University of Connecticut
Office of Research Compliance

DATE: July 22, 2011

TO: Cheryl Beck, DNSc
School of Nursing, Unit 2026

FROM: Deborah Dillon McDonald, RN, Ph.D. DDM|SMC
Chair, Institutional Review Board
FWA# 00007125

RE: Protocol #: H09-159, "Traumatic Pregnancy and/or Childbirth: The Fathers' Perspective"
Please refer to the Protocol# in all future correspondence with the IRB.
Funding Source: Unfunded
Re-approval Period: From: July 27, 2011 Valid Through: July 27, 2012
"Expiration Date"

The Institutional Review Board (IRB) re-approved this protocol on July 22, 2011. The research presents no more than minimal risk to human subjects and qualifies for expedited approval under category #7 - Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. Enclosed is the validated information sheet which is valid through July 27, 2012. A copy of the approved, validated information sheet (with the IRB's stamp) must be used to consent each subject.

All investigators of the University of Connecticut are responsible for complying with the "Responsibilities of Research Investigators" attached to this letter.

Re-approval: It is the investigator's responsibility to apply for re-approval of ongoing research at **least once yearly**, or more often if specified by the IRB. The Re-approval/Termination Form (IRB-2) and other applicable re-approval materials must be submitted **one month** prior to the expiration date noted above.

Modifications: If you wish to change any aspect of this study, such as the procedures, the consent forms, the investigators, or funding source, please submit the changes in writing to the IRB using

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web: compliance.uconn.edu

the Amendment Review Form (IRB-3). All modifications must be reviewed and approved by the IRB prior to initiation.

Audit: All protocols approved by the IRB may be audited by the Research Compliance Monitor.

Please keep this letter with your copy of the approved protocol.

Attachments:

1. Validated IRB-2
2. Validated Information Sheet
3. Validated Recruitment Advertisement
4. "Responsibilities of Research Investigators"

University of Connecticut Office of Research Compliance
Storrs and Regional Campuses

INSTITUTIONAL REVIEW BOARD
RESPONSIBILITIES OF RESEARCH INVESTIGATORS

Responsibilities of Principal Investigators

The IRB holds the PI responsible for the overall management of an approved study. Management of the study encompasses the ethical, technical, administrative, and fiscal elements of a project. The PI may delegate certain tasks, but retains ultimate responsibility and accountability. Principal investigators are required to:

- Acknowledge and accept their responsibility for protecting the rights and welfare of human research participants, including the equitable selection of research participants, ensuring that risks to participants are minimized, and that the risks are reasonable in relation to anticipated benefits,
- Fulfill the training requirement for the protection of human participants in research (CITI on-line training modules, www.citiprogram.org), and to understand the ethical standards and regulatory requirements governing research activities with human participants,
- Supervise all study personnel and ensure that all personnel abide by the ethical principals of respect for persons, beneficence and justice, as outlined in the Belmont Report,
- Ensure that all study personnel are knowledgeable of, and conduct the study in accordance with the approved protocol (including approved amendments),
- Ensure that all research activities have IRB approval and other approvals required by the institution before human participants are involved, and implement the research activity as it was approved by the IRB,
- Report any real or potential conflicts of interests of the PI or any study personnel in compliance with conflict of interest policies and management plans,
- Obtain informed consent from participants before participants are involved in the research, and document consent as approved by the IRB. A copy of the IRB-approved informed consent document must be used. Participants must be provided with a copy of the form after it has been signed, unless the IRB has specifically waived this requirement. Documented evidence of informed consent of the participants or their legally authorized representative is to be retained in a manner approved by the IRB. The consent process involves two required elements: 1) a discussion of the study by the person obtaining consent and the participants, and 2) an opportunity for participants to read the consent form. Please note that it is never appropriate to forgo the discussion, even if participants will then read the consent form. Participants must be given the opportunity to have the consent form read to them if they have difficulty reading,
- Maintain written records of IRB reviews, decisions, research records and informed consent documents,
- Obtain IRB approval for and notify the sponsor (if applicable) of any proposed change to the research protocol *prior to* its implementation, except when necessary to eliminate apparent immediate hazards to the participants,
- Obtain re-approval by reporting progress of approved research to the IRB, in the manner prescribed by the IRB, but not less than once per year,
- Promptly report to the IRB any adverse events, protocol deviations or other unanticipated problems involving risks to participants or others. PIs should not undertake any action with an external funding agency regarding an unanticipated problem or noncompliance without first contacting the IRB Chair or the DRC in order to determine the correct course of action,
- Verify that IRB approval has been obtained from all participating institutions in collaborative activities with other institutions, and that continuing review by other institutions is maintained,

