



# PEPFAR

U.S. President's Emergency Plan for AIDS Relief

## Evaluation Standards of Practice

Version 3.1.2

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U.S. Department of State  
Office of the U.S. Global AIDS Coordinator and Health Diplomacy

# PEPFAR EVALUATION STANDARDS OF PRACTICE

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## Acronyms

AC	Adherence Checklist
ADS	Associate Director for Science
AM	Activity Manager
AOR	Agreement Officer Representative
APR	Annual Program Results
COI	Conflict of Interest
COP	Country Operational Plan
COR	Contracting Officer Representative
DATIM	Data for Accountability, Transparency and Impact Monitoring
EI	Evaluation Inventory
ESoP	Evaluation Standards of Practice
GAO	Government Accountability Office
HQ	Headquarters
IAD	Implementing Agency Designee
IE	Impact Evaluation
IRB	Institutional Review Board
M&E	Monitoring and Evaluation
MER	Monitoring, Evaluation, and Reporting
NAM	National Academy of Medicine
S/GAC	State Department/Office of the U.S. Global AIDS Coordinator
OU	Operating Unit
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
PM	Project Manager
POC	Point of Contact
ROP	Regional Operational Plan
SI	Strategic Information
SOW	Scope of Work
USG	United States Government

# Preface

The President’s Emergency Plan for AIDS Relief (PEPFAR) Evaluation Standards of Practice (ESoP) was developed in response to the growing need to maximize the utility of evaluations and, more significantly, to respond to a call for strengthened evaluation quality and transparency from the Government Accounting Office (GAO) and the National Academy of Medicine (NAM; formerly the Institute of Medicine).

The inaugural version of the PEPFAR ESoP was published in January 2014, outlining the 11 standards of practice that should be followed to ensure high standards of evaluation planning, implementation, dissemination, and use. This latest release of the ESoP (v 3.1.2) maintains the original 11 standards, refines PEPFAR evaluation classification, and provides updated guidance on reporting requirements and processes. † The ESoP sets key parameters that inform PEPFAR evaluation quality assurance and reinforce the importance of using evaluation findings in programmatic decision-making.

The four tools that support application of this guidance are available on [DATIM support](#).

1. Evaluation Inventory (EI) template\*
2. Data Dictionary for the Evaluation Inventory
3. Adherence Checklist (AC) template\*
4. Webinar slides explaining how to use DATIM for data entry

*\*Note: The entry of Evaluation Inventory and Adherence Checklist data occurs in DATIM. The template of the two DATIM modules are available on [DATIM support](#) under Evaluation Standards of Practice (ESoP).*

ESoP v3.1.2 and the accompanying revised tools and materials will improve the quality of evaluation reporting and facilitate access and use of these data for program planning and decision-making across PEPFAR and OUs.

For further questions, please contact your evaluation Points of Contact at your Operating Unit and/or Agency. Any questions for S/GAC can be directed to [SGAC\\_SI@state.gov](mailto:SGAC_SI@state.gov)

† The primary changes between ESoP v 3.0 to ESoP v 3.1 is the reclassification of implementation science and operations research from evaluation to research. The changes between ESoP 3.1 vs ESoP 3.1.2 is an update in evaluation definitions.

# Introduction

The U.S. President's Emergency Plan for AIDS Relief (PEPFAR) has been at the forefront of implementing robust program monitoring to track progress toward reaching epidemic control. In addition to routine program data, evaluation data play a key role in generating evidence needed to know what works and how to implement efficient and cost-effective interventions to achieve epidemic control.

Evaluation is a useful tool for assessing implementation fidelity, identifying causes of ambiguous performance trends, demonstrating program efficacy and effectiveness, measuring intervention success at changing behavior, and understanding cost implications of introducing interventions. As an extension to the basic objective of an evaluation to determine if a program works, UNAIDS describes primary reasons for conducting evaluations<sup>1</sup>:

- 1) Program improvement, using evaluation results as feedback to program implementers to make the program function more effectively and efficiently, for the ongoing program or future programs.
- 2) Program accountability and transparency, so stakeholders and funders alike are aware of the progress of the program.
- 3) Program data sharing, disseminating results to help stakeholders and partners better understand what the program has accomplished and to replicate similar approaches in future.

The Evaluation Standards of Practice (ESoP) enables PEPFAR to collect data about ongoing programmatic activities including what questions are being asked, where and who is conducting evaluations, and how findings can be leveraged to inform programmatic decision-making across PEPFAR programs in a timely way. ESoP mandates the reporting of PEPFAR-funded evaluations through the Evaluation Inventory (EI) and outlines 11 standards of practice which evaluations must adhere to as reflected in the Adherence Checklist.

ESoP was developed, in part, as a response to recommendations from the Government Accountability Office (GAO) and the National Academy of Medicine or NAM (formerly the Institute of Medicine) on how to improve evaluation quality in PEPFAR. High quality evaluations which answer key questions driven by evidence gaps, implemented in line with quality standards, and for which results are disseminated publicly and used by relevant stakeholders are critical to achieve the 95-95-95 goals and reach epidemic control<sup>2,3</sup>. This is consistent with recommendations from GAO<sup>4</sup> and NAM<sup>5</sup>, and stipulations within congressional reauthorization to expand the utility of evaluation processes and data across PEPFAR programming for greater accountability and transparency. Further language in the *PEPFAR Stewardship and Oversight Act Of 2013*<sup>6</sup>, Paragraph 3R, requires that we collect and report on an annual basis:

***“(R) A description of program evaluations completed during the reporting period, including whether all completed evaluations have been published on a publicly available Internet website and whether any***

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<sup>1</sup> UNAIDS, 2019, UNAIDS Evaluation Policy. [https://www.unaids.org/sites/default/files/media\\_asset/UNAIDS\\_PCB44\\_UNAIDS-Evaluation-Policy\\_EN.pdf](https://www.unaids.org/sites/default/files/media_asset/UNAIDS_PCB44_UNAIDS-Evaluation-Policy_EN.pdf)

<sup>2</sup> Government Accountability Office (GAO), President's Emergency Plan for AIDS Relief: Agencies Can Enhance Evaluation Quality, Planning, and Dissemination, GAO-12-673, May 31, 2012.

<sup>3</sup> Institute of Medicine (IOM), 2013. Evaluation of PEPFAR, The National Academies Press: Washington, DC.

<sup>4</sup> GAO, 2012, *op. cit.*

<sup>5</sup> IOM, 2013, *op. cit.*

<sup>6</sup> Public Law 113–56—DEC. 2, 2013, PEPFAR Stewardship and Oversight Act of 2013 (S.1545).

