**Innovations for Poverty Action**

**IRB**

**Unexpected Event Form**

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| **IRB Protocol Number of Research Project(s) Affected:** | **Submission Date:** |
| **Title(s) of Research Project(s) Affected by the Incident:**  |
| **Principal Investigator Name and E-mail:** |
| **Project Contact Name:**  |

Upon submission of this unexpected event report, IPA IRB is charged with determining whether the incident in question meets the regulatory criteria of either (1) an unanticipated problem or (2) serious or continuing non-compliance. Please answer the questions in this form as clearly and completely as you can so that IPA IRB can make an accurate determination and advise on the appropriate next steps. If you have any questions about this form, you can see the Appendices at the end of the form with Frequently Asked Questions about unexpected events and additional definitions, and/or e-mail humansubjects@poverty-action.org.

# 1. Description of the incident:

Please describe the nature of the event that is being reported on. Include the date(s) when the deviation/incident occurred and when it was first noticed.

1. **Explain why this incident occurred as well as when and how it was detected. Please also discuss who was involved in the incident.**
2. **What was the outcome of the incident?**
3. **Is there a possibility that subjects are/were exposed to increased risk or increased harm because of this incident? How? Please explain.**

(Examples: Increased risk to subjects because their identified information is accessible to more people than originally planned, subject was hurt or died because of research participation, etc)

1. **Please state below a description of any changes to the protocol that the researchers propose as being necessary or beneficial to resolve this problem. Please be aware that if this report is approved, researchers are expected to implement these changes immediately.**

(If necessary, please submit a revised protocol and/or consent form along with the request for approval of amendment form found on the website).

1. **Please provide a detailed description of any other corrective, non-protocol actions that were taken to address this issue.**

(Example: Person X has been taken a refresher course in data security, human subjects protections, etc and has been reminded of the importance of data security in IPA protocols & procedures).

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Principal Investigator’s Signature Date

Appendices:

**A. FREQUENTLY ASKED QUESTIONS:**

*1. What is an unexpected event?*

An unexpected event is any incident that might meet the definition of an unanticipated problem or represent serious or continuing non-compliance on the part of the researchers.

*2. I’m unsure whether my incident qualifies as an unexpected events or would meet the standards of these definitions in Appendices B and C below. How do I know whether to submit?*

If there is any possibility that subjects or others experienced increased risks or additional harms as a result of your incident, and/or the protocol was not followed exactly, then you should report it with an unexpected event using this form. Submitting this form is NOT an admission of guilt; it does not necessarily mean the researchers or project staff did anything wrong. It is far better to be safe than sorry and to submit so that IPA IRB can officially tell you that nothing further is needed, rather than to have “hidden” an event that needed to be reported. Even if your event requires reporting, we are here to help you navigate all of corrective actions and reporting requirements.

*3. What is the timeline for receiving feedback on an unexpected event submission?*

Like any other submission to IPA IRB, you can expect to hear feedback on your unexpected event within 10 business days of submitting.

*4. What will happen to me or my project if this event is determined to be an unanticipated problem and/or serious or continuing non-compliance? Will my project be shut down or lose funding?*

It depends. If determined to be an unanticipated problem or serious or continuing non-compliance, IPA IRB will evaluate the event to see if the proposed changes to the protocol and non-protocol corrective actions are sufficient, if anything further is needed, or if the risks and harms are so great that IRB approval should be retracted. Events that qualify as UPs or SCN may need to be reported to various agencies, including the OHRP and donors. IPA IRB will work with the project in evaluating and communicating their reporting requirements. Though IPA IRB, OHRP, and donors all have the discretion to disapprove research or retract funding in response to UPs or SCN, this decision also considers the measures that have researchers to correct the issue.

**B. DEFINITION: Unanticipated Problem**

An unanticipated problem will meet ALL of the following criteria:

**(1) Problem is Unexpected** (in terms of nature, severity or frequency given the research and the subject population)

**(2) Problem Places Subjects or Others at Greater Risk** (potentially places subjects or others at greater risk than was previously known or recognized)

**(3) Problem is Related to Study Participation** (possibly, probably or definitely)

**C. DEFINITION: Serious or Continuing Non-Compliance**

Serious or continuing non-compliance will meet EITHER of the following criteria:

(1) significant deviation from IRB-approved study documentation (including protocols, consent forms, and questionnaires), including no informed consent obtained

(2) over an extended period of time, project / PI continues to not follow the requirements and conditions imposed by IPA IRB for approval of research

**D. PROCEDURES: Next Steps and Implications of a Determination**

IPA IRB will record in your approval letter and elsewhere in our files the following four items:

1. whether the unexpected event meets either of the above definitions
2. any additional required or recommended changes to study procedures
3. whether IRB study approval is retracted, AND
4. whether and where there are reporting requirements.

Reporting requirements to OHRP and/or donors may be triggered if the event is deemed to meet the standards described in Appendices B or C. This also depends on the project’s funding source and the terms of the projects’ grant agreements. If this qualifies as a reportable event (i.e. either an unanticipated problem or serious or continuing non-compliance), IPA IRB will reach out to the projects and the grants department to verify the projects’ funding sources and grant conditions. If required to report, IPA IRB is responsible for reporting to OHRP, and we will actively collaborate with the grants department in reporting to any relevant donor agency.

Events which meet either of the above definitions and have certain funding or grant features must be reported to OHRP according to [45 CFR 46.103(b)(5)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html). See [here](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html#Q1) for additional OHRP guidance on this.

If you have additional questions or concerns, please e-mail humansubjects@poverty-action.org.