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

# REQUEST TO RE-APPROVE OR CLOSE RESEARCH INVOLVING HUMAN SUBJECTS

**When complete, please file this application, including its attachments, via**[**poverty-action.org/irb**](https://www.poverty-action.org/irb)**.**

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

The only exception refers to the certification of human subjects training. If not already on file, please email these certificates to 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 (if no changes):**

[ ]  Completed renewal form

[ ]  Copy of current, clean consent

[ ]  Copy of current, clean protocol

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

[ ]  Brief progress report, detailing activities of the last year

**Supplementary Documents (if there are changes):**

[ ]  Protocol with tracked changes

[ ]  Protocol, clean

[ ]  Consent, with tracked changes, in **English**

[ ]  Consent, clean, in **English**

[ ]  Any new surveys (and their accompanying consents), in **English[[2]](#footnote-2)**

[ ]  Any new MOU

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

[ ]  Any new marketing materials to recruit subjects

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

[ ]  Proof of PI approval, if this form is not signed

[ ]  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.

**Would you like to renew or retire this study?** [ ]  **Renew** [ ]  **Retire** (A study can be retired once in final analysis, when no identifiers are being used and there is no expectation of returning to surveying subjects. This is at the discretion of the PI, many of whom prefer to keep a project under IRB oversight until papers have been written.)

**If this study is being retired, you may skip questions 2, 6, and 7. Otherwise, please respond to the following questions:**

 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** and therefore approved by the **full convened** board at IPA IRB at a monthly meeting?

 *(Note: Your approval letter would say “board approval” rather than “expedited approval” 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 withdraw 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.

**Adverse Events**

1. Please respond fully, even if previously reported to the committee. Were there any adverse or unexpected events experienced during this study that did or could affect human subjects involved? This refers to anything that had to be reported in an unexpected event report.

[ ]  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 involved

1. Were there any complaints 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. Deviations (Unexpected Events)

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?

 [ ]  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. **Only for studies originally approved before August 1, 2020:** Requested Changes (Amendments)

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

[x]  Yes **If yes, please explain all the changes in the text box below this question and submit two 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 which 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)
2. Please note that we no longer require surveys or other project documents to be submitted in local surveying language, but you must describe in your protocol document your procedures for their translation and back translation. [↑](#footnote-ref-2)