



# Monitoring, Evaluating, and Reporting PEPFAR's Essential Survey Indicators for Orphans and Vulnerable Children Programs Research Protocol Template

March 2018



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March 2018

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Cover: A young boy watches activity at a social center in Abidjan, Côte d’Ivoire, where Resources for the Elimination of the Vulnerability of Children (Ressources pour l’Élimination de la Vulnérabilité des Enfants, or REVE)—a project funded by the United States President’s Emergency Plan for AIDS Relief (PEPFAR)—is being implemented. Photo: Lisa Marie Albert, MEASURE Evaluation, Palladium

# PREFACE

## Instructions

MEASURE Evaluation developed this protocol template for organizations collecting the Monitoring, Evaluation, and Reporting (MER) Orphans and Vulnerable Children (OVC) Essential Survey Indicators (ESI) of the United States President's Emergency Plan for AIDS Relief (PEPFAR). This protocol template includes sections on background, study design, human subjects research, and fieldwork procedures for data collection of the nine MER OVC ESI.

Institutional review boards (IRBs) often have preferred or required formats, and this template should be adjusted to meet those requirements, as needed. Instructions to the user are provided in ***bold italic font***. When general instructions are given in paragraph format, the first line of the paragraph is highlighted in yellow. Template instructions should eventually be deleted from the final protocol document. Any normal font within the template is suggested text and should be updated and adapted to fit your study's specific needs.

This template assumes that the survey will be conducted using electronic tablets with paper questionnaires as backup in case of tablet failure.

Examples of the results of previous PEPFAR OVC MER ESI studies—tools, guidance documents, and frequently asked questions—can be found online at <https://ovcimpact.org>. Feel free to contact us through the website or at [ovcimpact@thepalladiumgroup.com](mailto:ovcimpact@thepalladiumgroup.com) with any questions. Likewise, if you are interested in submitting your study documents for us to share on the [ovcimpact.org](https://ovcimpact.org) site, please let us know.

## Purpose

A study protocol is a prerequisite to implementing PEPFAR's MER OVC ESI, for several reasons. The process of protocol development enables discussion of 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. 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 PEPFAR MER OVC ESI will need to develop a protocol that reflects the specific objectives of the study. We have developed this protocol template for the following reasons:

- To familiarize investigators with PEPFAR's expectations of how these tools should be implemented
- To standardize child protection and research ethics safeguards
- To reduce the burden on local and international researchers who want to implement the PEPFAR MER OVC ESI survey. 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 collecting the MER OVC ESI. We highly recommend that protocols be developed in a participatory manner, involving all study partners, including U.S. Government mission staff, PEPFAR implementing partner staff, the organizations responsible for designing and conducting MER surveys, local and international research partners and implementing partner project staff, and USG missions and headquarters staff. Early participation of key stakeholders can facilitate access to populations and use of study evidence in program design and policymaking.

## **Structure**

We have structured this document to resemble an actual research protocol, including appendixes. 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.

# Monitoring Outcomes of *Insert Project Name* Serving Orphans and Vulnerable Children

Submitted to:

*Insert name of ethics review board*

Submitted by:

*Insert name and mailing address of local partner*

*Insert name and mailing address of your organization*

Principal Investigators:

*Insert names of principal investigators*



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# CONTENTS

- TABLES..... 4
- FIGURES..... 4
- ABBREVIATIONS ..... 5
- 1. STUDY BACKGROUND ..... 6
  - 1.1 Study Rationale..... 6**
  - 1.2 Global Context ..... 6**
  - 1.3 Country Context..... 7**
  - 1.4 Description of OVC Project(s) Included in the Study..... 8**
- 2. STUDY OBJECTIVES, THEORY OF CHANGE, AND MER OVC ESI ..... 8
  - 2.1 Objectives..... 8**
  - 2.2 Theory of Change and Conceptual Framework ..... 9**
  - 2.3 MER OVC Essential Survey Indicators ..... 10**
- 3. METHODS..... 14
  - 3.1 Study Design ..... 14**
  - 3.2 Study Population..... 14**
  - 3.3 Statistical Power and Sample Size Calculations..... 15**
  - 3.4 Sampling..... 16**
  - 3.5 Sample Weights ..... 16**
- 4. DATA COLLECTION ..... 16
  - 4.1 Survey Tools and Pilot ..... 16**
  - 4.2 Data Collection Procedures..... 18**
    - 4.2.1 Sensitization of Communities Participating in the Household Survey..... 18
    - 4.2.2 Locating and Recruiting Survey Participants..... 18
    - 4.2.3 Conducting the Interview..... 19
  - 4.3 Recruiting and Training Enumerators ..... 19**
  - 4.4 Management of Fieldwork..... 20**
    - 4.4.1 Logistics and Supplies..... 20
    - 4.4.2 Scheduling and Deployment of Fieldwork ..... 20
  - 4.5 Data Handling and Analysis ..... 21**
    - 4.5.1 Data Quality Control ..... 21
    - 4.5.2 Data Security..... 22
    - 4.5.3 Data Analysis..... 23
    - 4.5.4 Data Sharing..... 23
- 5. HUMAN SUBJECTS, CONFIDENTIALITY, AND SECURITY ..... 24
  - 5.1 Human Subjects Considerations and IRB Review ..... 24**
  - 5.2 Risks and Benefits to Participants ..... 24**
  - 5.3 Informed Consent Process ..... 25**
  - 5.4 Confidentiality of Participants ..... 26**

<b>5.5 Child Protection</b> .....	<b>27</b>
<b>5.6 Compensation</b> .....	<b>28</b>
6. DISSEMINATION PLAN .....	28
7. STUDY LIMITATIONS .....	28
8. STUDY MANAGEMENT.....	29
9. STUDY TIMELINE .....	30
REFERENCES.....	31
Appendix 1: Survey Questionnaires.....	33
Appendix 2: Consent Forms.....	34
Appendix 3: Confidentiality Agreement for Study Team Members .....	35
Appendix 4: Biographies of Principal Investigators .....	36
Appendix 5: Study Budget (If Required) .....	37
Appendix 6: Study Timeline .....	38

## TABLES

Table 1. PEPFAR MER Essential Survey Indicators for OVC Programs (MEASURE Evaluation, 2015).....	11
Table 2. Supplemental indicators .....	13
Table 3. MER OVC Essential Survey Indicators Sampling Assumptions .....	15
Table 4. Study Budget .....	37
Table 5. Timeline of study activities .....	38

## FIGURES

Figure 1. Sample Conceptual Framework 1: Ressources pour l'élimination de la vulnérabilité des enfants (REVE) project in Cote d'Ivoire (Palladium, 2016) .....	9
Figure 2. Sample Conceptual Framework 2: Botswana Comprehensive Care and Support for OVC Project (BoCCaSO) Conceptual Framework (4Children, 2017) .....	10
Figure 3. Study Team Organigram .....	30

***Update the contents, table, figures, and appendices to reflect exactly what is included in your project's final protocol.***

## ABBREVIATIONS

ART	antiretroviral therapy
DHS	Demographic and Health Survey
ESI	Essential Survey Indicators
MER	monitoring, evaluation, and reporting
MICS	Multiple Indicator Cluster Survey
OVC	orphans and vulnerable children
PEPFAR	United States President's Emergency Plan for AIDS Relief
PMTCT	prevention of mother-to-child transmission

# 1. STUDY BACKGROUND

## 1.1 Study Rationale

**Provide a brief rationale for the study. A sample description is given below.**

The U.S. President’s Emergency Plan for AIDS Relief (PEPFAR) has invested considerable resources in OVC programs, but to date, outcomes of these investments as measured by well-being of OVC and their households have not been studied systematically or on a large scale. The purpose of this study is to collect the nine Monitoring, Evaluation, and Reporting (MER) Orphans and Vulnerable Children (OVC) Essential Survey Indicators (ESI) for outcomes monitoring of *insert name of project(s)* in *insert country name*.

