Child, Caregiver & Household Well-being Survey Tools for Orphans & Vulnerable Children Programs

MEASURE Evaluation
PROTOCOL TEMPLATE

Cover photograph by Zahra Reynolds, MEASURE Evaluation, of children in Liberia.

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This template has been supported by the President's Emergency Plan for AIDS Relief (PEPFAR) through the U.S. Agency for International Development (USAID) under the terms of MEASURE Evaluation cooperative agreement GHA-A-00-08-00003-00, which is implemented by the Carolina Population Center at the University of North Carolina at Chapel Hill, with Futures Group, ICF International, John Snow, Inc., Management Sciences for Health, and Tulane University. The views expressed in this publication do not necessarily reflect the views of PEPFAR, USAID or the United States government.

September 2013 MS-13-79

ACKNOWLEDGEMENTS

This protocol template was prepared by Dr. Jenifer Chapman, with key input from Drs. Karen Foreit, Lisa Parker, and Zulfiya Chariyeva at MEASURE Evaluation/Futures Group. At USAID, the protocol template was reviewed by Dr. Janet Shriberg, Erin Balch, Bourke Betz, and Virginia Lamprecht.

The development of this tool kit was highly participatory. Materials represent the current best practice around the measurement of OVC and caregiver well-being in the context of PEPFAR-funded OVC programs.

At USAID, the development of this toolkit was shepherded by Dr. Janet Shriberg and Gretchen Bachman, with key input from the wider PEPFAR Orphans and Vulnerable Children Technical Working Group, especially, Dr. Beverly Nyberg at Peace Corps and Dr. Nicole Benham at the Office of the Global AIDS Coordinator. We thank Dr. Krista Stewart for her guidance as the MEASURE Evaluation Agreement Officer Representative.

The important contributions of implementing partners, researchers, government staff and other stakeholders, too numerous to list, cannot be overstated. This is truly a community tool kit, and we are grateful to our colleagues for their generosity of time, resources and experience.

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PREFACE: USERS' GUIDANCE

Description and Purpose

A research protocol is a prerequisite to implementing the PEPFAR OVC Survey Tools, for several reasons. The process of protocol development enables discussion and agreement on the implementation strategy, and child protection issues, among other things. This process improves the study design, enables matching of resources to objectives, and ultimately improves the usability of the data generated from the study. A protocol is also required for peer-review (suggested), donor review, and ethical review (mandatory). Institutional review boards globally require a detailed study protocol including data collection tools. Finally, the protocol is a guidance document for all stakeholders throughout the study period, serving as a reminder to all stakeholders of the agreed strategy and timeline.

Groups wanting to implement the OVC Survey Tools will need to develop a protocol that reflects the specific objectives of the study. However, the structure of research and evaluation protocols are similar, regardless of study objectives, and there are issues related to child protection and research ethics that are relevant to all types of OVC studies, and all OVC research questions. In this document, we have aimed to provide as much guidance as possible on protocol development. We have developed this protocol *template* for several reasons, specifically:

1. To familiarize investigators with PEPFAR's expectations around how these tools should be implemented;
2. To standardize child protection and research ethics safeguards; and
3. To reduce the burden on local and international researchers who want to implement the OVC program evaluation tools. We hope that this template will reduce the level of effort needed to develop the study-specific protocol.

Audience

This template protocol has been developed for use by local and international investigators and other research stakeholders, such as program managers, donors and government. We highly recommend that protocols be developed in a participatory manner, involving all study partners,

including local and international research partners and program managers, donors and the host country Government. Early participation of key stakeholders can facilitate access to populations and even resources, and use of study evidence in program design and policy making.

Structure

We have structured this document to resemble an actual research protocol, including appendices. For each section, we have outlined the information that is required, as well as issues to consider when developing your own protocol. Where possible, we have included illustrative text and examples to improve clarity and further reduce the burden on investigators. Importantly, this document has been developed as a guide. Your own research questions and study design will determine the final outline and content of your study-specific protocol.

Please note that this template is a work in progress. As we learn from the users of our materials, we will improve upon them. We hope that this template is a useful starting point for you, in developing your own protocol. We would certainly welcome any feedback.

1. STUDY OVERVIEW

1.1. Funding agency

Name the funding source/s of the study, and the award number, if relevant.

1.2. Investigators

Provide a brief, 3-4 sentence biography of each named investigator. Investigators are the people responsible for the design and implementation of the study. While many people are involved in each study, investigators are ultimately accountable to both their organizations and the donor. One to two investigators per organization are typically involved in the study. When choosing investigators and particularly, the principal investigator, pay close attention to donor guidance. USAID encourages the participation of local researchers external to service delivery[1], and requires an external principal investigator[2]. Provide details about the specific role of each investigator on the study.

Name the principal point of contact for the study.

1.3. Protocol summary

Outline the aim, primary objective, and primary hypothesis, and summarize the methodology (study design, sampling strategy, sample size, data collection method/s, method of data analysis), and study timeline. This section should be up to one page.

1.4. Management and collaboration

Name the different organizations that have been involved in the design of the study and that will be involved in data collection, analysis, and report writing. Briefly outline the roles of each organization in the study. If any organization involved in the study is also involved in implementing the intervention or program under study, outline how any conflict of interest will be avoided.

[1] USAID. 2011. Evaluation Policy. Washington, D.C.: USAID.
[2] USAID. 2012. ADS Chapter 203. Assessing and Learning. Washington, D.C.: USAID.

Briefly outline the staffing structure for the study, and the structure and membership of any advisory or steering committees that will provide input into the study. Make sure to consider government collaborators.

This section should be less than one page.

