

Battelle

The Business of Innovation

**Centers for Public Health
Research and Evaluation**

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October 2, 2007

Diane Manninen, PhD
Battelle/CPHRE
1100 Dexter Avenue North
Suite 400
Seattle, WA 98109

Dear Dr. Manninen:

As Chair of the Battelle/CPHRE Institutional Review Board (IRB) I have reviewed the continuing review and modifications submission dated 9/27/2007 for the study entitled "Assessing Diabetes Detection Initiative for Policy Decisions" (FG487114-01) and grant expedited approval to continue with the study. The changes are minor and do not affect the risk/benefits ratio.

As with all Battelle/CPHRE studies, this study will be subject to continuing review again next year if still active. The current approval expires 10/1/2008. We will send you notification at the appropriate time. In the meantime, should any additional 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 R. Pennybacker, PhD, CIP
IRB Chair

cc: Brigette Brevard
Contracts
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: Diane Manninen

PROJECT TITLE: Assessing Diabetes Detection Initiative for Policy Decisions

CLIENT: CDC

PROTOCOL DATE: 9/27/07

BATTELLE PROJECT CODE: FG487114-01

or PROPOSAL NUMBER: (if preaward)

NATURE OF REVIEW: (check one)

<input type="checkbox"/>
<input checked="" type="checkbox"/>
<input type="checkbox"/>

FULL MEETING DATE: _____

EXPEDITED (specify reason): minimal risk; minor changes; no change to risk/benefits

EXEMPT (specify reason): _____

TYPE OF APPROVAL: (check one)

<input type="checkbox"/>
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<input type="checkbox"/>
<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>

PRELIMINARY. SCHEDULE NEXT REVIEW PRIOR TO INVOLVEMENT OF HUMAN SUBJECTS.

PRETEST/PILOT TEST. SCHEDULE NEXT REVIEW PRIOR TO FULL IMPLEMENTATION.

FULL IMPLEMENTATION.

RENEWAL/CONTINUING REVIEW.

AMENDMENT DATED 9/27/2007

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 on or before 10/1/08.

Margaret Pennybacker 10, 2, 07
IRB Chairperson Date

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

Copy of approved Informed Consent on file.

cc: Project Director
IRB Administrator