The results will be used will be used to:

- Support evidence-informed strategy, program planning, targeting, resource allocation, and implementation by *insert country name* stakeholders such as OVC policymakers and program managers
- Contribute to a global PEPFAR-wide evidence base on the effectiveness of PEPFAR OVC programming

## 1.2 Global Context

**Describe the current global OVC and HIV literature, as well as general information on the PEPFAR response and the purpose of the MER OVC ESI. This should be up to two pages long. A sample description is given below.**

The HIV epidemic has exacted a significant toll on children and their families and has contributed to an increase in the number of OVC worldwide. During the 30 years of the global HIV epidemic, an estimated 17 million children have lost one or both parents due to AIDS; ninety percent of these children live in sub-Saharan Africa. In addition, 3.4 million children under age 15 are living with HIV. Despite some decline in HIV adult prevalence worldwide and increasing access to treatment, the number of children affected by or vulnerable to HIV remains alarmingly high (UNAIDS, 2010).

The social and emotional effects of the disease are numerous and profound. As a result of the social effects of HIV/AIDS, millions of HIV-affected children are highly vulnerable, as they are more likely to be victims of abuse, live in institutional care or on the street, and engage in hazardous and/or exploitive labor. More specifically, children who live with an ill adult or who have been orphaned by AIDS have a dramatically greater risk of abuse and exploitation, dropping out of school (as children leave school to care for ailing family members), and psychosocial distress (Atwine, et al., 2005; Cluver, et al., 2011; Cluver, et al., 2012; Guo, et al., 2012). OVC are also far more likely to move from being “affected” by the virus to becoming infected, as well as facing other risks. This is especially true for adolescent girls who have lost a mother and who are then more likely to engage in risky sexual behavior (Operario, et al., 2011).

Children infected by the disease are significantly affected. Where there is no program for the prevention of mother-to-child transmission (PMTCT), children are often infected by the virus at birth or soon afterwards. Even with the mother on treatment, HIV-negative but exposed children experience delayed

cognitive development (Smith, et al., 2006; Sherr, et al., 2009). Additionally, children living with HIV sometimes have the compounded tragedy of being rejected by their families and abandoned to orphanages, further contributing to impaired cognitive and physical development (Nelson, et al., 2007).

Globally, PEPFAR support focuses on delivery of a comprehensive set of core interventions that include referrals for nutrition; the integration of antiretroviral therapy (ART) adherence into routine household monitoring; the promotion of positive parenting; the provision of psychosocial support to affected households; economic strengthening activities for households, such as group savings and loans, cash transfers, and food subsidies; and educational support (Bachman, 2015). Linking HIV-infected children and adolescents to HIV care and treatment services is a current priority (Bachman, 2015).

As part of its new MER guidance, the PEPFAR launched a set of outcome indicators for OVC programs in 2014. These outcome indicators are designated as “essential survey indicators,” which means that PEPFAR considers them critical to tracking progress within PEPFAR-funded projects and has, therefore, made them a reporting requirement. These outcome indicators aim to assess overall project effectiveness in improving the health and well-being of children and their families affected by HIV/AIDS, supplementing routine PEPFAR monitoring (primarily through program inputs and outputs) and project evaluations (MEASURE Evaluation, 2015).

### 1.3 Country Context

***Outline the current situation and response in the country or region of study, including relevant, available data, similar to the 9 MER OVC ESI that could eventually be compared with the MER OVC ESI study results. 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), OVC situational analyses, or other sources. This will be needed for the final report and can save time if included in the protocol.***

***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).***

## 1.4 Description of OVC Project(s) Included in the Study

**Insert a paragraph describing the OVC project(s) included in the study. This description should outline the project scope, objectives, detailed description of services and interventions provided (i.e., where they are implemented, how services are implemented, and by whom), number of target beneficiaries, geographic reach/coverage, implementation schedule, and the primary implementing organizations.**

**If this study covers more than one project, consider including a table to identify the differences in length of project implementation, services, modalities, targeted OVC subpopulations, including whether they overlap geographically or are in mutually exclusive geographic areas. Describe the methodology for each independent survey.**

**Include the location(s) of where program beneficiaries access program services (e.g., facility vs. community-based) and who is providing the service (e.g., nurse, community worker).**

## 2. STUDY OBJECTIVES, THEORY OF CHANGE, AND MER OVC ESI

### 2.1 Objectives

**Describe the overall study objectives of implementing the outcomes monitoring study of the nine MER OVC ESI. A sample description is given below.**

The overall objective of the study is to monitor the health and well-being of **insert name of OVC project** beneficiaries in **insert country name**. This outcomes monitoring survey is being conducted to fulfill a PEPFAR global reporting requirement that aims to measure and track the progress of PEPFAR-supported OVC programs. The current study will serve as the **insert round number (first or second)** round of data collection for **insert name of project(s)**. The current study will assess health and well-being among child beneficiaries currently enrolled and receiving services at least quarterly in **insert project name**.

**If this protocol is for the first round of data collection, then include a paragraph similar to the following:**

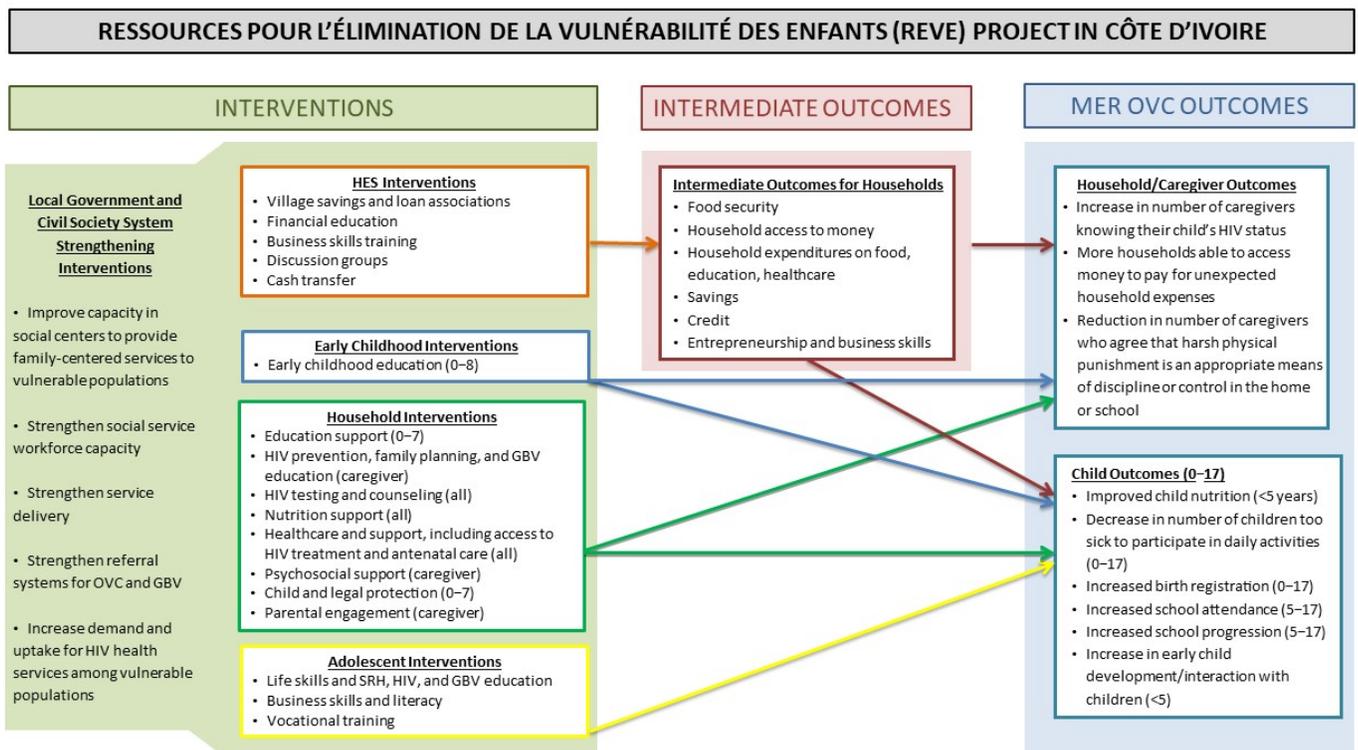
Future rounds of data collection (not included in this study protocol) will address the research question: Has the health and well-being of children participating in **insert project name** improved over time?

