

Surveys Returned for 4/17/07 PIP Meeting at 10101 Fondren, pg. 5



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**Community Consultation Survey for
Erythropoietin Clinical Trial**

Date of Meeting: 4/17/07
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 4/17/07 PIP Meeting at 10101 Fondren, pg. 6



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**Community Consultation Survey for
Erythropoietin Clinical Trial**

Date of Meeting: 4/17/07

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 4/17/07 PIP Meeting at 10101 Fondren, pg. 7



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Community Consultation Survey for
Erythropoietin Clinical Trial

Date of Meeting: 04/17/07
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

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

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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 4/17/07 PIP Meeting at 10101 Fondren, pg. 8



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**Community Consultation Survey for
Erythropoietin Clinical Trial**

Date of Meeting: 4-17-07
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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Surveys Returned for 4/17/07 PIP Meeting at 10101 Fondren, pg. 9



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**Community Consultation Survey for
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Date of Meeting: 4/17/07

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 4/17/07 PIP Meeting at 10101 Fondren, pg. 10



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**Community Consultation Survey for
Erythropoietin Clinical Trial**

Date of Meeting: 4/17/07
Please circle one answer for each question.

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Strongly agree Agree Disagree Strongly disagree

Surveys Returned for 4/17/07 PIP Meeting at 10101 Fondren, pg. 11



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**Community Consultation Survey for
Erythropoietin Clinical Trial**

Date of Meeting: 4/17/07
Please circle one answer for each question.

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Surveys Returned for 4/17/07 PIP Meeting at 10101 Fondren, pg. 12



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**Community Consultation Survey for
Erythropoietin Clinical Trial**

Date of Meeting: 4-17-07
Please circle one answer for each question.

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Strongly agree Agree Disagree Strongly disagree

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Strongly agree Agree Disagree Strongly disagree

Surveys Returned for 4/17/07 PIP Meeting at 10101 Fondren, pg. 13



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**Community Consultation Survey for
Erythropoietin Clinical Trial**

Date of Meeting: 4-17-07

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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**Community Consultation Survey for
Erythropoietin Clinical Trial**

Date of Meeting: 17 April, 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

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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 4/17/07 PIP Meeting at 10101 Fondren, pg. 15



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**Community Consultation Survey for
Erythropoietin Clinical Trial**

Date of Meeting: 4/17/07

Please circle one answer for each question.

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Strongly agree Agree Disagree Strongly disagree

Surveys Returned for 4/17/07 PIP Meeting at 10101 Fondren, pg. 16



**BEN TAUB
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1534 Taub Loop
Houston, Texas 77030
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**Community Consultation Survey for
Erythropoietin Clinical Trial**

Date of Meeting: 4/17/07

Please circle one answer for each question.

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Strongly agree Agree Disagree Strongly disagree



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**Community Consultation Survey for
Erythropoietin Clinical Trial**

Date of Meeting: 4-17-07

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Strongly agree Agree Disagree Strongly disagree

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Strongly agree Agree Disagree Strongly disagree

Surveys Returned for 4/17/07 PIP Meeting at 10101 Fondren, pg. 18



**BEN TAUB
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**Community Consultation Survey for
Erythropoietin Clinical Trial**

Date of Meeting: 4-17-07
Please circle one answer for each question.

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Strongly agree Agree Disagree Strongly disagree

Surveys Returned for 4/17/07 PIP Meeting at 10101 Fondren, pg. 19



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Community Consultation Survey for
Erythropoietin Clinical Trial

Date of Meeting: 4/17/07

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 4/17/07 PIP Meeting at 10101 Fondren, pg. 20



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**Community Consultation Survey for
Erythropoietin Clinical Trial**

Date of Meeting: 4/17/07
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 4/17/07 PIP Meeting at 10101 Fondren, pg. 21



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**Community Consultation Survey for
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Date of Meeting: 4-17-07
Please circle one answer for each question.

1. Do you understand the study?

Strongly agree Agree Disagree Strongly disagree

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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 4/17/07 PIP Meeting at 10101 Fondren, pg. 22



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**Community Consultation Survey for
Erythropoietin Clinical Trial**

Date of Meeting: 4/17/07
Please circle one answer for each question.

