

Consent Checklist

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 <u>here</u>.

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
1.	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)			
2.	Surveyor introduces him/herself and explains his/her affiliation			
3.	Statement that the study is research rather than routine care or programming (and explaining the difference as needed)			
4.	Describes the purpose of the research			
5.	Description of all procedures to be followed, and identification of any procedures which are experimental. <i>If applicable</i> , this includes a statement alerting participants about the random nature of the experiment.			
6.	Exculpatory and coercive language are excluded			
7.	Jargon and confusing language are excluded. Ensure phrasing is clear, comprehensible and concise.			
8.	Potential participant is " invited " not "chosen" to participate			
9.	The individual and global benefits of the study are both adequately described, as well as the contents of the survey (i.e. demographics, education, savings behaviors, etc.)			
10.	Risks and discomforts are adequately described (i.e. Might some of your questions make respondents feel uncomfortable?)			
11.	Statement that participation is voluntary			
12.	Statement that participants do not have to answer all questions and that there is no penalty for skipping any question			
	The overall duration of the study: Will there be a follow-up survey? When? How many follow-up surveys? <i>If applicable:</i> include space to ask whether they agree to be contacted by the researchers in the future, and the purpose of such future contact (i.e. new study, follow-up, etc.)			
	Researchers should not re-contact participants once the study is closed they have given their permission for them to do so for that purpose			



The time it will take to complete the survey is noted		
 14. Procedures for any audio or visual recording, including: That recordings will be taken and what type (audio or video) When the recordings will be taken if known; the consent can say "at a random time in the interview" if unknown Why the recordings will be taken What the recordings will be used for How the recordings will be kept confidential If and when the recordings will be destroyed Whether being recorded in this manner is a requirement of participation, and if not, then how participants can express that they would not like to participate 		
15. Notification of whether you intend to take GPS coordinates, why you are collecting GPS coordinates, whether this poses any risks to participants, and whether this is a requirement of participation		
16. An explanation that identifiable data will not be shared outside of predetermined, authorized parties.		
17. Sweeping statements that broadly guarantee absolute confidentiality are excluded. Avoid statements using "absolute/utmost confidentiality", "strictly confidential", and "your responses will be kept a secret"		
18. A statement about whether participants' information might be stripped of identifiers and used for future research		
19. For studies dealing with potentially criminal activities include a confidentiality disclaimer: "Researchers will keep your information confidential to the extent possible and allowable by law." From a human subject's perspective, it is less risky to collect this information in a manner that would not identify the respondent (ex. list randomization). Studies should also be aware of the country's reporting requirements, such that people are obligated to disclose certain kinds of information about illegal activities (including allegations of abuse or neglect, which sometimes must be reported to the police by law).		
20. Local, accessible contact for questions about the research study. <i>Must</i> <i>include a phone number</i> and must be someone who speaks their language or with easy and immediate access to a translator		
21. 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		
22. Statement that refusal to participate or withdrawal at any time will not lead to penalty or loss of benefits		
<i>If applicable: (a)</i> A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or		



will not share in this commercial profit			
<i>If applicable: (b)</i> 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 exclusion must be addressed in your submission materials.)			
23. Clearly state if there are any costs associated with study participation, and if so, specify what they are. If there are no costs, (which is usual for social-behavioral studies) this section may be omitted.			
24. Space to record response to consent (yes/no) and <i>if applicable</i> : space to record response to consent to audio/visual recording and GPS coordinates (if being collected).			
25. Check with the local Data Protection Officer in your country office to obtain the necessary information that needs to be included in the consent form per country data protection regulation requirements.			
26. Sufficient opportunity to ask questions			
27. <i>For written consent only:</i> Space for signature and/or thumbprint			
28. Circumstances where participation could be terminated by PI			
29. 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 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."			
<i>If applicable:</i> (a) description of any alternative procedures or treatment that may be available and advantageous to the subject			
<i>If applicable</i> : (b) a statement that the particular treatment or procedures may involve risks to the subjects that are currently unforeseeable			



Innovations for Poverty Action Institutional Review Board (IRB) Consent Form Requirements and Instructions

