**Innovations for Poverty Action**

**IRB**

**Unanticipated 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 Problem:** | |
| **Principal Investigator Name and E-mail:** | |
| **Project Contact Name:** | |

**\_\_\_**Yes **\_\_\_**No **Problem is Unexpected** (in terms of nature, severity or frequency given the research and the subject population)

**\_\_\_**Yes **\_\_\_**No **\_\_\_**Not sure **Problem Places Subjects at Greater Risk** (potentially places subjects at greater risk than was previously known or recognized)

**\_\_\_**Yes **\_\_\_**No **Problem is Related to study participation** (possibly, probably or definitely)

# Description of the Unanticipated Problem:

Please describe the nature of the problem. Include the date(s) when the deviation/problem occurred and when it was first noticed.

1. **Explain why the problem occurred as well as when and how it was detected:**
2. **What was the outcome of the problem?**
3. **Were the subjects adversely affected by the problem?**

If so, please explain.

1. **Please state below a description of any changes to the protocol that are required as a result of this problem.**

(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 what corrective actions will be taken to prevent future occurrences:**

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Principal Investigator’s Signature Date