OMB#: 0925-XXXX
EXPIRATION DATE: XX/XX/XXXX

UNIVERSITY OF MINNESOTA

Change In Protocol Request

Route this form to: See instructions below.

Rev: Jan 2010

Instructions:
Use this form when submitting change requests on IRB protocols. This form is for use when the changes are initiated by the PI. Do not use this form to respond when changes are requested by the IRB. Please do not use this form when responding to changes requested in a stipulation letter.

1. Submit this form to the Human Research Protection Program:

U.S. Mail Address:
Human Research Protection Program
MMC 820
420 Delaware St. SE
Minneapolis, MN 55455-0392

Campus Mail:
Human Research Protection Program
MMC 820
Minneapolis Campus

Deliver to:
D-528 Mayo Memorial Building
Minneapolis Campus
8-4:30, M-F

IRB Protocol Information

IRB Study Number:	**1101M94612**
Current Principal Investigator:	**Patricia M. McGovern**
Primary Title:	Self Reported Stress and Cortisol Measurement: Development of an Optimized Measure of Chronic Stress in Pregnancy
Submission Date	06/13/2011

Indicate the type of change/addition and attach all applicable documents:
☒ Protocol Amendment: Version , Dated
☐ Revised Investigator Brochure: Version , Dated
☐ Recruitment Changes/Advertisements
☐ Notice of Closure to Accrual
☒ Change(s) to Study Procedures
☒ Other: Revised versions of IRB approved study documents, including consent form

1. **Briefly summarize the change(s). For protocol amendments, do not say "See summary of changes provided with amendment." Rather, summarize the nature of the significant revisions.**

The following protocol changes are being submitted for local IRB review by each of the nine Study Centers collaborating in this formative research that is part of the National Children's Study. The significant changes to our currently approved protocol are:

1. We will ask participants to allow audio taping of their Stressful Life Events Schedule (SLES) interview, so that an accurate narration of their responses can be written by the interviewer after the study visit. No names will be used on the recordings. Each taped interview will be identified by a study number only and the recording will be destroyed once the written narration has been completed.
2. Participants will now be asked to complete the SLES only once, at their second study visit.
3. The amount of blood to be collected at each study visit has been reduced.
4. The method for collecting the hair sample has been improved to eliminate use of string.

A number of revisions have been made to existing study documents. Some items have been moved from previous documents to more appropriate documents, while other items that were not needed or not appropriate to pregnant women have been eliminated. "Don't Know/ Refused" response options have been added for each question of the Demographic and Stress Surveys.

A separate Participant Contact Information Sheet has been created to allow us to remove all personal identifiable information (PII) from the Enrollment Survey. This information will exist only on paper in the locally held participant file folder, and no PII will be included in the Study's central database.

All changes to the study documents are laid out by document in the attached Study Revisions List and we have attached each document. The collection and processing documents for blood, hair and salvia were not finalized at the time of our initial submission in January 2011 and we are including them now.

2. Describe the rationale for the change(s):

These changes are being made in order to minimize the inconvenience to participants while still guaranteeing the high quality of the data collected, sufficient to answer our research questions. By reducing the amount of blood drawn, asking the SLES only once, and audio taping to assure complete and accurate capture of the participant's SLES responses, we expect to preserve the quality of study information collected while reducing the burden on our participants. Separating the participant's PII from other study data allows better protection of each participant's identity and the privacy of their study information. The improved method for collecting the hair sample should make the procedure easier for both participant and researcher. Finally, changes to the items included in each instrument are intended to improve the cogency and ease of completion of study questionnaires.

3. In your opinion as principal investigator, how will these changes affect the overall risk to subjects in this study?

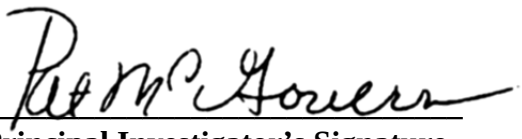
The overall low risk to participants in this study will not be increased by the proposed protocol changes. Because less blood will be collected, this risk may be reduced.

4. Do the changes to the study prompt changes to the consent form(s)?

☐ **No.** ☒ **Yes.**

If yes, attach a copy of the revised consent form(s) with changes tracked or highlighted as well as a clean copy. Use this space to further describe consent form changes if necessary:

Our consent form has been edited to reflect the audio taping and one-time administration of the SLES and the reduced amounts of blood to be drawn at each visit.



