey for
Erythropoietin Clinical Trial

Date of Meeting: February 9, 2007

Please circle one answer for each question.

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Strongly agree Agree Disagree Strongly disagree

6. Would you be willing to participate in the study if you were to have a head injury?

Strongly agree Agree Disagree Strongly disagree

Letter of Support from Mission Connect Director, pg. 1:



*TIRR Foundation
5100 Travis
Houston, Texas 77002-9746
Telephone (713)528-0123
Fax (713)528-4554*

**Claudia Robertson, MD
Professor, Department of Neurosurgery
Baylor College of Medicine
One Baylor Plaza
Houston, Texas 77030**

February 14, 2007

Dear Dr. Robertson,

Thank you for your very informative presentation regarding the importance of exemption from informed consent for your study funded by the National Institutes of Health, titled, "Effects of Erythropoietin (EpoE) on Cerebral Vascular Dysfunction and Anemia in Traumatic Brain Injury."

As you are aware, patients with severe brain injury have no satisfactory alternative treatment. Furthermore, intervention within the first 6 hours after injury is critical if the EpoE or any immediate intervention is to be efficacious. This window of therapeutic opportunity is too short to obtain informed patient consent from family members and the severely brain injured patient is unable to give informed consent because the patients are in a coma. Since it takes greater than 6 hours following injury to find family members, the proposed study is impractical without waived consent.

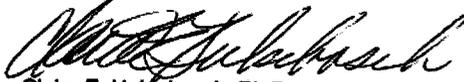
Mission Connect is a Gulf Coast area consortium consisting of research scientists and clinicians from the Baylor College of Medicine, Institute of Biosciences and Technology (of Texas A&M University Health Science Center), University of Texas Health Science Center of Houston and the University of Texas Medical Branch in Galveston. Mission Connect is a unique collaborative research effort, led by TIRR Foundation, that focuses on basic and clinical research with a goal to reverse the consequences of spinal cord injury, brain injury and neurological disorders.

Our group meets monthly and your presentation at our monthly meeting on Feb. 9, 2007, was extremely and positively received. All of the scientists present supported your exemption from informed consent as being the only reasonable way to proceed with clinical treatment of severe brain injury in general, and specifically for the EpoE intervention.

Letter of Support from Mission Connect Director, pg. 2:

Thus, we request that this study be allowed to continue with exemption from informed consent. This study is innovative, pioneering and has the potential to be ground breaking in advancing the recovery of function of people with severe brain injuries.

Sincerely



Claire E. Hulsebosch, Ph.D.
Director, Mission Connect
Vice-Chair and Professor, Neuroscience and Cell Biology
301 University Blvd. Rt. 1043
University of Texas Medical Branch
Galveston, Texas 77555-1043
phone: 409-772-2939, FAX: 409-772-3222, cehulseb@utmb.edu

Summary for MADD Meeting:

Meeting with Mother's Against Drunk Drivers (MADD) leadership held on 12 March 2007 @ 1:00 pm, Ben Taub NICU Classroom. Present were representatives from the study, (Claudia Robertson, MD Athena Baldwin, PA and Sharon Barnes, Sr. AA). Dr. Robertson presented a slide show demonstrating the emergency consent exception and explained why the Epo study protocol could have a positive impact on our patient population that are treated for severe head trauma.

Dr. Robertson outlined the research principles including patients having the right to participate or not, as well as patients rights to withdraw from the study.

Questions from the MADD representatives were:

“Who can give consent for research?”

Dr. Robertson answered that for patients who cannot give consent for themselves, spouses, parents, adult children, and siblings can give consent for research.

“How is the Informed Consent documented for research?”

Dr. Robertson answered that a written consent form is signed by the patient's relative.

Dr. Robertson discussed the exception from the informed consent in emergency research. She also discussed the benefits and risks of the Epo drug. The study design was discussed. Dr. Robertson explained how Epo is already approved by the FDA, but not for brain injury.

The language barrier between patient families was discussed. It was noted that family members often do not want to discuss a new study due to stress felt at time of loved one injury. The differences with the drug among religious groups were discussed. The MADD representatives appreciated the knowledge and will use it to discuss at their future meetings.

