BAYLOR
Research Institute
Affiliated with Baylor Health Care System

3310 Live Oak
Suite 501
Dallas, Texas 75204
(214) 820-2687
(214) 820-4952 Fax
BaylorHealth.com

APPROVAL - Continued Periodic Review

August 7, 2009

Claude Allen Stringer, M.D.
Oncology
Cvetko Patient Education Center
3500 Gaston Avenue
Dallas, TX 75246

Re: Prevalence and Characteristics of Perinatal Depression in Women Hospitalized with High-Risk Pregnancy
Project#: 005-123 Protocol#: N/A Protocol Dt: 09/11/2006

The following items received expedited review:

- Continuation Report - IRB004 (08/03/2009)
- Education Report (08/03/2009)
- IRB Form 1b (01/28/2005)
- Protocol History (08/03/2009)
- Abstract (J. Clin. Psychology 69:4, April 2008)
- Subjects Enrolled - Current Year - 21 (08/03/2009)
- Subjects Enrolled - To Date - 142 (08/03/2009)

Expedited Approval was granted 08/07/2009 for a period not to exceed 12 months and will expire on 08/06/2010. Your Continuing Review is scheduled for 07/13/2010. This Expedited review will be reported to the fully convened Institutional Review Board ~ Red on 09/08/2009.

On behalf of the Institutional Review Board, I have reviewed the above referenced research project in accordance with 45 CFR 46 & 164 and 21 CFR 50 & 56. This review was conducted in accordance with the expedited review process as outlined in 45 CFR 46.110(b). Based on the information presented, I have determined that the study meets the criteria specified below. NOTE: The list of categories is from the November 9, 1998 Federal Register.

45 CFR 46.110(b)(1)(8)(c):
(1) some or all of the research appearing on the category list and found by the reviewer(s) to involve no more than minimal risk:
(8) Continuing review of research previously approved by the convened IRB as follows:

(c) where the remaining research activities are limited to data analysis.

Based on this review, the above referenced items are approved for implementation.

The Board reminds you that Baylor Policy requires that that unless waived, fully documented informed consent must be obtained in accordance with 45 CFR 46.116 and 21 CFR50.20 from all human subjects involved in this research study. Informed consent must be obtained by the principal investigator or other key personnel as listed in this submission. Documentation of informed consent must be kept on file for a period of three years past completion or discontinuation of the study and will no doubt be subject to inspection in the future.

In addition, 45 CFR 164 requires that, unless waived by the IRB, authorization must be obtained for use and disclosure of Protected Health Information. If this project is currently open to new enrollment, the approved version of the consent form(s) is listed above. The document(s) reviewed in this submission has been determined to satisfy the requirements as outlined in 45 CFR 164.508.

DHHS and FDA regulations require you to submit periodic and terminal progress reports to Baylor's Institutional Review Board and to receive at least annual approval of your activity from this Committee.

You are also required to report to this Committee immediately any death, unanticipated problems invoving risks to subjects or others, or serious adverse incidents resulting from your study. These events must be reported in accordance with current BRI Policies 830 and 838.

Federal regulations and institutional policies require that the IRB review any and all changes in your research activity. This includes amendments, revisions, administrative changes, advertisements, or ANY other change in the information as presented at initial review. In other words, should your project change, another review by the Board is required. Failure to comply with any of the above requirements, federal regulations, or institutional policy may result in severe sanctions being placed on the Medical Center and on you as the Principal Investigator. These sanctions could result in your research being permanently terminated for non-compliance.

Receipt of approval does not convey institutional authority to gain additional patient information. It is your responsibility as Principal Investigator to abide by institutional and/or departmental policies regarding confidentiality, access, and release of patient data.

Please be advised: there may be additional administrative requirements from Baylor Research Institute that must be met before the study may begin enrolling subjects.

Sincerely,

Lawrence R. Schiller, MD, Chair
Institutional Review Board ~ Red

BAYLOR RESEARCH INSTITUTE
Baylor University Medical Center Antepartum Unit
Dallas, Texas

PARTICIPATION EXPLANATION AND CONSENT FORM

PROJECT TITLE: The Experience of Being Hospitalized During Pregnancy

Principal Investigator
Jon Rosnes, M.D.

Sub-Investigator
H. M. Evans, Ph.D.

Study Coordinator
Anna R. Brandon, Ph.D.

Investigators
Sandra Pitts, Ph.D.; Richard Robinson, Ph.D.; C.Allen Stringer, M.D.
Dana Broussard, M.A.; Cindy D. Huntzinger, B.A.; Paula Miltenberger, B.A., B.S.;
Jamie Rifkin, B.A.; Georgina Rangel; Laura Rowley

TELEPHONE NUMBER: 214-820-6224

INTRODUCTION:

Before you say that you will be in this research study you need to read this form. It is important for you to understand all the information in this form. This form will tell you what the study is about and how it will be done. It will tell you about some problems that might happen during the study. It will also tell you about the good things that might happen for you during the study. When you read a paper like this to learn about a research study, it is called "informed consent." The people who are doing this study are giving you very important information about the study. When you give your consent for something, it is the same as giving your permission. This consent form may contain words that you do not understand. Please talk with one of the doctors or their staff if you have questions. Do not sign this consent form unless all your questions have been answered and you feel comfortable with the information you have read. You will be given a copy of the form to keep.

You are being asked to take part in this study because you have been admitted to the BUMC Antepartum Unit with a complicated pregnancy.

Why Is This Study Being Done?

This study is being done to look at the emotional well-being of women such as yourself to help improve treatment during pregnancy and after childbirth.

What is the Status of Procedures?

The questionnaires and surveys that you are going to be asked to complete during this study are not considered standard of care and are still considered investigational.

How Many People Will Take Part In The Study?