Principal Investigator's Signature 06/13/2011 **Date**

APPROVED

By Christina Dobrovolny at 12:52 pm, Jun 16, 2011

IRB Expedited Review includes approval of consent form dated 6/14/2011 and study materials received 6/13/2011

UNIVERSITY OF MINNESOTA

Twin Cities Campus

Human Research Protection Program
Office of the Vice President for Research

D528 Mayo Memorial Building
420 Delaware Street S.E.
MMC 820
Minneapolis, MN 55455

Office: 612-626-5654
Fax: 612-626-6061
E-mail: irb@umn.edu or ibc@umn.edu
Website: http://research.umn.edu/subjects/

03/15/2011

Patricia M McGovern
Envrn Health Sciences
MMC 807
420 Delaware
Minneapolis, MN 55455

RE: "Self Reported Stress and Cortisol Measurement: Development of an Optimized Measure of Chronic Stress in Pregnancy"
IRB Code Number: **1101M94612**

Dear Dr. McGovern:

The Institutional Review Board (IRB) received your response to its stipulations. Since this information satisfies the federal criteria for approval at 45CFR46.111 and the requirements set by the IRB, final approval for the project (protocol version dated December 8, 2010) is noted in our files. Upon receipt of this letter, you may begin your research.

IRB approval of this study includes the consent form dated March 11, 2011 and the HIPAA form received January 7, 2011.

The IRB would like to stress that subjects who go through the consent process are considered enrolled participants and are counted toward the total number of subjects, even if they have no further participation in the study. Please keep this in mind when calculating the number of subjects you request. This study is currently approved for 200 subjects. If you desire an increase in the number of approved subjects, you will need to make a formal request to the IRB.

For your records and for grant certification purposes, the approval date for the referenced project is March 3, 2011 and the Assurance of Compliance number is FWA00000312 (Fairview Health Systems Research FWA00000325, Gillette Children's Specialty Healthcare FWA00004003). Research projects are subject to continuing review and renewal; approval will expire one year from that date. You will receive a report form two months before the expiration date. If you would like us to send certification of approval to a funding agency, please tell us the name and address of your contact person at the agency.

As Principal Investigator of this project, you are required by federal regulations to inform the IRB of any proposed changes in your research that will affect human subjects. Changes should not be initiated until written IRB approval is received. Unanticipated problems or serious unexpected adverse events should be reported to the IRB as they occur.

The IRB wishes you success with this research. If you have questions, please call the IRB office at 612-626-5654.

Sincerely,

Christina Dobrovolny, CIP
Research Compliance Supervisor
CD/ks

CC: Jill Cordes, Deborah Engelhard, Patricia Fontaine, Laurie Ukestad

University of Pittsburgh
Institutional Review Board

3500 Fifth Avenue
Pittsburgh, PA 15213
(412) 383-1480
(412) 383-1508 (fax)
http://www.irb.pitt.edu/

Memorandum

To: Hyagriv Simhan MD

From: Margaret Hsieh MD, Vice Chair

Date: 2/1/2011

IRB#: PRO11010057

Subject: Self Reported Stress and Cortisol Measurement: Development of an Optimized Measure of Chronic Stress in Pregnancy

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At its full board meeting on 1/18/2011, the University of Pittsburgh Institutional Review Board, Committee B, reviewed the above referenced research study and approved it pending minor modifications. Your responses to these comments have been reviewed and the research submission, in its currently modified form, adequately addresses the concerns of the IRB and is therefore approved.

Please note the following information:

The risk level designation is Minimal Risk.

Approval Date: 2/1/2011
Expiration Date: 1/17/2012

For studies being conducted in UPMC facilities, no clinical activities can be undertaken by investigators until they have received approval from the UPMC Fiscal Review Office.

Please note that it is the investigator's responsibility to report to the IRB any unanticipated problems involving risks to subjects or others [see 45 CFR 46.103(b)(5) and 21 CFR 56.108(b)]. The IRB Reference Manual (Chapter 3, Section 3.3) describes the reporting requirements for unanticipated problems which include, but are not limited to, adverse events. If you have any questions about this process, please contact the Adverse Events Coordinator at 412-383-1480.

The protocol and consent forms, along with a brief progress report must be resubmitted at least one month prior to the renewal date noted above as required by FWA00006790 (University of Pittsburgh), FWA00006735 (University of Pittsburgh Medical Center), FWA00000600 (Children's Hospital of Pittsburgh), FWA00003567 (Magee-Womens Health Corporation), FWA00003338 (University of Pittsburgh Medical Center Cancer Institute).

Please be advised that your research study may be audited periodically by the University of Pittsburgh Research Conduct and Compliance Office.