Information About MADD Organization, pg. 1:

MADD Online: Take the Wheel

Page 1 of 2



Houston, we have a drunk driving problem. Of the most populated counties in the United States, Harris County tops the list with more drunk driving deaths per capita than any other. That's why MADD is launching Take the Wheel an all-out effort that concentrates all of MADD's programs and services into a single community.

Our husbands, wives, children, neighbors, friends and colleagues are dying in record numbers. It's time for us to join together and take action. Take the Wheel calls on citizens and community leaders to help reduce alcohol-related deaths and injuries in the Houston area. With Take the Wheel, the power is in the hands of those of us who live here: the power to examine the problem of drunk driving and the power to do something about it.

Of the nearly 3.6 million people in Houston and Harris County, one in three of us will be directly involved in a drunk driving crash at some point in our lives. That means an estimated 1.2 million of us may experience property damage, suffer an injury, attend a funeral or be killed thanks to a drunk driver. It's time for a change.

[Officers arrest 29 for DWI on St. Patrick's Day](#) [Link](#)

Deemed a "great success" by Montgomery County Sheriff Tommy Gage, local law enforcement agencies plan a repeat of the DWI task force operation they conducted on St. Patrick's Day. [More...](#)

[MADD Launches New Local Initiative to Curb Drunk Driving](#)

Take the Wheel is a community-based arm of MADD's national Campaign to Eliminate Drunk Driving. The initiative has been put in place to help achieve the organization's national goals. [More...](#)

[What You Can Do to Stop Drunk Driving](#)

The problem of drunk driving will not solve itself. Each of us can do something about it. [More...](#)

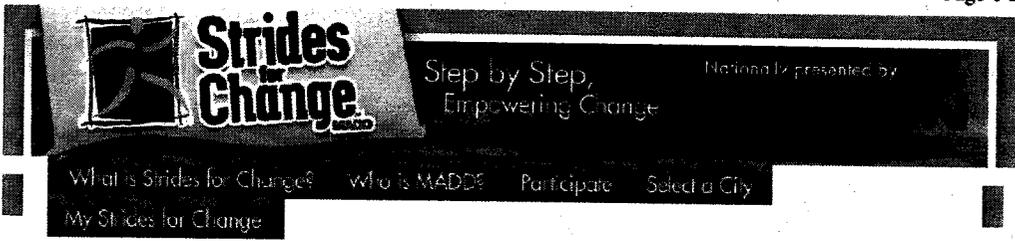
[What MADD Is Doing](#)

http://www.madd.org/madd_programs/11295

4/3/2007

Information About MADD Organization, pg. 2:

MADD Strides for Change: Who is MADD? Page 1 of 1



Strides for Change
Step by Step, Empowering Change
Nationally presented by

What is Strides for Change? Who is MADD? Participate Select a City
My Strides for Change

Who is MADD?

Mothers Against Drunk Driving (MADD) is a 501(c)(3) non-profit grass roots organization with around 600 chapters nationwide. MADD is not a crusade against alcohol consumption - MADD's mission is to stop drunk driving, support the victims of this violent crime, and prevent underage drinking.

Top information About MADD

- **Other Services**
MADD's National Programs Department specializes in developing and maintaining public awareness programs at the chapter, state, and national level, involving the community as a whole in supporting MADD's mission. The department continually looks for new ways for MADD to reach a diverse population, with particular attention focused on helping youth.
- **Why Does MADD Do a Walk?**
MADD does a walk to raise awareness and funds to support the much needed efforts for prevention, education, and enforcement about drunk driving and underage drinking in communities. 41% of fatal crashes are alcohol-related. It doesn't have to be that way.
- **What You Can Do to Stop Drunk Driving?**
Drunk driving and its consequences can be prevented. Tackling it requires the involvement of every concerned citizen. You can take action to make your community a healthier and safer place.
- **Safe Driving Tips**
Learn how to prevent a crash as well as what to do if a crash happens.

