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

**ORIGINAL APPLICATION**

Version date - March 2022

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 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.

COVER PAGE

Required Documents:

Completed cover page [first two pages of this application form]

Completed study protocol [the rest of the application form]

Survey(s) and other data collection materials in English[[1]](#footnote-1)

Informed consent(s) in English[[2]](#footnote-2)

CITI 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 the relevant partner or sponsoring organization(s)

Recruitment materials to recruit subjects, *if IPA is involved in designing or implementing*

*recruitment*

IRB approval from other institution(s), including any local IRB(s)/Ethics committee approval letter

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 <https://www.poverty-action.org/researchers/working-with-ipa/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 in which data will be collected (referred to as host countries**): Click here to enter text.  
  
**Anticipated Start Date & End Date (be specific about the date you plan to begin field collection in the study):**

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

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

## Certifications

By submitting this application for IRB review, 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.

Click here to enter text.

**Principal Investigator’s Information & Signature** 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 sections 1 through 9 (below) are called your “study protocol”, which will be referred to in later IRB submission forms, including renewals and amendments.

# Project Team and Study Collaborators with Access to Personal Identifiable Information (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.

Human subjects training is completed online through CITI ([www.citiprogram.org](http://www.citiprogram.org))

Enumerators in the field who have only restricted access to PII are not required to complete the CITI modules if they complete all other training for working safely with human subjects and to ensure compliance with IPA standards for data security. The Principal Investigator is responsible for ensuring the enumerators are adequately trained before beginning fieldwork. Study personnel responsible for transcribing study data containing PII (including audio/video files) must be listed here in the application and submit their CITI training certificates. Any study personnel, co-principal investigator(s), or external collaborator(s) who will only be sent de-identified dataset must be listed in the application under “will not see PII.”

**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 person with access to PII. Research personnel includes but are not limited to: research associates, research managers, data coordinators, country directors, and deputy country directors.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Name** | **Email** | **Role** | **Will not see PII** | **OR** | **Date of most recent Human Subjects Certification?** |
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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?** |
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Funding

Name of funding / sponsoring agencies and contact names, if known.

Click here to enter text.

Will this project receive any U.S. federal funding including via sub-contracts or sub-awards?

Yes

No

If yes, which institution/organization is the prime awardee or recipient of the federal grant or contract funding for this study?

Click here to enter text.

Partner Organization(s)

List any partner organizations and contact names. The partner organization can be any organization that is assisting in the research implementation, fieldwork, or data analysis.

Click here to enter text.

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

Yes

No

*If there is a data-sharing agreement, please include it with your application materials.*

Other IRB Approvals

List any other IRB/ethics committees that will be reviewing this study (and attach their approval letters as supplementary documents), including other IRBs at institutions in the United States or any research ethics boards/committees in other countries. You may do so by filling out this table, adding or deleting rows as necessary.

|  |  |  |
| --- | --- | --- |
| **Name of Reviewing Institution** (IRB or Ethics/Review Committee) with their Federal Wide Assurance# | **Status:**  (0) not yet applied  (1) applied, pending  (2) approved | **Local IRB?**  Yes or No |
| Institution 1 |  |  |
| Institution 2 |  |  |
| <no more to list> |  |  |

If the host country outside of the US where data collection is taking place does not require a local ethics review or one is not available, please specify that here.

Click here to enter text.

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.

Recruitment and Eligibility Screening

# If IPA is responsible for recruiting study participants, specify any recruitment techniques and materials to be used and describe your recruitment tactics (you must submit copies of the recruitment materials along with the rest of your application).

# We need to know how you will: 1) identify and locate individuals who may be eligible for the study; 2) how, where, and when contact will be made with people who may be eligible for the study; and 3) how you will access/collection information to determine which people are eligible to participate in the study.

# Note: If IPA is not responsible for designing or implementing the study recruitment process, you do not need to attach recruitment materials to your IRB application, but you do need to explain here which organization(s) will be conducting recruitment for the study.

Click here to enter text.

Research Procedures and Measures

* Describe the study design and research methodology including whether there will be any pilot studies, pre-testing as part of the study procedures. You will provide a detailed description of study procedures in the next question – for this question, just provide an overview of the study design including details on any planned pilots, pre-testing, or training activities prior to implementation. See definitions of each below and clearly describe if your project plans to include any of these activities with their timelines and sample sizes. Also describe any plans and format for the dissemination of study findings (ex. publications, abstracts, presentations etc.).
  + **Pilot:** A true pilot is any preliminary activity that is systematically conducted to evaluate the feasibility of a key study procedure or outcome. The data collected in a pilot is identifiable and used as part of the study outcomes and will contribute towards “generalizable knowledge.”
  + **Pre-testing:** Any activity that involves refining a tool (ex. evaluating whether text delivery will work, testing the length of survey questions, finding programming errors in SurveyCTO, etc.) where the results will be used to improve data quality and are not being used as part of the outcome measures (and it is in a "limited" population of fewer than ten individuals) then no "generalizable" knowledge would be generated.
  + **False launch:** Done primarily for training personnel (ex. enumerators by using a limited set of survey instruments to assess the efficacy of usage, timing etc. These activities are not meant to contribute to “generalizable knowledge.”