***completed evaluations did not adhere to the common evaluation standards of practice published under paragraph (4).”***

ESoP v3.1.2 reinforces the standards of evaluation practice deemed most relevant to conducting quality evaluations within PEPFAR and to inform improved decision-making. Many of these evaluation standards of practice are promoted through international and professional evaluation associations<sup>7,8</sup>, and to a large extent, are already integrated into PEPFAR implementing agency policies and strategy documents.<sup>9,10,11</sup> In addition to articulating the standards of practice, this document also contains guidance to assist in the implementation of these standards and the associated requirements. These sections offer an overview of PEPFAR evaluation planning, implementation, reporting, and review, as well as guidance on the roles and responsibilities of the relevant stakeholders and individuals who will implement, oversee, and report on the process. Anticipated users of this document include: evaluators, persons who commission and procure evaluation services, providers of technical assistance for evaluations, and host country partners, among others.

Operating Unit (OU)<sup>12</sup> representatives or other key personnel associated with evaluation management who identify a potential conflict(s) between different guidance documentation should contact the appropriate agency Point of Contact (e.g., Evaluation Point of Contact in the Program Office (USAID), ADS (CDC), program officer (NIH), Evaluation Point of Contact (DOD), contract officer, project officer) who can assist with providing a resolution.

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<sup>6</sup> USAID Learning Lab. [https://usaidlearninglab.org/sites/default/files/resource/files/dn-ex-post\\_evaluation\\_final2021.pdf](https://usaidlearninglab.org/sites/default/files/resource/files/dn-ex-post_evaluation_final2021.pdf)

<sup>7</sup> American Evaluation Association (AEA), An Evaluation Roadmap for a More Effective Government, February 2009. <http://comm.eval.org/HigherLogic/System/DownloadDocumentFile.ashx?DocumentFileKey=1add789-5d6e-42b8-aa75-266f0bc1d66c&forceDialog=0>

<sup>8</sup> African Evaluation Association, African Evaluation Guidelines - Standards and Norms, <https://afrea.org/the-african-evaluation-guidelines/>

<sup>9</sup> USAID, USAID Evaluation Policy, Learning from Experience. <https://www.usaid.gov/sites/default/files/documents/1870/USAIDEvaluationPolicy.pdf>

<sup>10</sup> CDC, CDC Evaluation Framework. <http://www.cdc.gov/eval/framework/index.htm>

<sup>11</sup> Department of State, DOS Program Evaluation Policy. 2012, <https://2009-2017.state.gov/s/d/rm/rls/evaluation/2012/184556.htm>

<sup>12</sup> The Operating Unit is the level at which COP planning occurs. This may be a single country or a group of countries.

## Section I—Key Terms and Concepts

In accordance with the United States Foreign Aid Transparency and Accountability Act of 2016 (FATAA) definition, PEPFAR defines evaluation as:

*...the systematic collection and analysis of information about the characteristics and outcomes of the program, including projects conducted under such program, as a basis for making judgments and evaluations regarding the program, improving program effectiveness, and informing decisions about current and future programming.*<sup>13</sup>

PEPFAR classifies evaluation into four types: process, outcome, economic and impact (see Table 1).

**Table 1. Evaluation Types**

<b>(1) PROCESS EVALUATION</b>	
An evaluation that assesses the extent to which a program is operating as it was intended <sup>14</sup> . This type of evaluation focuses on program/intervention implementation, including, but not limited to access to services, whether services reach the intended population, how services are delivered, client satisfaction and perceptions about needs and services, management practices. In addition, a process evaluation might provide an understanding of cultural, socio-political, legal, and economic contexts that affect implementation of the program/intervention <sup>14</sup> .	
<b>Example evaluation questions:</b>	<ul style="list-style-type: none"> <li>• To what extent were program activities/intervention(s) implemented as intended?</li> <li>• Were programs implemented according to quality standards?</li> <li>• To what extent was the right target population reached?</li> <li>• How did social/political/cultural factors hinder and/or facilitate program implementation?</li> <li>• To what extent did capacity building activities result in improved financial management, organizational planning, and procurement capacity, among institutions?</li> </ul>
<b>Timeframe:</b>	Assessments of the implementation process are conducted during implementation and/or immediately post-intervention.
<b>Data types, sources:</b>	Interviews, focus groups, audits, observations, surveys (i.e., qualitative and quantitative).
<b>Example indicators:</b>	Results as compared to goals/targets, counts of clients reached, products distributed, quality of service, providers trained, acceptability of services, and client satisfaction.
<b>(2) OUTCOME EVALUATION</b>	

<sup>13</sup> Foreign Aid Transparency and Accountability Act (2016). <https://www.whitehouse.gov/wp-content/uploads/2017/11/M-18-04-Final.pdf>

<sup>14</sup> Government Accountability Office (GAO), Performance Measurement and Evaluation: Definitions and Relationships, May 2011. <https://www.gao.gov/assets/80/77277.pdf>

<p>An evaluation that determines if, and by how much, intervention activities or services achieved their intended outcomes<sup>15</sup>. This form of evaluation assesses the extent to which a program achieves its outcome-oriented objectives. It focuses on outputs and outcomes (including unintended effects) to judge program effectiveness but may also assess program process to understand how outcomes are produced<sup>16</sup>.</p>	
<p><b>Example evaluation questions:</b></p>	<ul style="list-style-type: none"> <li>• To what extent did the program activities/intervention(s) reach expected short-term outcomes/changes/effects? (e.g., changes in participants’ knowledge, skills, attitudes, intentions, health status.)</li> <li>• To what extent did the program activities/intervention reach expected intermediate-term outcomes? (e.g., changes in behaviors, norms, procedures, policies, performance at the organizational and system level)</li> <li>• Did the program or intervention work, by what magnitude, and, if so, for whom?</li> <li>• Were providers who received the training more likely to effectively counsel, screen and treat patients than those who did not? Did the program have any unintended (beneficial or adverse) effects on the target population(s)?</li> </ul>
<p><b>Timeframe:</b></p>	<p>Short-term, intermediate, and/or long-term post program implementation.</p>
<p><b>Data types, sources:</b></p>	<p>Interviews, observations, focus groups, surveys, questionnaires, clinical assessments, lab values, dose effects, etc.</p>
<p><b>Example indicators:</b></p>	<p>Knowledge, risk behavior, infection status, or other endpoints, where groups are intended to serve as representative samples of the population or sub-population.</p>

### (3) ECONOMIC EVALUATION

<p>Use of applied analytical techniques to identify, measure, value and compare the costs and outcomes of alternative interventions. Economic evaluation is a systematic and transparent framework for assessing efficiency focusing on the economic costs and outcomes of alternative programs or interventions. This framework is based on a comparative analysis of both the costs (resources consumed) and outcomes (health, clinical, economic) of programs or interventions. Economic evaluations are also used to ensure that resources are used efficiently<sup>17</sup>.</p>	
<p><b>Example evaluation questions:</b></p>	<ul style="list-style-type: none"> <li>• What are the costs and benefits of differentiated models of care?</li> <li>• What is the cost effectiveness of a new treatment protocol?</li> <li>• How can programs minimize service delivery costs? What is the cost-effectiveness of this intervention in improving patient outcomes as compared to other treatment models?</li> </ul>
<p><b>Timeframe:</b></p>	<p>Economic evaluations are often conducted retrospectively, once a program has proven to be effective but before scaling. Sometimes, they can be done prospectively to ensure efficient allocation of resources.</p>
<p><b>Data types, sources:</b></p>	<p>Survey data, quantitative and qualitative program data on service delivery, cost and expenditure data</p>

<sup>15</sup> UNAIDS, 2008, Basic Terminology and Frameworks for Monitoring and Evaluation. UNAIDS Monitoring and Evaluation Fundamentals

<sup>16</sup> GAO, 2011, Performance Measurement And Evaluation Definitions and Relationships

<sup>17</sup> Chisholm, D. and D.B. Evans (2007). Economic evaluation in health: saving money or improving care? *Journal of Medical Economics*, **10**(3): p. 325-337.



