Attachment 3

Institutional Review Board Approval

Battelle
The Business of Innovation
Centers for Public Health Research and Evaluation
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August 3, 2007

Howard Fishbein, Dr. P.H.
Battelle CPHRE
2101 Wilson Boulevard
Suite 800
Arlington, VA 22201-3008

Dear Dr. Fishbein:

As Chair of the Battelle/CPHRE Institutional Review Board (IRB) I have reviewed the modifications submission dated 7/30/2007 for the study entitled "Program Assessments and Evaluations for NIEHS" (FG609916-DERTWA301) and grant expedited approval for the changes. The changes do not affect the risk/benefits ratio.

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

Sincerely,

Margaret Pennybacker

Margaret Pennybacker, PhD, CIP
IRB Chair

cc: Brigette Brevard
Contracts Office
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: Howard Fishbein

PROJECT TITLE: Program Assessments and Evaluations for NIEHS

CLIENT: NIEHS PROTOCOL DATE: 7/30/07

BATTELLE PROJECT CODE: FG609916-DERTWA301 or PROPOSAL NUMBER: _(if preaward)

NATURE OF REVIEW: *(check one)*

- [ ] FULL MEETING DATE: _____
- [X] EXPEDITED *(specify reason)*: no change to risk/benefits
- [ ] 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.
- [ ] FULL IMPLEMENTATION.
- [ ] RENEWAL/CONTINUING REVIEW.
- [X] AMENDMENT DATED 7/30/07

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 //08.

Margaret Pennybacker 8/3/07

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

SECTION 4: REQUEST FOR MODIFICATION TO AN IRB APPROVED PROTOCOL

1. Describe the proposed changes.

Include any proposed changes to the sampling plan, method of recruiting subjects, type or number of data collection procedures, length of data collection procedures, added questions or topics, or how informed consent will be obtained. Are there any changes to the potential risks and benefits of study participation?

The Battelle IRB previously granted approval for two activities involving human subjects. The first is to conduct formative key-informant interviews with 8 highly funded NIEHS asthma researchers, 1 NIEHS-funded institutional trainee grant recipient, and 1 small business researcher grant recipient who holds a U.S. Patent. These have been completed. The second activity involves interviews with end users of asthma research to measure impacts as assessed by each end user. These are curently ongoing. The third activity is to implement a survey developed with input from the first activity described above. The survey will be implemented with the universe of principal investigators who have received asthma funding from NIEHS or designated comparison agencies. This application is for approval of the survey.

Attach relevant documents

- ☐ Amended study protocol
- ☐ Revised informed consent form(s)
- ☒ Modified data collection form(s)
- ☐ Added topics or questions to be added to existing data collection forms
- ☐ Other, specify:

SECTION 5: REQUEST FOR INSTITUTIONAL REVIEW BOARD REVIEW

A. STUDY DESCRIPTION

1. Study aims/hypothesis (200-300 words)

   The purpose of the proposed primary data collection is to obtain information from grantees regarding the impact of their funded asthma research in the short-, intermediate- and long-term. This will be done through a survey of grantees that includes questions about the impact of funding on career development, the field of asthma research, public attitudes, commercial product development, clinical practice, business and industry practices, and long-term human and environmental health. The survey is attached.

2. Vulnerable populations (as defined by 45 CFR 46)

   - ☒ None
   - ☐ Minors
   - ☐ Newborns
   - ☐ Pregnant women
   - ☐ HIV infected
   - ☐ Prisoners
   - ☐ Alcohol, drug or mental health clients
   - ☐ Incompetent
   - ☐ Other, specify:

3. Describe sampling procedures (sampling plan; power calculations; stratifications)and eligibility criteria

   Survey respondents will be identified through a search of two databases for principle investigators with the word 'ASTHMA' in either research or training grant abstracts or titles: an NIH-wide database of extramural research and training grants (IMPAC II), and an EPA grants database. We will survey the universe of NIEHS-funded asthma researchers (N= 179) and comparison agency asthma researchers (N=1371). Comparison agencies include other NIH institutes (NICHD, NIAID, NIA, NHLBI), the CDC, AHRQ, and the EPA

4. Sample size: 1550

5. Describe participant recruitment procedures, including advertisements, flyers, brochures, etc. (50-100 words)

   An initial hardcopy letter on NIEHS letterhead will be sent to all survey respondents alerting them to the survey and noting that an email will come from Battelle asking them to complete a web-based survey related to asthma research. Returned letters will be tracked. An initial email will then be sent to the respondents identified through the NIH and EPA grants databases inviting them to participate in the survey, explaining the study, and obtaining informed consent. The email will provide the name and toll-free number of a staff member to call with questions about the study. The letter will also include the name and telephone number of a person to call with questions regarding Human Subjects protection. The text of the initial recruitment materials is attached.