Recruitment Advertisement

Traumatic Pregnancy and/or Childbirth: The Fathers' Perspective

In order to help health care professionals provide better care to fathers who are with their partners at the time of a traumatic pregnancy and/or childbirth, Cheryl Beck (Professor at the University of Connecticut) and Sue Watson (Chairperson of TABS) are now conducting a research study on this topic. Men who have been present during a traumatic pregnancy and/or childbirth involving their partner are invited to participate in this research study. In order to participate men need to be 18 years of age or older and be able to read and write English.

Just like Professor Beck's previous studies on birth trauma and posttraumatic stress disorder (PTSD) after childbirth, this study will be conducted over the Internet. Fathers who were with their partners at the time of their traumatic pregnancy and/or childbirth will be asked to describe their experiences.

If you are interested in participating in this research or wish to find more about the study, please contact Professor Cheryl Beck directly at the University of Connecticut. Her email address is Cheryl.beck@uconn.edu

Information Sheet for Participation in a Research Project

University of Connecticut

Principal Investigator: Cheryl Beck, DNSc
Co-Investigator: Sue Watson, Cert. Childbirth Education
Study Title: Traumatic Pregnancy and/or Childbirth: The Fathers' Perspective

1. Invitation to Participate

   You are invited to participate in this study so that we can better understand the experiences of fathers who were with their partners at the time of a traumatic pregnancy and/or childbirth and the impact that this event may have had on their lives.

2. Purpose

   The purpose of the study is to understand the experiences of fathers who were with their partners at the time of a traumatic pregnancy and/or childbirth and what impact that traumatic event may have had on their lives.

3. Description of Procedures

   Participation in this study consists of completing one interview by electronic mail. You will be asked to describe in as much detail as you wish your experience being with your partner at the time of a traumatic pregnancy and/or childbirth and the impact that may have had on your life. You can take as long as you like to complete your description. You may want to complete it in more than one session on the computer if you prefer. You will also be asked to provide some information about yourself, such as your age, marital status, and educational level. You will be asked if you or your partner has been diagnosed with posttraumatic stress disorder (PTSD) due to the traumatic hildbirth and if you are in therapy or counseling.

   After reading your description of your experiences of being present during your partner's traumatic pregnancy and/or childbirth, the researcher may email you with some follow up questions just to clarify what you had written or to ask you to expand on a point you had made. When the project is completed, if you would like, the researcher will send you by attachment a copy of the findings to see if you agree with them or not and be given an opportunity to explain why the findings may or may not reflect your experiences of being with your partner at the time of a traumatic childbirth and its impact on your life.

4. Risks and Inconveniences

   There are no known risks for your participating in this study over the Internet. If, however, you should become anxious or upset, you should take a break from writing your story. Talking with a friend or family member may help ease your anxiety. You can also write in your story what feelings are being triggered now as you relive the experience having been present with your partner during a traumatic childbirth. You are also free to withdraw from the study at any time.

5. Benefits

While there is no direct benefit for you participating in this study, the information you share may help health care professionals provide better care to fathers who are with their partners at the time of a traumatic pregnancy and/or childbirth.

6. Confidentiality

Since email is not anonymous and not a secure transmission method, your confidentiality cannot be guaranteed. For example, emails can be monitored by employers. Also emails are not encrypted. If your email is somehow diverted or lost in transmission, your story with your identification attached through your email address can be exposed.