Click here to enter text.

1. Specify each of the intervention/treatments and control groups in detail. If the study involves multiple arms, describe which procedures apply to each arm of the study.

Click here to enter text.

1. Please check the boxes for all applicable data collection procedures you plan to use:

One-on-one interviews

Focus Groups

Questionnaires/surveys

Analysis of secondary data ( educational records, government or private sector datasets, etc.)

Ethnographic observation

Physiological measurements

Biospecimen collection (saliva samples, blood draws, hair samples, etc.)

Mobile applications/data collection devices (e.g., Fitbits, actigraphs, etc.)

Behavioral decision-making tasks (e.g., puzzles, interactive games, etc.)

Physical activities such as walking and other forms of exercise

Other procedures (briefly list types of procedures here if not covered by the check-boxes above): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

For each of the procedures you checked off above, please describe the procedure and the timeline of data collection. We need to know how you will collect all of your study data and in what order data collection will occur. Describe the estimated duration of an individual’s participation in the study *for each study activity* and the estimated total time for each participant to complete all study activities.

Click here to enter text.

1. Specify the timing of any surveys and/or interviews/ focus group discussions that will be administered. Explain if there will be multiple rounds of data collection and over what anticipated time period. Do you anticipate that there may be future rounds of data collection as part of this study, and will data collected from the current study be used to re-contact participants for future data collection? Specify if there will be an initial survey/interview/focus group to collect eligibility and contact information to be used for the later data collection rounds.

Click here to enter text.

1. Explain whether the surveys and other data collection instruments 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, but we do need to know your translation procedures.

Click here to enter text.

1. If applicable, describe how the intervention/treatment will be delivered ( at individual or group level).

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. Will you record any audio, video, or photographs of study participants?

Yes

No

If yes, please describe whether the recording will be mandatory or optional for the participant, and the procedures for storing and destroying audio/video/photograph files. Note that you must inform participants about audio/video/ photographs recording procedures unless you can argue for why this element of the informed consent should be waived for your study. If recording or photography is required for study participation, explain why. If recordings or images will be used for public presentations and/or publications, you must obtain participants’ consent to those uses of the data.

Click here to enter text.

1. Will you collect any GPS data?

☐ Yes

☐ No

If yes, please describe why you are collecting GPS data and whether this poses additional risks to subjects.

Click here to enter text.

**J**. Will deception or non-disclosure be used in the study procedures? If so, please describe an appropriate debriefing plan

Click here to enter text.

**K.** 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/ geopolitical issues/ political/controversial opinions

Sexual Health or Behaviors

Physical Abuse

Involvement in Illegal Activities

Suicidal Ideation

Others (please describe below)

Elaborate below, if applicable, with measures to minimize the risks associated with studying these topics.

Click here to enter text.

**L.** 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? When will they be compensated? Please note that the value of compensation provided should be reasonable but not excessive for the area in which the study is being conducted.

Click here to enter text.

Study Participant Population

1. Describe who study participants are, list any inclusion and exclusion criteria that will be used during participant selection, how many participants do you seek to enroll in each arm, and in total and the age range of the target population.

Click here to enter text.

1. A. Will the study seek to enroll any of these vulnerable populations?

Children

Pregnant Women (where the research activities are expected to affect pregnancy/ mother’s health status and/or the fetus)

Prisoners

Veterans

Adults Unable to Consent/Cognitively Impaired Individuals

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

Elaborate below if you checked any of the boxes, and describe procedures that will be used to safeguard these subjects.

Click here to enter text.

Research with Children (complete this section ONLY if you indicated enrolling children as research participants in the question above)

* Describe how parental permission will be obtained and the assent process for child participants.

Click here to enter text.

* Waiver of parental permission

If you want to request a waiver of parental permission, explain why:

Click here to enter text.

**Note:** It is also possible to request a waiver of parental permission on the basis that parental permission is not a reasonable requirement to protect the participants (e.g., research with neglected or abused children or research with children while they are outside of parental control)—if you seek a waiver of parental permission on this basis, explain your rationale and what additional protections will be in place for child research participants. If there are other host country/region-specific reasons for not obtaining parental permission, specify them here.