<b>Example indicators:</b>	Program costs, participant costs, Quality adjusted life years (QALY), disability adjusted life year (DALY), Cost per infection averted, the incremental cost-effectiveness ratio (ICER), etc.
<b>Notes</b>	Economic evaluations are evaluations that primarily focus on identifying, measuring, valuing, and comparing the costs and outcomes of alternative interventions. Studies which fall under primarily under one of the other three evaluations, but which have a cost-effectiveness analysis incorporated should not fall under this evaluation type. Rather, the evaluators can note whether or not their evaluation study has a costing component incorporated.

#### (4) IMPACT EVALUATION

An evaluation that measures the change in an outcome that is attributable to a defined intervention by comparing actual impact to what would have happened in the absence of the intervention (the counterfactual scenario). Impact evaluations (IEs) are based on models of cause and effect and require a rigorously defined counterfactual to control for factors other than the intervention that might account for the observed change. There are a range of accepted approaches to applying a counterfactual analysis, although IEs in which comparisons are made between beneficiaries that are randomly assigned to either an intervention or a control group provide the strongest evidence of a relationship between the intervention under study and the outcome measured<sup>18</sup>.

<b>Example Evaluation Questions:</b>	<ul style="list-style-type: none"> <li>• Does an intervention result in behavior change as a direct result of the intervention?</li> <li>• Does the program improve HIV or its proxy endpoint at the population-level, when properly scaled?</li> <li>• What are the net effects of the program in achieving long term outcomes? (e.g., changes in prevalence, incidence, mortality, sustainability)</li> </ul>
<b>Timeframe:</b>	IEs are generally not measured accurately in the days or months post-intervention. Instead, they often require a much longer-term, post-implementation assessment.
<b>Data types, sources:</b>	Quantitative biological and/or behavioral survey data that may or may not include recipients who directly received the intervention, epidemiological surveillance, qualitative data, etc.
<b>Example indicators:</b>	Incidence, prevalence, mortality, transmission rates, etc.

<sup>18</sup> PEPFAR 2014 Country Operational Guidance and PEPFAR 2012 Supplemental Guidance on Implementation Science/Impact Evaluation.

### **Additional PEPFAR classification of evaluations**

Please note that evaluations will fall into one of the above four categories. In addition to these categories, all evaluations should be classified in terms of their CoAg/contract-level status and their ex-post designation:

- The term CoAg/Contract-level evaluation is used to denote a small-scale evaluation study attached to a specific Cooperative Agreement or contract of which the overall goal is to examine implementation fidelity and/or effectiveness of a specific activity under a CoAg/contact or of the entire CoAg.
- An ex-post evaluation is defined as a performance or impact evaluation that examines a strategy, project, activity, or intervention at least one year after it has ended. The ex-post evaluations mark evaluations that occur after program implementation is complete. These studies can provide crucial information on whether interventions and/or desired outcomes are sustained over time. It can also be used to answer questions about what factors and contexts help or hinder interventions and sustainable development outcomes.<sup>6</sup>

## Section II—PEPFAR Evaluation Standards of Practice

The US State Department's Office of the Global AIDS Coordinator (S/GAC) requires all PEPFAR implementing agencies and PEPFAR funding recipients who implement evaluations to commit themselves to the 11 evaluation standards of practice detailed below. Although many of these practices are already incorporated into agency policies and frameworks, consistent implementation remains a concern.<sup>19</sup> By adhering to a set of common standards and monitoring adherence to these standards, greater consistency and quality among PEPFAR evaluations is expected, as is reliable data for decision-making and programmatic improvement.

The PEPFAR evaluation standards of practice are introduced below in the order they are likely to be applied when conducting an evaluation, although the order may vary based on need. For example, evaluation usually starts by engaging stakeholders, but stakeholder engagement is not limited to the beginning of an evaluation. Stakeholders should also be engaged throughout the evaluation (e.g. implementation, reporting, dissemination, and utilization).

### THE STANDARDS OF PRACTICE

1. **ENGAGE STAKEHOLDERS**
2. **CLEARLY STATE EVALUATION QUESTIONS, PURPOSE, AND OBJECTIVES**
3. **USE APPROPRIATE EVALUATION DESIGN, METHODS, AND ANALYTICAL TECHNIQUES**
4. **ADDRESS ETHICAL CONSIDERATIONS AND ASSURANCES**
5. **IDENTIFY RESOURCES AND ARTICULATE BUDGET**
6. **CONSTRUCT DATA COLLECTION AND MANAGEMENT PLANS**
7. **ENSURE APPROPRIATE EVALUATOR QUALIFICATIONS AND EVALUATION INDEPENDENCE**
8. **MONITOR THE PLANNING AND IMPLEMENTATION OF AN EVALUATION**
9. **PRODUCE QUALITY EVALUATION REPORTS**
10. **DISSEMINATE RESULTS**
11. **USE FINDINGS FOR PROGRAM IMPROVEMENT**

### 1. ENGAGE STAKEHOLDERS

*Engage key stakeholders from the beginning and throughout the evaluation as appropriate, to ensure the success of the evaluation and implementation of the recommendations.*

The relevancy and utility of evaluation are enhanced through responsiveness to the needs of a diverse range of stakeholders. Stakeholders are any persons, organizations, and/or institutions that have an investment in what will result from an evaluation and what will be done with the results.

There are three critical groups of stakeholders who must be considered in planning an evaluation:

- 1) Persons involved in program operations (e.g., sponsors, collaborators, partners, funding officials, administrators, managers, and staff);

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<sup>19</sup> GAO, 2012, op. cit.

