January 27, 2009

Diane Manninen, PhD
Battelle CPHRE
1100 Dexter Avenue North
Suite 400
Seattle, WA 98109-3598

Dear Dr. Manninen:

As Chair of the Battelle/CPHRE Institutional Review Board (IRB) I have reviewed the continuing review/modifications submission with revised material and responses to the Board's January 31, 2008 review of the study entitled "Developing a Protocol for a Follow-up Study of HPV Testing Among Women Undergoing Routine Cervical Cancer Screening" (FG601906-01) and grant final approval contingent upon obtaining a Certificate of Confidentiality to provided added protections to the provider survey data. Please forward a copy of the Certificate of Confidentiality to the Board when it is received.

As with all Battelle/CPHRE studies, this study will be subject to continuing review again next year. The current approval expires 1/26/2010. 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 Pennybacker

Margaret R. Pennybacker, PhD
IRB Chair

cc: Brigette Brevard
Contracts
Jan Jaeger

Battelle/Centers for Public Health Research and Evaluation

100 Capitola Drive, Suite 200
Durham, NC 27713
Federal-wide Assurance No. FWA00004696 (IRB No. 284)

INSTITUTIONAL REVIEW BOARD NOTICE OF APPROVAL

PROJECT DIRECTOR: Diane Manninen, PhD

PROJECT TITLE: Developing a Protocol for a Follow-up Study of HPV Testing Among Women Undergoing Routine Cervical Cancer Screening

CLIENT: CDC PROTOCOL DATE: 1/3/08

BATTELLE PROJECT CODE: FG601906-01 or PROPOSAL NUMBER: ___*(if preaward)*

NATURE OF REVIEW: *(check one)*

- [X] FULL MEETING DATE: **1/31/2008; final approval by Chair 1/27/09**
- [ ] EXPEDITED *(specify reason)*: _____
- [ ] 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.
- [X] RENEWAL/CONTINUING REVIEW.
- [X] AMENDMENT DATED 1/22/2009

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 1/26/2010.

Margaret Pennybacker 1/27/09

IRB Chairperson Date

Margaret R. Pennybacker, PhD
Print or Type Name

X Copy of approved Informed Consent on file.

cc: Project Director
IRB Administrator