2. INTRODUCTION

2.1. Study background

Provide background information on the study. Investigators may choose to have several subheadings in this section. (Recall that the OVC survey tools have been designed for use in program evaluation, but may be adapted for use in intervention evaluation and situation analysis: Please see Tool Manual.) If you are doing a program evaluation, or if you are evaluating an intervention, we suggest the following sub-headings:

2.1.1. Overview of the program and/or intervention being evaluated

Outline the scope, objectives, target population, reach/coverage, implementation schedule of the program, and the primary implementing organizations.

2.1.2. Country context

Outline the current *situation and response* in the country or region of study, including relevant, available data. You may want to include information on the burden of HIV/AIDS in the country/region, estimates of the number of OVC, and the characteristics of OVC. It may be possible to obtain this information from a recent Demographic and Health Survey (DHS), Multiple Indicator Cluster Survey (MICS) (both available online), or other sources. You should also include information on the response to OVC in country, including government and donor initiatives, as well as the leadership and governance structure for OVC work (e.g., the Ministries leading the effort and the scope of national policy related to OVC). Indicate why the proposed study is a government priority, or fits within government priorities. Make sure you reference appropriately in this section, including all relevant government documents and data sources that you use.

If you are only conducting a situation analysis (versus an evaluation), the information in 2.1.2, above, is sufficient for this section.

This section should be two to three pages in total.

2.2. Study rationale

Answer these questions: Why is this study being conducted, and why now?

If you are evaluating a specific intervention, clearly explain how the intervention is expected to lead to the outcomes of interest, referencing the known and hypothesized causal pathways (a diagram is useful). This is referred to as the theoretical model underpinning the research.

For a program evaluation or a situation analysis, this section should be about half a page. For an intervention evaluation, this section should be one page or more.

2.3. Potential use of study findings

Describe how the data will be used by the program and other stakeholders, giving concrete examples where possible. For instance, consider how the government ministries responsible for OVC, other ministries, donors, and program managers might use the data. Consider the timeliness of the study and how various audiences might use findings in planned policy or programmatic decisions. If you are conducting a baseline or midline study for a program or intervention evaluation (versus a situation analysis) and the program is set to run for several more years, give examples of how the data can be used immediately to improve programs and policy. (Importantly, the objectives of the study and the study design proposed will determine how data should best be used: Please see the Data Use section of the Tool Manual.)

If findings will be relevant to an international audience, outline how they may be used. Note that the study will produce comparable outcome-level data to that collected from other OVC programs using the same tools in other countries, which will allow for more evidence-based decision making.

3. STUDY AIMS, RESEARCH QUESTIONS, AND HYPOTHESES

3.1. Aims

Outline the study aims. Depending on the study, it may have one or more aims. The phrasing of study aims differs depending on whether the study protocol refers to a program evaluation, an intervention evaluation, or a situation analysis. Here are some examples:

- To assess the contribution of the OVC program to child and caregiver well-being, in terms of health, education, social support, and protection, over time (program evaluation)
- To assess the impact of "Nutri," a nutrition education intervention, on children's well-being, over time (intervention evaluation)
- To determine the well-being of children and their caregivers in District One, in terms of health, education, social support, and protection (situation analysis)

3.2. Research questions

3.2.1. Primary research question

Outline the primary research question guiding the study. There should only be one primary research question, and it must be measureable and clear. It is this primary research question on which the sample size is based. Importantly, the outcomes listed in the research questions must be relevant, measureable, and should reflect data currently available. Please see related guidance on outcome measures in Section 4.4 below.

The phrasing and scope of primary research questions differs somewhat depending on whether the study protocol refers to a program evaluation, an intervention evaluation, or a situation analysis. Here are some examples of primary research questions for each type of study:

- What is the impact of OVC program participation on children's felt social support? (program evaluation)
- Are there differences in children's regular food consumption, measured as the percentage of children aged 2-17 years who have gone a whole day and night without eating in the last four weeks between children who participated in *"Nutri"*, and those that did not? (intervention evaluation)

- What are the characteristics of children in District One, in terms of health, education, social support, and protection? (situation analysis)

Note the differences in how aims and research questions are written. Aims are generally written as tasks, whereas, research questions are phrased as questions.

3.2.2. Secondary research questions

Outline the secondary research questions. It is appropriate to include three to five secondary research questions. The objectives should be measureable and clear. As above, the phrasing and scope of secondary research questions reflects whether the study protocol refers to a program evaluation, an intervention evaluation, or a situation analysis. Here are some examples:

- What is the impact of OVC program participation on caregiver's felt social support? (program evaluation)
- What is the impact of participation in program and/or intervention on children's dietary diversity? (program or intervention evaluation)
- What is the impact of participation in program and/or intervention on children's regular school attendance? (program or intervention evaluation)
- What is the impact of participation in program and/or intervention on children's birth certificate ownership? (program or intervention evaluation)
- How many OVC, per the national definition, live in District One? (situation analysis)
- What are the characteristics of OVC caregivers in District One? (situation analysis)
- What services are accessed by children and caregivers? (all study types)

3.3. Hypotheses

Outline hypotheses. There should be one primary hypothesis linked to the primary research question, and at least as many secondary hypotheses as there are secondary research questions. Hypotheses should be written to oppose the null hypothesis, which is always: the program or intervention had no effect. Considering the illustrative primary research questions outlined above, hypotheses may be:

- Children who are registered to receive services through the OVC program achieve greater improvements in food consumption, regular school attendance, birth certificate ownership, and felt social support by the end of the program, compared to children in comparison localities who are not registered to receive services.
- Children aged 2-17 who are registered to receive the *Nutri* intervention will achieve greater, improved food consumption compared to children aged 2-17 in comparison localities who are not registered to receive services as measured by percent of children aged 2-17 who have gone a whole day and night without eating in the last four weeks.
- Children living in District One have poor outcomes, in terms of health, education, social support and protection (situation analysis)

4. METHODS

4.1. Study design overview

Outline the study design (e.g. cross-sectional, quasi-experimental, randomized-controlled trial), and provide an overview of the methodological approach, including the study populations, sampling strategy (e.g., random sampling, cluster sampling, lot quality assurance sampling, purposive sample), and data collection methods (household survey). This section should be one to two paragraphs.