- 2) Persons served or affected by the program (e.g., clients, family members, community organizations, academic institutions, elected officials, advocacy groups, professional associations, and staff of related or competing organizations); and
- 3) Persons who make decisions regarding the program (e.g., country leadership, policy makers, program managers, sponsors)<sup>20</sup>

Stakeholders should be identified and engaged in the planning stages of evaluation, including prioritizing what to evaluate, budgeting and funding decisions, identification of the evaluation questions, and dissemination and use of findings and recommendations.<sup>21</sup> For evaluations of PEPFAR-funded programs, it is essential to involve both government and non-government stakeholders from the country in which the evaluation is conducted.

The stakeholders involved, as well as the scope and level of stakeholder involvement, will vary by evaluation and its context. For example, clients or certain priority stakeholders, such as evaluators in the community, can be directly involved in designing and conducting the evaluation. Other stakeholders, such as policy-makers, may be involved in the initial framing of evaluation questions, should be kept informed throughout the implementation process, and should receive the evaluation results. Configuring a communication strategy at the start of program planning is particularly relevant to ensure ongoing stakeholder engagement and support, particularly if an evaluation crosses organizational units with overlapping or complementary missions.

## **2. CLEARLY STATE EVALUATION QUESTIONS, PURPOSE, AND/OR OBJECTIVES**

*Make explicit the evaluation questions, purpose, and/or objectives.*

Evaluation planning should be part of program planning from the start and throughout program implementation. The first stage of planning an evaluation is to outline and agree upon the general purpose of the evaluation, evaluation objectives and key questions. The evaluation purpose and objectives must be understood from the beginning, and the evaluation questions should be simple and clear. The next step should be to synthesize the best available evidence regarding the intervention(s), i.e. what is already known about how well it works. Focus should then shift to:

- 1) What will be evaluated (specifically defining the intervention or aspects of an intervention)
- 2) Who wants the information
- 3) What do they want to know (various outputs or outcomes)
- 4) How the results will be linked to specific future decisions or programs<sup>22</sup>

Clarifying the intent and answers to these questions from the beginning will facilitate the subsequent decisions.

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<sup>20</sup> Centers for Disease Control and Prevention. Framework for program evaluation in public health. MMWR 1999; 48 (No. RR-11)

<sup>21</sup> Measure Evaluation, 2011. Tools for Data Demand and Use in the Health Sector: Stakeholder Engagement Tool  
<http://www.cpc.unc.edu/measure/publications/ms-11-46-e>

<sup>22</sup> USAID, Automated Directives System 203.3.1.4 11\_02\_2012

### 3. USE APPROPRIATE EVALUATION DESIGN, METHODS, AND ANALYTICAL TECHNIQUES

*The evaluation design and methods should be feasible, context sensitive, culturally relevant, rigorous, and appropriate to answer the evaluation questions.*

When selecting the design and methods, consider the program's maturity, the evaluation questions to be addressed, purpose and timeline for needing the results, the intended audience, and the available financial and other resources. After considering all factors mentioned, the best design, data collection and analysis methods should be used.

Because evaluations generally address multiple questions, a range of analytic methods is often needed. The most rigorous methods appropriate for the evaluation questions should be used. Carefully thinking through data needs and analytic techniques in advance will enhance the quality, credibility, and usefulness of an evaluation by increasing the strength and specificity of the findings and recommendations. In conjunction with evaluation design and methods, an analysis plan should be predetermined and described in an evaluation Scope of Work (SOW)/protocol.

### 4. ADDRESS ETHICAL CONSIDERATIONS AND ASSURANCES

*Address human subjects' protections when planning and implementing the evaluation.*

Evaluations must be conducted in a manner that is respectful to and protects human subjects, privacy, and confidentiality, and maintains the dignity of participants and other stakeholders.<sup>23</sup> U.S. government (USG) agencies follow regulatory standards regarding human protections<sup>24</sup> and these standards are based on principles and guidelines established in the international community.<sup>25</sup> These principles require evaluators to behave legally, ethically, and have regard for the physical and psychological welfare of those involved and those affected by an evaluation, including vulnerable populations. All personnel involved in planning and implementing an evaluation should be knowledgeable regarding agency policies, rules and regulations in this regard, and complete ethical certifications when indicated.

Procedures should ensure that participants who contribute information to an evaluation, especially if they may incur risks, do so willingly and with full knowledge of any potential risks. Participants should be informed that their eligibility to receive services is not contingent upon their participation in the evaluation (i.e., clients retain the right to refuse to participate in an evaluation). These protections are generally addressed in an informed consent agreement administered before participants agree to participate and respond to data collection inquiries. Such protections also should be described in the evaluation protocol governing the conduct of the evaluation.

Special protections are especially important when conducting evaluations involving children, prisoners, pregnant women, and other vulnerable groups.

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<sup>23</sup> AEA, 2010, Roadmap, *op.cit.*

<sup>24</sup> Department of Health and Human Services (45 CFR 46), United States Agency for International Development (22 CFR 225).

<sup>25</sup> The WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects

(<https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>) and the Council for International Organizations of Medical Sciences (CIOMS)

International Ethical Guidelines for Biomedical Research Involving Human Subjects

(<https://cioms.ch/shop/product/international-ethical-guidelines-for-biomedical-research-involving-human-subjects-2/>) are the documents used by agencies to articulate their rules and regulations regarding Human Subjects.

Evaluation scopes of work/protocols may have to be reviewed by and receive ethical clearance from an ethics and/or scientific regulatory board located in-country, (national and sometimes local), as well as a USG implementing agency, and/or when relevant, at the level of the implementing partner or the associated external institutional entity.

Please note, for evaluations where no human subject's data is used or for data where the primary intended purpose of initial data collection did not require informed consent based on HIPAA and the Common Rule<sup>26,27</sup>, informed consent may not be applicable. Please consult your institutional IRB and/or Evaluation POC for further detail.

## 5. IDENTIFY RESOURCES AND ARTICULATE BUDGET

*Identify the evaluation budget at the start of program planning.*

Successful execution of evaluations requires not only a commitment among program managers and implementers to incorporate evaluation into their efforts, but also sufficient resources to ensure the implementation of the appropriate type and design of evaluation. This commitment requires considerable forethought, since resource decisions are often made in the context of tension between program and evaluation priorities. As planning occurs, these priorities need to be balanced and adequate resources need to be made available.

Appropriate steps need to be taken to ensure resources are available to fulfill the requirements of the evaluation design from planning through full execution and results sharing.

## 6. CONSTRUCT DATA COLLECTION AND MANAGEMENT PLANS

*Create data collection and management plans prior to implementing the evaluation to ensure that data are valid, reliable, and accessible.*

Since the intent of data collection is to gather information that stakeholders perceive as trustworthy and relevant, evaluation SOWs/protocols should include data collection and management procedures that are in line with agency policies and specify the following: who will administer the data collection instruments; when these will be administered; how data will be gathered and checked in a systematic, comparable, precise, and unbiased way; how the data will be archived, transported, secured, confidentiality ensured, and disposed of (if applicable); how data-use agreements will be developed with partners and others; which institutions and individuals will have access to the data in its various forms; how long the data will be saved; how interview tapes or audio files will be managed and stored; whether or not they will be translated, transcribed; and how observations will be captured and stored.<sup>28</sup> The plan may include an agreement signed by evaluation team members which acknowledges their responsibilities.

