Attachment D: IRB Approval Documentation

Battelle
The Business of Innovation

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April 12, 2006

Jennifer Brustrom, PhD
Battelle CPHRE
2971 Flowers Road South
Suite 233
Atlanta, GA 30341-5404

Dear Dr. Brustrom:

As Chair of the Battelle/CPHRE Institutional Review Board (IRB) I have reviewed the full study implementation submission dated 4/5/2006 for the study entitled "Assessment and Evaluation of the Role of Care Coordination (Case Management) in Improving Access and Care within the Spina Bifida Clinic System" (FG487118-01) and grant expedited approval for the study. This study is minimal risk and the requirement for signed written consent is being waived for the focus groups and interviews. In addition, I have the following requirements.

(1) The clinics must be the first contact with patients. If they are not, then HIPAA will apply and you must resubmit to the IRB.
(2) Submit a continuing progress report when exact procedures for staff recruitment are developed.

Should any changes occur in your protocol or questionnaire, please inform the IRB and submit the changes for review. Similarly, the IRB needs to be notified in the event of any injury or unexpected outcome arising from this study.

Sincerely,

Margaret Pennybacher

Margaret Pennybacker, PhD, CIP
IRB Chair

cc: Brigette Brevard
Kevin Heaton
Jan Jaeger

Battelle/Centers for Public Health Research and Evaluation

100 Capitola Drive, Suite 301
Durham, NC 27713
Federal-wide Assurance No. FWA00004696 (IRB No. 284)

INSTITUTIONAL REVIEW BOARD NOTICE OF APPROVAL

PROJECT DIRECTOR: Jennifer Brustrom

PROJECT TITLE: Assessment & Evaluation of the Role of Care Coordination in Improving Access & Care within the Spina Bifida Clinic System

CLIENT: CDC PROTOCOL DATE: **4/5/06**

BATTELLE PROJECT CODE: FG487118-01 or PROPOSAL NUMBER: _*(if preaward)*

NATURE OF REVIEW: *(check one)*

- [ ] FULL MEETING DATE: _____
- [X] EXPEDITED *(specify reason)*: minimal risk; signed consent waived
- [ ] EXEMPT *(specify reason)*: _____

TYPE OF APPROVAL: *(check one)*

- [ ] PRELIMINARY. SCHEDULE NEXT REVIEW PRIOR TO INVOLVEMENT OF HUMAN SUBJECTS.
- [ ] PRETEST/PILOT TEST. SCHEDULE NEXT REVIEW PRIOR TO FULL IMPLEMENTATION.
- [X] FULL IMPLEMENTATION.
- [ ] RENEWAL/CONTINUING REVIEW.
- [ ] AMENDMENT DATED

Please note the following requirements:

PROBLEMS OR ADVERSE REACTIONS: If any problems in treatment of human subjects or unexpected adverse reactions occur as a result of this study, you must notify the IRB Chairperson immediately, then complete an Adverse Event/Incident Report and forward it to the CPHRE IRB Administrator.

CHANGES IN PROTOCOL: If there are any changes in procedures or study protocol, you must notify the IRB Chairperson and submit the revisions for review before they are implemented.

RENEWAL: You are required to apply for renewal of approval at least annually for as long as the study is active unless the Board finds it necessary to require more frequent reviews. Your next continuing review date should be as soon as procedures for staff recruitment are developed.

M. R. Pennybacker 4/12/06
IRB Chairperson Date

Margaret R. Pennybacker, PhD, CIP
Print or Type Name

__X__ Copy of approved Informed Consent on file.

cc: Project Director
IRB Administrator

Project Team Contacts

You may contact any of the following people if you have questions, concerns, or complaints about the research study.

Battelle Project Director:

Jennifer Brustrom
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brustromj@battelle.org

Centers for Disease Control and Prevention (CDC) Project Coordinator:

Judy Thibadeau
Centers for Disease Control and Prevention
Division of Human Development and Disability, MS-E-88
1600 Clifton Road, Atlanta, GA 30333
(404) 498-3559
(404) 498-3060 (fax)
jthibadeau@cdc.gov

If you have any questions or concerns about your rights as a research participant, please call:

Battelle Institutional Review Board Chair:

Battelle/CPHRE IRB Chair
100 Capitola Drive
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