Kaitlin A. Wolfe

From: eirbsystem@northwestern.edu
Sent: Tuesday, March 22, 2011 2:15 PM
To: k-wolfe@northwestern.edu
Subject: IRB Approval Letter Ready

Office for the Protection of Research Subjects

Northwestern University
750 North Lake Shore Drive
Suite 700
Chicago, Illinois 60611

irb@northwestern.edu
Phone 312-503-9338
Fax 312-503-0555

NORTHWESTERN UNIVERSITY

3/22/2011

Dr. Ann Borders
Assistant Professor
Obstetrics and Gynecology
250 E. Superior, 5th floor Suite 02-2175
Chicago IL 60611
abryant@md.northwestern.edu

IRB Project Number: STU00039484
Project Title: QUEX 01: Self Reported Stress and Cortisol Measurement: Development of an Optimized Measure of Chronic Stress in Pregnancy
Project Sites:

Northwestern Medical Faculty Foundation (NMFF)
Clinical Research Unit (CRU) formerly GCRC
Northwestern University (NU)
Northwestern Memorial Hospital (NMH)
Other: Lead sites involved in specimen processing: Northwestern University, University of Irvine, California, University of Texas, San Antonio, and University of Washington

Additional sites recruiting subjects: Brown University, Children's Hospital of Philadelphia, Tulane University School of Public Health and Tropical Medicine, University of Minnesota, and University of Pittsburgh

Sponsor Information (Grant #, if applicable):

View National Institutes of Health HHSN275200800016C

Submission Considered: New Submission **Submission Number:** STU00039484
Review Type: Expedited
Review Date: 3/21/2011

Status: APPROVED **Approval Period:** (3/21/2011 - 3/20/2012)

Dear Dr. Borders,

The IRB considered and approved your submission referenced above through 3/20/2012 . As Principal Investigator (P.I.), you have ultimate responsibility for the conduct of this study, the ethical performance of the project, and the protection of the rights and welfare of human subjects. You are required to comply with all NU policies and procedures, as well as with all applicable Federal, State and local laws regarding the protection of human subjects in research including, but not limited to the following:

- Not changing the approved protocol or consent form without prior IRB approval (except in an emergency, if necessary, to safeguard the well-being of human subjects).
- Obtaining proper informed consent from human subjects or their legally responsible representative, using only the currently approved, stamped consent form.
- Promptly reporting unanticipated problems involving risks to subjects or others, or promptly reportable non-compliance in accordance with IRB guidelines.
- Submit a continuing review application 45 days prior to the expiration of IRB approval. If IRB re-approval is not obtained by the end of the approval period indicated above, all research related activities must stop and no new subjects may be enrolled.

IRB approval includes the following:

Written Consent Form/Consent Form and Authorization for Research:

Name
NCS Stress Collaboration Consent Form 3.21.11.final.doc

Protocol Document:

Name
NCS Stress Collaboration IRB Protocol 2.17.11

Recruitment Materials:

Name
NCS Stress Collaboration Flier

Survey/Questionnaires:

Name
NCS_Stress_Collaboration_Stress_Surveys Revised 12 06 10 final.doc

For more information regarding OPRS submissions and guidelines, please consult http://www.northwestern.edu/research/OPRS/irb.
This Institution has an approved Federalwide Assurance with the Department of Health and Human Services: FWA00001549.

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UT HEALTH SCIENCE CENTER™
SAN ANTONIO

November 22, 2010

To: Douglas E. Williamson, PhD
c/o Deanne Hargita, MC 7792, MED 772E Psychiatry, UTHSCSA

From: Institutional Review Board

Subject: **Expedited Approval of a New Human Research Protocol (Initial Review)**

Protocol Number: HSC20110100H
Title: Self Reported Stress and Cortisol Measurement: Development of an Optimized Measure of Chronic Stress in Pregnancy

Dear Principal Investigator,

Your request to conduct this minimal risk research was approved by Expedited Review on November 19, 2010, under the following regulation(s):

45 CFR 46.110(b)(1) Category 2: Collection of blood samples by finger stick, ear stick, or venipuncture as follows: from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. The amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
45 CFR 46.110(b)(1) Category 3: Prospective collection of biological specimens for research purposes by noninvasive means.
45 CFR 46.110(b)(1) Category 5: Research involving materials (data, documents, records or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
45 CFR 46.110(b)(1) Category 6: Collection of data from voice, video, digital, or image recordings made for research purposes.
45 CFR 46.110(b)(1) Category 7: Research on individual or group characteristics or behavior; or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

The inclusion of children (not to include neonates) under **45 CFR 46.404** was also approved. The inclusion of pregnant women or fetuses, in this study, under **45 CFR 46.204** was also approved. Individuals engaged in the research may not have any part in any decisions as to the timing, method or procedures used to terminate a pregnancy or determining the viability of a neonate.

The IRB expiration date: November 19, 2011. Your progress report must be submitted to the IRB Office 34 days before the IRB meeting that will occur before the study's expiration date.

The following documents were reviewed: Signature Assurance Sheet; Form B - General Information; Form B-2 - Personnel List; Form C - Research Description; Form D - HSC Consent; Form K - Intent to Conduct Research at Another Institution; Form M - Data Collection Instrument(s); **Other:** Form B-1 Expedited Certification Form.

The attached informed consent document(s) digitally stamped with **IRB APPROVED November 19, 2010** must be used.

Approval of the following affiliated institutions: UTHSCSA University Health System

Sincerely,

Research Compliance Specialist

Please retain this document in your IRB correspondence file