## 2.2 Theory of Change and Conceptual Framework

**Describe your project's theory of change and provide this theory in a diagram (often called a conceptual framework or a theoretical framework).<sup>1</sup> There may already be a project-specific conceptual framework or theory of change. However, if it does not have one, study researchers can work with the project to develop it.**

**Two examples of conceptual frameworks are provided below.**

**Figure 1. Sample Conceptual Framework 1:** Ressources pour l'élimination de la vulnérabilité des enfants (REVE) project in Côte d'Ivoire (Palladium, 2016)



<sup>1</sup>Conceptual Framework of Family Planning Demand and Program Impact on Fertility:

<https://www.k4health.org/toolkits/measuring-success/conceptual-framework-guides-and-examples>

Reproductive Health Framework Designed by MEASURE Evaluation:

[https://www.measureevaluation.org/prh/rh\\_indicators/overview/conceptual-framework.html](https://www.measureevaluation.org/prh/rh_indicators/overview/conceptual-framework.html)

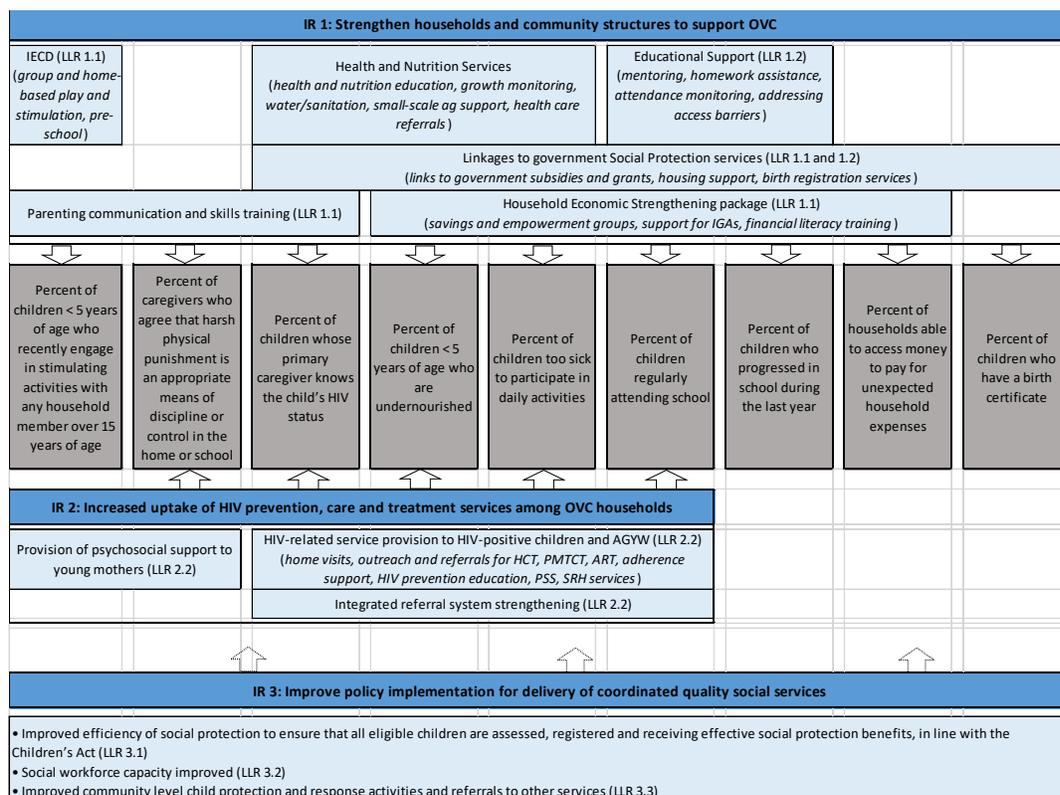
UN Women Monitoring and Evaluation Frameworks based on Theory of Change:

<http://www.endvawnow.org/en/articles/335-monitoring-and-evaluation-frameworks-3-parts.html>

Basic Terminology and Frameworks for Monitoring and Evaluation:

[http://files.unaids.org/en/media/unaids/contentassets/documents/document/2010/7\\_1-Basic-Terminology-and-Frameworks-MEF.pdf](http://files.unaids.org/en/media/unaids/contentassets/documents/document/2010/7_1-Basic-Terminology-and-Frameworks-MEF.pdf)

**Figure 2. Sample Conceptual Framework 2: Botswana Comprehensive Care and Support for OVC (BoCCaSO) project conceptual framework (4Children, 2017)**



### 2.3 MER OVC Essential Survey Indicators

**Describe the MER OVC ESI, their rationale for inclusion, and the program component of the project(s) that contribute to each indicator. A sample description is given below.**

The set of interventions delivered to members of households enrolled in the *insert project name* are expected to lead to improved health and well-being of children under age 18 and their households. Health and well-being will be measured through the nine MER OVC ESI shown in Table 1.

**Update column 3 in Table 1 according to the project(s) services.**

**Table 1. PEPFAR MER Essential Survey Indicators for OVC Programs (MEASURE Evaluation, 2015)**

No.	Outcome Indicator	Rationale for Inclusion	Insert Project Name Program Component That Contributes to the Indicator
<b>Health</b>			
OVC_SICK	Percent of children (aged 0–17 years) too sick to participate in daily activities	PEPFAR OVC programs support critical linkages to health services and treatment, aiming to reduce the number of sick children and improve functional well-being.	Curative measures for minor ailments such as diarrhea diseases, upper respiratory diseases. Sexuality education, sexually transmitted infection (STI) assessment and syndromic management for sexually active adolescents. Referrals to the facilities for treatment of moderate to major health problems.
OVC_HIVST	Percent of children (aged 0–17 years) whose primary caregiver knows the child’s HIV status	If a child’s HIV status is unknown to her/his caregiver, the child will not have access to life-saving care, treatment, and support interventions.	Health education on preventable diseases, personal and environmental hygiene, keying into programs; immunization, deworming, and other maternal and child health programs, HIV/AIDS education (with targeted testing). Referrals to the facilities for treatment of moderate to major health problems.
<b>Nutrition</b>			
OVC_NUT	Percent of children (aged 6–59 months) who are undernourished <i>For this indicator, the enumerator will obtain measurement of mid-upper arm circumference (MUAC) for children ages 6–59 months. It is the only indicator whose measurement requires direct interaction with a child.</i>	Nutrition is a critical factor in reducing infant mortality and builds a strong foundation for a child’s health, growth, and development.	Nutritional assessment and counseling, with provision of food supplementation for households in dire need. Collaboration with extended family and community on provision of food supplies to indigent households. Food demonstration. Referral to health programs in the community for nutritional support.
<b>Early Childhood Development</b>			
OVC_STIM	Percent of children <5 years of age who recently engaged in stimulating activities with any household member over 15 years of age	Early childhood cognitive, social, and physical stimulation is essential for promotion of long-term learning, growth, and health.	Kids’ club activities: recreational activities; football tournaments, debates, quiz competition, life skills training, indoor games, etc. Caregivers’ forum.

No.	Outcome Indicator	Rationale for Inclusion	<i>Insert Project Name</i> Program Component That Contributes to the Indicator
<b>Legal Rights</b>			
OVC_BCERT	Percent of children (aged 0–17 years) who have a birth certificate	Ensuring children access to basic legal rights, such as birth certificates, enables them to access other essential services and opportunities, including health, education, legal services, and legal employment when they grow older.	Establishment/strengthening of child protection committees (CPCs) in the community. Facilitation of obtainment of birth certificates.
<b>Education</b>			
OVC_SCHATT	Percent of children (aged 5–17 years) regularly attending school	Despite being important in its own right, efforts to keep children in school have positive impacts on HIV prevention.	Enrollment into public schools for formal education and monitoring for regular attendance. Collaboration with school authorities and parent–teacher associations (PTAs) for waivers on fees. Organization of after-school lessons. Collaboration with community on scholarship programs for educationally disadvantaged children, e.g., physically challenged.
OVC_PROG	Percent of children (aged 5–17 years) who progressed in school during the last year	Studies in many countries have linked higher education levels with increased AIDS awareness and knowledge, higher rates of contraceptive use, and greater communication regarding HIV prevention among partners.	Enrollment into public schools for formal education and monitoring for regular attendance. Collaboration with school authorities and PTAs for waivers on fees. Organization of after-school lessons. Collaboration with community on scholarship programs for educationally disadvantaged children, e.g. physically challenged.
<b>Attitudes about Child Punishment</b>			
OVC_CP	Percent of caregivers who agree that harsh physical punishment is an appropriate means of discipline or control in the home or school	Reducing harsh physical discipline, violence and abuse against children is a PEPFAR priority. Perceptions of physical discipline have been linked to actual use of physical discipline against children.	Establishment/Strengthening of Child Protection Committees (CPC) in the community Referrals to State Social welfare departments on cases of abuse, assault, molestation, violence and neglects.