4.2. Study population

List and describe the study populations: caregivers, children aged 0-9 years, and children aged 10-17 years. If you are collecting information from other study populations (e.g., heads of household, service providers, or participants in specific interventions, such as savings groups), include this here as well. Outline the inclusion and exclusion criteria for each population group. For example, for a program evaluation, your inclusion criteria for households may be:

- At least one household member is registered to receive services with the program (intervention groups) or no household members are registered to receive services with the program (comparison group); and
- At least one child under the age of 18 lives in the household.

Your exclusion criteria may be:

- No consent for caregiver participation given by caregiver; and
- No consent for child participation given by caregiver or other guardian.

4.3. Study timeline

Outline the period of performance of the study, including key milestones such as protocol development, ethics submission and expected approval, data collection, data entry, data analysis, report writing, and dissemination. Include a detailed timeline, such as a Gantt Chart, in the appendix.

4.4. Outcome measures and exposures

Describe the primary outcome measure and the primary exposure, as well as secondary outcome measures and exposures. Outcome measures are indicators that investigators hypothesize will change as a result program intervention. For example, *food security* and *felt social support* are outcome measures of OVC programs, but the *number of orphans* and *disability* are not. Importantly, your outcome measures must be directly related to the study research questions.

Although it is most important to name a single primary outcome measure for intervention evaluation, it is also useful for program evaluation to name primary outcome measures. However, for a program evaluation you may be interested in a large number of outcome measures and may have a hard time naming one as "primary." This is acceptable. (One of the reasons we choose a primary outcome measure is to enable the sample size calculation. In program evaluation, a statistician may calculate sample size for a range of primary outcome measures, choosing the largest sample size calculated.) Importantly, naming a particular outcome measure as primary does not preclude the collection of data related to the other outcome measures of interest.

In choosing a primary outcome measure, you will want to consider the theory of change that you outlined in Section 2.2 above. The primary outcome measure should reflect a) what is of interest and b) what is measureable during the study period. For instance, if you are interested in nutritional outcomes, such as body mass index, but are concerned that the study period is too short to show changes in this outcome measure, you may wish to consider a lower-level outcome indicator such as food security. Also, it is best to choose a primary outcome measure or set of measures for which some data are available (e.g., a DHS or MICS variable). For instance, if you are interested in finding out if the program led to increased felt social support among the target population, but lack information at the outset about current levels of felt social support among the population, this variable cannot easily be used to calculate the sample size. Again, this does not mean that the study will not produce useful information on felt social support.

Outcome measures relevant to OVC program or intervention evaluation include:

- Percent of children malnourished
- Percent of children <5 years with recent diarrhea

- Percent of children <5 years with recent fever
- Percent of children who are too sick to participate in daily activities
- Percent of children >2 years with reported irregular food intake
- Percent of children aged 1-5 years fully immunized
- Percent of children with basic shelter
- Percent of children aged 10-17 years reporting basic support
- Percent of children who have a birth certificate/identification card
- Percent of children >5 years currently enrolled in school
- Percent of children >5 years regularly attending school
- Percent of children >5 years who progressed in school over time
- Percent of households in which caregiver reports basic support
- Percent of households able to access money to meet important family needs
- Percent of households that are food insecure due to lack of resources

4.5. Sampling plan, sample size, and power calculation

4.5.1. Sampling plan

Describe the plan for sampling both intervention and comparison group participants (for evaluations), or the general population if you are conducting a situation analysis. The rigor of the sampling strategy is extremely important. If the sampling strategy is inadequate, the utility of the data will be compromised.

There are a number of things to consider when developing your sampling strategy, such as:

- The information you want. For example, do you want to be able to compare indicators between states or provinces, or are national-level indicators sufficient? Similarly, do you want to be able to compare indicators between rural and urban locations?
- The information you have. Do you know, or can you find out:
    - The location and number of program beneficiaries, by locality?
    - The names and addresses of program beneficiaries?
    - Where other donor-funded or government programs operate that may influence outcome measures?
    - The geographic features of eligible localities?

    - The demographic characteristics of populations living in eligible localities?
- The implementation schedule of the program or intervention. If the program has already rolled out to a majority of localities in the country of study, this will affect your sampling strategy (and your study design), as there may not be a clear comparison group. If the program has not started and the implementation schedule is unclear, it is important to work with the program to design the study sampling strategy to align with the implementation schedule (to avoid "contamination," where individuals or geographic areas listed by the research team as the comparison group actually receive services, and conversely, where individuals or geographic areas listed by the research team as the intervention group do not receive services).
- The resources you have available. Both material and human resources will affect the scope of the study and how many localities can be visited.
- Your data collection schedule, including how much time you have for data collection (if you have less time, you may need to restrict the number of geographic areas that you sample from), and when you plan to collect data (some areas of the country may be inaccessible due to flooding, etc., at certain times of the year).
- Political stability in study areas.

Many of these factors will involve a trade-off with rigor and the generalizability of findings. It is important to seek the support of an expert in sampling before finalizing the sampling strategy.