© 2007 Mother's Against Drunk Driving :: [MADD Home](#) | [Strides for Change Home](#) [Privacy Policy](#) | [Questions?](#) [Contact Us](#)

http://support.madd.org/site/PageServer?pagename=wn1_who_is_MADD 4/3/2007

Slides for MADD Meeting, pg. 1:

Epo Clinical Trial

- Federal regulations for research consent
- Epo trial-background and enrollment to date
- Our proposal for using the emergency consent exception
- Discussion/survey

Research Principles

- Individual decision to participate, based on knowledge of potential risks and benefits
- Individual right to withdraw at any time

Informed Consent

- Fundamental principle of research
- Difficult to achieve in emergency research
 - Treatment must be given urgently
 - Difficult for individual to make an informed decision in the time of a medical crisis

Who can give consent for research?

- Legally authorized representative (LAR)
- Family (in order)
 - Spouse
 - Parent
 - Adult Child
 - Sibling



How is Informed Consent Documented for Research?

- Written informed consent document must be signed
- No phone consents, but can be faxed
- Innovative ways to do this for emergency projects

Exception from Informed Consent in Emergency Research

- 21 CFR 50.24
- Designed for implementation of research in emergency settings when exception from informed consent is not possible



<http://www.fda.gov/oc/compliance/21cfr50.24.pdf>

Slides for MADD Meeting, pg. 2:

Criteria

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Erythropoietin (Epo)

- A hematopoietic growth factor, produced in the kidney
- Stimulates production of RBCs
- Clinical use – chronic anemia associated with kidney disease, cancer, HIV

Slides for MADD Meeting, pg. 3:

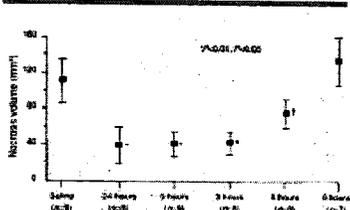
Anemia in TBI Patients

- Anemia in severe trauma is the result of a complex interaction of factors:
 - bleeding
 - blunted Epo response to low hemoglobin concentrations
 - inflammatory mediators
 - decreased iron stores
- An estimated 40-50% of all critically ill trauma patients receive a transfusion of blood products.

Epo Also Has Neuroprotective Actions

- *Experimental stroke* (Kumral 2006, Junk 2002, Catania 2002, Siren 2001, Bernaudin 1998, Brines 2000, Sakanska 1998)
- *Experimental traumatic brain injury* (Brines 2000)
- *Glutamate neurotoxicity* (Morishika 1997)
- *Spinal cord ischemia* (Celik 2002)
- *Spinal cord trauma* (Gorio 2002)
- *Subarachnoid hemorrhage* (Grasso 2001, Alafaci 2000, Springborg 2002, Iwasaki 2002)

Time Window for Epo Neuroprotection
rat stroke model in rats, Brines et al. 2002



Risk/Benefit for Epo

- Potential benefit
 - Increased red blood cell count, reduced need for blood transfusion
 - Improved neurological outcome
- Potential Risk
 - Hypertension
 - Thrombotic events (DVT, PE, AMI) have mostly occurred when a normal red blood cell count is targeted)

Pilot Clinical Trial in Stroke Patients
(Ehrenreich et al., Molecular Medicine 8:495-505, 2002)

- 40 patients randomly assigned to Epo 33,000 IU q24h x 3
- No safety concerns
- CSF Epo levels 60-100 x times greater in treated group
- Trend for improved neurological outcome

Epo Clinical Trial: Primary Objective

- To determine the effect of early administration of Epo on long-term neurological outcome after severe TBI.
- Hypothesis: early administration of Epo improves global neurological outcome at 6 months post-injury.

