**APPLICATION TO INNOVATIONS FOR POVERTY ACTION INSTITUTIONAL REVIEW BOARD (IRB)**

**The cover page and study protocol template included in this application provide researchers with an opportunity to describe their study and, in particular, efforts to effectively manage any risks or effects toward human subjects. IPA’s IRB will review the study using the cover page and study protocol as well as all required and supplementary documents to determine if the design effectively safeguards participants.**

**Required Documents:**

* Completed cover page [first two pages of this application form]
* Completed study protocol [the rest of the application form]
* Survey(s) in **English[[1]](#footnote-1)**
* Informed consent(s) in **English[[2]](#footnote-2)**
* NIH or equivalent human subjects certifications for all research staff, if not already on file[[3]](#footnote-3)

**Supplementary Documents[[4]](#footnote-4):**

* **MOU** or letter of support from partner organization(s)
* **Data use sharing agreement** with relevant partner or sponsoring organization(s)
* Marketing materials to recruit subjects
* IRB approval from other institution(s), including any local IRB(s)
* Exemption form, if applying for exempti**o**n from IRB review
* Proof of PI approval via email, if this form is not signed or submitted by PI
* Any other relevant documentation

**When complete, please file this application form, including all its attachments, via** [**poverty-action.org/irb**](file:///C:\Users\vbhatia\Box%20Sync\IPA_IRB_Documents\02_Forms\IPA%20IRB%20Forms\poverty-action.orb\irb)**.**

Do **not** file this application via [humansubjects@poverty-action.org](mailto:humansubjects@poverty-action.org) unless you cannot submit it through the website due to a technical error.

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](mailto:humansubjects@poverty-action.org). Please do not hesitate to reach out to [humansubjects@poverty-action.org](mailto: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).

**COVER PAGE**

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

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

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

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

**Countries & Locations:** Click here to enter text.

**Anticipated Start Date & End Date (be specific about date you plan to begin fielding study):**

**Start:** Click here to enter a date.

**End:** Click here to enter a date.

# Exemption

**Will you apply for an exemption from continuous IRB review?**

**☐ Yes**

**☐ No**

**If “Yes”, please complement this application with an additional, separate application for exemption. The corresponding form can be found at, and submitted through** [**poverty-action.org/irb**](http://www.poverty-action.org/irb)**.**

# Certifications

**I certify that the statements herein are accurate and complete. I agree to inform the Board should there be any changes in the protocol or problems arising from this protocol. I accept responsibility for the conduct of this research, the supervision of research personnel and human subjects, and the maintenance of informed consent documentation as required.**

**Do you or any family members (spouse, child, or domestic partner) have any incentives or interests, financial or otherwise, that may affect or be affected by the conduct of this research or that may affect the protection of the human subjects involved in this project?**

☐ Yes ☐ No

**If yes please attach a description of the interest.**

Click here to enter text.

**Primary Investigator's name, typed**

Click here to enter text.

**Primary Investigator's signature**

**(or attach email with PI’s acknowledgement of this application)**

**Date** Click here to enter a date. **Signature**

**STUDY PROTOCOL**

**Note that points I. through VIII. (below) are called your “study protocol”, which will be referred to in later IRB submission forms, including renewals and amendments.**

# I. Project Team and Study Collaborators with Access to PII

IPA IRB must have records of current human subjects certifications on file for **ALL Principal Investigators** as well as any other research staff with access to PII. These last for only **three years** before a refresher course must be taken.

**Principal Investigator(s):**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name | Email | Will **not** see PII | Gets other IRB approval | Date of most recent Human Subjects Certification? |
| Click here to enter text. | Click here to enter text. | ☐ | ☐ | MM/DD/YYYY |
| Click here to enter text. | Click here to enter text. | ☐ | ☐ | MM/DD/YYYY |
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| Click here to enter text. | Click here to enter text. | ☐ | ☐ | MM/DD/YYYY |

**If any of the above PIs will be getting IRB approval at their institutions, please submit copies of these documents.**

**Name, Address, Phone Number, e-mail address of Primary Investigator:**

Click here to enter text.

**All other research personnel** **and / or any personnel with access to more than 10% of your sample’s PII. Research personnel include but are not limited to: research associates, research managers, data coordinators, country directors, and deputy country directors. Note if personnel will not see PII:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Name | Email | Role | Will **not** see PII | **OR** | Date of most recent Human Subjects Certification? |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | ☐ | **OR** | MM/DD/YYYY |
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| Click here to enter text. | Click here to enter text. | Click here to enter text. | ☐ | **OR** | MM/DD/YYYY |

**Will anyone else have access to your study’s PII (this may include implementing partners)?**

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Email | Role | Date of most recent human subjects certification? |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | MM/DD/YYYY |
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# Funding

**Name of sponsoring agencies and contact names, if known.**

Click here to enter text.

**Will this project receive ANY federal funding[[5]](#footnote-5)?**

* **Yes**
* **No**

# Partner Organization(s)

List any partner organizations and contact names.