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Strongly agree Agree Disagree Strongly disagree

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Surveys Returned for 4/17/07 PIP Meeting at 10101 Fondren, pg. 23



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**Community Consultation Survey for
Erythropoietin Clinical Trial**

Date of Meeting: 4-17-07

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**Community Consultation Survey for
Erythropoietin Clinical Trial**

Date of Meeting: 4-17-07

Please circle one answer for each question.

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Strongly agree Agree Disagree Strongly disagree

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**Community Consultation Survey for
Erythropoietin Clinical Trial**

Date of Meeting: 5-17-07

Please circle one answer for each question.

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Surveys Returned for 4/17/07 PIP Meeting at 10101 Fondren, pg. 26



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**Community Consultation Survey for
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Date of Meeting: 4/17/06
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Summary of PIP Meeting at Southwest Multi-service Center on 4/24/07

Approximately 50 community members were present for a regular meeting of PIP. Athena Baldwin provided handouts with a written description of the study, gave a short 5 minute description of the study, and briefly answered several questions. At the end of the meeting 35 of the participants returned the survey.

The questions that were asked and/or comments that were made included the following:

“Is this drug FDA approved?”

Dr. Baldwin answered that Epo is FDA approved to treat chronic anemia associated with cancer, HIV, and chronic renal failure

“Doctors give drugs all the time without permission. If this is FDA-approved, why do you need permission for this?”

Dr. Baldwin answered that although a physician can prescribe Epo for an off label indication like traumatic brain injury, they would not be likely to do so unless there is a study like this demonstrates that it improves outcome.

“Can it help drowning victims?”

Dr. Baldwin answered that it might also protect the brain after drowning, but it has not been studied.

“Can it be used on children?”

Dr. Baldwin answered that Epo can be given to children, but children under the age of 15 are not included in this study.

“So once this study is done, will you have to give placebo anymore?”

Dr. Baldwin answered that once the study is complete, if the study showed that Epo improved neurological outcome, then Epo could be given too all patients.

“Can the family request to not get the placebo?”

Dr. Baldwin answered that it would not be possible to request that a patient not be given the placebo. If they participate in the study, then there would be a 50:50 chance of receiving the placebo.

“So are you making a list of people who would want to be in the study?”

Dr. Baldwin answered that we are asking people for their opinions about enrolling patients in this study, in particular whether they would be willing to have this done in their community.

“I'm gonna put a tatoo on my arm that says "Yes, I want Epo!"”

“Well, all that extra attention you get being in a study is definitely worth mentioning - even if you only get placebo!”



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I but I would hate to get a placebo.



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Date of Meeting: 04-24-07
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Surveys Returned for 4/24/07 PIP Meeting at Southwest Multi-service Center, pg. 5
(date is incorrect on form)



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**Community Consultation Survey for
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Date of Meeting: 4/14/07
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Surveys Returned for 4/24/07 PIP Meeting at Southwest Multi-service Center, pg. 7
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**Community Consultation Survey for
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Date of Meeting: Tues Apr 24, 2007
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↳ want Epo definitively

Surveys Returned for 4/24/07 PIP Meeting at Southwest Multi-service Center, pg. 10
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**Community Consultation Survey for
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Date of Meeting: April 25, 2007
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Surveys Returned for 4/24/07 PIP Meeting at Southwest Multi-service Center, pg. 15



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Summary of Community Meeting at Southwest Multi-service Center, 4/24/07

Approximately 20 people participated in this meeting. Dr. Robertson and Dr. Rene Celis gave the presentations in English and Spanish. Dr. Mariscalco attended as an IRB representative. Most of the participants were invited from people attending the WIC clinic at the center. Most of the participants were Hispanic and Spanish-speaking. After the presentations, 13 filled out surveys and returned them.

Some of the questions that were asked included the following:

“Is the Epo given to the patient or to the family?”

Dr. Celis explained that the study drug would be given to the injured patient.

“Would the drug be helpful to someone who has had a head injury months or years ago, and who still has neurological problems?”

Dr. Celis answered that it is not likely that Epo would reverse longstanding neurological deficits.

