

# 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)

<b>Level of Review:</b>	
<b>Exemption from Regulation:</b>	<b>Exemption per 45 CFR 46.104(b)(2)(i)</b>
This research activity poses a minimal risk to human subjects	(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:
	(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;
<b>Basis for Ruling</b>	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).
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.	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.
<b>Issued as Rev 3.0</b>	


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
-------	------	-----------	------



**Certificate Of Completion**

Envelope Id: EF2D6BEB2B7144169C92A4C09F9045E2	Status: Completed
Subject: Complete with DocuSign: NoticeofExemption IRB 0840 Rev 3.0 September 2024.docx	
Source Envelope:	
Document Pages: 1	Signatures: 1
Certificate Pages: 5	Initials: 0
AutoNav: Enabled	Envelope Originator:
Envelope Stamping: Disabled	Gary Sapp
Time Zone: (UTC-05:00) Eastern Time (US & Canada)	505 King Ave.
	Columbus, OH 43201
	sappg@battelle.org
	IP Address: 131.167.254.200

**Record Tracking**

Status: Original	Holder: Gary Sapp	Location: DocuSign
9/30/2024 2:53:32 PM	sappg@battelle.org	
Security Appliance Status: Connected	Pool: FedRamp	
Storage Appliance Status: Connected	Pool: Battelle CFR Part 11 Compliant	Location: DocuSign

**Signer Events**

Signer Events	Signature	Timestamp
Gary Sapp	<i>Gary Sapp</i>	Sent: 9/30/2024 2:54:15 PM
sappg@battelle.org		Viewed: 9/30/2024 2:54:33 PM
Security Level: Email, Account Authentication (Required), Login with SSO		Signed: 9/30/2024 2:54:59 PM
	Signature Adoption: Pre-selected Style	
	Signature ID:	
	E93C6571-6C4D-46B0-AA1D-C994695C1FDA	
	Using IP Address: 131.167.254.200	
	With Signing Authentication via DocuSign password	
	With Signing Reasons (on each tab):	
	I approve this document	

**Electronic Record and Signature Disclosure:**  
 Accepted: 2/14/2023 2:56:09 PM  
 ID: 2df30876-5bd2-484f-8c75-c2553b610406

In Person Signer Events	Signature	Timestamp
Editor Delivery Events	Status	Timestamp
Agent Delivery Events	Status	Timestamp
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
Completed	Security Checked	9/30/2024 2:54:59 PM

**Payment Events**

**Status**

**Timestamps**

**Electronic Record and Signature Disclosure**

## **ELECTRONIC RECORD AND SIGNATURE DISCLOSURE**

From time to time, Battelle CFR Part 11 (we, us or Company) may be required by law to provide to you certain written notices or disclosures. Described below are the terms and conditions for providing to you such notices and disclosures electronically through the DocuSign system. Please read the information below carefully and thoroughly, and if you can access this information electronically to your satisfaction and agree to this Electronic Record and Signature Disclosure (ERSD), please confirm your agreement by selecting the check-box next to 'I agree to use electronic records and signatures' before clicking 'CONTINUE' within the DocuSign system.

### **Getting paper copies**

At any time, you may request from us a paper copy of any record provided or made available electronically to you by us. You will have the ability to download and print documents we send to you through the DocuSign system during and immediately after the signing session and, if you elect to create a DocuSign account, you may access the documents for a limited period of time (usually 30 days) after such documents are first sent to you. After such time, if you wish for us to send you paper copies of any such documents from our office to you, you will be charged a \$0.00 per-page fee. You may request delivery of such paper copies from us by following the procedure described below.

### **Withdrawing your consent**

If you decide to receive notices and disclosures from us electronically, you may at any time change your mind and tell us that thereafter you want to receive required notices and disclosures only in paper format. How you must inform us of your decision to receive future notices and disclosure in paper format and withdraw your consent to receive notices and disclosures electronically is described below.