Slides for MADD Meeting, pg. 4:

Inclusion Criteria

- Age \geq 15 yrs
- Motor GCS \leq 5 (not following commands)
- Enrolled within 6hrs of injury

Interventions

- All patients will also receive standard management of TBI
- Patients will be randomly assigned to one of four treatment groups:

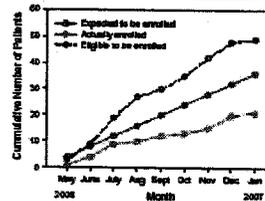
Treatment with Epo Transfusion trigger of \geq 10 g/dl	Treatment with Placebo Transfusion trigger of $<$ 10 g/dl
Treatment with Epo Transfusion trigger of $<$ 7 g/dl	Treatment with Placebo Transfusion trigger of $<$ 7 g/dl

- Epo 500 IU/kg IV q24h x 3 doses, then qwk x 2 additional doses

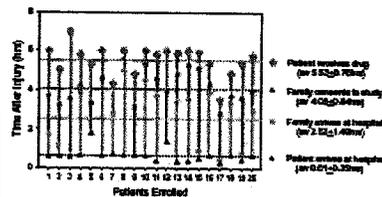
Enrollment in Study

- Plan to enroll 200 patients over 5 years
- 40 patients per year
- Enrollment started in May 2006
- 22 patients have been enrolled so far (10 months)
- Average time of first dose of drug 5.5 hr post-injury

Enrollment in Epo Trial



Timing of First Epo Dose



Proposed Plan

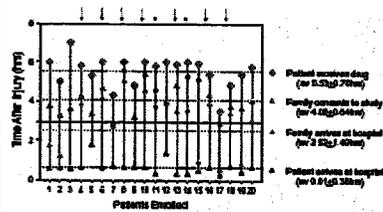
- Look for family for up to 3hr post-injury
 - If family is available at hospital, only enroll patient if written informed consent is obtained
 - If family is contacted by phone, but not available at hospital enroll patient if family agrees after explanation of the study over the phone
 - When family arrives at hospital, full explanation of study will be provided and written consent to continue to participate in the study will be obtained
- If family is not available
 - Enroll patient under the emergency consent exception
 - When family arrives, inform them about the study and obtain consent for the patient to continue to participate in the study

Slides for MADD Meeting, pg. 5:

Proposed Plan

- More patients (2.5 X more) will be eligible for the study
- The study drug will be given earlier when it has the best chance to be effective
- But most patients will be enrolled in the study under the emergency consent exception

Timing of First Epo Dose



Surveys Returned for MADD Meeting, pg. 1:

Community Consultation Survey for
Erythropoietin Clinical Trial

Date of Meeting: 12 Mrch 2007

Please circle one answer for each question.

1. Do you understand the study?

Strongly agree Agree Disagree Strongly disagree

2. Do you understand that most of the patients will be enrolled in the study initially without their consent?

Strongly agree Agree Disagree Strongly disagree

3. Do you understand that patients will be randomly assigned to receive erythropoietin or placebo?

Strongly agree Agree Disagree Strongly disagree

4. Do you understand that all patients will receive standard care for head injury, regardless of whether or not they receive erythropoietin?

Strongly agree Agree Disagree Strongly disagree

5. Are you willing for this study to be done in your community?

Strongly agree Agree Disagree Strongly disagree

6. Would you be willing to participate in the study if you were to have a head injury?

Strongly agree Agree Disagree Strongly disagree

Surveys Returned for MADD Meeting, pg. 3:

Community Consultation Survey for
Erythropoietin Clinical Trial

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Surveys Returned for MADD Meeting, pg. 4:

Community Consultation Survey for
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Date of Meeting: 12 March 2007

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Summary for Gateway to Care Meeting, pg. 1:

Dr. Robertson presented the proposal to use the emergency consent exception for enrolling patients in the Epo study during a meeting of the organization Gateway to Care, which is a 501(c)(3) collaborative comprised of 167 public and private safety net health systems, coalitions, advocacy groups and social service providers working together to assist the approximately 2.2 million medically indigent residents in the Greater Houston Area in receiving medical care at the most appropriate setting. Approximately 60 members were present and listened to the presentation. A number of questions were asked following the presentation, and about half of the participants filled out the survey at the end of the presentation.

Questions that were asked included:

“Most people don’t know a lot about research protocols. Are there people available to explain how the study works and answer any questions?”

Dr. Robertson answered that one of our jobs when talking with people about the research protocol is to explain the protocol and answer any questions that they might have.