However, the confidentiality of your description of your experiences of being present at your partner's traumatic childbirth will be protected in a number of ways. If any identifying names are included in your description, the researcher will delete them. The hard copy of your description will be kept in a locked file cabinet in the researcher's office at the University of Connecticut. The researcher's computer is password protected. In any research reports that are written concerning this study, fathers' names will never be used.

You should also know that the UConn Institutional Review Board (IRB) and the Office of Research Compliance may inspect study records as part of its auditing program, but these reviews will only focus on the researchers and not on your responses or involvement. The IRB is a group of people that reviews research studies to protect the rights and welfare of participants.

7. Voluntary Participation

You do not have to be in this study if you do not want to. If you agree to be in the study, but later change your mind, you may drop out at any time. There are no penalties or consequences of any kind if you decide that you do not want to participate.

8. Do You Have Any Questions?

Take as long as you like before you make a decision. We will be happy to answer any question you have about this study. If you have further questions about this project or if you have a research-related problem, you may contact the principal investigator, Dr. Cheryl Beck by telephone (860) 486-0547 or by email (cheryl.beck@uconn.edu) If you have any questions concerning your rights as a research subject, you may contact the University of Connecticut Institutional Review Board (IRB) at 860-486-8802.

RECEIVED
JUN 16 2011
OFFICE OF RESEARCH COMPLIANCE

7/27/11

University of Connecticut

Protocol # H09-159
Re-Approval X Completion ___

(IRB-2) Re-approval/Completion Form

Institutional Review Board, Office of Research Compliance

Whetten Graduate Center, Rm #214, 438 Whitney Road Ext., Unit 1246, Storrs, CT 06269-1246 860-486-8802

This form must be completed at the time of continuing review or study completion.
All questions relate to the *last* approval period.

SECTION 1: General Information

Nature of Study: (Place an "X" in the column. Check one.)				
	X	Faculty Research		Graduate Research
		Dissertation		Undergraduate Research
		Masters Thesis		Staff Research

Study Title: _Traumatic Pregnancy and/or Childbirth: The Fathers' Perspective

PI, Student Investigator, Correspondent Information:

	Principal Investigator (PI)	**Student Investigator** (only for Student Initiated Research)	**Correspondent** (primary point of contact for correspondence, if applicable)
Name (First, Last, Degree):	Cheryl Beck, DNSc ✓		
Department:	Nursing		
Mailing Address	Storrs hall Room 316		
Preferred Phone #:	486-0547		
Emergency Phone # (Required Full Board, More than Min. Risk only):			
Preferred E-Mail Address:	Cheryl.beck@uconn.edu		

Status of Study:

Check **ONE** of the following...	
x	**On-Going.** If so, …
	Are participants still being enrolled in the study? X **Yes** ___ **No**
	Have all enrolled participants completed all study interventions? X **Yes** ___ **No**
	Is the research active only for long-term follow-up of enrolled participants? ___ **Yes** X **No**
	Data Analysis. A study is considered to be in "Data Analysis" if data is being analyzed, and/or maintained for purposes of publication (i.e., a manuscript has been submitted but the publisher may ask for revisions that would require re-analysis of data).
	Completed. A study is considered to be "Completed" if data analysis is done, and there is no additional research beyond the original intent planned for this data. Use of this data for other research purposes requires submission of a new protocol application. **Date of Completion**: _____

UCONN IRB
Approved On 7/27/11
Approved Until 7/27/12
Approved By [signature]

At the time of proposal submission to the Office for Sponsored Programs (OSP), all investigators and key personnel are required to submit a Significant Financial Interest Review Form to OSP. For more information, please go to the Conflict of Interest Committee website, http://www.compliance.uconn.edu/conflict.php.