Click here to enter text.

Do you have a data sharing agreement with any of your partner organizations?

* Yes
* No

## II. Purpose/Background/Significance.

**Briefly describe the purpose of the proposed study, including a brief background or context to the evaluation and an explanation of why the study is valuable and significant.**

Click here to enter text.

## III. Test Procedures and Measures.

1. **Describe the study design**

Click here to enter text.

1. **Specify treatments and control groups.**

Click here to enter text.

1. **Specify any marketing used**

Click here to enter text.

1. **Specify the timing of any surveys that will be administered. Clarify whether the surveys will be translated into local languages, and who will be responsible for translations.**

Click here to enter text.

1. **If applicable, describe how the treatment will be delivered.**

Click here to enter text.

1. **Provide an explanation of measures to be collected and sources for all data to be obtained.**

Click here to enter text.

1. Provide any other information relevant to test procedures and methods.

## IV. Subject Population

**Describe who study participants are, how many will be involved, and how you will gain access to the population.**

Click here to enter text.

**Will the study seek out any of these vulnerable populations?**

**☐ Children**

**☐ Pregnant Women**

**☐ Prisoners**

**☐ Mentally disabled**

**☐ Veterans**

**☐ Others (please describe below)**

**Elaborate below if applicable, and describe any special procedures used to safeguard these subjects.**Click here to enter text.

**Will the study ask about any of the following sensitive topics? This does not mean the study is high risk, however, a topic that is innocuous in one context may be sensitive in another.**

**☐ Governance issues**

**☐ Sexual Health or Behaviors**

**☐ Physical Abuse**

**☐ Involvement in Illegal Activities**

**☐ Mental Health**

**☐ Others (please describe below)**

**Elaborate below if applicable.**

Click here to enter text.

**Will study participants be compensated for their time?**

☐ Yes, participants will be compensated

☐ No, participants will not be compensated

**If so, what value and form will the compensation take? How was this decided? (Make sure you have reviewed IPA IRB’s policies on incentives.)**

Click here to enter text.

## V. Informed Consent

## **How will the informed consent be obtained?**

**Please specify whether the consent will be written, verbal, or of any other type.**

☐ Written

☐ Verbal

☐ Other (e.g. in cases of deception)

**If “verbal”, explain why you seek permission for verbal consent, e.g. why written consent will not be practically feasible.**

Click here to enter text.

**If “other”, please specify. If you wish to use deception, for example, clarify how participants will be contacted at a later point.**

Click here to enter text.

**Will you record any audio?**

☐ Yes

☐ No

**If yes, please describe procedures for storing and destroying audio files.**

Click here to enter text.

**Will you collect any GPS data?**

☐ Yes

☐ No

**Who will pay for the surveyors, IPA or the Partner Organization?**

☐ IPA

☐ Partner Organization

☐ Other. Specify: Click here to enter text.

VI. Data Collection Procedures

**How will the data be collected? Check all that apply.**

☐ Electronically

☐ Paper

☐ Third party administrative data

☐ Recordings

☐ Other

**Add any details you deem instructive.**

Click here to enter text.

VII. Possible risks of the study, including for participants and IPA or partner organization staff

**Discuss possible risks and benefits to study participants. This includes financial, physical or emotional risk. Regarding a risky study location and potential risks to staff, please elaborate. Please describe plans to manage or mitigate all risks.**

Click here to enter text.

## VIII. Treatment of Data

**Describe all data security procedures the project will take to maintain confidentiality of human subjects, including: 1) paper data security procedures (collection, transfer and storage), 2) data security procedures for digital data collection data security procedures, 3) monitoring of data security procedures to ensure adherence.**

**APPENDIX:**

**CONSENT**

The following provides you with a checklist of items that will be assessed when examining your consent procedures. Below, you will also find a consent template.

