DATE: November 6, 2015

TO: Ronne Ostby, Elizabeth Goodman, Lindsay Dashefsky, and Zoe Donnell

FROM: Janet D. Griffith, IRB Chair

SUBJECT: Institutional Review Board (IRB) Review Forms

Attached are the following forms for the recent IRB review of your research project:

1. *IRB Review Findings Form,* which documents the review and approval of the project.

2. Instructions on *Reporting Adverse Events and Unanticipated Problems*, which defines unexpected adverse events and unanticipated problems and details when and how the IRB should be notified of such events and problems. **Note—any problem or incident that could be an adverse event must be reported to the IRB according to the instructions in this form. Failure to comply with the adverse event reporting requirements could result in the suspension of your right to submit studies to the IRB and/or the suspension of IRB approval of this study.**

3. *Agreement to Comply with Human Subject Protection Requirements,* which ***must be signed*** by you and returned to the IRB. By signing this form, you agree to adhere to the human subject protection procedures that were approved by the IRB and to inform the IRB chair of any changes made to the approved procedures.

The first two forms are for your files; the signed electronic copy of the third form must be sent to the IRB at IRB@icfi.com and will be kept in the IRB files. Please maintain a copy of the third form for your records. If you have any questions about these forms, please email IRB@icfi.com or contact the IRB toll-free at 877-556-2218.

Institutional Review Board Findings Form
ICF IRB Choose an item.

Project Director(s): Ronne Ostby, Elizabeth Goodman, Lindsay Dashefsky, and Zoe Donnell

Project Title: Parents' Perceptions of Public Service Announcement Concepts on Electronic Nicotine Delivery Systems

ICF Project Number: 635211.0.026.00.005

Type of Review:

☒ New ☐ Modification ☐ Annual review

Findings of the Board:

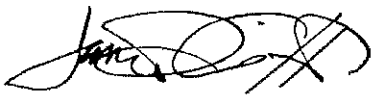
☒ Project complies with all of the requirements of 45 CFR 46, "Protection of Human Subjects"

☐ Project is exempt from IRB review (See IRB Exemption Form)

☐ Project does not comply with all of the requirements of 45 CFR 46

Project Approved Until: February 5, 2016

Next Annual Review Date: N/A



Chair, Institutional Review Board

November 6, 2015
Date

(Revised 07/18/2014)

List of Approved Project Materials:

1. Informed Consent
2. Screener
3. Moderator's Guide
4. ENDS Fact Sheet
5. Confirmation Reminder Script
6. Concept Storyboards

ICF International Institutional Review Board
Reporting Adverse Events and Unanticipated Problems

Federal human subject protection regulations require the principal investigator (PI) or project director (PD) of an IRB approved research study to report to the IRB any *unexpected adverse events* and *unanticipated problems* that occur during the conduct of the research.

What Is an Unexpected Adverse Event?

Some adverse events are expected to occur during research, while others are unexpected. An *adverse event* is considered an undesirable and unintended effect of the research occurring in study subjects or others as a result of (a) the interventions and/or interactions used in the research; or (b) the collection of identifiable private information under the research. Such events are included among the risks of participating in the research. Even though an event is unintended, we often expect that a certain number of adverse events will happen during the course of the research. For example, when conducting telephone surveys, we expect some complaints from individuals who are called. Each complaint is an adverse event and should be documented, but it is not unexpected. Research protocols should include procedures for dealing with expected adverse events (risks). An *unexpected adverse event* is one that was not anticipated in the research protocol. During the IRB review of a research study, the IRB tries to make sure that all anticipated risks have been identified and included in the informed consent form, and that there are procedures in place to minimize and address those risks.

What Is an Unanticipated Problem?

An *unanticipated problem* is considered to be any event that (a) was not expected given the nature of the research procedures and the subject population being studied; and (b) suggests that the research places subjects or others at a greater risk of harm or discomfort than was previously known or recognized. Note that it is only when both conditions (a and b) are present, that a problem is defined as *unanticipated*. Unexpected adverse events are also unanticipated problems, but there can be unanticipated problems that do not meet the definition of an unexpected adverse event.

What Must Be Reported to the IRB?

Many adverse events are anticipated possible risks of participating in the research and do not need to be reported to the IRB. For example, emotional discomfort may be a risk of participating in an interview and is identified as a risk in the informed consent form. An interview that is terminated by a subject because of emotional discomfort is an adverse event, but it is expected that some interviews will be terminated for such reasons and it should not be reported to the IRB. Only adverse events that are *unexpected* need to be reported to the IRB. If the study subject threatened suicide during the interview and suicidal ideation is not identified in the study protocol and in the informed consent as a risk of participating in the interview, the suicide threat would be an unexpected adverse event and must be reported to the IRB. Also, if the researcher anticipated that very few interviews would be terminated because of emotional discomfort, but finds that a higher number of interviews than expected are being terminated for discomfort, the risk of emotional discomfort is greater than expected and must be reported to the IRB.