4.5.2. Sample size and power calculation

Outline the sample size calculation. We highly recommend involving a statistician in calculating the sample size and writing this section.

You will need to identify a variable or set of variables on which to base the sample size (see Section 4.4 on Outcome Measures above). This is your primary outcome measure, which also relates to your primary objective. For example, if your primary outcome measure was the percent of children >5 years who are enrolled in school, you could obtain a current value from the most recent DHS. If the DHS data indicated that 50 percent of children were enrolled, investigators would determine what change they could expect over time as a result of program intervention. The most important decision for investigators involved in the sample size calculation is to

determine the level of impact or change that is programmatically relevant. If the intervention leads to a 2 percent change in school enrollment, is this sufficient to instigate roll-out of the intervention nationally? What about if the intervention leads to a change in enrollment by 10 percent, or 20 percent? The smaller the change needed to mandate policy or program change, the larger the sample size. It is a waste of resources to design a study that will only detect a small change in impact and will therefore not lead to change in policy. Investigators should work with program managers, the government, and donors to determine the level of impact that will prompt change.

For illustrative purposes, keeping our example of school enrollment, let's say that the documented (additive) impact in the intervention group needs to be 10 percent to lead to change in policy and programs. This means that if available data indicate that 50 percent of children are enrolled, investigators expect to find at least 60 percent enrollment among intervention group participants at endline, no or minor change in comparison group participants, and statistically significant differences between intervention and comparison groups at endline.[3] The baseline and endline value of the indicator (50 percent and 60 percent in our example), the level of statistical significance that you want to achieve, the power (or probability that the study will pick up this change[4]), and something called a "Type 1 error value"[5], are combined in a calculation (usually carried out in a computer program) to give the sample size of each arm (intervention, comparison). Investigators may then increase the sample size by various factors to account for inter-class correlation (the likelihood that nearby households will respond similarly), likely non-response, attrition in multi-year studies (depending on the mobility and mortality of the study population), and sub-group analysis (e.g. males/females).

[3] It is important to consider that the higher the initial (baseline) proportion, the harder it is to achieve change. For instance, it is much harder to see a change from 90 percent to 100 percent, than from 50 percent to 60 percent. This is because most people who were able to "change" have done so already. Those who have not changed may be the hardest to change and the hardest to reach. So if the value of your chosen primary outcome measure is already high, you may want to consider a different primary outcome measure.

[4] Investigators will need to agree the level at which to power the study. Often, 0.80 is chosen, which means that there is an 80% chance that the data will show the difference in impact indicated in the sample calculation.

[5] Type 1 error is a measure of the likelihood of showing a difference in impact when one does not exist (false positive). Often, 0.05 is used to denote the Type 1 error value, but this needs to be agreed with the study team.

4.6. Recruitment

Outline the procedures for recruiting participants (for evaluations, outline the differences in the recruitment strategy between intervention and comparison groups). Include the process for gaining informed consent and assent of potential participants, and reference consent and assent forms included in the appendix. If a service provider, program staff member or volunteer, or community member or leader will support recruitment, explain how they will be involved, and how information about a household's decision whether to participate will be kept confidential. If data collectors will make multiple visits to the household to achieve a full household response (all caregiver and child interviews), explain this. (Three "calls" to a household is customary to achieve high response rates.) If location information will be collected using GPS locators or other devices, explain this, and note how this information will be stored. If an individual or household from the sample is not able to participate for any reason and will be "replaced," explain how replacement will occur. If the study has multiple rounds of data collection with the same participants, outline any special mechanisms proposed for improving participant retention in the study.

4.7. Data collection

4.7.1. Instruments

Outline the data collection tools and procedures specific to your study. Illustrative text follows:

There are three household survey tools:

- *Primary Caregiver Questionnaire (household composition; background information on household and caregiver; household food security; caregiver well-being; HIV/AIDS knowledge, attitudes, and behaviors; and access to HIV prevention, care, and support)*
- *Child Questionnaire, ages 0-9 years, directed to primary caregiver (health and protection; education and work; food consumption; access to HIV prevention, care and support; anthropometric measures)*
- *Child Questionnaire, ages 10-17 (background information; diary; education; chores and work; food and alcohol consumption; health, support, and protection; HIV/AIDS knowledge, attitudes and beliefs; access to HIV prevention, care, and support; anthropometric measures)*

Data collection instruments have been translated into local languages: [insert languages], and translated versions of these instruments are included in the appendix. Full translated data collection instruments will be field-tested with at least 10 respondents each, following ethics approval in the United States and country of study.

4.7.2. Procedures

Data collectors will operate in teams of two to ensure their own and the participant's safety and data quality. In every household, each data collection tool will be administered only once.[6] *The process is as follows:*

1. *Data collectors will enter the household and greet household members. They will explain the purpose of their visit and ask to speak to the caregiver (if not present).*
2. *Data collectors will seek informed consent from the caregiver for his/her participation and participation of children in household.*
3. *Data collectors will document consent.*
4. *Data collectors will administer the caregiver questionnaire. Caregivers will be interviewed out of earshot of school-age children and other adults in the household, including their spouse.*
5. *Data collectors will sample one child aged 0-9 years listed in the household schedule of the caregiver questionnaire. If there are no children in the household aged 0-9 years, data collectors will skip steps 6, 7, and 8.*
6. *Data collectors will administer the questionnaire for children aged 0-9 years to the caregiver, in reference to the sampled child.*
7. *Data collectors will seek and document informed assent from the sampled child to collect the anthropometric measurements.*
8. *Data collector will collect height, weight, and mid-upper arm circumference information from the child.*

[6] In some cases, investigators may wish to implement the intervention for all children in the household, or to assess intra-household equity between males and females, biological and non-biological children, or children of different age groups. The costs of this will need to be weighed against the added value of the information. For illustrative purposes, this section is written assuming only one child in each age group (0-9, 10-17 years) will be interviewed per household.