Please note: If you believe including any of the below will bias the study, tell the Human Subjects Committee why in the body of your email.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Yes** | **No** | **n/a** |
| Consent is submitted in **English** and local surveying language | ☐ | ☐ | ☐ |
| Exculpatory language is excluded | ☐ | ☐ | ☐ |
| Coercive language is excluded | ☐ | ☐ | ☐ |
| Jargon is excluded |  |  |  |
| Surveyor introduces him/herself and explains his/her affiliation | ☐ | ☐ | ☐ |
| Potential participant is “**invited**” not “chosen” to participate | ☐ | ☐ | ☐ |
| Includes description of the research | ☐ | ☐ | ☐ |
| The individual and/or global benefit of the study is described | ☐ | ☐ | ☐ |
| Risks and discomforts adequately described | ☐ | ☐ | ☐ |
| Statement that participation is voluntary | ☐ | ☐ | ☐ |
| The duration of overall study: i.e. will you be returning for follow-up? When? How many times? | ☐ | ☐ | ☐ |
| The time it will take to complete survey is noted | ☐ | ☐ | ☐ |
| Content of the survey is adequately described: i.e. demographics, education, savings behaviors, etc. | ☐ | ☐ | ☐ |
| Procedures for any audio or visual recording, whether recording is a requirement of participation, and, if not, an opportunity to opt out | ☐ | ☐ | ☐ |
| Explanation that researchers are the only ones with access to **identifiable** data: i.e. “All your responses will be anonymous / held in confidence. Only the researchers involved in this study and those responsible for research oversight will have access to the information you provide**which identifies you.”** | ☐ | ☐ | ☐ |
| Confidentiality provisions for identified data described: i.e. “Yourresponses will be numbered and the code linking your number with your name will be stored in *(insert secure location)*.” | ☐ | ☐ | ☐ |
| Confidentiality disclaimer: “Researchers will keep your information confidential to the extent possible and allowable by law.” | ☐ | ☐ | ☐ |
| Local contact (name AND number) for questions about the research | ☐ | ☐ | ☐ |
| Statement that refusal to participate will not lead to penalty or loss of benefits | ☐ | ☐ | ☐ |
| Statement that may withdraw participation at anytime | ☐ | ☐ | ☐ |
| Will the subject be paid or gifted. Be specific | ☐ | ☐ | ☐ |
| Any potential costs to participants | ☐ | ☐ | ☐ |
| Circumstances where participation could be terminated by PI | ☐ | ☐ | ☐ |
| Consequences of withdrawal and any requirements for orderly withdrawal | ☐ | ☐ | ☐ |

***The following is intended as a sample; it should be modified to fit the specific study.***

**\_\_\_\_\_Respondent Code**

***Informed Consent****Study Title*

Sir (Madam),

Hello, my name is \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

I am a researcher for Innovations for Poverty Action, a non-profit organization dedicated to finding innovative solutions to development issues in various countries.

I am visiting you today because we are a conducting a study about…

1. **Purpose:**

*☐The purpose of this survey is to better understand characteristics of small and medium businesses in X, Y, Z districts, and also to learn relevant information about entrepreneurs who own their own businesses.*

*☐ You are invited to participate in this study.*

1. **Procedures:**

*☐ If you choose to participate, you will be asked to complete a survey/interview/ behavioral games.*

*☐ The survey will cover…*

* + *Members of your household*
  + *Education of household members*

*☐* The survey will require approximately 3 hours of your time.

*☐ For participating in this survey, you will receive one bar of soap.*

*☐ I (or a member of the research team) will need to return in 6 months, but you can choose not to participate in the follow-up interview if you wish.*

* *(If applicable) We hope to record a component of your interview for quality assurance purposes. If you would prefer not to be recorded, you can participate without this component.*

1. **Risks and Benefits:**

*☐ This research will help us better understand the needs of the community in order to improve future interventions directed toward entrepreneurs in this region.*

*☐ You may experience distress over the nature of some of the questions*. *You are free to skip any question that makes you feel uncomforatable.(OR We do not anticipate any risks to you from study participation.)*

1. **Confidentiality:**

*☐ No names will be stored with survey responses and no names will be published from the study.*

*☐ Only research staff will have access any data that could potentially identify you.*

* *“Your**responses will be numbered and the code linking your number with your name will be stored in (insert secure location).”*
* *Confidentiality Disclaimer: “Researchers will keep your information confidential to the extent possible and allowable by law.”*

1. **Voluntary Participation:**

*☐ Declining will not affect chances of receiving an intervention or respondent’s status with local organizations involved in the study. (If applicable) You will not be denied any government benefits for choosing not to participate.*

*☐ Ending participation at any time for any reason will not have any negative consequences.*

*☐ Refusal to answer any individual questions will not have any negative consequences.*

1. **Contact (Further Questions) – Please list both:**

*☐* Project Associate/Coordinator name and **local** phone number

*☐* Country Director name and phone number

1. **Questions:**

*☐* *Do you have any further questions?*

**Response:**If I have answered all your questions, do you agree to participate in this study? (Surveyor should indicate subject’s response or have them sign their name.)

Yes\_\_\_\_

No\_\_\_\_

**Remember, NO coercive language, and NO exculpatory language!!**

Example of coercive language: “You should take part in this study because…”; “your family and friends are counting on you...”

Example of exculpatory language: “By signing this form, I forfeit access rights to my study data…; to legal recourse against the research staff…”

1. Note: We **no longer** require projects to submit any documentation in local languages. [↑](#footnote-ref-1)
2. Pro-tip! See template at the end of this document for guidance on creating your informed consent! [↑](#footnote-ref-2)
3. **Pro-tip! If you are an IPA employee with a full Salesforce account, you can check whether we have the HSC on file by looking up at individual contact records on Salesforce.** [↑](#footnote-ref-3)
4. These are required if they exist and apply to the study project; however, not every project has them. [↑](#footnote-ref-4)
5. A project is considered federally funded whenever funds come directly from a US Government Agency, funds come from a federal contractor, or funds come from another organization that is receiving funds from a US Government Agency. Please check your grant agreement to verify your own federal funding status. [↑](#footnote-ref-5)