6. Will participants receive monetary or other compensation? ☐ Yes ☒ No If Yes, describe.

B. DATA COLLECTION PROCEDURES

1. Type(s) (check all that apply, indicate methods):

   Survey: ☐ No ☒ Yes

   ☐ Mail return

☐ Self-administered at site
☐ Telephone/CATI questionnaire
☐ In-person interview/CAPI
☒ Other, specify: web survey with paper option

Record Abstraction/Match: ☒ No ☐ Yes

☐ Computerized data
☐ Hard copy data
☐ Other, specify:

Biological Specimen Collection: ☒ No ☐ Yes

Describe Type of Specimen: _____

Environmental Specimens/Measures: ☒ No ☐ Yes

☐ Air
☐ Soil
☐ Water
☐ Food
☐ Other, specify:

Laboratory Procedure or Measurement: ☒ No ☐ Yes
Describe Type of Laboratory Procedure: _____

☐ Psychological
☐ Physical
☐ Focus group
☐ Other, specify:

Other (e.g., device, drug) ☒ No ☐ Yes
Describe: _____

Private Health Information (PHI) Provided by a "HIPAA Covered Entity": ☒ No ☐ Yes

If Yes, is a Business Associate Agreement (BAA) Required? ☐ No ☐ Yes (attach copy of BAA)

2. Describe the data collection procedures (200-300 words)

There will be web and paper options for completing the survey. The initial email will provide a link and secure login to complete the survey by web. The initial email will also include an email address and telephone number to request a paper version of the survey. A paper copy of the survey with a postage-paid return envelope will be sent via express mail to all those respondents who request a paper version or for whom we do not have a valid email address. Within two weeks of this mailing, a mailed reminder postcard will be sent to all non-respondents. After tracing and verifying bounced-back emails, and after three email follow-up reminders, those respondents who have not yet completed the survey via the web will also be sent a paper copy. Survey email invitations will be sent continuously over a one-month period. Battelle will track all returned surveys in the computer system upon receipt. Within one week of the initial email, a reminder email will be sent to each respondent to encourage survey completion. Two subsequent email reminders will be sent at 4-day intervals if the survey has not yet been completed. The email (Attachment 3-3) will include a toll-free number that can be called if a respondent has any questions about completing the survey or needs to have a copy of the survey mailed. Within two weeks of sending the final email reminder, a mailing of the survey packet via express mail will be sent to non-respondents. Within two weeks of mailing the survey, one telephone follow-up call will be made to all remaining non-respondents to remind them to complete the survey. If the person is reached directly the interviewer will offer to conduct the interview over the telephone, otherwise a message will be left.

3. Is there a data analysis plan? ☐ No ☒ Yes If yes, please describe

The survey data will be analyzed using standard univariate and bivariate descriptive statistics (e.g. means, frequencies, crosstabs) and multivariate analyses. The following types of variables will be examined:

Intermediate Outcomes:

Laws, regulations and standards
Healthcare guidelines and recommendations
Accumulation of knowledge
Knowledge and attitudes

Outputs and Short-term Outcomes:
Dissemination

Training and career development
Training and certifications
Curricula/Interventions
Patents and new drug applications
Community outreach
Communities of science
Replication and new research
Commercial products and drugs
Public awareness
Commissions, Task Forces, Advisory Panels, Workgroups

C. INFORMED CONSENT PROCEDURES

Informed consent must be obtained. Copies of the informed consent forms must be attached to this application.