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<sup>26</sup> Ibid., 10

<sup>27</sup> Department of Health and Human Services (45 CFR 160 and 164),

<sup>28</sup> Yarbrough, D. B., Shulha, L. M., Hopson, R. K., and Caruthers, F. A. (2011). *The Program Evaluation Standards: A Guide for Evaluators and Evaluation Users* (3rd ed.). Thousand Oaks, CA: Sage.

## 7. ENSURE APPROPRIATE EVALUATOR QUALIFICATIONS AND INDEPENDENCE

*Ensure evaluators have appropriate experience and capabilities. Manage any conflicts of interest (COIs) of the evaluators (or team) and mitigate any untoward pressures that could be applied to the evaluator or evaluation team that would influence its independence.*

It is important that evaluation team members:

- are qualified to conduct the evaluation through knowledge and experience;
- disclose any potential conflict of interest with the evaluation; and
- are protected from any undue pressure or influence that would affect the independence of the evaluation or objectivity of the evaluator(s).

Only evaluation teams (whether internal or external) that possess the education, capabilities, skills and experience appropriate to undertake the tasks proposed in the SOW/protocol should conduct evaluations. Professional evaluators typically have advanced training in social science or public health. Depending on the nature of the program and the evaluation questions, the evaluation team might also require members with specialized subject area expertise (e.g., epidemiology, clinical skills, economics, statistics, qualitative analysis).

It is also vital to manage any conflicts of interest of the evaluator and/or the evaluation team to ensure credibility and mitigate bias. In advance, everyone on the evaluation team must disclose any personal, financial, or other relationships they have that might pose a conflict of interest (or the appearance of a conflict) in their role as evaluators. This is frequently accomplished by having the evaluation team sign a conflict-of-interest statement prior to conducting the evaluation. The COI statements should be kept with all other evaluation data and shown to stakeholders as appropriate. The COI statements should be in line with the implementing agency conflict of interest policy (if there is one) and should be included in both the protocol/SOW and the appendices of the final evaluation report.

Managing the independence of the evaluation includes informing and educating all those participating in the evaluation (including those collecting data, funding, reviewing, or approving the evaluation) that the planning, implementation, and results of the evaluation should not be manipulated in any way to suggest undue influence. Suggested strategies to improve evaluator independence include but are not limited to: having evaluation units that are separate from program units; using external evaluations and evaluators; or establishing formal conflict-of-interest procedures and declarations for internal and external evaluators. In some instances, if certain procedures or activities are likely to produce misleading information or conclusions, the evaluation team has the responsibility to communicate their concerns to relevant stakeholders and colleagues. The team should identify proper ways to proceed (e.g., discussions at a higher level, a dissenting cover letter or appendix, refusal to sign the final report, documenting concern and make a disclaimer, or submitting a Statement of Difference letter.<sup>29,30,31</sup>

## 8. MONITOR THE PLANNING AND IMPLEMENTATION OF AN EVALUATION

*Monitoring how an evaluation is planned and implemented is essential for ensuring quality evaluations; controlling redundancy, time and costs; and identifying and solving unexpected problems as they arise.*

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<sup>29</sup> USAID-specific procedure.

<sup>30</sup> World Bank, Independence and Impartiality in Conducting Evaluations, Chap 3. World Bank, Washington, D.C. [http://siteresources.worldbank.org/EXTGLOREGPARPROG/Resources/grpp\\_sourcebook\\_chap3.pdf](http://siteresources.worldbank.org/EXTGLOREGPARPROG/Resources/grpp_sourcebook_chap3.pdf)

<sup>31</sup> American Evaluation Association (AEA), Guiding Principles for Evaluators, <http://www.eval.org/p/cm/ld/fid=51>

This monitoring activity should start with the appropriate agency lead, the evaluation lead and relevant stakeholders tracking development and completion of the evaluation protocol. Once the evaluation has begun, it is important to oversee progress in accordance with the evaluation design, and document any contextual changes, deviations from the evaluation plan/protocol, or quality issues. All relevant stakeholders should be kept informed of the evaluation progress.

Data limitations or new information about the project or program being evaluated may arise as the evaluation is being conducted and this may have implications on the adequacy of the original plan or the feasibility of answering the evaluation questions. If adjustments are necessary, the evaluation team should document these changes, along with the rationale, and submit modifications through the appropriate channels. Monitoring and documenting the progress of an evaluation and communicating with stakeholders is a primary responsibility of the evaluation lead(s). The evaluation team simultaneously has the responsibility for safeguarding its quality, adhering to the SOW/protocol, and applying the evaluation standards throughout.

## 9. PRODUCE QUALITY EVALUATION REPORTS

*The final evaluation report should be a quality report that ensures the transparency of the evaluation and captures the other 10 elements of the ESoP.*

The evaluation report should represent a thoughtful, methodologically sound, and well-organized effort to describe the process and findings of the evaluation. The content of an evaluation report should allow the reader to fully understand the implementation context/background, the rationale for conducting the evaluation, the evaluation questions to be answered, the methods and analyses that were used, and the findings. Any limitations to the evaluation findings (e.g., spillover, lost to follow up, or poor quality or missing data) should be fully described. For the findings to be useful, explicit, actionable, realistic, and specific recommendations should be made.

Appendix B includes the required components that must be included in the final reports for all PEPFAR-funded evaluations. The table also includes suggested content for each component and the relevant standards. This checklist helps to ensure all required reporting components per the ESoP are included and can also be used as a basis for peer review of the final report to help improve report quality. Information contained in an evaluation report enables formal review for compliance with the ESoP. Inclusion of all required elements is essential.<sup>32</sup>

## 10. DISSEMINATE RESULTS

*Evaluation results should be disseminated to all stakeholders, the public and funders.*

In accordance with FATAA requirements, the PEPFAR approach to dissemination of evaluation results is two-fold: internal dissemination within the PEPFAR community, and external, public release of results (post-embargo period, as applicable). This two-fold approach both avoids delays in the use of evaluation findings for internal PEPFAR programming purposes as well as meets embargo requirements for results stipulated by most peer-reviewed journals prior to publication. Internal reports may provide findings with limited specificity in cases where release of data/findings is restricted, classified, or embargoed. However, recommendations must still be actionable for immediate programmatic use. Further, reports where notation of embargoed findings is

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<sup>32</sup> The **PEPFAR Evaluation Standards of Practice, versions 1.0-3.0** made an allowance for the substitution of published articles for final reports. This accommodation is no longer permitted. All evaluations must submit a final report in line with ESoP v3.1.



present must be updated with the relevant findings and/or link to publication, once the findings are available in the public domain.