No.	Outcome Indicator	Rationale for Inclusion	<i>Insert Project Name</i> Program Component That Contributes to the Indicator
<b>Household Economic Wellbeing and Resilience</b>			
OVC_MONEY	Percent of households able to access money to pay for unexpected household expenses	The key goal of household economic strengthening programs is to improve household's resilience to economic shocks, such as unexpected household expenses. Child well-being is assumed to be affected by the household's resilience to economic shocks.	Establishment/strengthening of village savings and loan association (VSLA) groups. Training on income-generating activities, financial management, and development of business plan with appropriate monitoring. Linkage to microfinance initiatives, cooperatives, and organizations for soft loans.

These indicators were vetted and selected by PEPFAR OVC program and strategic information technical leaders in 2014. Several criteria were applied in selecting the MER indicators. For example, only indicators that are amenable to change in a two-year period were selected. Additionally, indicators had to be relevant across the various countries where PEPFAR provides OVC program support. All selection criteria and the indicator reference sheets that define the indicators can be found in the MEASURE Evaluation guidance developed for the surveys (MEASURE Evaluation, 2015).

***Describe in a paragraph any additional country-specific indicators being measured in the study and insert additional details in a table such as Table 2.***

**Table 2. Supplemental indicators**

No.	Additional Indicator		Rationale for Inclusion	<i>Insert Project Name</i> Program Component That Contributes to the Indicator
S.1				
S.2				

## 3. METHODS

### 3.1 Study Design

**Provide a detailed description of the study design and methodological approach of your study. Please refer to the MER OVC Essential Survey Indicators Frequently Asked Questions (FAQs) document (MEASURE, 2017) for recommended study designs. An example paragraph is given below.**

In order to survey a manageable number of household participants to estimate the health and well-being of the larger population, the survey design will use a cross-sectional study using two-stage cluster sampling for administering a household survey using electronic tablets. Primary sampling units (PSUs) will be villages and secondary sampling units (SSUs) will be households. A 33x15 design will be used, randomly selecting 33 villages using probability proportionate to size. Within each selected PSU (villages), a random sample of 15 SSUs (households) will be selected.

### 3.2 Study Population

**List and describe the study populations: caregivers and children ages 6–59 months.**

Primary caregivers of children 0–17 years of age living in the selected households will be interviewed about themselves, the household, and the children residing in the household. All children under age 18 who slept in the household on the night before the interview are considered eligible.

MUAC measurements will also be collected from all children 0–4 years of age with consent of the primary caregiver.

**Outline the inclusion and exclusion criteria for each population group. Your inclusion criteria for households may be:**

- *At least one household member is registered to receive services with the project.*
- *At least one registered OVC under the age of 18 lives in the household.*

**Your exclusion criteria may be:**

- *No consent for caregiver participation given by caregiver*

**Describe consideration for emancipated minors with children and child-headed households. Local country laws and IRB practices may determine whether or not emancipated minors may participate and whether they can consent for themselves (if they are the primary caregiver in the household), or if they need their own guardian to consent for them. Consider what approach would be needed if that minor's guardian is not available.**

### 3.3 Statistical Power and Sample Size Calculations

**We recommend consulting a survey statistician to help determine the sample size for your study. In this section, provide a description of the sample size calculations (using 80% power and alpha = 0.05) used to determine the sample size, based on the study design chosen for your project. The primary indicator(s) on which the study power is being calculated should be described, with references to any current estimates used in the power calculation. Please refer to MER OVC Essential Survey Indicators Frequently Asked Questions (FAQs) document (MEASURE Evaluation, 2017). Suggested text is given below. These assumptions can be modified if the project being surveyed has specific information on design effect, nonresponse, or proportion of households with a child ages 0–4 years.**

To reliably measure an absolute difference of 15 percent in a given indicator over time (e.g., from 50% to 65%) at least 482 households will need to be selected. This will be accomplished with the 33x15 two-staged randomized cluster design.

The table below gives sample sizes for cluster sampling, assuming 80 percent power and 95 percent confidence intervals, a design effect of two, a nonresponse rate of 10 percent (some selected households may have moved away or may decline to participate in the survey), and an 80 percent likelihood of finding a child 0–4 years of age living in a household (as this is the smallest subset of children for which an indicator will be measured). This sample size will allow disaggregation of the MER Essential Survey Indicators by two age groups: 0–4 years and 5–17 years.

**Table 3. MER OVC Essential Survey Indicators sampling assumptions**

Number of children per indicator, assuming 80% power and 95% confidence intervals and 15% change over time	175
Assumption of design effect of 2	2
Assumption of nonresponse rate of 10%	1.1
Assumption that each household will have one child 5–17 years of age and 80% of households will have one child 0–4 years of age	1.25
Final HH sample size = $175 * 2 * 1.1 * 1.25$	482

### 3.4 Sampling

**Describe how your study will work with the local implementing partner and community-based organizations (CBOs) to ensure that the sampling frame for the study is accurate and includes information that will allow the field team to locate the selected households. An illustrative description is given below.**

To obtain the most up-to-date information on active household beneficiaries, we will work directly with the implementing partner, CBOs, and community workers to obtain a full listing of active beneficiaries in the selected clusters. We will follow the steps as listed below:

- 1) Review the project registration database and work with the implementing partner to delete duplicates and correct any errors related to geographic information such as village or ward that will help in determining clusters.
- 2) Using the cleaned project registration database, select 33 primary sampling units (clusters) using probability proportionate to size (PPS) (number of beneficiary households).
- 3) In each of the selected 33 clusters, study supervisors and enumerators will meet with community workers to verify the project registration database and list all active household beneficiaries based on the community worker registers, including information necessary to locate the household.
- 4) Once the listing is complete, randomly select 15 households in each cluster for an interview.

### 3.5 Sample Weights

**Describe how your study will apply sampling weights based on the sample design. An example description appears below.**

After fieldwork has been completed and data have been cleaned and prepared for analysis, we will apply sampling weights to account for the fact that clusters were selected using probability proportionate to estimated size versus the actual size as determined through the listing process (Turner, 2003).

## 4. DATA COLLECTION

### 4.1 Survey Tools and Pilot

**Describe the survey tools, including any modifications made for your project, and how modifications will be made based on pilot testing. Mention which software will be used if the survey is tablet based. A sample description is given below.**

Interviews will be conducted with caregivers using a questionnaire designed to capture responses that will be used to calculate the MER OVC ESI (MEASURE, 2015).

The study team made minor modifications to the standardized questionnaire to adapt it to the *insert country name* context. **List adaptations here.**

The questionnaire includes two key sections:

1. Questions to the caregiver about the household well-being and composition
2. Questions to the caregiver about all children ages 0–17 years living in the household

This questionnaire and the consent forms were created in English and have been translated into *insert local language*. Responses to the questionnaire will be electronically recorded into *insert brand name* (i.e., Android) tablets which will be programmed using *insert software name and version*. All language versions will be pilot tested for comprehension. Based on pilot test results, wording of questions will be adjusted as needed to enhance clarity of the translations. The questionnaire is provided in Appendix 1.

***Describe the approach your study team will take to pilot the questionnaires and tablets. A sample description is given below. Include how many days the pilot will last, who will participate, and where the pilot will take place (should be outside of study locations).***

### Pretest

The study team will perform an internal pretest of the programmed tablets, paper questionnaires, and consent forms before the enumerator training. This will be done by several staff self-administering the electronic questionnaire one question at a time. Staff will ensure that each question, all response options, and the instructions are identical between the final electronic and paper questionnaires. Skip patterns will also be tested. Modifications will be made to electronic and paper questionnaires as needed based on findings of the pretest.