9. *Data collectors will sample one child aged 10–17 years listed in the household schedule of the caregiver questionnaire. If there are no children in the household aged 10–17 years, data collectors will skip steps 10 and 11.*
10. *Data collectors will seek informed assent from this child, and if given, document informed assent.*
11. *Data collectors will administer the questionnaire for children aged 10–17 years directly to the child. Children will be interviewed within plain sight, but out of earshot, of their guardians/other adults.*
12. *Data collectors thank the household member for participating and leave contact card with information of the study coordinator and local IRB.*

4.7.3. Data flow and quality control

Outline procedures that have been put in place for quality control, and how data will flow. We recommend at least three sub-sections: selection and training of data collection staff; data flow and quality control; and monitoring program/intervention fidelity.

Selection and training of data collectors

Explain how data collectors will be recruited and trained. Some illustrative text follows:

Data collectors will have prior experience in collecting household-level data (e.g., through DHS, sexual behavior survey, MICS, etc.), will have at least completed secondary school, will be proficient in one of the local languages of study in addition to English, and will be cognizant of the socio-cultural values and sensitivities of the target group/study communities. We will also consider gender balance on the data collection team. More experienced data collectors will act as "supervisors" in the field during data collection. Data collectors will complete a one-week training, which will orient them to the study, ensure familiarity with questionnaires and recruitment methods, and emphasize the importance of gaining informed consent and child assent, maintaining confidentiality, ensuring participant privacy, and conducting research with children. All data collectors will be required to "pass" a research ethics quiz at the end of training, prior to beginning field work.

Data flow and editing

Explain the organization of data collection, including who will be involved and how questionnaires will be edited and transported. Some illustrative text follows:

Household survey data will be collected by [insert number] data collection teams, each including [insert number] *pairs of data collectors and one supervisor. The supervisor will check all completed questionnaires before delivery to the central study office. Researchers will monitor each data collection team throughout the data collection period, moving among teams to check on progress and quality of work, clarify questions in the questionnaire, supply additional questionnaires and stationery, and advise on how to solve logistical problems. Supervisors will be given cell phones and will communicate any challenges to senior research staff immediately. Following data collection, all supervisors and researchers will be required to submit a report on field activities, including any challenges, to the study coordinator.*

Ensuring program/intervention fidelity (evaluation only)

Changes or delays to the implementation model or schedule are one of the biggest risks to successful evaluation. Describe how the study team will a) know if the intervention or program was implemented as planned (both the content and the schedule), and b) address any changes in the program implementation model and schedule.

4.8. Data handling

4.8.1. Data entry

Describe the process for entering data, noting who will be entering the data and the software to be used. If any double entry is planned, note the degree of double entry and any other planned data entry validation procedures.

4.8.2. Data analysis

Outline the plans for data analysis. The way you analyze the data will depend on your study objectives and design; however, we strongly suggest using the data analysis plan developed for the OVC Survey Toolkit as a guide. Some illustrative text follows:

Our data analysis plan builds on the MEASURE Evaluation OVC Survey Data Analysis Guides. Data analysis will involve descriptive statistics (e.g., frequency distribution, univariate analysis) as

well as binary and multivariate analyses. Statistical software [name of software] will be used for the analysis.

4.9. Study limitations

Outline any limitations to your study including any limitations to the generalizability of findings. The content of this section will depend on your study design, sampling strategy, and sample size, among other things.

5. HUMAN SUBJECTS, CONFIDENTIALITY, AND SECURITY CONSIDERATIONS

5.1. Human subjects considerations and IRB review

Outline your process of ethical review. We have included an explanation of suggested procedures/text that could be adapted to your study and included in this section:

All evaluation activities will adhere strictly to U.S. and international research ethics guidelines, including 45CFR46 and CIOMS. We are seeking IRB review and approval in both the U.S. [insert name of IRB] and in [insert country of study and name of IRB].

5.2. Assessment of risks and benefits to participants

Describe your assessment of the *risks and benefits* to both caregivers and children participating in this study. We have included some illustrative text that could be adapted to your study and included in this section:

We believe that participation in this study presents minimal risk to respondents. However, this research covers a broad range of issues that could be sensitive, such as information related to HIV and other chronic illnesses, as well as psychosocial issues, exploitation and abuse, and other issues specific to OVC and their caregivers. The investigators recognize that many of the problems that participants may be faced with are sensitive and stigmatizing issues, and particular care will be taken to ensure that all questions are asked in a supportive and non-judgmental manner. The interview team will be selected carefully to ensure they have experience conducting interviews and that they have good interpersonal skills. Interviewers will receive training to make them aware of the potential reactions participants may have and will agree to terminate the interview if the respondent shows significant distress. Staff and procedures will adhere to a study-specific Child Protection Policy, which is included as an appendix to this protocol. Interviewers will be trained in specific techniques for working with children and will be required to sign a Participant Privacy Agreement. Data entry staff will be carefully trained and required to sign a Confidentiality Agreement.

Although there is no immediate direct benefit to participants, the data generated from this study will improve service provision for this group in the short and long term.

5.3. Informed consent process

Describe the process by which data collectors will seek and document:

- Informed consent from adult caregivers to participate in the study
- Informed consent from adult caregivers for any children aged 10-17 to participate in the study
- Informed assent from children aged 10-17

We have included some illustrative text that could be adapted to your study and included in this section:

Before collecting any information, data collectors will seek and document caregiver informed consent to participate. Caregivers will be asked to consent to their own participation and to the participation of any children under their care. In line with international best practice, child participants aged 5 to 17 will also be required to assent to participation. Importantly, children aged 0-9 years will not be asked direct questions; however, we will aim to gather anthropometric measurements from children of all ages, with guardian consent and child assent. Consent and assent to participate will be verbal, but documented by the interviewer with his/her signature, name, and date.