### **Consequences of changing your mind**

If you elect to receive required notices and disclosures only in paper format, it will slow the speed at which we can complete certain steps in transactions with you and delivering services to you because we will need first to send the required notices or disclosures to you in paper format, and then wait until we receive back from you your acknowledgment of your receipt of such paper notices or disclosures. Further, you will no longer be able to use the DocuSign system to receive required notices and consents electronically from us or to sign electronically documents from us.

### **All notices and disclosures will be sent to you electronically**

Unless you tell us otherwise in accordance with the procedures described herein, we will provide electronically to you through the DocuSign system all required notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you during the course of our relationship with you. To reduce the chance of you inadvertently not receiving any notice or disclosure, we prefer to provide all of the required notices and disclosures to you by the same method and to the same address that you have given us. Thus, you can receive all the disclosures and notices electronically or in paper format through the paper mail delivery system. If you do not agree with this process, please let us know as described below. Please also see the paragraph immediately above that describes the consequences of your electing not to receive delivery of the notices and disclosures electronically from us.

### **How to contact Battelle CFR Part 11:**

You may contact us to let us know of your changes as to how we may contact you electronically, to request paper copies of certain information from us, and to withdraw your prior consent to receive notices and disclosures electronically as follows:

To contact us by email send messages to: [CITServiceDesk@battelle.org](mailto:CITServiceDesk@battelle.org)

### **To advise Battelle CFR Part 11 of your new email address**

To let us know of a change in your email address where we should send notices and disclosures electronically to you, you must send an email message to us at [CITServiceDesk@battelle.org](mailto:CITServiceDesk@battelle.org) and in the body of such request you must state: your previous email address, your new email address. We do not require any other information from you to change your email address.

If you created a DocuSign account, you may update it with your new email address through your account preferences.

### **To request paper copies from Battelle CFR Part 11**

To request delivery from us of paper copies of the notices and disclosures previously provided by us to you electronically, you must send us an email to [CITServiceDesk@battelle.org](mailto:CITServiceDesk@battelle.org) and in the body of such request you must state your email address, full name, mailing address, and telephone number. We will bill you for any fees at that time, if any.

### **To withdraw your consent with Battelle CFR Part 11**

To inform us that you no longer wish to receive future notices and disclosures in electronic format you may:

- i. decline to sign a document from within your signing session, and on the subsequent page, select the check-box indicating you wish to withdraw your consent, or you may;
- ii. send us an email to [CITServiceDesk@battelle.org](mailto:CITServiceDesk@battelle.org) and in the body of such request you must state your email, full name, mailing address, and telephone number. We do not need any other information from you to withdraw consent.. The consequences of your withdrawing consent for online documents will be that transactions may take a longer time to process..

### **Required hardware and software**

The minimum system requirements for using the DocuSign system may change over time. The current system requirements are found here: <https://support.docusign.com/guides/signer-guide-signing-system-requirements>.

### **Acknowledging your access and consent to receive and sign documents electronically**

To confirm to us that you can access this information electronically, which will be similar to other electronic notices and disclosures that we will provide to you, please confirm that you have read this ERSD, and (i) that you are able to print on paper or electronically save this ERSD for your future reference and access; or (ii) that you are able to email this ERSD to an email address where you will be able to print on paper or save it for your future reference and access. Further, if you consent to receiving notices and disclosures exclusively in electronic format as described herein, then select the check-box next to ‘I agree to use electronic records and signatures’ before clicking ‘CONTINUE’ within the DocuSign system.

By selecting the check-box next to ‘I agree to use electronic records and signatures’, you confirm that:

- You can access and read this Electronic Record and Signature Disclosure; and
- You can print on paper this Electronic Record and Signature Disclosure, or save or send this Electronic Record and Disclosure to a location where you can print it, for future reference and access; and
- Until or unless you notify Battelle CFR Part 11 as described above, you consent to receive exclusively through electronic means all notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you by Battelle CFR Part 11 during the course of your relationship with Battelle CFR Part 11.