- Consent documents should be submitted to IPA IRB **in English** (and administered in the respondent's native language, with translations and back translations performed to ensure accuracy). You do not need to submit the translated versions of consent documents to the IPA IRB after the IRB has approved the English-language versions.
- Sweeping statements about data confidentiality should not be included in the consent avoid statements using language about data confidentiality such as "absolutely or completely confidential," "strictly confidential," "your responses will never be shared beyond the research team," or "your responses will be kept a secret."
- If you plan to collect data from individuals in the European Economic Area (EEA), you must consider the General Data Protection Regulations (GDPR). The EEA includes all of the member states of the European Union (EU), Iceland, Liechtenstein, and Norway. Additional consent language may be required for studies impacted by GDPR—contact the IPA Research Ethics team for additional GDPR language before submitting the consent form. For research conducted in non-European countries, check with the local Data Protection Officer in your country office to obtain the necessary information that needs to be included in the consent form to reflect any country-specific data protection laws.
- Contact the IPA Research Ethics team if you plan to share research results or findings back with the research participants either at the end of the study or at any other point of time in the study. You must indicate whether you will do so individually or in an aggregated and anonymized way. If you plan to return individual results, please include a detailed plan in the research protocol/application form about how and where you will share the results back with an appropriate rationale. Sharing individual results is not common and must only be done after obtaining prior permission of participants and by respecting the wishes of the participants regarding the way they would like the information to be shared with them.
- Delete all instructional language not relevant to your study from the template before submission so that the consent form contains only study-specific information. Do not use template language from other versions or older versions of consent forms.



Informed Consent Form Template

The following is intended to be used as a template; it should be modified to fit the specifics of your study. If there are components in the template that do not apply to your study, then feel free to delete them.

<Insert Respondent Code>

Title of the Research Study: <enter the title of study here>

Principal Investigator(s): <enter the name of PI(s) and Co-PIs here>

Hello, my name is <insert enumerator name>

I am a researcher for Innovations for Poverty Action (IPA), a research and policy non-profit that finds and promotes effective solutions to global poverty and other problems. We are doing a research study on behalf of *<add funding agency/organization or other institution commissioning the research.>* [Include only if there's a financial conflict of interest applicable, *<add study personnel with conflict's name>* has received payment from *<insert sponsor's name>* of *<insert an amount range>* as *<explain why, such as advisor, board member, etc.>*]

- We are inviting you to participate in this study about <add a summary of the overall purpose of the study in lay language> because <add eligibility/screening/inclusion criteria>. This study involves research, which is different from receiving routine care or other program services because we are trying to learn more about certain aspects of the study < add study specific examples> rather than only providing services. We hope that this research will help us better understand <add specific research aim/hypothesis> in order to improve future < add how the research will impact public good>.
- You do not have to be in this study—it is completely voluntary. You will not lose any benefits you currently receive if you choose not to be in this study. You can skip any question and stop participating at any time. It will take a total of about <add total time expected in participation in minutes/hours> to complete all the research procedures as part of this study <add survey/interview/other procedure>
- <u>Procedures</u>:

If you choose to participate in this study, we will ask you to do the following: [Indicate which research procedures will be used. You can also list them or summarize them in a table with timelines and customize it for your study].



Study procedure	Baseline	Midline	Endline	Long term follow up	Compensation and amount (yes/no)
Survey	<day month<br="">timeline></day>	<day month<br="">timeline></day>	<day month<br="">timeline></day>	<day month<br="">timeline></day>	
In-depth interview					
Focus groups					

[For studies that do not require a table and/or include only single-use surveys or other

procedures] if you choose to participate, you will be asked to complete a survey/interview/behavioral games/other procedures. We will ask you questions about <*describe the topics to be covered, such as your household information, education, savings behaviors, etc.*>

[For studies that require participation by the same sub-group of participants in more than one study procedure (ex. survey and a focus group and an in-depth interview as part of the study)] you may also be required to complete *<insert which additional procedures with expected time commitment for each procedure as part of the study>*, where we will ask you questions about *<describe the topics to be covered, such as your household information, education, savings behaviors, etc.>*

[For studies using a randomized control study design] In this study, participants are *randomly assigned* (*for ex. by using a lottery*) to different versions/groups/ interventions. Which group you are assigned to is decided by chance and there is a *<add probability % >* chance that you will be assigned into any of the groups. [If applicable, neither you nor the researchers choose the group to which you will be assigned]. While you will be fully informed about the version/group/treatment of this study that you have been randomly assigned to, you will not be informed about the different versions/groups/treatments of this study that other participants are in.