Click here to enter text.

* Waiver of child assent

If you are seeking a waiver of child assent, check the applicable box below and explain why you are requesting a waiver of assent.

The capability of some or all of the children to be enrolled is so limited that they cannot reasonably be consulted (for example, the study will collect data from babies or toddlers who are too young to understand an assent process)

Other

Click here to enter text.

Informed Consent and Request for Waivers of Consent

# Please describe the consent process, including how will the informed consent be obtained, where and when the consent process will take place. Specify whether a written, signed consent form will be used or a verbal process with a consent script, online consent script preceding a survey, etc. If consent will be obtained in different ways for different participants groups or study phases, describe the consent process that will be used for each participant group and/or study phase.

* What sociocultural factors could affect the consent process in the countries/regions where you will collect data? For example, are there low rates of literacy, cultural customs that require consent from a community or family leader, etc.?

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

Written

Verbal ( provide an explanation below in question 2c)

Requesting Waiver (Partial or Full)

1. Request for Waiver/ alternation of Informed Consent
2. A waiver of consent is different from a waiver of the participant signature requirement—if you are ONLY requesting a waiver of the participant signature, do not complete this section—complete Question 2c below. The most common scenario for requesting a complete waiver of the consent process is for studies that are only analyzing secondary data (data collected for purposes other than the current research study). If this is not applicable to your study, indicate N/A

Click here to enter text.

1. If the research involves using identifiable private data and/or identifiable biospecimens, you must also explain why the research could not practicably be carried out without using the data or biospecimens in an identifiable format.

Click here to enter text.

1. Request for Waiver of Participant Signature on Informed Consent

Under the federal IRB regulations, the standard is that consent should be documented by having the adult participant sign the consent form. However, there are many situations where obtaining a participant’s signature on the consent document is not feasible (e.g., interviews and surveys via phone/Skype, online platforms, data collection about activities that are otherwise sensitive). If you do not plan to obtain the participant’s signature on the consent, explain the reason that applies to your study.

Click here to enter text.

**Note:** If this waiver is granted, the IRB may still request that the research team provide participants with an Information Sheet containing the elements of a consent form but formatted appropriately (i.e., without signature lines) and/or a Script for Oral Consent reflecting the researcher’s side of the consent dialogue.

Possible Risks and Anticipated Benefits of the Study

# Discuss all possible risks and anticipated benefits to the prospective study participants. The risks can be physical, psychological, social, financial, or legal risks to individuals as well as communities.\*\*\*\* add additional instructions on risks of incidental findings in higher-risk studies\*\*\* Please elaborate if there is a risky study location with potential risks to staff in addition to participants. Please describe in detail plans to manage or mitigate all risks including the risks of loss of privacy, describe the steps you will take to protect participant privacy. For example, how will you conduct interviews that ask sensitive questions in locations where the interview cannot be overheard by others.

Click here to enter text.

In addition, please specify if there will be any anticipated benefit(s) to the study participants and the larger population or community. Please note that monetary compensation or reimbursement for the participant’s time is not considered a benefit. If there are no direct anticipated benefits, please state so.

Click here to enter text.

Recordkeeping

Describe how you plan to ensure that the study team will follow the study protocol and will properly record and store study data collection forms, IRB regulatory submissions, and correspondence including deviations, unexpected events, timely submission of closure reports, and other study-related documentation.

Electronically (e.g, MyRA)

Others

Click here to enter text.

Data Collection Procedures

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

Electronically (ex. using survey CTO, WhatsApp, etc.)

Paper

Third-party administrative data

Recordings

Other (e.g. mobile apps for research)

Add any details you deem instructive.

Click here to enter text.

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

IPA

Partner Organization

Other. Specify: Click here to enter text.

10. Data Protection and Confidentiality

**A.** Please refer to the table below to indicate which personally identifiable information (PII) will be collected to answer the questions below to describe how confidentiality will be maintained.

|  |  |  |
| --- | --- | --- |
|  | **Recruitment** | **Data Collection** |
| Name, signature, initials, or other identifiable code |  |  |
| Geographic identifier: address, GPS location, etc. |  |  |
| Dates: birth, death, dates of service, assessments, etc. |  |  |
| Contact information: phone numbers, email address, etc. |  |  |
| ID: Social Security Number or equivalent, driver’s license number, etc. |  |  |
| Health record identifiers: medical record, insurance plan number, etc. |  |  |
| Account numbers (ex. bank accounts or other financial info) |  |  |
| Device identifiers: (ex. implants) |  |  |
| Internet identifiers: IP address, social media accounts |  |  |
| Biometric identifiers, including finger and voice prints |  |  |
| Audio recordings |  |  |
| Video or full-face photographic images |  |  |
| Any other unique identifying number, characteristic, or code (note: this does not mean the unique code assigned by the investigator to code the data) |  |  |
| Other: Click here to enter text. |  |  |