“Explain question #3”

Dr. Celis answered that all of the patients participating in the study would still receive the same usual treatment of the head injury, which they would receive even if they did not participate in the study. In addition to this usual treatment, half of the patients would receive the active drug and half would receive the placebo or inactive drug. Question #3 asks if you understand and agree that all patients in the study would receive the usual treatment of head injury, as well as the study drug.

Handout (English version) for Community Meeting at Southwest Multi-service Center on 4/24/07



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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 (Spanish version) for Community Meeting at Southwest Multi-service Center on 4/24/07



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Excepción para el Consentimiento Informado del Estudio de la Eritropoyetina

El Departamento de Neurocirugía de Baylor College of Medicine en el Hospital Ben Taub, esta conduciendo una prueba clínica de una droga llamada Eritropoyetina (Epo) en pacientes que han sufrido una lesión traumática cerebral. Nos gustaría platicarles acerca de este estudio, I preguntarle su opinión acerca de el.

La droga que estamos estudiando, Epo, es una droga aprobada por la FDA y es administrada a los pacientes para tratar un conteo sanguíneo bajo. Estamos tratando de ver si Epo pudiera mejorar la recuperación de las lesiones cerebrales después de una lesión severa. Los pacientes que serán enrolados en este estudio recibirán el tratamiento estándar para su lesión de cabeza. En adición al tratamiento estándar, la mitad de los pacientes recibirán Epo y la otra mitad recibirán placebo. Todos los pacientes serán seguidos por un periodo de 6 meses después de su lesión para ver que tan bien fue su recuperación. Los beneficios potenciales de participar en el estudio son: Epo pudiera mejorar el conteo sanguíneo y reducir el numero de transfusiones sanguíneas que pudieran ser necesitadas. Epo pudiera reducir el daño cerebral. Los riesgos potenciales de Epo son, pudiera causar o agravar una alza de la presión sanguínea, y que pudiera producir coágulos sanguíneos.

Normalmente para una investigación como esta, nos gustaría preguntar al paciente o a la familia del paciente si les gustaría participar en el estudio y obtener una firma de consentimiento el cual explica todos los beneficios potenciales y riesgos del estudio y donde explica los derechos como sujeto de investigación. Sin embargo, para este estudio la droga debe de ser administrada tan pronto posible después de la lesión cerebral. Muchos pacientes no tienen familiares disponibles en el hospital lo suficientemente rápido para proveernos con consentimiento informado para el estudio. Cuando este es el caso, la ley federal permite a los investigadores aplicar la excepción al usual consentimiento informado. En lugar de un consentimiento informado escrito, los investigadores deben de notificar a la comunidad que el estudio tendrá lugar sin consentimiento, y preguntar a la comunidad acerca si ellos piensan que el estudio debe de tomar lugar sin el consentimiento informado usual para todos los pacientes.

Nosotros trataremos de encontrar parientes del pacientes hasta por 3 horas después de la lesión. Si encontramos algún familiar nosotros solamente enrolaremos al paciente si el pariente acepta y firma el consentimiento informado. Si ningún familiar es encontrado en 3 horas después de la lesión, nosotros enrolaremos al paciente en el estudio. después cuando los familiares sean encontrados o si el paciente se recupera, le diremos acerca de el estudio y les dejaremos decidir si desean continuar participando en el estudio o si quisieran retirarse del estudio. Como en cualquier estudio de investigación, los pacientes pueden retirarse de el estudio en cualquier momento que ellos deseen.



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**Encuesta de Comunidad para la Prueba
Clinica de Eritropoyetina**

Fecha de Reunion 4-24-07
Porfavor elija circule una respuesta para cada pregunta.

1. Usted entendio el estudio?

Fuertemente en favor A favor En contra Fuertemente en contra

2. Usted entendi que la mayoría de los paccintes seran enrolados en el estudio en un principio sin ningun consentimiento?

Fuertemente en favor A favor En contra Fuertemente en contra

3. Usted entiende que los pacientes seran asignados aleatoriamente ha recibir eritropoyetina o placebo?

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4. Usted entiende que todos los pacientes recibiran los cuidados estandares para la lesion de cabeza, independientemente si recibieron la eritropoyetina?

