**Innovations for Poverty Action Institutional Review Board (IRB)**

# REQUEST TO RE-APPROVE/RENEW RESEARCH INVOLVING HUMAN SUBJECTS

**When complete, please file this renewal form and all other required documents via** [**poverty-action.org/irb**](https://www.poverty-action.org/irb)**.**

Do **NOT** file this application via humansubjects@poverty-action.org.

Please do not hesitate to reach out to humansubjects@poverty-action.org with any additional questions you may have. In your email’s subject, please mention your study’s name, your country, and your study protocol’s number (from your approval letter, if already available).

**Required Documents:**

*Straightforward request for renewal with no changes:*

[ ]  Completed renewal form (i.e., this form)

[ ]  Copy of current, clean protocol

[ ]  Clean copies of all consents currently in use

[ ]  Clean copies of all surveys which will be re-used (with no changes) in the upcoming year

[ ]  CITI or equivalent human subjects certifications for all research staff, if expired or not already on file[[1]](#footnote-1)

*Request for renewal with changes:*

[ ]  Completed renewal form (i.e., this form)

[ ]  Protocol with tracked changes and clean versions

[ ]  Consents with tracked changes and clean versions

[ ]  Surveys with tracked changes and clean versions

[ ]  CITI or equivalent human subjects certifications for all research staff, if expired or not already on file1

*Other materials:*

[ ]  Any new marketing materials to recruit subjects

[ ]  Any new MOU or new data use sharing agreement with relevant partner or sponsoring organization(s)

[ ]  Any new IRB approval from other institution(s), including any local IRB(s)

[ ]  Any other documentation relevant to the protection of human subjects in the context of your specific study

**RENEWAL FORM**

**Date of Application**: Click here to enter a date.

**IPA IRB Protocol Number**: Click here to enter text.

**Title of Study:** Click here to enter text.

 **Former or alternate titles if known:** Click here to enter text.

 **Project IRB Contact:** Click here to enter text.

 1. What is the current status of the project?

 [ ]  On-going

 [ ]  Completed Date of completion: Click here to enter a date.

 [ ]  Still in Proposal Stage

 [ ]  On hold/stopped (please explain)

 [ ]  Other (please explain)

**Risk Status:**

2. Has any component of this project **ever (as an original application or for any amendment to the protocol)** been considered **more than minimal risk**? *(Note: Your approval letter would say “greater than minimal risk” rather than “minimal risk” if this was the case.)*

[ ]  No

[ ]  Yes

**Enrollment of human subjects:**

3. Have you enrolled any human subjects in your research so far?

[ ]  No

[ ]  Yes Estimated number: Click here to enter text.

4. Do you intend to enroll additional subjects over the next year?

 [ ]  No

 [ ]  Yes Estimated number: Click here to enter text.

1. Do you intend to collect additional data from enrolled subjects over the next year or re-contact enrolled subjects?

 [ ]  No

 [ ]  Yes Estimated number or percentage: Click here to enter text.

1. Have any subjects withdrawn from the study?

[ ]  No

[ ]  Yes If yes, how many? Click here to enter text.

Describe the circumstances and reasons given, if known.

Click here to enter text.

**Reportable Events:**

Please respond fully, even if previously reported to the IRB.

1. Adverse Events

Were there any adverse or unexpected events experienced during this study that did or could affect the human subjects involved? This refers to any incident that had to be reported in an unexpected event report. (For example a computer tablet used for research was lost or stolen.)

[ ]  No

[ ]  Yes

If yes, please explain, using continuation sheets as necessary, including the nature of the events, how they were handled, and number of subjects or PII involved.

Click here to enter text.

1. Were there any complaints from research participants about the research?

[ ]  No

[ ]  Yes If yes, how many? Click here to enter text.

Describe the circumstances and nature of the complaints.

Click here to enter text.

1. Protocol Deviations

Have there been any deviations from the study protocol or any other previously approved IRB documents that did *not* receive approval before they were implemented? (For example: implementing a midline survey without prior IRB approval.)

 [ ]  No

 [ ]  Yes

If yes, please explain in detail all the deviations from the protocol or other approved study documents below. You will receive additional instructions on how to proceed when your documents are reviewed, depending on the severity and extent of the deviation.

Click here to enter text.

1. Progress Report

Please write a brief (200 words of less) report describing the progress of your research thus far. Please cover any recruitment, enrollment, data collection, etc. activities that have been completed so far and highlight which activities have occurred within the last renewal period. If data collection is complete and you have moved to data analysis only, please indicate this.

Click here to enter text.

1. Requested Changes

Are you requesting any changes to the protocol or that have not yet received IRB approval and review and have not yet been implemented?

[ ]  No

[ ]  Yes

If yes, please explain all the changes in the text box below this question and submit updated copies of the study’s protocol, one with track changes to show all modifications and one clean copy.

Click here to enter text.

1. Is there any other new information that affects the risk-benefit ratio of this study, either from the literature or your own findings and/or observations? Attach copies of relevant publications.

[ ]  No

[ ]  Yes If yes, please explain.

Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Signature

Typed Name: Click here to enter text. Date: Click here to enter a date.

\* An email from the PI, acknowledging this renewal, can substitute for a signature if necessary due to constraints of travel.

1. Pro-tip! You can check whether we have the HSC on file by looking up their contact record on Salesforce. [↑](#footnote-ref-1)