### Pilot Test

The study team will conduct an external pilot test of the survey tools and processes in a geographical area outside the study locations. The aims of this pilot test are to check for any errors within the tools, assess comprehension of the wording of the interview questions and consent forms, identify aspects or questions that might be difficult or sensitive to ask, test the ease of use of tablets and paper questionnaires, test data transmission, and fine-tune logistics for the actual survey.

The amount of time needed to complete each household interview will be determined to fine-tune the scheduling of the pilot test. The survey team will hold a debriefing meeting to discuss key lessons learned from the pilot test, make necessary changes before the tools are deployed for use, and address areas that need attention during field operations. These issues will be discussed during training of enumerators. The pilot test will be conducted for two days after the field team training (see Section 4.3 for information about the training) and will include all supervisors and enumerators.

Following this pilot test, the software developers will incorporate any changes that might arise into the data entry screens.

## 4.2 Data Collection Procedures

***Describe how communities will be informed of the study. One approach is outlined, but consider your survey settings and what is most appropriate given the geographic spread of the survey and what is most feasible within your budget.***

***Describe the procedures your study will use for locating and recruiting survey participants. Describe how interviews will be conducted. This should include information on whether it will be paper-based or tablet-based and procedures for conducting the MUAC as part of the study. Include a description of how the survey will be conducted in case of tablet failure. A sample description is given below.***

### 4.2.1 Sensitization of Communities Participating in the Household Survey

1. The study team will liaise first with the project team to make sure they understand the study and will provide a brief list of responsibilities to facilitate the collaboration necessary to accomplish the study. This includes:
  - The study team sharing the tentative field schedule with the project team.
  - Requesting the project to connect with the CBOs to explain the study, share the tentative field schedule, and ask permission to share the CBOs' contact information with the study team.
2. An advance field team, including the field coordinator and the supervisors from the study, will arrive and meet with the CBOs before fieldwork is to begin.
3. Together with the CBO, this team will greet local representatives in the community (e.g., OVC project managers, chiefs, village elders, community volunteer workers, and other facilitators) to brief them on the activities and to enlist their assistance to help guide the team in locating the selected households.

### 4.2.2 Locating and Recruiting Survey Participants

1. The survey teams will identify households selected for the surveys based on the sample listings and support from local community guides.
2. The survey teams will work with local guides (e.g., OVC project managers, chiefs, village elders, community workers, and other facilitators) to locate the selected households using information from the OVC registration databases. If needed, the field coordinator may ask a local guide to accompany the team to help locate the selected households. However, the guide will not be present at the house when the enumerator conducts the consent process and the interview.
3. Once the survey team has located and confirmed the household, one enumerator will enter the household and greet household members.

### 4.2.3 Conducting the Interview

1. The enumerator will explain the purpose of their visit and ask to speak to the primary caregiver. If the caregiver is not at home at the time the enumerator visits the household, s/he will return up to three times to request the interview. Similarly, if a child who needs MUAC assessment is away, the enumerator will return up to three times to obtain the measurement.
2. The enumerator will seek informed consent from the caregiver for his/her participation and the participation of 6–59-month-old children in the household for MUAC assessments.
3. Enumerators will document consent.
4. Enumerators will verbally administer the questionnaire to the caregiver, recording responses on the electronic tablet. In case of tablet failure or loss of battery power, paper questionnaires will be used to administer the interview and recording responses.
5. Caregivers will be interviewed out of earshot of school-aged children and other adults in the household, including spouses.
6. Enumerators will perform MUAC assessments on all children ages 6–59 months listed in the child listing of the caregiver questionnaire.
7. Once the interview is complete, enumerators will thank the caregiver for their participation.
8. If paper questionnaires were administered, the enumerator will enter data on tablets each night once the tablets are available and charged.

## 4.3 Recruiting and Training Enumerators

*Edit the paragraphs below to describe the team that will conduct the survey. Update the number of fieldworkers and number of teams to match your team makeup. Ensure that information on how fieldworkers (supervisors and enumerators) will be evaluated reflects the actual evaluation procedures you will use to determine hiring. Insert selection recruitment criteria if any additional team members are included, such as a data manager. If using tablet surveys, ensure that sufficient time is allotted in the training to incorporate instructional and practice sessions with tablets. Sample paragraphs are given below, with instructions.*

There will be a total of **30** fieldworkers distributed across **six** survey teams with **five** fieldworkers on each team. The fieldworkers are supervised by the field coordinator (FC).

Field team composition is as follows:

- **Four** enumerators
- **One** supervisor

The study team will initially recruit a total of **33** candidate fieldworkers. At the conclusion of the training and pilot test, the study field manager will select **30 of the 33** candidates to serve on the teams.

Enumerators will have prior experience in collecting household-level data (e.g., DHS, sexual behavior survey, MICS), will have at least completed secondary school, will be proficient in one of the local languages of the study in addition to English, and will be cognizant of the sociocultural values and sensitivities of the target group/study communities. We will also consider gender balance among the data collection team.

Enumerators will complete a one-week training, following guidelines as proposed in the MEASURE Evaluation MER OVC ESI Facilitator’s Guide to Data Collector Training (MEASURE, 2016). This training will orient them to the study; ensure familiarity with recruitment methods and tablet and paper questionnaires; emphasize the importance of gaining informed consent, maintaining confidentiality, and ensuring participant privacy; and train enumerators on conducting research with children. All data collectors will be required to “pass” a research ethics quiz at the end of training, prior to beginning fieldwork.

## 4.4 Management of Fieldwork

### 4.4.1 Logistics and Supplies

***Describe the transportation logistics and supplies that will be required during fieldwork, including extra supplies if tablets are being used. A sample description is given below.***

Transportation to and within the field will use hired vehicles. Each team will have one vehicle to allow for transportation of team members and local facilitators. In places where the road infrastructure might not allow the cars to get the team to the cluster, the field team will use local means, such as motorbikes.

Individual field supplies (bags and stationery) shall be distributed before the close of training and prior to the start of fieldwork.

Each tablet will come with a power bank, cover, and charger and will be maintained by supervisors throughout the survey. About seven extra tablets and power banks will also be taken to the field in case replacements are needed.

### 4.4.2 Scheduling and Deployment of Fieldwork

***Describe the length of expected fieldwork, deployment of the field team, and expected interviews to be completed each day based on the project’s timeline, sample size, and team makeup. A sample description is given below.***

The survey will start two days after the pilot test. It is expected that three households (HHs) will be visited per enumerator per day and that each team will accomplish 12 interviews per day (4 field enumerators x 3 HHs = 12 HHs/day). Therefore, all teams will accomplish approximately 72 household interviews in one day (12 HHs/day x 6 teams=72 HHs/day). Data collection then will be expected to last about seven working days in order to reach the desired sample size.

Field teams will complete all interviews (including call-backs) in a given cluster before moving on to the next cluster. This approach will ensure that work is done within the shortest possible time per cluster and also to facilitate the transportation of enumerators. The teams will take one day off per week to rest.

## 4.5 Data Handling and Analysis

### 4.5.1 Data Quality Control

***Describe what mechanisms your field team will use to ensure high data quality in the field. This should include how supervisors will monitor field enumerators, address problems, and track nonresponse. Include a paragraph describing how problems with electronic tablets will be handled during piloting and data collection. Include how paper surveys will be validated and checked for errors. Even if tablets are being used, paper surveys may be needed for backup in case of tablet failure. A sample description is below.***

Quality assurance will be implemented through a continuous process of data quality control.