We recognize the difference between consent and informed consent. We will provide potential participants with appropriate information about the study and their involvement in the study so they can make an informed choice. At the start of all interviews, potential participants will be informed verbally of the purpose and nature of the study and the expected risks and benefits. All potential participants will be made aware that their participation is voluntary and does not affect their eligibility to receive services from any programs now or in the future. All participants will be informed that the data collected will be held in strict confidence. To ensure that participants are aware that the survey includes questions on highly personal and sensitive topics, the interviewer will forewarn them that some topics are difficult to talk about. The respondent will be made aware at the outset that he or she is free to terminate the interview at any point, and to skip any questions that he or she does not wish to respond to. In the case of the child assent forms, particular age appropriate statements will be included to ensure that the research is understood and to prevent participants from feeling obliged to participate.

5.4. Compensation

If there is provision for compensating households for their time spent participating in the study, whether this is a drink and snack, transport (reimbursement), or a voucher or cash, outline the specific plans for compensating participants. Information on who will be compensated and what they will receive (and the value of compensation, if not monetary) should be provided. There are pros and cons to compensating study participants, which should be discussed with the wider study team and informed by local standards.

5.5. Confidentiality considerations

Outline procedures for ensuring that the privacy and confidentiality of participants will be maintained through (a) data collection, (b) data management, and (c) reporting. One exception to maintaining confidentiality is if a data collector or other study staff member has concern that a child may be in danger. Procedures for addressing suspected abuse or neglect must be clearly outlined in the Child Protection section of the protocol (see 5.6 below), and child participants aged 10-17 must be informed of these procedures. We have included some illustrative text that could be adapted to your study and included in this section:

All information gained from interviews will be kept confidential. Researchers, supervisors, data collectors and data entry staff will be required to sign a confidentiality agreement (see appendix). Adult participants will be interviewed out of earshot of others including their children and spouse. Child participants will be interviewed within plain sight, but out of earshot, of their guardians/other adults.

There is one exception as to when confidentiality may be breached. If the interviewer learns of a current abusive situation or if there is evidence that the child is in serious danger (emergency), then data collectors will follow the study emergency reporting protocol (see appendix). The data collector will report the case to the field supervisor, who will seek assistance from a program staff member or volunteer to resolve the issue. The child will be made aware of this exception through the following statement included on the assent form:

> *Everything you say today is confidential. That means that no one will know whom this information came from, not even the people from the program who provide services. There is one exception. If you tell us about experiences where someone is presently hurting you or if you think*

you might need some sort of counseling, we will inform a program staff member to make sure you are helped.

With the exception of the above instances where a breach of confidentiality is necessary for child protection, programs and program staff will not be made aware of individual survey results of any child or caregiver.

Following data entry, all hard-copy questionnaires and consent forms will be stored in a secure location, under the custodial care of the principal investigator. Hard copies will be kept for five years beyond the end of the study, and then destroyed.

Prior to analysis, data will be de-identified. Unique identification numbers will be used on all questionnaires to enable the production of the de-identified data sets. Particular care will be taken during the presentation of the research findings that the information presented is sufficiently aggregated to ensure that no single individual can be identified.

5.6. Child protection

Outline study-specific procedures in place for child protection. This should include:

- Procedures for checking the references of data collectors and others who will have direct contact with children;
- Stipulations that interviews with children will be conducted in plain sight of an adult guardian (though out of earshot);
- Training on working with and interviewing children for data collectors and others who will have direct contact with children;
- Stipulations that adult guardians must provide specific, informed consent for any children under their care to participate in the study and that children must provide informed assent, and that both consent and assent will be documented;
- Referral protocols for all children. We suggest that all children interviewed be given contact information for appropriate services;
- Referral protocols for children thought to be in distress or experiencing an emergency. If data collectors or others with direct contact with children find evidence of child abuse,

neglect, or other sign of distress or emergency, this needs to be reported to a service or individual that can mediate the situation. These reporting or referral protocols need to be documented and data collectors need to be trained on how to handle any child protection issues sensitively;

- A "whistle-blower" policy disseminated to everyone involved in the study and to program volunteers, with information on whom to contact if unprofessional behavior related to child protection concerns is witnessed in the field;
- Stipulation that all caregivers will receive a contact card or similar with contact information for the study coordinator and local IRB, whom they may contact if they have any concerns about the study or anyone involved in the study.

This information should be conveyed in a study-specific child protection policy, which should be disseminated to all study staff and volunteers.

6. DISSEMINATION PLAN

Outline products and plans for disseminating findings from each round of data collection (if there will be more than one round) to stakeholders including: a) research participants and communities, b) sub-national government structures, c) national government structures, d) the program being evaluated, e) the donor/s, and f) the international community. Investigators should consider multiple products, including a full report, brief reports, one-pagers, and verbal communication. Investigators should also consider submitting findings to peer-reviewed journals and national and international conferences to ensure dissemination to the international community. An example of how products can be organized is presented in the table below.

Product	Frequency	Intended audience
Final report	End of project	National government, international audiences, program, academics
…		

Further, the dissemination strategy should clearly articulate the methodology of information exchange with each group of stakeholders, considering their diverse information needs, subject matter expertise, literacy, and languages. The strategy used to disseminate findings to the national government will be very different from that used to share findings with communities. Investigators should focus on promoting the use of findings, and strategize on how best to encourage their use in policy and programs with different stakeholders. An illustrative way of organizing dissemination strategies is outlined in the table below.

