

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

**IRB 0840-
G32713.XX.X3
Rev 3.0**

Battelle Institutional Review Board

Principal Investigator/Project Manager / Project Director: Lisa John / Stephanie Peak / Andrew Davis

Proposal/Project Title: National Tobacco Education Campaign – (NTEC / TIPS Campaign) Rough Cut Testing with Adults Who Smoke Cigarettes

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

IRB No: IRB 0840-G32713.XX.X3 Rev 3.0 **Date of Submission to IRB:** Dated 9/24/2024; received by IRB on 9/30/2024

OPP Number / Contract No: OPP226786 / CON00032713 – No change planned at this time **Project Code:** G32713.XX.X3.303F.000001 (Formerly G32713.XX.X1.0001.OY1F10)

Subcontract to Battelle from: N/A

Subcontract from Battelle to: Sago (Adnan Habib; PM)

Level of Review:	
<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>Basis for Ruling</p> <p>This is an Approval of Amendments, including the addition of a new study survey expected to engage 10,800 respondents and the addition of new study personnel (personnel will not have access to identifying information) Survey to include minor edits from historic survey, including OMB-updated categories for demographic categories. No planned deviation from previously established panels.</p> <p style="text-align: center;">Issued as Rev 3.0</p>	<p>Amendment to include a new survey to test 12 short ads. 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), Plowshare (Lead Investigator) and for the Sago organization and its partner panels (recruiting and data collection).</p> <p>Perceived minimal risk to human subjects. Subject population will be legal adults, English speakers, who have voluntarily chosen to use tobacco products and/or other nicotine-containing products AND who have voluntarily chosen to take part in focus groups/surveys/interviews administered participate in surveys/in-depth interviews via the Sago online survey/questionnaire web-based data collection(s). Respondents are self-described U.S. residents who have voluntarily agreed to the terms of Sago's and its associated vendor/panels' published Privacy/Confidentiality Policies. Data collection results will be maintained by Sago in accordance with their established privacy policies and will be provided to Battelle (and, hence, to Plowshare/CDC) with no participant's identifiable, private information. All results/project outputs will be reported in aggregate and there will be no association between Sago-held information and project outputs. Respondents' demographic information may include sensitive information but is voluntarily disclosed and all privacy and data confidentiality measures are adequate. Small remuneration offered for participation. The respondent's agreement to participate will be documented via the study recruiting 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.XX.X3 Rev 3.0 will continue under Battelle IRB oversight.

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.

Approved on behalf of Battelle and the Battelle Institutional Review Board

Signed by: *Gary Sapp* 30 September 2024

 Signer Name: Gary Sapp
 Signing Reason: I approve this document
 Signing Time: 30 September 2024 | 2:54:39 PM EDT
 E93C65716C4D46B0AA1DC994695C1FDA

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

Title	Name	Signature	Date
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	Columbus, OH 43201
	sappg@battelle.org
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Intermediary Delivery Events	Status	Timestamp
Certified Delivery Events	Status	Timestamp
Carbon Copy Events	Status	Timestamp
Witness Events	Signature	Timestamp
Notary Events	Signature	Timestamp
Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	9/30/2024 2:54:15 PM
Certified Delivered	Security Checked	9/30/2024 2:54:33 PM
Signing Complete	Security Checked	9/30/2024 2:54:59 PM
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