1. In the first week of data collection, a software developer will be available to perform on-site support where needed. Thereafter, remote connection tools like TeamViewer will be used to offer support to troubleshoot any problems that may arise with data capture and transmission using the tablets.
2. Consistency checks will be built into the data capture software to ensure that no missing information or implausible values are accepted. For example, the data entry screens will include controls for variables range, skips, duplicated individuals, and consistency checks within and across modules. This will reduce or eliminate errors usually introduced at the data capture stage.
3. All enumerators will be expected to review each questionnaire before leaving the households to be sure that every appropriate question has been asked and that answers are clear and reasonable. They will also check that the skip instructions are correctly followed (i.e., for skip rules that are not automatically programmed into the tablets).
4. Supervisors will work with their teams at the end of each day to review data captured on the tablets, looking for any remaining errors, such as incorrectly completed forms, missing data, and inconsistencies.
5. Supervisors will observe each enumerator at least once during the survey implementation. This will help him/her verify that the enumerator is following all the procedures taught in the training and ensure that the interviews are being conducted to the highest standards.
6. Supervisors will complete daily progress sheets based on information gathered from the enumerators to document the outcome for each household visited and any problems encountered.
7. During the data collection period, supervisors will consult regularly with the central coordination team on achievements and constraints of the operation. These consultations will facilitate any necessary adjustments to the data collection process.
8. Supervisors and field coordinators will use control sheets to track enumerators' work. Upon completion of field work in a given location and when all quality checks have been done, the supervisors and coordinators will complete a questionnaire accounting sheet that records the total number of full questionnaires completed and any cases of nonresponse per location.

#### 4.5.2 Data Security

**Describe how your team will mitigate risks of loss of confidentiality. If tablets are used for data collection, describe how they will be protected to guard against unauthorized access in case of loss of a tablet. Describe data security throughout the process of data collection, including uploading tablet data to server/data backup. Describe the data transmission, data entry process, and the software and technology used. Address issues related to theft of tablets and how security and confidentiality will be maintained. Mention whether any names will be collected during the survey, and if so, how they will be secured or filed separately (in a password protected look-up file) on the tablet, and how they will be deleted from the analysis files. Include information about how tablets will be cleared of data, and at what frequency, after data collection has been completed and data uploaded to servers. Describe what happens to data after it is transmitted from the field. Who will manage the data and ensure security of the data? A sample description is given below.**

Data handling procedures will be implemented as follows:

- Each tablet will be encrypted with a unique bit locker password, which enumerators must memorize.
- Tablets will be with enumerators at all times throughout the day.
- During data collection, any completed paper questionnaires will be stored securely within the locked study vehicles.
- At the end of each day, supervisors will store the paper surveys in a locked box or cabinet, and tablets will be recharged at predetermined local sites.
- Paper questionnaires will be returned to the local research partner's headquarters on at least a weekly basis, where the surveys will be stored in a locked cabinet.
- Electronic data will be uploaded to a secure server nightly (or weekly if in remote areas without Internet access).
- Any electronic sharing of the survey database will be done through an encrypted secure electronic method, using encrypted password-protected zip files. Electronic data sharing can be done through a secure FTP site set up by **insert your Institution name** or another approved method by the study team. Passwords will never be shared in the same correspondence where electronic data are shared.
- At the end of data collection in each cluster, study data are moved from enumerator tablets to a backup tablet or backup directory on a secure server (i.e., the data from that cluster no longer exists on the enumerator tablet after this point). This backup is in addition to the nightly uploads to the secure server. This ensures data can be recovered from at least two sources, in the event that one transfer fails. This also removes the study data from the tablets where enumerators could access them easily and potentially corrupt files.
- Data quality checks will be conducted in the field and at the **insert name of office** once the data are uploaded to the server.
- Protocols and checklists will be developed to check for accuracy of IDs, completeness, acceptable ranges of responses, and consistency. Use of tablets for electronic data capture will allow for many checks to be conducted at the point of data capture, thus minimizing errors.
- Once data collection is complete, the tablets will be completely erased of all study data.
- If tablets are lost or stolen, the study team will register that tablet's unique barcode with the manufacturer. If the tablet is rebooted or an attempt is made to reformat the tablet for personal use

while in a zone with cell phone coverage, coordinates of the tablet are sent to the manufacturer and the manufacturer will disable the tablet entirely.

- All electronic data will be de-identified, only containing unique identification codes that enable linking data on children and to the primary caregiver. No names will be stored in the electronic database.
- Electronic copies of the study database will be stored on a secure password-protected server under the custodial care of the principal investigators at **insert institution name**, who will be performing data processing and analysis, for **insert number** years, after which it will be electronically shredded.
- Paper surveys will be stored at the local research partner's headquarters in a locked cabinet until instructions are given from **insert name of your organization** to dispose of the paper surveys, or as long as the **insert country name** IRB requires storage.
- Final analytic data sets will be stored on password-protected encrypted computers or servers. Particular care will be taken during the presentation of the study findings that the information presented is sufficiently aggregated to ensure that no single individual can be identified.

#### 4.5.3 Data Analysis

**Describe the process of data analysis and who will be responsible for data analysis. Note that if there are multiple projects there should be different analysis files for each project. A sample description is given below.**

**Insert institution name** will be responsible for initial data management, cleaning, and analysis. After data collection is complete and all data have been uploaded to the secure server, analysis files will be created using **insert software name and version** statistical package and analyzed using **insert software name and version**. In addition, data dictionaries, variable and value labels, and metadata will also be created. Data imputations may be performed as needed for nonresponse to items.

The MER indicators will be calculated as specified in the MER OVC ESI Indicator Reference Sheets and presented in table format as specified in *Collecting PEPFAR Essential Survey Indicators: A Supplement to the OVC Survey Tools* document (MEASURE Evaluation, 2015).

The principal investigators will lead the drafting of the study report. They will draw upon information obtained from the USAID implementing partners regarding project design and implementation to interpret the findings. When possible, they will also review project monitoring data collected by the projects to triangulate and further interpret survey results.

#### 4.5.4 Data Sharing

**Describe project's data sharing policies and agreements with partners and USAID. A sample description is given below.**

Upon review and finalization of the MER OVC ESI estimates by the PEPFAR **insert country name** team and the service delivery project managers, **insert institution name** will share an electronic file of the estimates (disaggregated by sex and age) with each of the service delivery projects, who will then be responsible for uploading these data to the PEPFAR reporting database, DATIM.

In accordance with the U.S. Government contract under which this study is being conducted, data from the study will comply with USAID Data Development Library (DDL) requirements. The DDL is USAID's public repository of Agency-funded, machine readable data and part of USAID's commitment to evidence-based programming and rigorous evaluation, while supporting the principles of the U.S. President's Open Government Initiative (USAID, 2014). ***Insert name of your organization*** will work with USAID to ensure that electronic files of the de-identified survey data are prepared and uploaded to the appropriate source in compliance with this requirement.

## 5. HUMAN SUBJECTS, CONFIDENTIALITY, AND SECURITY

### 5.1 Human Subjects Considerations and IRB Review

***Describe how your project will adhere to international research ethics guidelines and the process of your IRB reviews. A sample description is given below.***

All study activities will adhere strictly to U.S. and international research ethics guidelines, including 45CFR46 and CIOMS.

In line with ethical practices, stringent procedures to uphold the fundamental principles governing research on human participants will be followed. All members of the study team have undertaken an ethics course and their research ethics certification is current. Field teams will be trained and sensitized on ethical issues during data collection. Importantly, during data collection, the study field manager will carry out spot checks to ensure that research ethics are upheld and that the participants are not harmed or exposed to unnecessary risk.

We are seeking IRB review and approval from ***insert local IRB name*** and will simultaneously seek review in the U.S. from ***insert U.S. IRB name***.

### 5.2 Risks and Benefits to Participants

***Describe the risks and benefits to participants who participate in your study. A sample description is given below.***

The study team believes that participation in this study presents minimal risk to respondents. However, the interview addresses issues that could be sensitive, such as information related to HIV, as well as psychosocial issues and other issues specific to OVC and their caregivers. The investigators recognize that many of the problems participants may face are sensitive and stigmatizing. Particular care will be taken to ensure that all questions are asked in a supportive and nonjudgmental manner. Enumerators will be selected carefully to ensure that they have experience conducting interviews and that they have good interpersonal skills. As part of their training, they will be made aware of the potential reactions participants may have and will agree to terminate the interview if the respondent shows significant distress. Enumerators will be trained in techniques for working with children (i.e., for the MUAC assessment). Maximum efforts will be made to ensure that all participants are not harmed physically, emotionally, socially, or in any other ways.