Stakeholder	Dissemination strategy	Timeline
National government	One day dissemination event	Following each round of data collection/analysis
…		

7. DATA WAREHOUSING AND SHARING PLAN

Outline plans for data warehousing and any plans for data sharing between organizations. A data warehousing plan outlines where and how data will be kept, and for how long. It also describes how identifying information is kept – with the original data set, in a separate file, or not at all. Outline whether or not files will be password-protected, who their custodian will be, and who will have access to them.

If identifiable data are to be shared between organizations after the study is completed, this needs to be explicitly stated in all study information sheets, and consent forms. All participants must consent to the sharing of their identifiable information with another organization. Data sharing may be of particular relevance if Governments want access to data, and/or if a different organization is planning on conducting the midline or endline, than the organization that conducted the baseline. Note that if participants do not explicitly consent to this data sharing, data cannot be shared.

REFERENCES

Include any data sources that you have referred to in the protocol. Follow an international journal standard for listing these resources.

APPENDICES

Appendix 1: Translated data collection tools

Append the data collection tools to the protocol. Protocol readers, generally IRBs, will want to see the translated versions of the questionnaires you plan to use. The versions of the data collection tools sent to the IRB will be draft. Investigators should forward the final data collection tools to both the U.S. and national IRB, indicating any changes.

Appendix 2: Information and consent forms

Sample information and consent and assent forms are included here. The language used should reflect your target population both in terms of complexity and structure. Child assent forms should reflect the level of comprehension expected for a 10-year-old in the geographic area of research. All information and consent/assent forms must be translated into the language/s of data collection.

INFORMATION AND CONSENT FORM FOR CAREGIVERS AGED 18 AND OVER

Introduction

Hello. My name is _____ and I am working with [insert name of organization and donor, if applicable]. We are conducting a survey about child and caregiver well-being so that we can improve the impact of our services and programs. To gather this information we are interviewing caregivers and older children in some households. We have randomly chosen to visit your household.

We would very much appreciate your participation in this survey. Participation involves an interview with you about your household, and one child in your care between the ages of 0-9 years. We would also like to directly interview a child in your household aged 10-17 years.

PART A. Consent for own participation

The interview with you will take between 30-45 minutes to complete. If you agree to participate, we will ask you questions from a printed questionnaire and we will note your answers on the questionnaire. Some of the questions are personal and some people may find them difficult to answer. You do not need to answer any questions that you do not want to.

The risks to you as a participant in this study are minimal. During the interview you may decide to share information that is personal in nature. But, again, you may skip any questions that you do not wish to answer or stop the interview at any time, without giving any reasons.

Other people will not know if you are in this study. We will put things we learn about you together with things we learn about other people from your community, so no one can tell what things came from you. When we tell other people about this research, we will never use your name, so no one will ever know what answers you gave me. Only a few researchers will have access to this information, and all information will be stored in a locked cabinet under the care of the principal investigator until it is destroyed in [*insert time*].

Your participation in this study will not benefit you directly, but it may benefit others in the future, as your responses will improve our understanding about ways to provide better services to people in communities like yours.

Your participation in this study is voluntary. If you don't want to be in the study, it is OK. If you want to be in the study now and change your mind later, that's OK too. You can stop at any time. If you agree to participate, you can decide not to answer certain questions and can stop the interview at any time. Your decision about whether to participate in this study or to answer any specific questions will in no way affect any services that you receive.

Before you say **yes or no** to being in this study, we will answer any questions you have. If you join the study, you can ask me questions at any time. Do you have any questions now?

[Pause & answer all questions]

If you have any questions later, you may contact the survey coordinator at _____.

CONSENT STATEMENT FOR SIGNATURE

I have read this entire consent form, or had it read to me, and any questions have been answered to my satisfaction. I agree to participate in this study.

Signature or thumbprint of Respondent (optional depending on local regulations): _____

Signature of Interviewer: _____ Date: _____

For Interviewer:

RESPONDENT AGREES TO BE INTERVIEWED . . . 1

RESPONDENT DOES NOT AGREE TO BE INTERVIEWED . . . 2 END

PART B. Parental consent for child aged 10-17 to participate

As I said earlier, we would also like to speak to one child/children aged 10-17 in this household. We would like to tell you more about what your child's participation would involve, and then ask for your consent for him/her to participate. If you consent, we will also tell the child the about study and what his/her participation in it will involve, and ask for agreement to participate.

As we said before, we are interested in finding out more about how our programs may benefit children. The interview with the child will take between 30-45 minutes. Similar to the procedure we will follow with you, we will ask the child questions from a printed questionnaire and note their answers on the questionnaire.

The risks to the child as a participant in this study are minimal. Some of the questions might be a bit personal and some children may find them difficult to answer. But he or she does not have to answer any questions that he or she is not comfortable with, and may end the discussion at any time. We would prefer to speak to the child alone but within your sight, but he or she can request to have you present during the interview at any time during our talk.

People outside your household will not know if the child participates in this study. We will put things we learn about the child together with things we learn about other children from your community, so no one can tell what information came from this household. When we tell other people about this research, we will never use names, so

no one will ever know what answers the child gave me. Only a few researchers will have access to this information, and all information will be stored in a locked cabinet until it is destroyed in [*insert time*].

The child's participation in this study will not benefit him or her directly, but it may benefit others in the future, as his or her responses will improve our understanding about ways to provide better services for children and young people.

