2021 and 2023 National Youth Risk Behavior Survey

Attachment J

IRB Approval Letters

DATE: July 31, 2019

TO: Alice Roberts

FROM: Carole V. Harris, 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.* **Note—any event that could be considered as an Unanticipated Problem or Adverse Event must be reported to the IRB within 2 business days. Failure to comply with the reporting requirements could result in the suspension of IRB approval of this study and other consequences.**

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 study 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.

Institutional Review Board Findings Form
ICF IRB FWA00002349 Exp. 07/12/2023

Project Director(s): Alice Roberts

Project Title: National Youth Risk Behavior Survey

ICF Project Number: 171727

Type of Review:

☐ New Convened ☐ New Expedited ☐ Modification ☒ Continuing 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: July 30, 2020*

**All non-exempt studies require review at least annually. Continuing Review materials should be submitted to the IRB no later than 6 weeks prior to expiration of approval.*

Chair, Institutional Review Board

July 31, 2019

Date

(Revised 06/12/2018)

List of Approved Project Materials:

1. IRB Continuing Review Form

ICF International Institutional Review Board
Reporting Unanticipated Problems and Adverse Events

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 ***unanticipated problems*** or ***adverse events*** that occur during the conduct of the research.

What Is an Unanticipated Problem[1]?

An *unanticipated problem* is any event that meets all of the criteria below. The event:

a) was not expected (in terms of nature, severity, or frequency) given the research procedures described in the study protocol and IRB documents, such as the consent form, and the subject population being studied; and
b) was related or possibly related to participation in this research; possibly related means there is a reasonable possibility that the study procedures may have caused or created the event; and
c) suggests that the research places the subjects or others at a greater *risk of harm or discomfort* than was previously known or recognized. Risk of harm includes physical, psychological, economic or social harm. Note – actual harm does not need to be confirmed.

*An unanticipated problem does not have to also qualify as an adverse event.

Unanticipated problems often involve the research team and relate to the execution of the research protocol. For example:

- A field interviewer has her laptop computer stolen. The study subjects may be at greater risk of harm from breach in confidentiality of the study, so this must be reported to the IRB.
- Unethical behavior on the part of a study team member when interacting with study participants or using study data also qualifies as an unanticipated problem and must be reported to the IRB. Even if the unexpected problem is unlikely to happen again.

What Is an Adverse Event?

As defined by OHRP Guidance[2], adverse events are untoward or unfavorable occurrences in human subjects, including abnormal medical findings, symptoms, diseases or activities that are temporally associated with the subject's participation in the research, even if they are not considered to be related to the subject's participation. Adverse events include physical and psychological harms and they can occur in biomedical, social or behavioral research.

Some adverse events are expected to occur during research (e.g., a participant may feel sad when describing past suicidal ideation), and these events are included among the risks of participating in the research. Other adverse events are unexpected (e.g., a subject arrives for an interview intoxicated and unable to participate).

We may 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. Research protocols should include procedures for dealing with expected adverse events (also called "risks"). 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.

[1] https://www.hhs.gov/ohrp/sites/default/files/ohrp/policy/advevntguid.pdf
[2] Same as above

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 does not need to be reported to the IRB.

Only adverse events that are ***unexpected*** (not identified as a risk of the study), ***serious*** (indicate a risk of harm to a subject or research staff member) or occur at a ***higher than expected rate*** need to be reported to the IRB.

- If a study subject reported feeling uncomfortable (but not suicidal) during an interview, and discomfort was noted as a risk on the consent form and IRB protocol, the adverse event would not need to be reported to the IRB.
- If a study subject reported suicidal thoughts during the interview (even if suicidal ideation was listed as a risk of participating in the interview), the suicidal ideation should be reported to the IRB because it is a serious event. The IRB would confer with investigators to ensure participant protections were in place, being followed by research staff, and adequate to address identified concerns.
- If several subjects reported discomfort with interviews and discomfort was expected to occur at a low rate, the event(s) should be reported to the IRB. In this case, the risk of emotional discomfort is greater than expected or occurred at a higher rate than expected.

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

If you are uncertain that an event or problem should be reported to the IRB, contact the IRB Chair by phone (404) 929-8310 or email (Carole.Harris@icf.com or IRB@icfi.com). You may also contact the IRB Coordinator, April Carswell, at April.Carswell@icf.com.

When Should the IRB Be Notified?

The IRB should be notified as soon as possible from the time an event occurs, but no later than 2 business days 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 go the IRB SharePoint site (https://icfonline.sharepoint.com/sites/IRB/SitePages/Home.aspx) or 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.

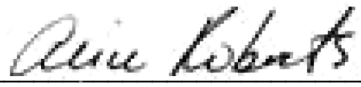
Project Title:	National Youth Risk Behavior Survey
Principal Investigator/Project Director(s):	Alice Robers
ICF Project Number:	171727
Approval Date:	July 31, 2019

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, Carole V. Harris (Carole.Harris@icfi.com), to discuss your concerns.

Also, as the responsible principal investigator or project director, I agree to cooperate with the IRB continuing review(s) of this project. I understand it is my responsibility to initiate the continuing review(s) process no later than 4 weeks prior to the next review date listed above. The IRB Project Continuing Review Form can be found on the IRB SharePoint site or obtained by contacting the IRB at IRB@icfi.com. The purposes of the IRB Project Continuing 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.



(signature)

5 August 2019

(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-06/12/2018)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)

Memorandum

Date November 7, 2019

From Denise M. Marshall, BS
IRB Administrator, Human Research Protection Office

Subject **UPDATED** CDC IRB Approval of Continuation #21 of Protocol #1969.0, "National Youth Risk Behavior Survey" (Expedited)

To Nancy Brener, PhD
NCHHSTP/DASH

CDC IRB Committee 1 has reviewed and approved the request to continue protocol #1969.0, "**National Youth Risk Behavior Survey**", for the maximum allowable period of one year. CDC IRB approval will expire on **11/10/2020**. The continuation action was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), category 4.

If other institutions involved in this protocol are being awarded CDC funds through the CDC Procurement and Grants Office (PGO), you are required to send a copy of this IRB approval to the CDC PGO award specialist handling the award. You are also required to verify with the award specialist that the awardee has provided PGO with the required documentation and has approval to begin or continue research involving human subjects as described in this protocol.

As a reminder, the IRB must review and approve all human subjects research protocols at intervals appropriate to the degree of risk, but not less than once per year. There is no grace period beyond one year from the last IRB approval date. It is ultimately your responsibility to submit your research protocol for continuation review and approval by the IRB along with available IRB approvals from all collaborators. Please keep this approval in your protocol file as proof of IRB approval and as a reminder of the expiration date. **To avoid lapses in approval of your research and the possible suspension of subject enrollment and/or termination of the protocol, please submit your continuation request along with all completed supporting documentation at least six weeks before the protocol's expiration date of 11/10/2020.**

Any problems of a serious nature must be brought to the immediate attention of the CDC IRB, and any proposed changes to the protocol are required to be submitted as an amendment to the protocol for CDC IRB approval before they are implemented.

If you have any questions, please contact your National Center Human Subjects Contact or the CDC Human Research Protection Office at (404) 639-5256 or e-mail: huma@cdc.gov.

cc: NCHHSTP Human Studies (CDC)
Nicole (Nicky) Cohen, MD