Fuertemente en favor A favor En contra Fuertemente en contra

5. Usted desea que este estudio sea realizado en su comunidad?

Fuertemente en favor A favor En contra Fuertemente en contra

6. Usted estaria dispuesto en participar en el estudio si usted tuviera una lesion de cabeza?

Fuertemente en favor A favor En contra Fuertemente en contra

Surveys Returned for 4/24/07 Community Meeting at Southwest Multi-service Center, pg. 2



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**Encuesta de Comunidad para la Prueba
Clinica de Eritropoyetina**

Fecha de Reunion 4-24-07

Por favor elija circule una respuesta para cada pregunta.

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Surveys Returned for 4/24/07 Community Meeting at Southwest Multi-service Center, pg. 3



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**Encuesta de Comunidad para la Prueba
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Fecha de Reunion 4/24/07

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Surveys Returned for 4/24/07 Community Meeting at Southwest Multi-service Center, pg. 4



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**Encuesta de Comunidad para la Prueba
Clinica de Eritropoyetina**

Fecha de Reunion 4/24/07

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**Encuesta de Comunidad para la Prueba
Clinica de Eritropoyetina**

Fecha de Reunion 4/24/07

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**Encuesta de Comunidad para la Prueba
Clinica de Eritropoyetina**

Fecha de Reunion 4/24/07

Porfavor eliga circule una respuesta para cada pregunta.

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**Encuesta de Comunidad para la Prueba
Clinica de Eritropoyetina**

Fecha de Reunion 04-24-07

Porfavor elija circule una respuesta para cada pregunta.

1. Usted entendio el estudio?

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Fuertemente en favor A favor En contra Fuertemente en contra

Surveys Returned for 4/24/07 Community Meeting at Southwest Multi-service Center, pg. 8



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**Encuesta de Comunidad para la Prueba
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Fecha de Reunion 04-24-07

Porfavor eliga circule una respuesta para cada pregunta.

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Surveys Returned for 4/24/07 Community Meeting at Southwest Multi-service Center, pg. 9



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**Encuesta de Comunidad para la Prueba
Clinica de Eritropoyetina**

Fecha de Reunion 4/24/07

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Fuertemente en favor A favor En contra Fuertemente en contra

9



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**Encuesta de Comunidad para la Prueba
Clinica de Eritropoyetina**

Fecha de Reunion 04-24-07

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Fuertemente en favor A favor En contra Fuertemente en contra

Surveys Returned for 4/24/07 Community Meeting at Southwest Multi-service Center, pg. 11



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**Community Consultation Survey for
Erythropoietin Clinical Trial**

Date of Meeting: 4/24/07

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 4/24/07 Community Meeting at Southwest Multi-service Center, pg. 12



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**Community Consultation Survey for
Erythropoietin Clinical Trial**

Date of Meeting: 4/24/07

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 4/24/07 Community Meeting at Southwest Multi-service Center, pg. 13



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**Community Consultation Survey for
Erythropoietin Clinical Trial**

Date of Meeting: 4/24/07
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Strongly agree Agree Disagree Strongly disagree

13

Summary for 4/26/07 PIP meeting at 10101 Fondren

Approximately 25 community members were present for a regular meeting of PIP. Athena Baldwin provided handouts with a written description of the study, gave a short 5 minute description of the study, and briefly answered several questions. At the end of the meeting 15 of the participants returned the survey.

The questions that were asked included the following:

"I have a question. My son was 4 months old and, well, we don't know what happened, but the babysitter said he stopped breathing. The ambulance revived him after CPR, but they don't know how long he was without air. After he got to the hospital, they said he was brain dead. They kept him on life support for a week, but we had to let him go. I was just wondering if you think this drug might have helped him, you know, if they had it on the ambulance, to maybe help get more oxygen to his brain?"

Dr. Baldwin answered that Epo is being studied in another clinical trial for use in anoxic injury, such as you describe. It may be useful for that type of brain injury.

"Do you think it would be good to keep a prescription around the house?"

Dr. Baldwin answered that Epo is not yet approved for this purpose.

Surveys Returned for 4/26/07 PIP meeting at 10101 Fondren, pg. 1



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**Community Consultation Survey for
Erythropoietin Clinical Trial**

Date of Meeting: 4-26-07
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Surveys Returned for 4/26/07 PIP meeting at 10101 Fondren, pg. 2



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**Community Consultation Survey for
Erythropoietin Clinical Trial**

Date of Meeting: April 26, 2007
Please circle one answer for each question.