1. Type (Check all that apply)

CONSENT # 1 **Form Title:** **Invitation letter and invitation email**

☒ Written, not signed
☐ Written and signed
☐ Verbal, not signed

CONSENT # 2 **Form Title:**

☐ Written, not signed
☐ Written and signed
☐ Verbal, not signed

CONSENT # 3 **Form Title:**

☐ Written, not signed
☐ Written and signed
☐ Verbal, not signed

2. Is/are copy(ies) of the consent form(s) left with the respondent? : ☐ No ☐ Yes

3. Informed consent is a process. Describe how participants will be informed and how their questions will be answered (200-300 words)

For the web survey, respondents will first receive an invitation letter that states the purpose of the survey, tells them why they were selected, and gives them information about how long the survey will take. The subsequent email reiterates the purpose and provides telephone numbers for respondents to call to clarify questions they may have about the survey, the purpose of the study, and how data will be used. Respondents are told that their participation is voluntary and that they have the option to skip any question they would prefer not to answer and to quit the survey at any time. We will not ask respondents to complete a consent form. We assume that after reading through the invitation materials, their willingness to go to the link and complete the survey (or complete a hardcopy version) is evidence of implied consent.

D. POTENTIAL RISKS

1. Type (check all that apply)

☐ Minimal physical
☒ Minimal psychological/social/legal
☐ Substantial physical

☐ Substantial psychological/social/legal

2. Description of potential risks (100-200 words)

There is no physical risk or direct benefit to participants in this study. Psychological risks and benefits are estimated to be minimal. Respondents may feel uncomfortable answering questions, although the questions are not personal in nature

E. POTENTIAL BENEFITS

1. Information provided to study participants

☒ No direct benefit
☐ Medical or physical data
☐ Sociological data
☐ Psychological data
☐ Environmental data
☐ Other, specify:

2. Services provided to study participants

☒ No direct services provided
☐ Medical or rehabilitation treatment
☐ Social/economic service
☐ Psychological counseling
☐ Environmental cleanup or correction
☐ Other, specify:

F. PROTECTION OF SUBJECTS

1. Guarantees

☐ Anonymity (no link between individual and data)
☒ Confidentiality

2. Special procedures to reduce or alleviate risks

☐ Medical treatment
☐ Counseling
☐ Environmental remediation
☐ Application has been made for a Certificate of Confidentiality
☒ Other, specify: see below

3. Describe any other procedures to reduce or alleviate risks including measures to protect confidentiality (100-200 words)

In training project staff, we will emphasize the steps that will be taken to protect the confidentiality of the data that are collected. Completed hardcopy survey questionnaires will be stored in locked file cabinets. All project files will be password protected and access to the files will be limited to authorized project staff. Surveys entered online will be password protected and will not allow access once the respondent has completed the survey. The web survey will be hosted on a secure server protected with a Secure Sockets Layer (SSL) certificate and 128-bit encryption, the strongest online data encryption protection available. Project reports will not identify individuals who completed the survey.

G. RISK/BENEFIT RATIO

1. Weigh the potential risks and benefits of participation (100-200 words)

   There is no physical risk to participating and psychological risks are minimal. Respondents may feel uncomfortable answering questions, however, the questions are not personal in nature. Participants are also free to not answer a question if they choose. There are no direct benefits from participating, although participants may feel that by sharing their opinions they are making a valuable contribution to our understanding of the impact of NIEHS and other agency funded asthma research

2. Special issues, type of risk

   - [x] None
   - [ ] Collaborative research
   - [ ] Follow-on studies
   - [ ] Required to release information to authorities (e.g., reporting suspected child abuse)
   - [ ] Other, specify:

3. Conclusion

   - [x] Minimal risk, minimal benefit
   - [ ] Minimal risk, substantial benefit
   - [ ] Substantial risk, substantial individual benefit
   - [ ] Substantial risk, substantial research/society benefit
   - [ ] Other, describe:

REMEMBER TO ATTACH COPIES OF PROPOSED CONSENT FORMS, INTERVIEW SCRIPTS, DATA COLLECTION INSTRUMENTS, DESCRIPTION OF RECRUITMENT MATERIALS,IF ANY, AND ANY OTHER RELEVANT DOCUMENTS YOU FEEL WILL BE HELPFUL TO THE BOARD IN THIS REVIEW. THANK YOU.