It is up to you if you would like your child to participate. If you do not want him/her to participate, it is OK. Your decision about whether to allow your child to participate in this study or to answer any specific questions will in no way affect any services that you receive.

Before you say **yes or no** to your child being in this study, we will answer any questions you have. Do you have any questions now?

[Pause & answer all questions]

If you have any questions later, you may contact the survey coordinator at _____.

PARENTAL CONSENT STATEMENT FOR SIGNATURE

I have read this entire consent form, or had it read to me, and any questions have been answered to my satisfaction. I consent to my child/ren or the child/ren under my care to participate in this study.

Signature or thumbprint of Caregiver (optional depending on local regulations): _____

Signature of Interviewer: _____ Date: _____

For Interviewer:

RESPONDENT AGREES FOR CHILD/REN TO BE INTERVIEWED . . . 1

RESPONDENT DOES NOT AGREE FOR CHILD/REN TO BE INTERVIEWED . . . 2 END

THERE ARE NO CHILDREN AGED 10-17 IN THE HOUSEHOLD….3

INFORMATION AND ASSENT FORM FOR CHILDREN AGED 10–17 YEARS

My name is [researcher name]. I am trying to learn more about what children like you need so that we can offer better services and support through our programs.

If you would like, you can be in my study. Before you decide, let me tell you more about what participation involves. If you decide you want to be in my study, I will ask you some questions about your life, your health, and well-being. Some of the questions might be a bit personal and you may find them difficult to answer. But you do not have to answer any questions that you do not feel comfortable with, and you may end this talk at any time you want to. The questions we will ask are only about what you think. There are no right or wrong answers. This is not a test. However, your honest answers to these questions will help us better understand what you and children like you need.

Other people will not know if you are in my study. I will put things I learn about you together with things I learn about other children, so no one can tell what things came from you. When I tell other people about my research, I will not use your name, so no one can tell whom I am talking about.

Everything you say today is confidential. That means that no one will know whom this information came from, not even the people from the program who provide services. However, there is one exception. If you tell us about experiences where someone is hurting you or if you think you might need some sort of counseling, we will inform a program staff member to make sure you get help.

Your participation in this study is voluntary. If you don't want to be in the study, no one will be mad at you. If you want to be in the study now and change your mind later, that's OK. You can stop at any time. You can have your parent/guardian come in and sit with us if you would like. We can ask her/him to come in at any time that you think you want them to come in.

Your decision about whether to participate in this study or to answer any specific questions will in no way affect any services that you receive. Your participation in this study will not benefit you directly, but it may benefit others in the future, if it helps to increase our understanding about ways to provide better services for children like you.

The interview will take between 30-45 minutes.

Before you say **yes or no** to being in this study, we will answer any questions you have. If you join the study, you can ask questions at any time. Do you have any questions now?

[Pause & answer all questions]

GIVE INFORMATION TO CHILD INCLUDING INFORMATION ON NEARBY SERVICES

Do you want to participate in this study?

ASSENT STATEMENT FOR SIGNATURE

I confirm that after listening to me read this entire assent form and having had the opportunity to ask questions, the child assented to participate. I have given the child information on nearby services that he or she may want to access.

Signature of Interviewer: _____

Date: _____

For Interviewer:

RESPONDENT AGREES TO BE INTERVIEWED . . . 1

RESPONDENT DOES NOT AGREE TO BE INTERVIEWED . . . 2 END

Appendix 3: Detailed study timeline

Investigators should include and adhere to a detailed study timeline. An example of how to organize the timeline is included here. Note that this example outlines major activities only; your timeline should include all study activities.

Activity	Year 1				Year 2				Year 3			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Convene research management group	X		X									
Finalize study protocol and tools	X											
Submit protocol and tools to 2+ IRBs	X											
Receive IRB approvals		X										
Conduct data collector training			X									
Conduct data collection			X									
Enter data			X									
Analyze data				X								
Write report				X								
Disseminate results				X								

Appendix 4: Child protection policy

All studies should have a study-specific child protection policy which outlines the investigators' approach to working with children, and the specific accommodations and mitigation strategies that have been put in place to improve the protection of children involved in the study.

Appendix 5: Confidentiality agreement

It is useful to ask researchers, data collectors, and data entry staff to sign a confidentiality agreement. This agreement is not binding per se, but signing may encourage those involved in the study to seriously consider their role in maintaining participant confidentiality. An example agreement follows.

CONFIDENTIALITY AGREEMENT

As a member of this research team I understand that I may have access to confidential information about study sites and participants. By signing this statement, I am indicating my understanding of my responsibilities to maintain confidentiality and agree to the following:

- I understand that names and any other identifying information about study sites and participants are completely confidential.
- I agree not to divulge, publish, or otherwise make known to unauthorized persons or to the public any information obtained in the course of this research project that could identify the persons who participated in the study.
- I understand that all information about study sites or participants obtained or accessed by me in the course of my work is confidential. I agree not to divulge or otherwise make known to unauthorized persons any of this information, unless specifically authorized to do so by approved protocol or by the local principal investigator acting in response to applicable law or court order, or public health or clinical need.
- I understand that I am not to read information about study sites or participants, or any other confidential documents, nor ask questions of study participants for my own personal information but only to the extent and for the purpose of performing my assigned duties on this research project.
- I agree to notify the local principal investigator immediately should I become aware of an actual breach of confidentiality or a situation which could potentially result in a breach, whether this be on my part or on the part of another person.

Signature: _____

Printed name: _____

Date: _____

Appendix 6: Referral protocol for children in emergencies

Investigators should outline the study-specific referral protocol for children in emergencies. The referral protocol must consider the availability and accessibility of local services, and any sensitivities around reporting abuse or neglect to local or community leaders.