Although there is no immediate direct benefit to participants, the data generated from this study are expected to improve service provision for children and caregivers served by the OVC service delivery project 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 child ages 6–59 months to have their MUAC assessment**

**If a caregiver is a minor, we recommend getting consent from the minor caregiver as well as their guardian, if they are available. If the minor caregiver’s guardian is not available, the process should follow local laws and IRB approval. Specify if your project plans to leave a copy of the consent form or an informational sheet with the investigators contact information.**

The study team recognizes the difference between consent and informed consent. Enumerators will provide potential participants with appropriate information about the study and their involvement in the study so that they can make an informed choice. Once the enumerator has identified the caregiver in the household, before beginning the questionnaire, potential participants will be informed verbally of the purpose and nature of the study, the expected risks and benefits, and how long the session will last. The caregiver will be made aware that her/his participation is voluntary and does not affect eligibility to receive or continue services. Adult caregivers (i.e., those age 18 years and above) will be asked to consent to their own participation and to the participation of children in the household ages 6–59 months for the middle-upper-arm-circumference (MUAC) assessment. In households where the caregiver is under the age of 18, consent will be requested first from her/his guardian, followed by request for consent from the (minor) caregiver.

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 personal and sensitive topics, the enumerator will forewarn them that some topics are difficult to discuss. The respondent will be made aware at the outset that s/he is free to terminate the interview at any point, and to skip any questions that s/he does not wish to respond to. Caregivers will be given the opportunity to ask questions. Once the enumerator ensures that all of the caregiver’s questions are answered, and if the caregiver consents to participate, consent will then be sought and documented from the caregiver, with emphasis that her/his participation is voluntary. Consent to participate will be documented in written form. The consent forms that will be used are provided in Appendix 2. They will be translated into **list local language(s)**, as necessary. These consent forms will also be piloted to ensure comprehension (see section 4.1 on piloting).

## 5.4 Confidentiality of Participants

**Describe how your project will ensure confidentiality of respondent information, including their names, locations, and data collected. Describe if there are any possibilities of breach of confidentiality, such as abuse cases that are discovered, how this risk is described to the participant in the consent form, and how these cases will be handled.**

All information gained from interviews will be kept confidential and will not be communicated, divulged, disclosed, or otherwise used directly or indirectly. Researchers, supervisors, data collectors, and data entry staff will sign a confidentiality agreement to ensure that privacy of participants is maintained (see Appendix 3). Adult participants will be interviewed out of earshot of others, including their children and spouse. MUAC assessments on children ages 6–59 months will be obtained within the presence of the caregiver.

There is one exception as to when confidentiality may be breached. Should any field team member observe an instance or evidence of child abuse or identify a child to be in serious danger (emergency), s/he will report the case to her/his immediate supervisor, following the study's emergency reporting protocol. The respondents will be made aware of this exception through the following statement included on the consent 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.*

Following data entry, all hardcopy questionnaires and consent forms will be stored in a secure location, under the care of study investigators. 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 for caregiver respondent and children (ages 0–17 years) will be used on all questionnaires to enable the production of the de-identified data sets. Unique household identification numbers will be used to link all household members. 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.

## 5.5 Child Protection

**Describe how your study will maintain the best interests of the child, protecting them from risks and harm. Ensure that this section is in agreement with your study criteria, particularly as it relates to emancipated minors who are caregivers.**

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

- **Procedures for checking the references of enumerators and others who will have direct contact with children**
- **Training on working with and interviewing children for enumerators and others who will have direct contact with children**
- **Stipulations that adult guardians must provide specific, informed consent for any children under their care ages 6–59 months to participate in the MUAC assessment and that consent will be documented**
- **Referral protocols for children thought to be in distress or experiencing an emergency. If enumerators or others with direct contact with children find evidence of child abuse, neglect, or other signs 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 enumerators need to be trained on how to handle any child protection issues sensitively.**
- **A “whistleblower” 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.**

## 5.6 Compensation

**Describe any compensation to be given to respondents. If the local IRB requires the survey to provide a token of appreciation, this should be listed here, explaining how it will not coerce beneficiaries to participate in the survey. A sample description is given below.**

The study team is committed to ensuring that survey participation is on a voluntary basis and that no inducements for participation are made. Survey participants will be made aware that the enumerator is only there to ask questions and not to provide any gifts or assistance. No compensation will be provided for participation in the survey. Community guides who support the identification of sampled households will be provided with a small gift in cash or kind to compensate for their time.

## 6. DISSEMINATION PLAN

**Describe your study's plans for communicating and disseminating the study findings. This should include who will be leading the drafting of the study report, and the primary audiences for the final report. Any workshops or presentations planned with the study's budget should be described here. A sample description is given below.**

The primary audience for the final report summarizing the study results is the PEPFAR **insert country name** team and the managers of the **insert project name**. They will use the findings to discuss program implications and develop recommendations to strengthen program strategies, as appropriate. Secondary audiences include PEPFAR headquarters management including the PEPFAR OVC Technical Working Group, who will compile and review results at the global level to inform PEPFAR policies and technical guidance.

The study team will convene a workshop with the PEPFAR **insert country name** team and the management and technical staff of the **insert project name** to review draft findings and solicit their feedback and input on interpretation of the findings before finalizing the report. The study team will also prepare a PowerPoint presentation of the findings to use at the workshop and to share with workshop participants who may then use the presentation to share the study findings with their stakeholders.

## 7. STUDY LIMITATIONS

**Describe your project's study limitations in detail, including weaknesses in the study design, lack of statistical power due to limitations of the sample size, and any bias or spill-over effects expected in the results. Also describe how you will address the limitations. A sample description is given below.**

This study has several limitations:

- Sample sizes are insufficient to provide highly precise estimates at a subnational level or sufficient statistical power to allow for some comparisons of indicator estimates that may be of interest to potential users of the findings. In this study, the need for additional information or comparisons is balanced with the extra time and costs required to collect, analyze, and report the nine OVC MER ESI. Therefore, cluster sampling will be used, which helps keep costs down. The sample size in this study will allow investigators to disaggregate the MER OVC ESI by two age groups: 0–4 years and 5–17 years, which is sufficient for PEPFAR reporting requirements.

- As with all studies in which self-report is used, social desirability and recall biases may affect the results. However, this is true for any household-based survey. We will train enumerators to administer the questionnaires using methods that minimize these biases.
- Survey findings represent only the beneficiary populations of **insert project name** and are not generalizable to the overall population or other subpopulations of OVC in **insert country name**. The purpose of the MER OVC ESI is not to generalize to all children in a country, but specifically to monitor outcomes within the beneficiary population of **insert project name** over time.

## 8. STUDY MANAGEMENT

**Insert a paragraph or two describing how this MER study is funded, any cooperative agreement numbers, and partners or consortiums under the cooperative agreement. Briefly outline the roles in the study (study design, data collection, analysis, and report writing) of USG, local government, local implementing partners, subcontractors, and community-based organizations. 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.**

**Describe the management structure and remainder of the team, ideally using an organogram. Sample paragraphs are given below:**

This study is funded by PEPFAR through the U.S. Agency for International Development (USAID) **insert project name** project under terms of Cooperative Agreement **insert cooperative agreement number**. **Insert project name** is implemented by **insert organization(s) name(s)** in partnership with **insert name(s) of organization(s)**.