“And what about people who don’t speak English? There’s a large Asian community here. Are there translators for languages besides Spanish?”

Dr. Robertson answered that our research personnel are bilingual, and for languages other than Spanish that translators are usually available at Ben Taub.

“Can you tell me again, What are the possible side effects?”

Dr. Robertson answered that the two possible side effects are hypertension and an increased risk of blood clots, such as deep vein thrombosis or pulmonary embolus. These are problems that patients with brain injuries can have, and the Epo could potentially increase the risk of having these problems.

“You said only half of the patients who qualify actually get enrolled. If you don’t change the consent, is the problem that it would take a longer amount of time to do the study? What is the urgency of getting this study done faster?”

Dr. Robertson answered that enrolling more patients in the study is only part of the issue. The patients that we are able to enroll in the study are currently getting the drug near the end of the 6 hour time window when the drug is less likely to be effective. The only way that we will be able to give the drug early, when the drug is most likely to be effective, is with the emergency consent exception.

“Are stroke patients considered to have a brain injury? Does it help stroke patients, too?”

Dr. Robertson answered that this study only includes patients with brain injury due to trauma, but experimental studies do suggest that stroke patients may also benefit from the drug. There is currently ongoing a multi-center trial of Epo in stroke patients.

“The FDA has a policy for allowing studies to be conducted like this?”

Summary for Gateway to Care Meeting, pg. 2:

Dr. Robertson said that federal law does allow this type of consent procedure in the very special circumstance of emergency research where the treatment must be given very rapidly after injury.

“What I’m thinking about is the people in Iraq and all the head trauma – you could get this drug out a lot quicker this way couldn’t you?”

Dr. Robertson answered that yes this might be a drug that could help the soldiers injured in Iraq if our study is successful.

Handout for Gateway to Care Meeting, pg. 1:



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Exception from Informed Consent for Erythropoietin Study

The Neurosurgery Department at Baylor College of Medicine and Ben Taub General Hospital is conducting a clinical trial of a drug called Erythropoietin (or Epo) in patients who have suffered a severe brain injury from trauma. We would like to tell you about this study, and ask your opinion about it.

The drug that we are studying, Epo, is an FDA-approved drug that is given to patients to treat a low blood count. We are trying to see if Epo may also improve recovery of brain function after a severe injury. Patients who are enrolled in this study will all receive standard treatment for their head injury. In addition to standard treatment, half of the patients will receive Epo and half will receive placebo. All of the patients will be followed for 6 months after their injury to see how well they recover. The potential benefits of participating in the study are: Epo may improve the blood count and reduce the number of blood transfusions that are needed. Epo may reduce damage to the brain. The potential risks of Epo are that it may cause or worsen high blood pressure, and that it may cause blood clots.

Normally for a research study like this, we would ask the patient or the patient's family if they would like to participate in the study and have them sign a consent form explaining all of potential benefits and risks of the study and explaining their rights as a research subject. However, for this study the drug must be given very soon after the brain injury to help. The patients will not be able to give consent because of their brain injury. Many patients do have not family members available at the hospital rapidly enough to give the usual informed consent for the study. When this is the case, federal law allows investigators to apply for an exception to the usual informed consent. In the place of initial written informed consent, the investigators must notify the community that the study will be taking place without consent, and ask the community for feedback about whether they think that the study should take place without the usual informed consent for all patients.

We will try to find relatives of patients for up to 3 hours after injury. If we find a relative, we will only enroll the patient if the relative agrees and signs a consent form. If no relatives are found within 3 hours after injury, we will enroll the patient in the study. Then when relatives are located or if the patient recovers, we will tell them about the study and let them decide if they wish to continue to participate or withdraw from the study. As with any research study, patients can withdraw from the study any time that they wish.