[If applicable: This interview/survey is part of a larger research study that will involve future data collection]. We will return <add number of times> in the next <add total timeframe> for a follow-up survey/interview, but you are free to decline participation in the follow-up if you wish.

For participating in this survey or other study procedure *<specify which one*>, you will/ will not receive compensation. Describe additional details of how compensation will be provided to the participants in addition to the summary in the table above like when it will be provided and how it will be provided (ex. gift card, phone recharge etc.).

[If audio/video recordings will be used]:

To ensure the accuracy of our findings, quality control, and additional research on designing and evaluating surveys by IPA, we would like to record a portion or all of *<insert which procedure>* by using audio/video recordings for later transcription and review by the research team. You can *<insert either still or cannot>* participate in this study if you do not consent to audio recording/video. The audio/video recordings will be destroyed after *<insert when they will be destroyed>* and only anonymous responses will be stored for future use.



[If photography will be used]:

We would like to take photographs of *<insert the participant, participant's family members, participant, and participant's children—be as specific as possible>* to document *insert activities to be photographed/purpose of photographs>*. Photography *<insert either is or is not>* required. You can *<insert either still or cannot>* participate in this study if you do not consent to have *<insert yourself/your family>* photographed. The photographs will be destroyed after *<insert when they will be destroyed>*

[If participation in the study is linked to the recordings such that the participants cannot participate unless they agree to be recorded please clearly explain the reasons above].

Note: Audio and video recordings and photographs cannot be used in presentations and publications about study results or shared for future research without you explicitly agreeing to those uses of the recordings/photos. Also, you can withdraw your consent to be recorded at any time during the study even if you initially agreed without any negative consequences.

[If GPS location data will be collected]:

We wish to record the GPS coordinates of this interview for *<insert reason>* purposes. This is voluntary, so you are free to decline if you feel uncomfortable.

Potential Risks and Anticipated Benefits:

Participation in this research study is completely voluntary. We will use careful procedures to protect the information we collect from you and keep it confidential.

Other potential risks from study participation include, *<insert other risks* due to procedures described above in lay language, avoiding any technical terms. Risks should be described in relation to a specific procedure.>

Some of the questions may make you uncomfortable or upset. You can skip any question you don't want to answer or stop this interview at any time. You can also stop and return to the questions at a later time when you feel more comfortable.

[If applicable]: Because some of the questions are sensitive, we will make sure you are in a place where you have privacy before we start the interview.

[FOR GREATER THAN MINIMAL RISK RESEARCH STUDIES ONLY]: Research procedures described above may involve risks that cannot be anticipated at this time. If we learn of anything that may affect your decision to participate, we will inform you as soon as possible. You will then have a chance to reconsider your continuing participation in the research.

Also, <insert an explanation as to the availability of medical treatment or compensation in the case of research-related injury, including who will pay for the treatments or interventions and whether another financial compensation is available>



Anticipated Benefits:

Note: Compensation cannot be described as a benefit of research participation—do not describe compensation in this section of the consent.

You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study.

OR

You might benefit from being in the study <insert any direct benefits.>

• New Information:

You will be notified about any new information regarding this study that may affect your willingness to participate in a timely manner.

• <u>Alternatives to Participation:</u> This section is required ONLY for research that involves treatment interventions like physical or behavioral procedures

<Describe any viable alternatives that should be considered before the participant decides whether to participate in the research. If applicable, explain why any routinely available options are being withheld. If there are no alternatives, state that an alternative is not to participate in the research.>

1. <u>Confidentiality:</u>

[Include for a Focus Group Discussion]: We ask all members of this group to respect each other's privacy and not repeat later what people said in today's discussion. Please keep in mind that because we are in a group setting, we cannot guarantee that others in the group will not repeat what you said after you leave today. If you would like your discussion statements to be removed from any research materials, you should contact xx at sampleemail@organization.org.

We will make our best efforts to maintain the confidentiality of any information and/or responses that are collected during this research study. Your information or information that may identify you will be kept as confidential as possible, to the extent applicable to the study and as allowed by local standards. We will disclose this information only with your permission or as required by law. We will protect your confidentiality by ensuring all the research data is collected and stored only on password-protected and encrypted devices in a manner consistent with all data security procedures.