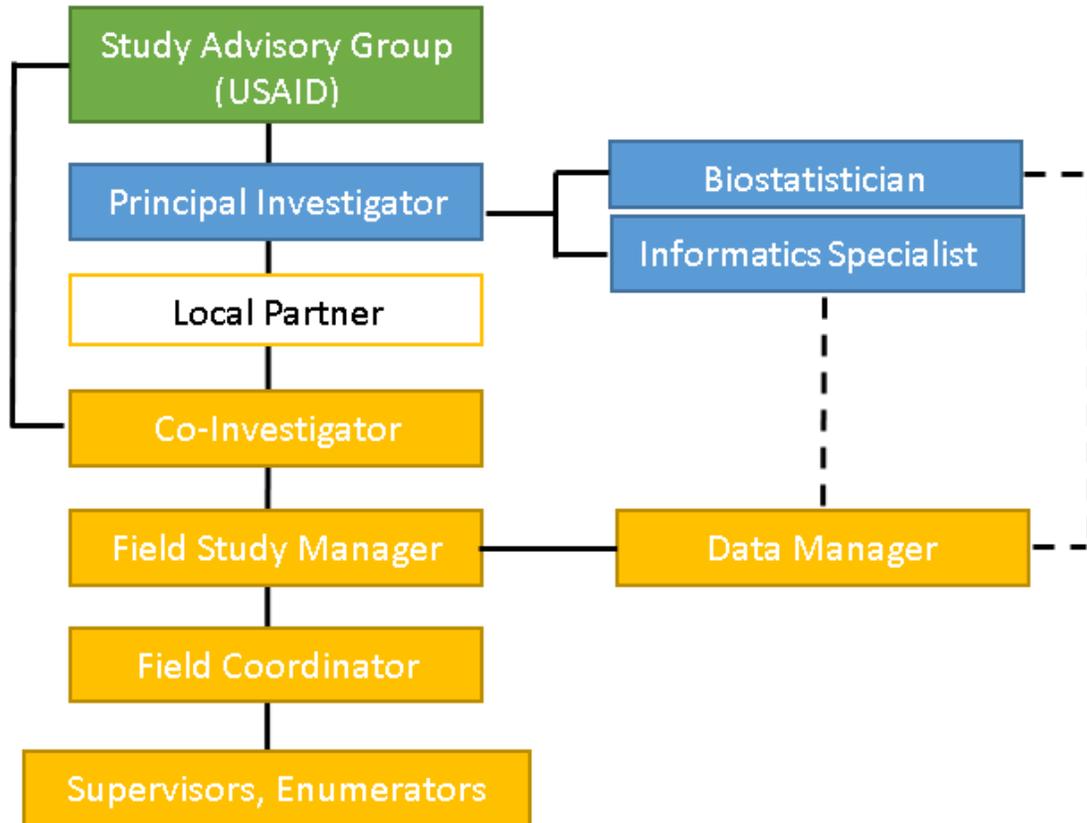
To ensure objectivity, the PEPFAR guidance for this reporting requirement indicates that the MER OVC ESI data be collected by an organization that is external to project service delivery. In **insert country name**, the PEPFAR team has requested the assistance of **insert name of your organization** to help fulfill this PEPFAR reporting requirement. **Insert name of your organization**, in partnership with its subcontractor, **insert name of subcontractor**, will conduct a study to collect the MER ESI data using a standardized survey methodology and tools that MEASURE Evaluation developed on behalf of PEPFAR for this purpose (see *Collecting PEPFAR Essential Survey Indicators: A Supplement to the OVC Survey Tools*) (MEASURE Evaluation, 2015).

**Insert name of your organization** will provide overall leadership for the study and is responsible to USAID for all activities undertaken by the project. The **insert name of your organization and role of principal investigator or activity lead** holds overall technical, management, and supervisory responsibility for the study, including development of the study protocol, quality assurance, analysis, technical writing, and dissemination of findings. The principle investigators are responsible for assuring that the study is conducted in accordance with the protocol and for the safety and protection of study participants.

The field team comprising field coordinators, supervisors, and field enumerators will be recruited as discussed in Section 4.3. Additionally, administrative and financial teams at **insert institution name** and **insert name of local project if applicable** will support the study team in managing finances and providing administrative and logistical support for travel, workshops, meetings, and procurement.

**It may be helpful to include a study team organogram. An example is given below.**

Figure 3. Sample study team organogram



## 9. 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 (see Appendix 6 for a sample timeline).**

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## Appendix 1: Survey Questionnaires

*Insert final questionnaires.*

## Appendix 2: Consent Forms

***Insert English and translated consent forms.***

## Appendix 3: Confidentiality Agreement for Study Team Members

### CONFIDENTIALITY AGREEMENT

As a member of *insert study team name* study 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 is on my part or on the part of another person.

Signature: \_\_\_\_\_

Printed name: \_\_\_\_\_

Date: \_\_\_\_\_

## Appendix 4: Biographies of Principal Investigators

*Insert short biographies of principal investigators.*

## Appendix 5: Study Budget (If Required)

**Insert a basic study budget.**

The study will be implemented for a budget of US\$ *insert amount*, as itemized in Table 3.

Table 4. Study budget

Budget Item	Amount (USD)
Total labor cost	
Total travel	
Total other direct costs (ODCs)	
Indirect costs	
TOTAL BUDGET	

## Appendix 6: Study Timeline

**Insert a table describing deliverables and estimated timeline. A suggested table is provided below. Update table items and dates according to project.**

Key study activities and their timelines are presented in Table 4. This timeline might change, depending on the IRB procedures and political situation in *insert country name*. Timeline will be adjusted from the approval dates of this SOW.

**Table 5. Timeline of study activities**

Tasks	Responsible Party	Insert Range of Years													
		Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr
<b>1. Orient local teams to study methodology and survey design</b>															
1.1 Meet with the USAID/ <i>insert country name</i> to present the survey parameters and reach agreement on indicators and survey sampling.	<i>Insert responsible party</i>														
1.2 Meet with managers of <i>insert client name</i> to present and discuss survey design and study implementation.	<i>Insert responsible party</i>														
<b>2. Identify local research institution</b>															
2.1 Recruit, identify, and establish a subcontract agreement with a local research institution.	<i>Insert responsible party</i>														
2.2 Conduct an evaluation capacity assessment and develop a capacity building plan for the local research institution.	<i>Insert responsible parties</i>														

Tasks	Responsible Party	Insert Range of Years													
		Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr
<b>3. Develop study protocol</b>															
3.1 Adapt the MEASURE Evaluation survey protocol and tools for outcomes monitoring based on the final study design.	<i>Insert responsible parties</i>														
3.2 Translate survey tools.	<i>Insert responsible parties</i>														
3.3 Submit a draft protocol and tools to the PEPFAR/DRC, OVC TWG, and <i>insert client name</i> for review.	<i>Insert responsible parties</i>														
3.4 Submit the protocol to US and local ethics review boards as outlined in the survey manual and as required by the Government of DRC.	<i>Insert responsible parties</i>														
<b>4. Review OVC project documentation and registry databases</b>															
4.1 Conduct interviews with <i>insert client name</i> project managers (and a selection of local implementing partners).	<i>Insert responsible parties</i>														
4.2 Conduct analysis of the <i>insert client name</i> project beneficiary databases that will be used to select the survey sample.	<i>Insert responsible parties</i>														
<b>5. Conduct fieldwork preparations</b>															

Tasks	Responsible Party	Insert Range of Years													
		Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr
5.1 Operations manual and field logistics plan	<i>Insert responsible parties</i>														
5.2 Pre-testing	<i>Insert responsible parties</i>														
5.3 Conduct community trace and verify activity as part of beneficiary listing.	<i>Insert responsible parties</i>														
5.4 Update beneficiary listing, if necessary.	<i>Insert responsible parties</i>														
5.5 Sampling	<i>Insert responsible parties</i>														
5.6 Electronic data collection tools	<i>Insert responsible parties</i>														
5.7 Data collection team training	<i>Insert responsible parties</i>														
5.8 Pilot test and finalize data collection tools and processes.	<i>Insert responsible parties</i>														
<b>6. Carry out fieldwork</b>															
6.1 Conduct the survey for the OVC Project.	<i>Insert responsible parties</i>														

Tasks	Responsible Party	Insert Range of Years													
		Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr
6.2 Document the process and compliance with standard operating procedures/quality assurance process.	<i>Insert responsible parties</i>														
<b>7. Complete data quality audit and data cleaning</b>															
7.1 Perform edit checks on the data files, document problems, and clean the data.	<i>Insert responsible parties</i>														
7.2 Create analysis files.	<i>Insert responsible parties</i>														
7.3 Finalize files for data sharing.	<i>Insert responsible parties</i>														
<b>8. Complete data analysis and survey report</b>															
8.1 Perform data analysis in accordance with the survey protocol analysis plan.	<i>Insert responsible parties</i>														
8.2 Draft the survey report.	<i>Insert responsible parties</i>														
8.3 Submit the report for reviews.	<i>Insert responsible parties</i>														
8.4 Finalize the report.	<i>Insert responsible parties</i>														
<b>9. Assess evaluation capacity</b>															

Tasks	Responsible Party	Insert Range of Years													
		Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr
9.1 Assess progress and achievements toward capacity-building plan objectives in collaboration with the local research organization.	<i>Insert responsible parties</i>														

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