**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. 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 the Human Subjects Committee why in the body of your email.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **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 withdrawali.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…”