Handout for Gateway to Care Meeting, pg. 2:



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**Community Consultation Survey for
Erythropoietin Clinical Trial**

Date of Meeting: March 20, 2007

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Strongly agree Agree Disagree Strongly disagree

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- [Vision and Mission](#)
- [What Is A Navigator](#)
- [AmeriCorps](#)
- [Ask Your Nurse](#)
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- [Provider Health Network](#)



Opening Doors to Healthcare

Gateway to Care is a 501(c)(3) collaborative comprised of 167 public and private safety net health systems, coalitions, advocacy groups and social service providers working together to assist the approximately 2.2 million medically indigent residents in the Greater Houston Area in receiving medical care at the most appropriate setting. Since 2000, the *Collaborative* has been focused on the provision of primary care. Now its major initiatives include the *Provider Health Network, Medical Reserve Corps, Federally Qualified Health Centers, Clinic Management Software System* as well as many other important programs. If your organization would like to become a part of the *Gateway to Care Collaborative*, please contact us at 713.783.4616.



Navigation Services
connects residents of Harris County to appropriate resources and to help establish a health home. Navigators are located at various sites within the Harris County region.

Provider Health Network (PHN)

The Provider Health Network is a network of over 100 physicians and ancillary providers who have decided to dedicate a portion of their practices to work pro-bono caring for the uninsured. Patients who qualify will have access to free lab, diagnostic, transportation and limited pharmaceutical services. The PHN staff also will help in coordinating the care for these services, thus relieving much of the burden on physicians' offices.

For more information or to participate in the program, contact Tan Kaleemullah, PHN Manager at 713.783.4616 or tKaleemullah@gatewaytocare.org.

Please read the letters of endorsement from one of

NAVIGATOR ASSOCIATE TRAINING

Gateway to Care Training Institution has developed a 32-hour curriculum that will help people learn the ins and outs of healthcare programs and systems and expand their knowledge of resources. The training is offered to organizations, agencies or church communities that can recruit at least 12 volunteers to participate in the training and provide a space. There is *no charge* for the training.

Information About Gateway to Care Organization, pg. 2:

If you would like to participate in Navigation Associate Training, please call 713.783.4616 and ask for the Training Coordinator. To read about our Community Health Worker Certification, download our BROCHURE.

Clinic Management Software Sys



For information regarding this web page, please email: sbaker@gatewaytocare.org

our major participants--The Indian Doctors Association (IDA).

[Link to Formulary](#)

[Link to PLEDGE CARD](#)

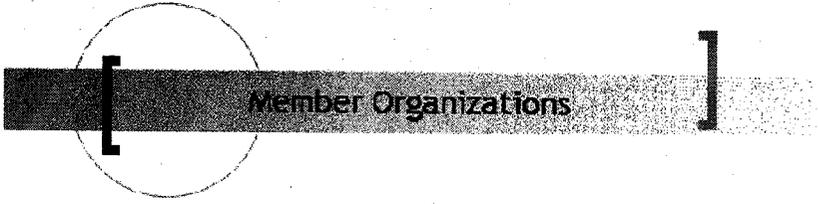
"Ask Your Nurse" is a 24-hour telephone triage service (713.633.CALL). "Ask Your Nurse" is a free service to residents of Harris County to answer urgent healthcare questions. It gives the patient a quick, easy and free way to decide if they should go to an emergency center.

If you are inquiring about the *Facilitation Fund*, please contact Ron Cookston, Executive Director at 713.783.4616 (Ext. 223).

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For problems or questions regarding this web contact [Gateway to Care](#).
Last updated: 03/05/07.

Information About Gateway to Care Organization, pg. 3:

Member Organizations	Page 1 of 3
<ul style="list-style-type: none">HomeCHC DevelopmentIn The NewsMy Medicare MattersVision and MissionWhat Is A NavigatorAmeriCorpsAsk Your NurseCollaborative MembersMember OrganizationsCaregiverHospitalsClinicsYour StoryProvider Health Network	
	<p>AIDS Foundation Houston, Inc. Alief Multicultural Collaborative Task Force Alliance for Multicultural Community Services Alvin Community Health Endeavor American Red Cross Greater Houston Chapter Asian American Health Coalition - HOPE Clinic Association for the Advancement of Mexican Americans, Inc. (AAMA) AVANCE Head Start Baylor College of Medicine/Transitional Clinic Baylor Dept. of Family and Community Medicine Bering Omega Community Services Better Business Bureau Education Foundation Blue Cross Blue Shield Boat People SOS Bonita Street "House of Hope" Bread of Life, Inc. Catholic Charities of the Diocese of Galveston-Houston Center for Health Disparities Center for Research on Minority Health - UT MD Anderson Cancer Center ChildBuilders, Inc. Children at Risk Christ Clinic Christ the Good Shepherd Catholic Community Christus Medical Group-Southwest Community Health Center City of Houston City of Houston Department of Health & Human Services Clear Lake Emergency Medical Corps Coalition for the Homeless of Houston/Harris County, Inc. Coalition of Behavioral Health Services Communities in Schools Community Doula Program Community Education & Preventative Health Community Health Choice - Harris County Hospital District Cullen Pediatric & Adolescent Health Center de Madres a Madres DeBlin Health Concepts & Associates, Inc. Dental Health Task Force of the Greater Houston Metropolitan Area Donald R. Watkins Memorial Foundation Early Childhood Intervention (ECI) of MHMRA East End Healthy Children Collaborative ECHOS - Epiphany Community Health Outreach Services El Centro de Corazon Families Under Urban and Social Attack</p>
http://www.gatewaytocare.org/member_organizations.htm	3/21/2007

Information About Gateway to Care Organization, pg. 4:

Member Organizations

Page 2 of 3

[Good Neighbor Health Care Center](#)
[Gulf Coast CHIP Coalition](#)
[Gulf Coast Community Services Association](#)
[Harris County](#)
[Harris County Area Agency on Aging](#)
[Harris County Breastfeeding Coalition](#)
[Harris County Health Department](#)
[Harris County Hospital District](#)
[Harris County Social Services](#)
[Health Access Texas](#)
[Healthcare for the Homeless-Houston, Inc.](#)
[Healthy Houston Foundation](#)
[HIV Services Section, PHES](#)
[Hope Through Grace](#)
[Houston Center for Independent Living](#)
[Houston Community Health Centers, Inc. \(aka Denver Harbor Community Health Center\)](#)
[Immunization Coalition of Greater Houston](#)
[Ibn Sina Foundation](#)
[IntraCare Hospital](#)
[Laboratory Corporation of America](#)
[Legacy Community Health Center \(formerly Montrose Clinic\)](#)
[Living Bank](#)
[Lone Star Family Health Center](#)
[Medical Insights & Care Unlimited](#)
[Memorial Hermann](#)
[MHMRA of Harris County](#)
[Mental Health Association of Greater Houston](#)
[Montrose Counseling Center](#)
[Motherland, Inc.](#)
[NAMI - Metropolitan Houston](#)
[Neighborhood Centers, Inc.](#)
[Northeast Community Health Clinic](#)
[Northside Redevelopment Center](#)
[Northwest Assistance Ministries Children's Clinic](#)
[Pasadena Community Health Center](#)
[Patient Always First](#)
[Planned Parenthood of Houston and Southeast Texas, Inc.](#)
[ProSalud \(Promotoras de Salud\) GANO](#)
[Ryan White Planning Council](#)
[San Jose Clinic](#)
[Save Our ERs](#)
[SBA Health Ministry/Spring Branch Seventh-day Adventist Church](#)
[Shalom Mobile Health Ministry](#)
[Shifa Clinic](#)
[South Central Houston Community Health Center](#)
[Southwest Area Ministries](#)
[Spring Branch Community Health Center](#)
[Spring Branch Family Development Center](#)
[St. Hope Foundation, Inc.](#)
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[Texas Health Care Purchasing Alliance, Inc.](#)
[The Community Clinic](#)
[The Rose/Communities Conquering Cancer](#)

http://www.gatewaytocare.org/member_organizations.htm

3/21/2007

Information About Gateway to Care Organization, pg. 5:

Member Organizations

Page 3 of 3

TheirBirthRight (the Village)

TIRR Systems

TOMAGWA Medical Ministries

Trade Mark Insurance Agency

Transcom CDC

United Way of the Texas Gulf Coast

University of Houston College of Optometry

University of Houston Graduate School of Social Work

University of Texas School of Health Information Sciences - Houston

Urban Center for Health & Wellness

Women's Resource Center for Women & their Families

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Last updated: 03/05/07.

