

Notice of Exemption from Federal Regulations for the Protection of Human Subjects Form

**IRB 0840-
G32713.OY1F10
Rev 0.0**

Battelle Institutional Review Board

Lisa John / Stephanie Peak

Principal Investigator/Project Manager: _____

Proposal/Project Title: _____ National Tobacco Education Campaign – (NTEC / TIPS Campaign)

Client/Funding Agency: _____ PlowShare Group (Lead Organization) /
Centers for Disease Control and Prevention (Funding Agency)

IRB No: _____ IRB 0840-G32713.OY1F10, Rev 0.0 **Date of Submission to IRB:** _____ 4/28/2022

Contract No: _____ CON00032713 **Project Code:** _____ G32713.XX.X1.0001.OY1F10
(OY1 - OY1TASKF10-Formativ)

Subcontract to Battelle from: _____ N/A

Subcontract from Battelle to: _____ N/A

<p style="text-align: center;">Level of Review:</p> <p>Exemption from Regulation:</p> <p>This research activity poses a minimal risk to human subjects</p>	<p style="text-align: center;">Exemption per 45 CFR 46.104(b)(2)(i)</p> <p>(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), <u>survey procedures</u>, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:</p> <p>(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;</p>
<p style="text-align: center;">Basis for Ruling</p>	<p>Survey research to assess efficacy of proposed advertisements to promote cessation of use for nicotine-containing products. This ruling applies to the scope(s) of work for Battelle (data analysis/reporting) and for the Qualtrics organization (data collection).</p> <p>Perceived minimal risk to human subjects. Subject population will be legal adults who have voluntarily chosen to use tobacco products and/or other nicotine-containing products AND to participate in surveys/in-depth interviews via the Toluna web-based panel service(s). Respondents are self-described U.S. residents who have agreed to the terms of Toluna's published Privacy/ Confidentiality Policies. Survey implementation assures that all collected study data will be disconnected from respondents' identities and IP address. Toluna will have no access to study data and Qualtrics, Battelle and CDC will have no access to any respondent's identifiable, private information. Respondents' demographic information may include sensitive information but is voluntarily disclosed and all privacy and data confidentiality measures are adequate. All project outputs will be recorded in aggregate. Small remuneration offered for participation. The respondent's agreement to participate will be documented via the study screener.</p>

While this study qualifies for a formal EXEMPTION from federal regulations (2018 Common Rule at 45 CFR 46, Subpart A) for the protection of human subjects, IRB 0840-G32713.OY1F10, Rev 0.0. will continue under Battelle IRB oversight. 2023.

Oversight requirements include:

- The IRB will request a status update of this project at least once every 365 days.
- Events or other conditions potentially resulting in a loss of human subjects' privacy or lapse of data confidentiality must be reported to the IRB.
- Any audit, inspection or inquiry by a federal agency must be reported to the IRB.
- If changes, amendments, or addenda to the Work Plan are anticipated, advise the IRB. If the IRB determines that an application for amendment is warranted, submit the application and supporting documentation to the IRB before instituting Work Plan changes.

Human Protections Administrator Gary M. Sapp, MS, CIP, CIM

Title

Name

Signature

Date