IRB APPROVAL CERTIFICATION

Modification - Study

Salus IRB Board 5 #IRB00013544
Roster dated 16September2022

IRB Signature

Signature Jean Taylor-Woodbury By LW 11/14/2022
Jean Taylor-Woodbury, RN, MS, ANP-BC, Chair Leslie Wilson Date

Review and Approval Information

Salus IRB Study Number 22095 - 01A
Approval Date Sunday, November 13, 2022
Review Process Expedited
Expiration Date Friday, June 2, 2023 at 11:59 PM

This document certifies the IRB's approval of the bolded items identified under "Documents Approved" to be conducted by the named Principal Investigator.

A waiver of the requirement for documentation of informed consent is granted according to 45 CFR 46.117(c)(2).

In accordance with 45 CFR §46.404, the IRB made the following determinations:
- No greater than minimal risk to children is presented (§46.404).
- Assent is required of some of the children, as defined in the protocol (§46.408(c)).
- Assent will be documented, using the approved assent form or as outlined in the protocol (§46.408(g)).
- Permission of one parent/guardian is sufficient even if the other parent/guardian is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child, unless restricted by state law (§46.408).
- Permission by parents/guardians shall be documented in accordance with §46.117(a).
- Wards may not be included (§46.409).

All translated documents must be submitted to the IRB, including certifications, prior to enrollment of Non-English speaking subjects.

In accordance with §46.109(f), the requirement for continuing review does not apply to this study. IRB approval will not expire on the stated expiration date, however a continuing review check-in process must be completed on or before the stated expiration date. Any changes to research activity continue to require IRB approval prior to implementation, except when necessary to eliminate apparent immediate hazards to the subject.

NOTE: Subjects must be asked for their consent using the most recently approved, stamped version(s). All IRB approved consent documents are version controlled and may not be modified in any way without prior IRB approval. Use of an unapproved document may constitute non-compliance.

Study

2022 Hispanic/Latino Youth and Young Adult Tobacco Use Online Survey Study

Client IQ Solutions, Inc.
Sponsor US Food and Drug Administration

Principal Investigator

Everly Macario, Sc.D, MS, Ed.M

E&I PI Number 16705 - 001

Address

IQ Solutions, Inc.
11300 Rockville Pike, Suite 901
Rockville, MD 20852

Performance Sites

IQ Solutions, Inc., 11300 Rockville Pike, Suite 901, Rockville, MD 20852

Documents Approved	Document #	Version	Date
Protocol		**3**	**11/2/2022**
Web-Assent/Consent Form	E&I 06/07/2022	2	May 18, 2022
Web-Cognitive Interview Consent Form	E&I 06/07/2022	2	May 18, 2022

This is a multi-sided document.

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Web-Parental Opt-Out Form	E&I 06/07/2022	3	June 1, 2022
Survey Screener	**Attachment C**		**11.2.22**
Survey Instrument	**Attachment D**		**11/2/2022**
Cognitive Interview Recruitment Screener	Attachment E		4.18.22
Cognitive Interview Screener Contact Sheet	Attachment F		4.18.22
Cognitive Interview Guide	Attachment K		4.18.22

Stipulations of Approval

1. No subjects may be involved in any study procedure prior to the IRB approval date or after the expiration date, unless otherwise stated in this letter. Investigators and sponsors are responsible for initiating Continuing Review proceedings.
2. All protocol modifications must be IRB approved prior to implementation. This includes any addition or change of recruitment materials, change of investigator, or performance site address. (Exception: If necessary to eliminate apparent immediate hazard to subjects.)
3. Report to Salus IRB within ten working days of learning if any of the following occur:
   - Unanticipated problems involving risk to human subjects or others;
   - Unanticipated Serious Adverse Events and Safety Reports;
   - Protocol deviations, violations, and exceptions that impact subject welfare or safety or study integrity including changes intended to reduce immediate risk to subjects;
   - Use of an investigational product in an emergency situation; and
   - Claims for compensation or for medical care for research-related injury.
4. Advertising and recruitment materials must be approved by Salus RIB prior to use or publication.

END

This is a multi-sided document.

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