Surveys Returned for Gateway to Care Meeting, pg. 1:



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**Community Consultation Survey for
Erythropoietin Clinical Trial**

Date of Meeting: March 28, 2007

Please circle one answer for each question.

1. Do you understand the study?

Strongly agree Agree Disagree Strongly disagree

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Surveys Returned for Gateway to Care Meeting, pg. 2:



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Surveys Returned for Getway to Care Meeting, pg. 4:



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6. Would you be willing to participate in the study if you were to have a head injury?

Strongly agree Agree Disagree Strongly disagree

Surveys Returned for Gateway to Care Meeting, pg. 5:



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**Community Consultation Survey for
Erythropoietin Clinical Trial**

Date of Meeting: March 20, 2007

Please circle one answer for each question.

1. Do you understand the study?

Strongly agree Agree Disagree Strongly disagree

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Strongly agree Agree Disagree Strongly disagree

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Strongly agree Agree Disagree Strongly disagree

Surveys Returned for Gateway to Care Meeting, pg. 6:



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**Community Consultation Survey for
Erythropoietin Clinical Trial**

Date of Meeting: March 20, 2007

Please circle one answer for each question.

1. Do you understand the study?

Strongly agree

Agree

Disagree

Strongly disagree

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Strongly disagree

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Disagree

Strongly disagree

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Strongly agree

Agree

Disagree

Strongly disagree

Surveys Returned for Gateway to Care Meeting, pg. 7:



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**Community Consultation Survey for
Erythropoietin Clinical Trial**

Date of Meeting: March 20, 2007

Please circle one answer for each question.

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Surveys Returned for Gateway to Care Meeting, pg. 8:



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**Community Consultation Survey for
Erythropoietin Clinical Trial**

Date of Meeting: March 20, 2007

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Surveys Returned for Gateway to Care Meeting, pg. 9:



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**Community Consultation Survey for
Erythropoietin Clinical Trial**

Date of Meeting: March 20, 2007

Please circle one answer for each question.

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Strongly agree Agree Disagree Strongly disagree

Surveys Returned for Gateway to Care Meeting, pg. 10:



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**Community Consultation Survey for
Erythropoietin Clinical Trial**

Date of Meeting: March 20, 2007

Please circle one answer for each question.

1. Do you understand the study?

Strongly agree Agree Disagree Strongly disagree

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Surveys Returned for Gateway to Care Meeting, pg. 11:



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**Community Consultation Survey for
Erythropoietin Clinical Trial**

Date of Meeting: March 20, 2007

Please circle one answer for each question.

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Surveys Returned for Gateway to Care Meeting, pg. 12:



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**Community Consultation Survey for
Erythropoietin Clinical Trial**

Date of Meeting: March 26, 2007

Please circle one answer for each question.

1. Do you understand the study?

Strongly agree Agree Disagree Strongly disagree

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Surveys Returned for Gateway to Care Meeting, pg. 12:



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**Community Consultation Survey for
Erythropoietin Clinical Trial**

Date of Meeting: March 20, 2007

Please circle one answer for each question.

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Surveys Returned for Gateway to Care Meeting, pg. 13:



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**Community Consultation Survey for
Erythropoietin Clinical Trial**

Date of Meeting: March 20, 2007

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5. Are you willing for this study to be done in your community? *→ You need to have widespread media coverage of this study to inform the community*

Strongly agree Agree Disagree Strongly disagree

6. Would you be willing to participate in the study if you were to have a head injury? *inform the community*

Strongly agree Agree Disagree Strongly disagree

Surveys Returned for Gateway to Care Meeting, pg. 14:



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**Community Consultation Survey for
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Date of Meeting: March 20, 2007

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Surveys Returned for Gateway to Care Meeting, pg. 15:



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**Community Consultation Survey for
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Date of Meeting: March 20, 2007

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