[For GREATER THAN MINIMAL RISK RESEARCH STUDIES ONLY] *< If there are any mandated reporter requirements, and this research study may result in information that you are mandated to report, describe the possibility of such disclosures here.>*

The responses you provide will only be accessible to the research team and individuals from IPA who oversees the research. The research team may include people from other organizations that are involved in this study, such as universities and other non-profit organizations.



IPA will anonymize your personal data as soon as we no longer need it for IPA's research. If results of this study are published or presented, information that could identify you will not be included only information that does not identify you may be shared with other people or organizations. You may be contacted to participate in a follow-up or another study at a future date.

We may use or share your research information for future research studies that may be about different topics than this study. If we share your information with other people for future research studies, we will first remove your name and other information that could directly identify you. Other research studies may be about completely different topics, and we will not ask for your informed consent for those studies if we are only sharing information that does not identify you.

[ONLY If you plan to share identifiable research information for other future research studies]: We would like to share your identifiable information with other researchers for future research. We will ask for your consent to do so at the end of this form. You can be a part of this current research project without agreeing to this future use of your identifiable information.

1. Participants' Rights:

- Your participation in this research study is entirely **voluntary**. If you decide not to participate, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.
- Your participation or nonparticipation in this study will in no way affect your employment at <*insert employer here.>*
- You can decide to withdraw your consent and stop participating in the research at any time, without any penalty by informing the research contact person listed under the contact information section.

2. Contact Information:

If you have any questions, comments, or concerns about this research study or you would like to talk to someone about this study please contact any of the following listed below:

<*Insert Project Associate/Coordinator name and local phone number, must be someone who speaks their language or with easy and immediate access to a translator> OR,*

<*Insert name and contact information of regional country office point of contact or principal investigator(s)*>

If you have questions or concerns about your rights as a research participant or you have comments or concerns that you would like to discuss with someone other than the researchers, you can contact the IPA IRB—the IRB is a committee that protects the rights of people participating in research studies. You can contact the IPA IRB by email at <u>humansubjects@poverty-action.org</u>.

Include contact information for a local IRB as well if applicable.

Questions:

Do you have any further questions?



Response:

If I have answered all your questions, do you agree to participate in this study?

<u>Signature</u>	of Participant or their Legally Au	<u>uthoriz</u>	<u>ed Representative:</u>			
Signature/Thumbprint		Date				
<u>Signature</u>	of the Individual Obtaining Con	<u>sent</u>				
Printed Na	me of Individual Obtaining Conser	it				
Signature	of Individual Obtaining Consent		Date			
If only obt	taining verbal consent:					
Yes	No		Date			
Do you ag	ree to be contacted in the future fo	or follow	-up parts of this study?			
Yes	No					
	earchers should not re-contact part their permission for that purpose.	•	once the study is closed unless participants			
[When ap	plicable, delete whichever parts	are not	applicable for your study]:			
a.	Do you agree to be audio-recorde	ed or vic	leo-recorded or photographed, as applicable?			
Ye	s <insert apply="" procedures="" that=""></insert>	No	<insert apply="" procedures="" that=""></insert>			
b.	b. Do you give permission for audio recordings or video recordings or photographs, as applicable made of you as part of this research to be used in publications and presentations about the study?					
Ye	s <insert apply="" ones="" which=""></insert>	No	<insert apply="" procedures="" that=""></insert>			
C.	Do you agree to have the GPS loc	ation co	ordinates recorded?			
Ye	s No					



[OPTIONAL Consent to use and/or share your identifiable information for future research. This separate consent provision is not necessary if you will only use de-identified data].

The researchers would like to use your identifiable information for future research that may be similar to or completely different from this research project. Identifiable means that the data will contain information that can be used to directly identify you. The study team will not contact you for additional consent to this future research. We may also share your identifiable information with other researchers. You can contact us at any time to ask us to stop using your information. However, we will not be able to take back your information from research projects that have already used it.

- _____Yes, I agree to let the researchers use or share my personally identifiable information for future research.
- _____No, I do not agree to let the researchers use or share my personally identifiable information for future research.