About 200 pregnant women who are admitted to BUMC antepartum unit will be invited to participate in this research.

What Is Involved In The Study?

While you are here at BUMC, you will be asked to give us information about yourself, your medical and psychiatric history, and your family. You will be asked to complete a variety of forms that ask questions about your feelings. We will also review your medical records from this hospital stay, as well as future visits to your doctor, to see how you are doing. At several other points in time you will be asked to complete other forms. We will either make arrangements to meet you here at BUMC, or we will send them to you in the mail with a stamped addressed envelope for their return.

How Long Will I Be In The Study?

You will be in the study for twelve months. We will contact you during your hospitalization, when your baby is 6 weeks old, 3 months old, 6 months old, and 12 months old.

You can stop participating in this study at any time. However, if you decide to stop participating in the study, we encourage you to talk to the researcher and your regular doctor first.

What Are The Risks and Benefits of The Study and What Are My Options?

There are no risks or benefits to you for participating in this study. Your alternative is not to participate in this study. We hope that the information learned from this study will benefit other women who must undergo hospitalization during pregnancy.

What About Confidentiality?

You have a right to privacy. This means that only people working on the study can look at all the information about you from this study. The results of this study may be published in a scientific book or journal. If this is done, your name will not be used. All information about you from this research project will be kept in a locked office.

Sometimes other groups of people need to look at your health information to make sure the study is done correctly. The kinds of health information that might be given to these people include results from lab tests or other tests like x-rays. This information might also be notes written by your doctor from your medical record or notes written by your doctor asking for tests to be done on you. The information might be about diseases like Human Immunodeficiency Virus ("HIV") or Acquired Immune Deficiency Syndrome ("AIDS"). This could also be information about mental illness (except for specific notes of psychotherapy sessions), or information about drug or alcohol abuse. The individuals who will be looking over this information include people who work for Baylor Research Institute, some government agencies like the US Food and Drug Administration, the Office for Human Research Protections and the Association for the Accreditation of Human Research Protection Programs. Others involved might be researchers associated with University of Texas Southwestern Medical School at Dallas. The privacy law requires that Baylor Research Institute get your permission before giving any of your health information to other people or groups. Some of these people or groups might need to look at or copy your information while they are examining the study. We usually remove your name from the information, but the people or groups looking at this information may not be required to follow the privacy law, or they may be able to figure out who you are. If that happens, we cannot promise that your information will still be protected by this law. When you sign this form you are saying it is okay for the Baylor Research Institute to give these other people or groups information about your health if they need to review it for the research study.

You do not have to give your permission for us to release this information, and it is all right to refuse to sign this form. But if you do not sign this form, you cannot be in the research study. If you decide not to be in the study, your treatment will proceed as usual here at BUMC.

If you change your mind and later want to withdraw your permission, you may do so. You must notify Baylor Research Institute in writing at 3434 Live Oak, Suite 125, Dallas, TX 75204. If you decide to do this, it will not apply to information that was given before you withdrew your permission.

You may not be allowed to look at your health information during this study. However, at a later time, you will be able to look at this information. This later time will be sometime after the study is completed.

Unless permission is withdrawn, this permission will not expire at the end of the study.

Will I Be Paid For Participating in This Study and What Will It Cost?

You will not be paid for participating in this study. You will not be charged anything extra to be in the study. All the charges related to your regular hospital visit will still be your responsibility or your insurance company's responsibility as normal.

What Are My Rights As a Participant?

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. If you agree to take part and then decide against it, you can withdraw for any reason. Deciding not to be in the study, or leaving the study early, will not result in any penalty or loss of benefits that you would otherwise receive.

We will tell you about any new information that may affect your health, welfare, or willingness to stay in this study.

All of the people working on the project must be careful not to carelessly harm you. If you are hurt during this project, you have the right to seek legal counsel. Nothing in this consent form takes away that right if you are hurt during this research.

Whom Do I Call If I have Questions or Problems?

If you have questions about the study or have a research-related injury, contact the principal investigators, Dr. Monty Evans or Dr. Jon Rosnes, at 214-820-6224 or 214-820-6015 respectively. For questions about your rights as a research subject, contact Lawrence R. Schiller, M.D., IRB Chair, at 214-820-2687.

Statement of Person Obtaining Consent:

I have explained to _____ the purpose of the research project, the procedures required and the possible risks and benefits to the best of my ability. They have been encouraged to ask questions related to participation.

_____ _____

Signature of Person Obtaining Consent Date and Time

Statement of Principal Investigator:

As Principal Investigator of this study, I confirm that to the best of my knowledge this subject has voluntarily agreed to participate in this study and has had an opportunity to ask questions and has received answers to these questions. If another individual was responsible for obtaining informed consent, then this individual has signed above.

_____ _____

Signature of Principal Investigator Date and Time

Baylor Research Institute
IRB Approval
This project is approved from
11·16·06 to 11·15·07

Confirmation of Consent by Research Subject:

You are making a decision about being in this research study. You will be asked to give your written consent if you want to be in the study. Giving consent is like giving permission. You should not give your permission to be in this study until you have read and understood all the pages in this form. If you cannot read, then someone can read the form to you. Make sure that all your questions about this research project have been answered before you sign this form. When you sign this form, you are giving your permission to be in the study. By signing this form, you have not given up any of your legal rights or released anyone from liability for negligence.

_____ has explained to me the purpose of the research project, the study procedures that I will have, and the possible risks and discomforts that may happen. I have read (or have been read) this consent form. I have been given a chance to ask questions about the research study and the procedures involved. I believe that I have enough information to make my decision. I have also been told my other options. To the best of my knowledge, I am not in any other medical research. Therefore, I agree to give my consent to participate as a subject in this research project.

_____ _____

Signature of Subject Date

_____

Time