Many unanticipated problems are also adverse events in that the problems are unexpected consequences of exposure to the research design and/or methods. However, there are some unanticipated problems that are not related to the research but must be reported to the IRB. For example, a field interviewer has her laptop computer stolen and the interview data are not encrypted. The study subjects have been placed at greater risk of harm from breach in confidentiality of the study. Another example of an unanticipated problem is unethical behavior on the part of a study team member when interacting with study participants or using study data. Even if an unexpected problem is not likely to happen again, it must be reported to the IRB.

Problems that do not place study subjects at increased risk of harm or discomfort do not need to be reported to the IRB. For example, the termination of employment for a field data collector because he reported administering surveys that were never administered. This problem does not have to be reported to the IRB because it did not place the study subject(s) at greater risk.

What If I'm Unsure If an Event or Problem Needs to Be Reported to the IRB?

If it is unclear to you that an event or problem should be reported to the IRB, email the IRB at IRB@icfi.com. You may also contact the Chair, Janet Griffith, at Janet.Griffith@icfi.com; the IRB Administrator, Alexandra Conway, at Alexandra.Conway@icfi.com. The IRB can also be reached toll-free at (877) 556-2218.

When Should the IRB Be Notified?

The IRB should be notified as soon as possible from the time a determination is made that an event represents an unanticipated problem or unexpected adverse event. The notification must be made within 2 weeks of the event or problem.

How Should the IRB Be Notified?

If an adverse event occurs during an IRB approved study, the PI or PD must report the event to the IRB using the IRB Adverse Event Report. Please email IRB@icfi.com to obtain a copy of the IRB Adverse Event Report.

Can I Suggest Changes In the Research Protocol When I Report the Adverse Event?

Yes. You may suggest changes, and the IRB chair will consider your suggestions. Also, the Adverse Event Report requires that you document any changes that were made as a result of the event or problem. The IRB chair will determine if such changes are adequate or if other changes are needed to protect the study subjects.

What Does the IRB Do When an Adverse Event or Unexpected Problem Is Reported?

The IRB reviews the research protocol to determine if changes are needed in the study procedures to protect subjects from the identified risk or increase in risk. The IRB has the authority to require changes in the study procedures to minimize the risk of harm to subjects. The IRB will send the PI or PD an Adverse Event Findings Form that will document any required changes to the study procedures. The IRB also submits a report to the Office of Human Research Protections (within DHHS) that documents the event or problem and any actions taken by the IRB.

Institutional Review Board

Agreement to Comply with Human Subject Protection Requirements

The following project has been found by the Institutional Review Board (IRB) to be in compliance with the human subject protection requirements as specified in 45 CFR 46.

Project Title:	Parents' Perceptions of Public Service Announcement Concepts on Electronic Nicotine Delivery Systems
Principal Investigator/Project Director(s):	Ronne Ostby, Elizabeth Goodman, Lindsay Dashefsky, and Zoe Donnell
ICF Project Number:	635211.0.026.00.005
Approval Date:	November 6, 2015
Next Continuous Review Date:	**N/A**

As the responsible principal investigator/Project Director for this project, I agree to adhere to the human subject protection procedures that were approved by the IRB and to inform the chair of the IRB when any changes are made in the approved procedures. The approved procedures include all of the following:

- Subject selection and recruitment procedures
- Data collection procedures
- Informed consent procedures
- Protection of privacy and confidentiality procedures
- Data security procedures
- Additional safeguards specified by the IRB.

If you have any questions regarding changes in procedures that are subject to IRB review, please contact the IRB Chair, Janet D. Griffith (Janet.Griffith@icfi.com), to discuss your concerns.

Also, as the responsible principal investigator or project director, I agree to cooperate with the IRB continuous annual review(s) of this project. Several weeks prior to the next annual review date listed above, the IRB Administrator will send the IRB Project Continuous Review Form or identify where to obtain the form, to complete and submit to the IRB before the annual review date. The purposes of the IRB Project Continuous Review Form are 1) to provide the IRB with updated information on the procedures used to protect the human subjects who are involved in this project, and 2) to help the IRB determine if the project is in compliance with the requirements in 45 CFR 46.

Ronne Ostby
(signature)

11/10/15
(date)

Please email an original signed copy of this form to the IRB at IRB@icfi.com. A copy of the signed form should also be maintained with your study files.

(Revised-07/18/2014)