

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

IRB 0637- 100071230 Rev 0.0
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**Battelle Institutional Review Board**

**Principal Investigator/Project Manager:** \_\_\_\_\_ Robert Alexander / Lisa John  
**Proposal/Project Title:** \_\_\_\_\_ "National Tobacco Education Campaign – Creative Concepts Phase"  
**Client/Funding Agency:** \_\_\_\_\_ PlowShare Group (Client) /  
 \_\_\_\_\_ Centers for Disease Control and Prevention (Funding Agency)  
**IRB No:** \_\_\_\_\_ IRB 0637-100071230, Rev 0.0      **Date of Submission to IRB:** \_\_\_\_\_ 12/06/2016  
**Contract No:** \_\_\_\_\_ CON00024586      **Project No:** \_\_\_\_\_ 100071230-TASKE6  
**Subcontract to Battelle from:** \_\_\_\_\_ N/A  
**Subcontract from Battelle to:** \_\_\_\_\_ N/A

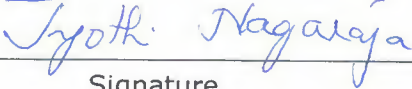
<b>Level of Review: Exemption</b>	Exemption per 45 CFR 46.101(b)(2), 2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; <u>and</u> (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
<b>Basis for Ruling</b>	This ruling applies to the scope(s) of work for Battelle (data analysis/ reporting) and for the Qualtrics organization (coordination – data collection).  Perceived minimal risk to human subjects. Subject population are legal adults who have voluntarily chosen to use tobacco products/E-cigarettes and to participate in surveys/in-depth interviews/focus groups via the Toluna web-based panel services. Respondents have agreed to Toluna's published Privacy/Confidentiality Policies. Qualtrics, Battelle and CDC will have no direct access to any subject identifiers. Privacy and data confidentiality measures are adequate. All project outputs will be recorded in aggregate. The IRB acknowledges that a prospective subject's agreement to participate in the Focus Group will be documented via the Focus Group questionnaire.

While this study qualifies for a formal EXEMPTION from federal regulations (45 CFR 46, Subpart A) for the protection of human subjects, IRB 0637-100071230 Rev 0.0. will continue under Battelle IRB oversight to 5 December 2017.

Oversight requirements include:

- The IRB will request a status update of this project at least once every 365 days.
- Unforeseen 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.

This phase of the project (IRB 0637; "Creative Concepts") follows the "Message Platform Testing" phase (previously approved by the Battelle IRB as IRB 0627-100071230, Rev 0.0). Data collection for the "Message Platform Testing" phase has ended and the project is analyzing study data. Upon final analysis of data, IRB 0627 will be closed out.

IRB Member	Jyothi Nagaraja, MS	 _____	12/08/2016 _____
Title	Name	Signature	Date
Primary Reviewer, Battelle Institutional Review Board (IRB)			