INSTITUTIONAL REVIEW BOARD NOTICE OF APPROVAL

IRB No. 0652-100086358 Rev 0.0

Principal Investigator/Project Manager : Gary Chovnick

Proposal/Project Title : Evaluation of the SAMHSA Naloxone Education and Distribution Program

Client/Funding Agency : NIH/National Centers for Disease Control and Prevention

IRB No. : 0652-100086358 Rev 0.0 **Date of Submission to IRB:** 16 May 2017

Proposal No. : OPP204267 **Project No. :** 100086358-Task2

Subcontract to Battelle from N/A (if applicable)

Subcontract from Battelle to N/A (if applicable)

Level of Review – Initial IRB Review and Approval

☒ Expedited. Minimal risk to participants. 45 CFR 46.110 (b)(1) Category 7, "Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies"

HIPAA not indicated. Controls to assure privacy and data confidentiality for data collected from key informants, stakeholders, and laypersons are adequate. The Battelle IRB does not require that the study solicit or obtain a NIH Certificate of Confidentiality.

IAW 45 CFR 46.117(c), the Battelle IRB waives the requirement for the Investigator to obtain a signed informed consent form for ALL human subjects in the research. The Battelle IRB has found that the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality.

The Investigator will ask each human subject if he / she wants documentation linking the subject with the research, and the subject's wishes will govern. However, since many study interactions with human subjects will occur remotely, e.g., as telephone conversations, the IRB does not require the Investigator to provide subjects with a written statement regarding the research.

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

☒ Requires prior U.S. OMB review and approval before engaging any human subjects in research. Battelle IRB's approval continues to 16 May 2018.

Rosalee Meyer 5/23/2017

Signature Date

Co-Chair, Battelle Institutional Review Board

Rosalee Meyer, Ph.D.

Print or Type Name

Requirements and Restrictions

A. **All study documentation requires prior review and approval by U.S. Office of Management and Budget (OMB) before the study may engage ANY Human Subjects in research**
B. Any problems of a serious nature resulting from implementation of this protocol should be brought to the attention of the Battelle IRB, and any proposed changes should be submitted for IRB approval before they are implemented.
C. 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.
D. 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. If the formal study remains pending approval by 16 May 2018 (the final day of approval), apply for continuing approval of IRB No. 0652-100086358 Rev 0.0

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 four (4) hours of discovery. See definition of Unforeseen Event on page 3 of 3.
- 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.

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 regulation.

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 – A Battelle-coined term that has no regulatory equivalent, but that may summarize one or more of the following terms: (1) adverse events; (2) unanticipated problems involving subjects or others; or (3) non-conformances. Unforeseen Events must be reported to an IRB via an established reporting process

Unanticipated Problem Involving Subjects or Others - 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.