Battelle Memorial Institute
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Federalwide Assurance FWA00004696
Battelle Institutional Review Board: CPHRE Line of Review No.IRB00000284

INSTITUTIONAL REVIEW BOARD NOTICE OF APPROVAL

Principal Investigator/Project Manager : Carlyn Orians

Proposal/Project Title : Evaluating the Implementation and Outcomes of Policy and Environmental Cancer Control Interventions

Client/Funding Agency : CDC

IRB No. : N/A **Date of Submission to IRB :** 11/29/2012

Proposal No. : N/A **Project No. :** 100007582-Option1-1
(including Task Order and/or Delivery Order)

Subcontract to Battelle from N/A (if applicable)

Subcontract from Battelle to N/A (if applicable)

Level of Review

☒ __Expedited approval granted 12/13/2012_____ *(Category/Reason)*

Minimal risk, no problems reported.

Type of Approval – See Page 2 of 3 for Requirements and Restrictions

☒ Continuing review & full study implementation

Margaret Pennybacker

_____ ____12/13/2012_____
Signature Date
Official, Battelle Institutional Review Board, CPHRE Line of Review

__Margaret R. Pennybacker, PhD_____
Print or Type Name

Requirements and Restrictions

IRB Requirements: _____.

Per 45 CFR 46.109(e), the IRB has the authority to observe or to have a third party observe the consent process and the research.

Per 45 CFR 46.113, the IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects.

Continuing Review/Approval. Federal regulations require that human subjects research protocols maintain IRB approval for the entire duration of the research study, including data analysis and report writing. Apply for continuing approval of 100007582-Option1-1 prior to_**12/12/2013**_, the final day of approval.

Approval for Amendments. Seek the IRB's approval for any proposed amendments/ revisions to the protocol, including changes to study documents and recruiting materials. Federal regulations require that the IRB re-review and re-approve human subjects research prior to implementing any proposed amendments or revisions. Complete and submit an application for amendment to the IRB manager.

Reporting. The following events must always be reported to the IRB:

- Unforeseen events (within one (1) hour of discovery). If, during the course of the research study, there are any unforeseen events (see definition of unforeseen event on page 3), notify the IRB manager within one (1) hour of discovery, then follow IRB instructions
- Protocol violations that
  - Placed a human subject at risk, or
  - Were caused by the action or inaction of a researcher
- New or changed risks to human subjects, including new findings
- Failure to follow regulations or IRB requirements
- Unresolved complaint by a human subject
- Audit, inspection, or inquiry by a federal agency
- Breach of confidentiality
- Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a human subject
- Incarceration of a human subject.

Documentation Control Requirements. Study documents and records, e.g., informed consent documents and data collection instruments, must be maintained in accordance with established confidentiality measures. Federal regulations require that all documents and records be retained for at least three (3) years after a study is formally closed. Battelle policy or client requirements may require a longer retention.

☒ Copy of approved informed consent document(s) on file.

Definitions

Expedited Review – Review of proposed research by the IRB chair or a designated voting member or group of voting members rather than by the entire IRB. Federal regulations at 45 CFR 46.110 permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research. Only the IRB can determine if a proposed research activity meets the requirements for expedited review.

Adverse Event - An event or incident not previously known or not anticipated to result from:

- The interactions or interventions used in the research;
- The collection of privately identifiable information under the research;
- An underlying disease, disorder or condition of a human subject, and/or,
- Other circumstances unrelated to the research or any underlying disease, disorder or condition of the subject.

Minimal Risk - The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Depending upon applicable regulations, “minimal risk” may be defined differently for minors and other vulnerable populations.

Nonconformance - A determination that some aspect of a research study has not been performed in accordance with applicable laws and regulations, ethical standards, Battelle policies, IRB requirements, or contractual obligations.

Unforeseen Event - An event that was unforeseen or unexpected, was related to the research, and had the potential to adversely impact a human subject or the conduct of a human subjects study. Unforeseen event(s) are reported to an IRB via an established reporting process and may include incidents that could be categorized as: (1) adverse events; (2) unanticipated problems; or (3) non-conformances.

Unanticipated Problem - An event in a human research study that is not expected given the nature of the research procedures and the subject population being studied, and suggests that the research places subjects or others at a greater risk of harm or discomfort related to the research than was previously known or recognized.