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2



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**Community Consultation Survey for
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Date of Meeting: 04/26/2007
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Surveys Returned for 4/26/07 PIP meeting at 10101 Fondren, pg. 4



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Rosie Alonzo

**Community Consultation Survey for
Erythropoietin Clinical Trial**

Date of Meeting: 04-26-07
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Surveys Returned for 4/26/07 PIP meeting at 10101 Fondren, pg. 6



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Erythropoietin Clinical Trial**

Date of Meeting: 4-26-2007

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*I think I would like to have
the real thing.*



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I do not feel that anybody has the right to vote as a whole to force a study on someone else. 9



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**Community Consultation Survey for
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Date of Meeting: April 26, 07

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Surveys Returned for 4/26/07 PIP meeting at 10101 Fondren, pg. 11



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15
IF this medication will save ~~one~~ a life
It sounds great.

Summary of 4/27/07 Kashmere Community Meeting

Attending the meeting were Dr. Robertson, Dr. Gopinath, Athena Baldwin PA, and Sharon Barnes, Sr AA. Two groups were invited to participate in the discussions, the senior citizens at the center for the daily activities and people attending at a prenatal clinic at the center.

In addition, one participant at the meeting came because of our ad that was placed in the newspaper. She is a member of the Texas Traumatic Brain Injury Advisory Council, which is a group that gives advice to the state legislature. She has a son that suffered a head injury 16 years ago, and was treated at Ben Taub. Her son is currently enrolled in a study at UTMB, examining the effects of growth hormone replacement after TBI. She was initially very concerned about the prospect of enrolling patients in a research study without individual consent, and had many questions about the legality of this procedure, and about the risks/benefits of the study drug. Dr. Robertson and Dr. Gopinath answered all of her questions about the study, and she will take this information back to the other members of the TBI Advisory Council.

The senior citizen group had mixed interest in the project, but several people were interested and asked some insightful questions, including:

“Instead of using the waiver, is there some way that people who want to participate in the study could be enrolled before they have an injury?”

Dr. Robertson answered that for disorders where it can be predicted who is likely to develop the disorder it is possible to pre-consent for research studies. However, anyone in the city of Houston can be the victim of a head injury, and it is not really practical to pre-consent for this study. One additional method that some emergency studies have utilized to allow people to opt out of enrollment is to make available an alert bracelet that can be worn. This is something that could be done for this study if there was enough interest to do so.

“Why can't everyone in the study get the drug?”

Dr. Robertson answered that it is not likely that any drug is going to make every patient with a severe head injury wake up normal. It is more likely that Epo may improve the degree of recovery for patients. In order to determine if the drug is really effective at improving outcome, we have to compare the group of patients who receive the drug to another group of patients who do not receive the drug.

“How long have you been doing this trial, and have you had good success with the drug so far?”

Dr. Robertson answered that we have been enrolling patients into the trial for about one year. We are blinded to the treatment that has been given to each patient so that we will not know until the trial is over which patients received the active drug. This is done so that we won't bias the results of the trial through the other treatments that we might give patients.

Surveys Returned for 4/27/07 Kashmere Community Meeting, pg. 1

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Community Consultation Survey for
Erythropoietin Clinical Trial

Date of Meeting: April 27, 07
Please circle one answer for each question.

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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?

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**Community Consultation Survey for
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Date of Meeting: 4/29/07
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4-27-07

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3



**BEN TALIB
GENERAL
HOSPITAL**

email: tbi@bcm.edu

BCM Baylor
College
of Medicine

**Community Consultation Survey for
Erythropoietin Clinical Trial**

Date of Meeting: 4/27/07

Please circle one answer for each question.

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Surveys Returned for 4/27/07 Kashmere Community Meeting, pg. 5



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Date of Meeting: 4-27-07

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**Community Consultation Survey for
Erythropoietin Clinical Trial**

Date of Meeting: April 27, 11-12, Kashmere Multi service Center
Please circle one answer for each question.

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? many
I don't know the anticipated percentage.
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