External, public dissemination is also congressionally mandated by the *PEPFAR Stewardship and Oversight Act*.<sup>33</sup> Accordingly, all completed PEPFAR evaluation reports must be maintained and made available via a website of the implementing agency within 90 days after the completion of the evaluation (Foreign Aid Transparency and Accountability Act of 2016 (FATAA)). Additional access will be provided through links from a central PEPFAR site (e.g., [www.PEPFAR.gov](http://www.PEPFAR.gov)).

As with other elements of evaluation, dissemination should be discussed and planned with stakeholders and must follow agency evaluation dissemination guidance. These steps will ensure that the information needs of relevant audiences will be met, which requires consideration of the timing, style, tone, message source, vehicle and format of information products (e.g., publications, briefings, newsletter). Evaluation results and recommendations should be presented clearly and simply so that stakeholders and other parties can easily understand the evaluation process, results and recommendations.<sup>34</sup> Examples of results dissemination vehicles include evaluation reports as described above, publications, oral presentations, websites, annual reports, and briefings.

## **11. USE FINDINGS FOR PROGRAM IMPROVEMENT**

*Evaluation findings and recommendations should be utilized for decision-making and program improvement.*

An evaluation is a worthwhile endeavor when the results are used. Well-planned evaluations provide evidence to inform real-world decision-making and contribute to learning agendas that have national, regional, or global importance. Evaluation results can be used to demonstrate the effectiveness of a program, gauge its efficiency, plan new procurements, make mid-stream adjustments to improve programs, and demonstrate accountability. The evaluation objective(s) as well as the intended audience identified in the planning phase of the evaluation should guide use of the evaluation results.

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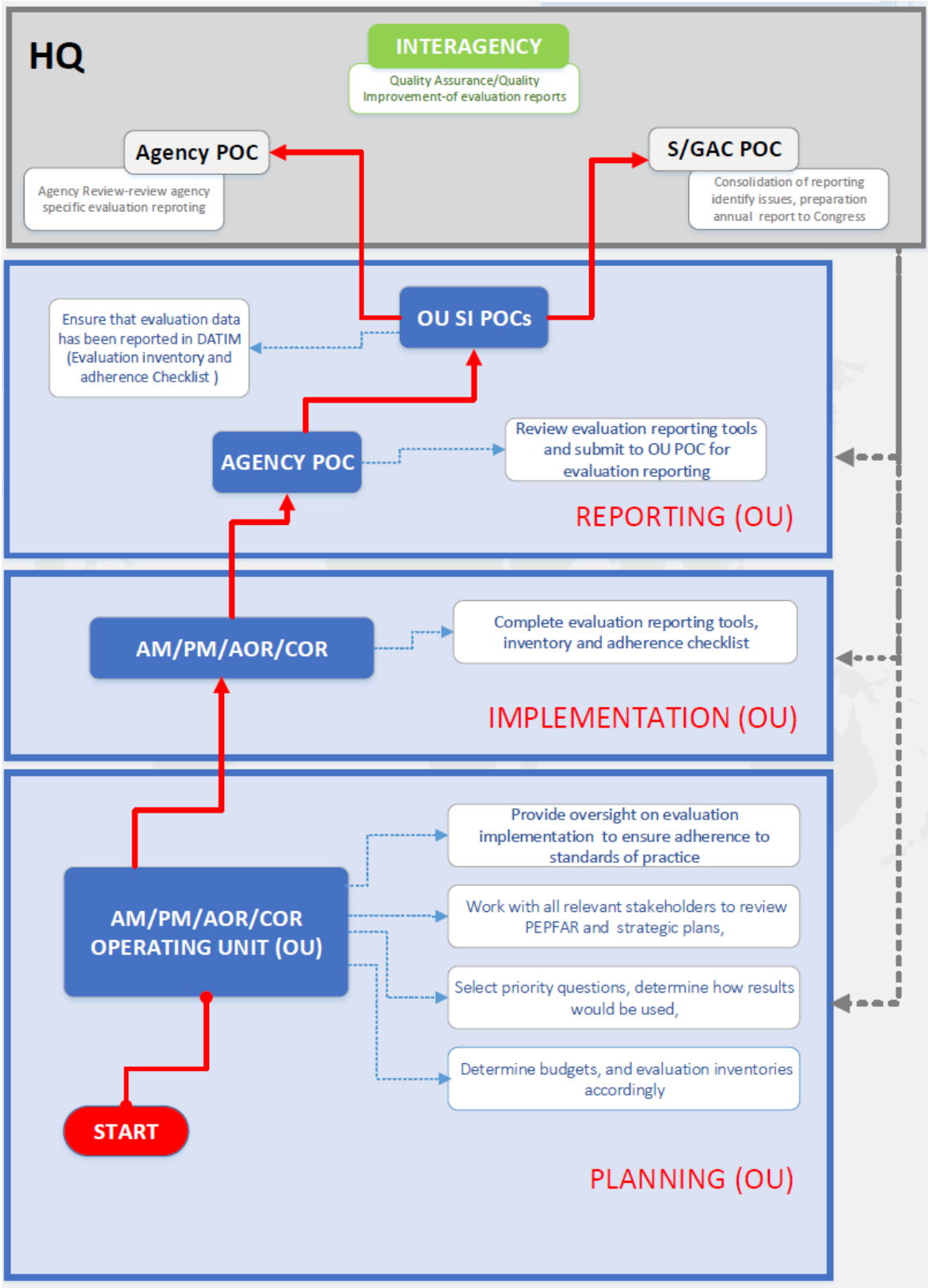
<sup>34</sup> GAO, 2012, *Designing Evaluations, Revision*, GAO-12-208G. Washington, D.C. January 2012.

## Section III—Planning, Implementation, Reporting, and Review

As OUs approach strategic planning for evaluations, it is critical to keep in mind that **ALL** PEPFAR-funded evaluations, no matter what the type, who is conducting them, or the funding source, need to be situated within the larger context of regionally, nationally, and globally defined priorities and relevant information gaps.

Interagency collaboration, as well as completeness and transparency of information, are essential to inform this strategic planning. In addition, select information regarding all PEPFAR-funded evaluations is required to be reported to headquarters and Congress. This section describes the entire cycle of evaluation planning, implementation, reporting, and review (Figure 1).

Figure 1. Evaluation planning, implementation, reporting, and review process



## EVALUATION PLANNING

Evaluation planning is important to ensure that resources are allocated appropriately and in concert with overall evaluation priorities.<sup>35</sup> The American Evaluation Association, which has a target audience of the US Federal Agencies, states:

*“...Each Federal agency should require its major program components to prepare annual and multi-year evaluation plans of the studies and other evaluation activities that they will undertake. The plans should be updated annually. The planning should consider the needs of evaluation results for informing program budgeting, reauthorization, agency strategic plans, ongoing program development and management and responses to critical issues that arise concerning program effectiveness, efficiency, and waste. These plans should include an appropriate mix of short- and long-term studies to ensure that evaluation results of appropriate scope and rigor are available when short- or long-term policy or management decisions must be made. To the extent practical, the plans should be developed in consultation with program stakeholders who are involved in or affected by the programs.”<sup>36</sup>*

Although PEPFAR does not require formal Evaluation Plans, PEPFAR evaluations are incorporated in the annual Country Operational Plan (COP) planning process, ensuring evaluation activities align with the strategic direction of each PEPFAR country in its goal of reaching epidemic control.