Is any investigator listed on this protocol required to submit the follow-up form, "supplemental" Significant Financial Interest Review Form? ___ Yes X No

If yes, please identify each individual: _____

SECTION IV: Study Summary and Progress Report

Findings
Describe the current status of the research (e.g., phase 1 completed, phase 2 scheduled to start in two months); provide a summary of findings/analysis conducted during the approval period; state whether the findings are consistent with what you expected; and provide a brief description of the plans for the study during the upcoming approval period. IMPORTANT - Please note that it is not acceptable to simply copy last year's findings section. The IRB must review the activity that occurred within the last approval period. If no work was conducted on this study during the last approval period, please state so and explain why (e.g., too busy with other projects, delay in funding, unable to hire a graduate student to work on the project, etc.). If closing the study, please attach a copy of any publications or manuscripts resulting from the study.

To date 9 fathers have participated in this Internet study. Recruitment is slower than had been expected. Only one father was recruited into the study this past year.I plan to be recruiting subjects for the next year. It is too early to start data analysis but when reading over the narratives the 9 fathers submitted the findings are consistent with what I had expected.

Are there any new findings that may impact a participant's willingness to continue this study? Indicate "Yes" or "No." If yes, please describe the findings, and explain how these findings have been communicated to participants.

No

If applicable, provide a summary of the findings of the data safety monitoring plans/board meetings and the date of the last DSMB meeting.

Literature
Provide a summary of the recent literature by other authors that provides new information bearing on this study's risk/benefit analysis, and attach copies of such articles to this form. If a search was conducted in good faith, and you believe that no such literature exists, indicate "**No literature exists**" in the space below this text border.

No literature exists

SECTION V: Amendments

1. Is the protocol being amended per this submission? ___ **Yes** X **No**
   If yes, an Amendment Review Form (IRB-3) needs to be completed and attached to this submission. **Please note that an Amendment may require revisions to the protocol application and/or to the consent form. If applicable, submit 2 copies of the appropriately revised IRB-1 protocol and/or consent form(s) for review.**

2. Was the protocol amended during the last IRB approval period? ___ **Yes** X **No**

If data is available, state the number of participants enrolled to date in each of the categories below. This information is required for NIH funded research.

	American Indian or Alaskan	Asian or Pacific Islander	Black, not of Hispanic Origin	Hispanic	White, not of Hispanic Origin	Other or Unknown	Total
Female							
Male					9		9
Trans-Gender							
Unknown							
Total							9

Please Note: If participants were enrolled during the last IRB approval period, you must submit copies of 5 signed Consent/Assent forms to the IRB for verification purposes with the participants' last names blacked-out. Do not provide the IRB with original consent forms. If fewer than 5 participants have been enrolled during the last approval period, copies of all signed Consent/Assent forms obtained during this period must be submitted. If you have used more than one IRB-approved Consent/Assent form, (e.g., Adult, Parental Permission, Assent, Translations, etc.), please submit at least one example of each type used.

SECTION VII: Events to be Reported at Re-Approval

Please Note: Adverse Events and Protocol Deviations, both anticipated and unanticipated, must be reported in writing to the IRB in accordance with the Adverse Event/Protocol Deviation policy. Please see the IRB website for further information. Place your response BELOW, not within, the box containing each item's description.

Were adverse events and/or protocol deviations reported to the IRB during the last approval period? ___ **Yes** X **No**

If yes, please list the IRB acknowledgment letter date(s) for each event in the table below. Note: a description of these previously reported events is NOT required.

Adverse Event/Protocol Deviation Acknowledgement Date(s):

Note: Add additional rows to the table as needed.

1. Describe any *previously unreported* events that were not serious and were not related to study procedures.

none

2. Describe if the frequency of these event(s) was different from what you anticipated. Indicate "Yes" or "No." If yes, please explain in the space below the text border.

N/A

3. Did the PI or member of the research team remove a subject from the study during the last approval period? Indicate "Yes" or "No." If Yes, please describe how many participants were removed and the circumstances and reasons for each withdrawal. Include your opinion about whether any of the withdrawals were related to the research procedures.

8. That each individual listed as study personnel in this application possesses the necessary training and experience for conducting research activities in the role described for them in this research study.

Furthermore, by signing below, I also attest that I have appropriate facilities and resources for conducting the study.

George Beck	6-15-11
Original Signature of Principal Investigator	**Date**

Original Signature of Student Investigator (Only for Student-Initiated Research)	**Date**