**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

**Supplementary Documents[[3]](#footnote-3):**

**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, *if IPA is involved in designing or implementing recruitment*

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 an email stating 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 |
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**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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**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[[4]](#footnote-4)?**

**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

*If you have a data sharing agreement, please include it with your application materials.*

## 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. **If IPA is responsible for marketing, specify any marketing used and describe your recruitment tactics (if you are using marketing, you must attach copies of the marketing materials along with the rest of your application). You may leave this blank if IPA is not responsible for designing or implementing recruitment materials.**

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. You do not need to provide copies of surveys in local languages; we only need to hear your translation procedures.**

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 ALL measures to be collected and sources for ALL data to be obtained. This includes both intermediary and outcome measurements.**

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**

**Veterans**

**Others (please describe below)** *Vulnerable populations are any group whose ability to provide a free, voluntary, and informed consent is constrained.*

**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**

**Suicidal Ideation**

**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?**

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

Requesting Waiver (Partial or Full)

**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 you are requesting a waiver of consent, please note OHRP’s standards (sections c and d of** [45 CFR 46.116](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.116)**) for waivers. Explain below (a) whether the project poses minimal risk to subjects, (b) whether the waiver will adversely affect the rights and welfare of subjects, (c) whether the research could be practicably carried out without a waiver, and (d) how the study team plans to follow up to provide subjects with additional pertinent information, as appropriate.**

Click here to enter text.

**Will you record any audio?**

Yes

No

**If yes, please describe procedures for storing and destroying audio files. Note that you must inform participants about audio recording procedures unless you can argue for why this element of the informed consent should be waived for your study.**

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 this, you will also find a consent template. You can also reference OHRP’s consent form requirements [here](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.116).

Please note: If you believe including any of the below will bias the study, tell IPA IRB why in your application or within your supporting documents.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Yes** | **No** | **n/a** |
| Consent is submitted to IPA IRB in **English** (and administered in the respondent’s language, with both translations and back translations performed to ensure accuracy) |  |  |  |
| Surveyor introduces him/herself and **explains** his/her affiliation |  |  |  |
| Statement that the study is **research** rather than routine care or programming (and explaining the difference as needed) |  |  |  |
| Describes the purpose of the research |  |  |  |
| Description of all procedures to be followed, and identification of any procedures which are experimental |  |  |  |
| Exculpatory language is excluded |  |  |  |
| Coercive language is excluded |  |  |  |
| Jargon and confusing language are excluded |  |  |  |
| Potential participant is “**invited**” not “chosen” to participate |  |  |  |
| The individual and global benefits of the study are both described |  |  |  |
| Risks and discomforts are adequately described (i.e. Might some of your questions make respondents feel uncomfortable?) |  |  |  |
| 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 confidential and protected. The researchers involved in this study and those responsible for research oversight will not share any information you provide**which identifies you.”** |  |  |  |
| Sweeping statements that broadly **guarantee** absolute confidentiality are excluded |  |  |  |
| *For studies dealing with potentially criminal activities -* Confidentiality disclaimer: “Researchers will keep your information confidential to the extent possible and allowable by law.” (study should also be aware of their **reporting requirements**) |  |  |  |
| Local, **accessible** contact for questions about the research. Must include a phone number (not an e-mail address) and must be someone who speaks their language or with easy and immediate access to a translator |  |  |  |
| Contact for subjects that have questions about their rights as research participants (not research team; must be an IRB or REC), and information about whom to contact in the event of a research-related injury |  |  |  |
| Statement that refusal to participate will not lead to penalty or loss of benefits |  |  |  |
| Statement that may withdraw participation at anytime |  |  |  |
| Any compensation for participation, such as a payment or gift. Be specific (This may be waived if there is reason to believe it would bias the study results, but inclusion/exclusion must be addressed in your submission materials.) |  |  |  |
| Any potential costs to participants |  |  |  |
| Space for to record response to consent (yes/no) |  |  |  |
| Sufficient opportunity to ask questions |  |  |  |
| *For written consent only:* Space for signature |  |  |  |
| *If applicable:* Space for thumbprint |  |  |  |
| Circumstances where participation could be terminated by PI |  |  |  |
| Consequences of withdrawal and any requirements for orderly withdrawal  i.e. For a Focus Group Discussion, “If decide you would like to leave the discussion at any time, please exit the room quickly and quietly so as to minimize disruption to the other participants. If you would like your discussion statements to be removed from any research materials, you should contact xx at sampleemail@organization.org within one week.” |  |  |  |
| *If applicable:* description of any alternative procedures or treatment that may be available and advantageous to the subject |  |  |  |
| *If applicable:* a statement that the particular treatment or procedures may involve risks to the subjects that are currently unforeseeable |  |  |  |

Sample Consent Form Template

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

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

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

Hello, my name is \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. (Enumerator name)

I am a researcher for Innovations for Poverty Action, a research and policy non-profit that discovers and promotes effective solutions to global poverty problems. We are **inviting** you to participate in this study. This study involves research, which is different from routine care or programming, because we are trying to learn about certain things rather than only providing services.

I am visiting you today because we are a conducting a study about \_\_\_\_\_\_\_\_\_ (i.e. pre-school education in Lilongwe, agricultural microfinance products in Mali, etc).

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.*

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 take 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:**

*We hope that 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 uncomfortable. (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.*

*The research staff will not share your personal information with anyone outside the study, and they will do their best to protect your information.*

*Confidentiality Disclaimer, if dealing with illegal activities: “Researchers will keep your information confidential to the extent possible and allowable by law.”*

1. **Voluntary Participation:**

Participation in this study is voluntary. That means you do not have to participate if you do not want to.

*You will not be penalized for declining to participate, and declining participation will not affect your chances of receiving any benefits to which you are otherwise entitled, such as those from the government. (If applicable)*

*Ending participation at any time for any reason will not have any negative consequences for you. You may withdraw at any time, which you can do by simply telling me that you no longer want to be part of the study.*

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

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

Project Associate/Coordinator name and **local** phone number, if they have questions about the research

A reviewing IRB / REC and their contact information, if they have questions about their rights as research participants

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, NO exculpatory language, NO jargon, NO sweeping statements guaranteeing absolute confidentiality (or anything that you cannot promise, or would go against your data publication requirements)!!**

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…; I am agreeing to participation in all future surveys with this study…”

Example of sweeping statement: “We guarantee that only the researchers will ever be able to access any of the data you provide…”

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. These are required if they exist and apply to the study project; however, not every project has them. [↑](#footnote-ref-3)
4. 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. The rules and regulations for human subjects research are different for federally funded and non-federally funded studies. [↑](#footnote-ref-4)