## EVALUATION IMPLEMENTATION

Evaluators should implement the evaluation as per the SOW/protocol and in close communication with the AM/PM/AOR/COR/IAD that commissioned the evaluation. The AM/PM/AOR/COR/IAD will provide evaluators with the ESoP to ensure that they are aware of the standards and associated measures of adherence. The AM/PM/AOR/COR/IAD should provide oversight of the evaluation implementation including in-briefing, reviewing work plans and data collection tools, ensuring ethical procedures, participating in the site selection, and de-briefing with the evaluation team.

## EVALUATION REPORTING

Upon completion of an evaluation, evaluators will use the components listed in Appendix B to create a final evaluation report for the purpose of PEPFAR. Reports must be disseminated publicly within 90 days the report being completed, in line with congressionally mandated reporting requirements and the ESoP. This external reporting requirement does not preclude publication or other ways of disseminating results in fulfillment of a required scope of work. Furthermore:

- **Evaluation Inventory:** Agency representatives at the OU level are required to report on the status of PEPFAR/COP-approved evaluations by *completing* the Evaluation Inventory for all planned and newly commencing evaluations for the current fiscal year and *updating* the Evaluation Inventory for all, ongoing, discontinued, and completed evaluations. The Inventory entries will be shared across Agencies

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<sup>35</sup> GAO, 2012, PEPFAR Evaluation, *op. cit.*

<sup>36</sup> American Evaluation Association, 2010, Roadmap, *op. cit.*, P. 6.

to promote visibility and usability of PEPFAR-funded evaluations' results regardless of implementing Agency or OU.

- **Adherence Checklist:** Agency representatives at the OU level are also required to fill out an Adherence Checklist for **all completed** evaluations. The primary purpose of the Checklist is to assess adherence of PEPFAR evaluations to the 11 standards. The evaluation final report should be used as the primary reference documents to complete this section of the tool. The responses to the Adherence Checklist will be used in the Annual Report to Congress.

Evaluation data should be reported in DATIM semi-annually. Refer to the PEPFAR Data Calendar for data entry open and close dates. For guidance on how to create and update Evaluation Inventory and Adherence Checklist entries, please refer to the guidance on [DATIM Support](#).

## EVALUATION REVIEW

Evaluation reviews should occur at Agency, OU, and S/GAC levels. Review processes may vary by Agency. Once evaluation reporting has been completed and submitted to S/GAC via DATIM, the appropriate headquarters agency POCs will examine data for completeness. If there is incomplete information reported, Agency Evaluation POCs will work with missions to ensure completeness and accuracy.

S/GAC will compile evaluation data and facilitate an annual interagency review. Data drawn from the Adherence Checklists and Evaluation Inventory will be incorporated into the Annual Report to Congress, in compliance with legislative requirements of the *PEPFAR Stewardship and Oversight Act*.

## Section IV—Roles and Responsibilities

S/GAC, Implementing Agencies, and OUs all have specific responsibilities and extensive shared interests in ensuring that evaluation activities are well-integrated within PEPFAR programs. Consequently, work needs to be coordinated across the partners to prevent duplication of effort. Communication channels should be established among the various Points of Contact in the field and at HQ to support coordination and improve the quality of evaluation implementation. To facilitate this, Evaluation Inventory information on all PEPFAR-funded evaluations shall be provided to all agencies via DATIM.

It is essential to recognize that Implementing Agencies have existing business practices, evaluation guidance, policies and frameworks<sup>37,38</sup> which are generally inclusive of the standards of practice described. These variations should be articulated in agency-specific translational documents and provide guidance on the integration of ESoP requirements with agency-specific policies and procedures. Table 2 illustrates ESoP roles and responsibilities by stakeholder entity, and Table 3 illustrates roles and responsibilities for individuals.

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<sup>37</sup> USAID, Evaluation Policy, *op. cit.*

<sup>38</sup> CDC, Evaluation Framework, *op. cit.*

**Table 2. Stakeholder roles and responsibilities**

Stakeholders	Roles & Responsibilities
<b>S/GAC</b>	<ul style="list-style-type: none"> <li>• Coordinate interagency process to support implementation of evaluation standards of practice and use of high-quality evaluations in PEPFAR-supported programs.</li> <li>• Coordinate interagency evaluation experts to develop and disseminate guidance, orient the field on the ESoP, and respond to high-level inquiries from the field and headquarters.</li> <li>• Consolidate and review agency and OU reporting of all evaluations and ESoP Adherence Checklists.</li> <li>• Coordinate efforts to provide technical assistance to strengthen agency, OU, and implementing partner evaluation capacity, as appropriate.</li> <li>• Coordinate interagency efforts to disseminate lessons learned, best practices, and evaluation results to relevant stakeholders including the public to promote use of findings and improve PEPFAR programs.</li> <li>• Coordinate public dissemination of evaluation reports via <a href="http://pepfar.gov">pepfar.gov</a>.</li> <li>• Coordinate the development of an annual report to Congress on the descriptions of all PEPFAR funded evaluations, public dissemination of evaluation reports, and adherence to ESoP.</li> </ul>
<b>Interagency Evaluation Experts</b>	<ul style="list-style-type: none"> <li>• Develop and update ESoP and orient the field and headquarter staff through webinars and other dissemination fora.</li> <li>• Serve as a resource group to answer questions and provide technical assistance to OUs and headquarters regarding implementation and use of the ESoP, as appropriate.</li> <li>• Review and revise ESoP and relevant tools and templates as needed.</li> <li>• Collaborate and support S/GAC activities, as needed.</li> <li>• Orient the field on ESoP reporting requirements in APR as well as COP/HOP and other planning requirements.</li> </ul>
<b>Implementing Agencies</b>	<ul style="list-style-type: none"> <li>• Identify Implementing Agency Evaluation Point of Contact at headquarters and in each OU who will be responsible for planning, organizing technical assistance, collecting relevant data for all evaluations (inclusive of centrally funded, multi-country, and other evaluations), and reporting on ESoP.</li> <li>• Support dissemination and orientation of ESoP to OUs.</li> <li>• Develop agency-specific guidance documents to translate PEPFAR ESoP for integration with agency policies, where appropriate.</li> <li>• Lead agency efforts to ensure and improve adherence to the ESoP through orientation/training, rollout, oversight, as well as SOW/protocol and evaluation report review.</li> <li>• Contribute to completion and review of Evaluation Inventories and Adherence Checklists in OUs, and support submission for SAPR and APR reporting in DATIM and for the Annual Report to Congress.</li> <li>• Provide agency-specific technical assistance to OUs to strengthen evaluation capacity and participate in interagency technical assistance when appropriate.</li> </ul>