**B.** When you respond to the following questions below, refer back to the table above and think of all PII collected during recruitment, consent, data collection, and other study purposes.  
**i.** Will you use the encrypted Survey CTO platform at all levels of data collection, transfer, and storage?    
 Yes  No, please explain  
**ii.** For paper forms, will you store all research files and data securely in a locked cabinet or room with restricted access only to study personnel?  
 Yes  No, please explain  
**iii.** Will the data be collected or stored on a password-protected and encrypted portable device (laptop, mobile phone, tablet, PDA)   
 Yes  No , please explain  
**iv.** Will you store the research data be on a secure server (ex. Box cryptor)  
 Yes  No , please explain  
**v.** If study IDs/Codes are used, will the key be stored separately from the study data? Yes ☐ No ☐, please explain  
**vi.** Will you destroy the hard copies/paper forms containing all PII immediately after data transcription, abstraction and cleaning are complete?   
 Yes  No , please explain the plan for future storage and use of research data  
**vii.** ONLY FOR STUDIES USING MOBILE APPS: When the use of a mobile app is approved solely for research use, the IRB either requires that it be restricted to people who consented to the research, or when a screen/script is used, for participants to understand that this is not a medical tool or a public app, but is for use only in a research study only. Please check the appropriate box(es) below that describe your study:

Use of the app is restricted to people in the research, with access limited to those who have consented to the study.

The consent information for participants clarifies that the app is not for clinical or public use but is restricted to this research study

**viii.** Any other detail that you would like to provide regarding data usage, storage, and confidentiality that is applicable to your study

Click here to enter text.

**C.** Are there specific laws governing the collection, sharing, and export of research data in the country/region where research will be conducted? If yes, indicate what those are and whether you have obtained approval from the appropriate local agencies, or it is under review.  
  
 Yes, *please explain -* Click here to enter text.

No

APPENDIX

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

CONSENT FORM CHECKLIST AND TEMPLATE

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. *If applicable*, this includes a statement alerting participants about the random nature of the experiment. |  |  |  |
| Exculpatory and coercive language are excluded |  |  |  |
| Jargon and confusing language are excluded. Ensure phrasing is clear, comprehensible and concise. |  |  |  |
| Potential participant is “invited” not “chosen” to participate |  |  |  |
| 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.) |  |  |  |
| Risks and discomforts are adequately described (i.e. Might some of your questions make respondents feel uncomfortable?) |  |  |  |
| Statement that participation is voluntary |  |  |  |
| Statement that participants do not have to answer all questions and that there is no penalty for skipping any question |  |  |  |
| The duration of overall study: Will there be a follow-up survey? When? How many follow-up surveys? *If applicable:* 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.)  Note: Researchers should not re-contact participants once the study is closed unless they have given their permission for them to do so for that purpose |  |  |  |
| The time it will take to complete survey is noted |  |  |  |
| Procedures for any audio or visual recording including:   1. That recordings will be taken and what type (audio or video) 2. When the recordings will be taken if known; the consent can say “at a random time in the interview” if unknown 3. Why the recordings will be taken 4. What the recordings will be used for 5. How the recordings will be kept confidential 6. If and when the recordings will be destroyed 7. 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 |  |  |  |
| 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 |  |  |  |
| Explanation that identifiable data will not be shared outside of predetermined, authorized parties. |  |  |  |
| 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” |  |  |  |
| A statement about whether participants' information might be stripped of identifiers and used for future research |  |  |  |
| *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, e.g. 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.) |  |  |  |
| Local, accessible contact for questions about the research study. *Must include a phone number* 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 or withdrawal at any time will not lead to penalty or loss of benefits |  |  |  |
| *If applicable:* 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 |  |  |  |
| *If applicable:* 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.) |  |  |  |
| 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. |  |  |  |
| Space to record response to consent (yes/no) and *if applicable*: space to record response to consent to audio/visual recording and GPS coordinates (if being collected). |  |  |  |
| 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. |  |  |  |
| Sufficient opportunity to ask questions |  |  |  |
| *For written consent only:* Space for signature and/or 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 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 |  |  |  |

1. Note: We **no longer** require projects to submit any documentation in local languages. However, you must explain in the application the procedures that will be used to translate the recruitment, consent, and data collection materials in the local languages(s). [↑](#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)