	<ul style="list-style-type: none"> <li>• Disseminate lessons learned, best practices, and evaluation results to relevant stakeholders and the public.</li> <li>• Disseminate all completed PEPFAR evaluation reports (e.g., OU-implemented, agency-implemented, headquarters-implemented) on publicly accessible agency website and submit website address(es) to S/GAC.</li> <li>• Support use of evaluation results for decision-making and program improvement within the agency.</li> </ul>
<b>Operating Units</b>	<ul style="list-style-type: none"> <li>• Understand and utilize ESoP for evaluation planning, implementation, and reporting.</li> <li>• Ensure all, partially or fully, PEPFAR-funded evaluations are entered into the Evaluation Inventory.</li> <li>• Ensure that all completed PEPFAR evaluations are described and assessed for adherence to the standards using the Adherence Checklist.</li> <li>• Ensure that Adherence Checklists are completed within expected timeframes (i.e., 90 days after final evaluation report is completed).</li> <li>• Ensure that all planned PEPFAR evaluations are designed and budgeted appropriately during Country Operational Planning process.</li> <li>• Facilitate capacity building needs of OU staff on evaluation planning, implementation, budgeting, and oversight.</li> <li>• Request ESoP-related technical assistance through Agency POC who will coordinate with interagency evaluation experts and/or others to provide support as needed.</li> <li>• Disseminate lessons learned, best practices, and evaluation results with relevant in-country stakeholders and the public as appropriate.</li> <li>• Ensure use of evaluation results for decision-making and program improvement.</li> </ul>
<b>Evaluators</b>	<ul style="list-style-type: none"> <li>• Collaborate with relevant implementing agency and external or internal agency evaluators to provide access to data, information, human resources, and sites.</li> <li>• Apply ESoP when developing and implementing PEPFAR-funded evaluations.</li> <li>• Participate in evaluation process as key informants regarding the projects and interventions being implemented.</li> <li>• Use evaluation findings for program improvement.</li> </ul>



**Table 3. Individual roles and responsibilities**

Individuals	Roles & Responsibilities
<b>AM/PM/AOR/ COR or Implementing Agency Designee</b>	<ul style="list-style-type: none"> <li>· Identify which projects will be evaluated and provide relevant information to the SI Liaison during COP.</li> <li>· Develop evaluation Scopes of Work or protocols, which must be approved through relevant agency procedures and processes.</li> <li>· Select and procure the services of competent and qualified evaluators to conduct evaluations.</li> <li>· Provide management/oversight of evaluators, providing them with the ESoP including relevant tools and templates.</li> </ul>
<b>Implementing Agency ESoP POC (HQ)</b>	<ul style="list-style-type: none"> <li>· Support dissemination and orientation of ESoP to OUs.</li> <li>· Develop agency-specific guidance documents to translate ESoP for integration with agency policies, when appropriate.</li> <li>· Provide agency-specific technical assistance to OUs to strengthen evaluation planning, implementation, and reporting.</li> <li>· Ensure dissemination of completed PEPFAR evaluation reports on agency website and submission of agency website link to S/GAC.</li> </ul>
<b>Implementing Agency ESoP POC (OU)</b>	<ul style="list-style-type: none"> <li>· After the evaluation activity is implemented, complete the Evaluation Inventory and, when appropriate, the Adherence Checklist to SI Liaisons through Agency POC within 90 days after the final evaluation report is completed.</li> <li>· Submit completed evaluation reports to Implementing Agency HQ ESoP POC.</li> </ul>
<b>Evaluator(s)</b>	<ul style="list-style-type: none"> <li>· Review and understand PEPFAR ESoP.</li> <li>· Ensure evaluations adhere to the 11 standards.</li> <li>· Provide completed, high quality evaluation reports ensuring the inclusion at least of the Standard Final Evaluation Report Template.</li> <li>· Provide findings, conclusions, and recommendations, which are feasible, actionable, and specific to inform program planning and facilitate program improvement.</li> </ul>

# Appendices

## Appendix A: Definition of Terms

*Please note, agencies (as well as global partners) use generally comparable definitions for these terms, but some variation does exist and may have implications for specific work performed.*

**ACTIVITY:** “An activity is a component of a project that contributes to a project purpose. It refers to an award (such as a contract, grant or cooperative agreement), or a component of a project such as training or technical assistance.”<sup>39</sup>

**CONFLICT OF INTEREST:** “A situation in which a party has interests that could improperly influence that party’s performance of official duties or responsibilities, contractual obligations, or compliance with applicable laws and regulations”.<sup>40</sup> A real or perceived conflict of interest of an evaluator translates to a lack of “impartiality, objectivity, and integrity”<sup>41</sup> and could jeopardize the credibility and validity of the findings.

**ECONOMIC EVALUATION:** Use of applied analytical techniques to identify, measure, value, and compare the costs and outcomes of alternative interventions. Economic evaluation is a systematic and transparent framework for assessing efficiency focusing on the economic costs and outcomes of alternative programs or interventions. This framework is based on a comparative analysis of both the costs (resources consumed) and outcomes (health, clinical, economic) of programs or interventions. Main types of economic evaluation are cost minimization analysis (CMA), cost-effectiveness analysis (CEA), cost-benefit analysis (CBA), and cost-utility analysis (CUA).<sup>42</sup>

**EVALUATION:** “Evaluation is systematic collection and analysis of information about the characteristics and outcomes of the program, including projects conducted under such program, as a basis for making judgments and evaluations regarding the program; improving program effectiveness; and informing decisions about current and future programming.”<sup>43</sup>

**EVALUATOR INDEPENDENCE:** There are multiple facets pertaining to independence that need to be considered. One facet refers to having “no fiduciary relationship with the implementing partner” that is being evaluated”.<sup>44</sup> In addition, “independence provides legitimacy to evaluation and reduces the potential for conflict of interest which could arise if policy makers and managers were solely responsible for evaluating their own activities”.<sup>45</sup> Also “evaluators are independent from the development intervention, including its policy, operations and management functions, as well as intended beneficiaries. The evaluation team is able to work freely and without interference. It is assured of co-operation and access to all relevant information”.<sup>46</sup>

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<sup>39</sup> Department of State, Evaluation Policy, *op. cit.*

<sup>40</sup> Asian Development Bank. 2005. Guidelines to avoid conflict of interest in independent evaluations. P. 46.

<sup>41</sup> *Ibid.*

<sup>42</sup> Drummond 2005.

<sup>43</sup> Foreign Aid Transparency and Accountability Act (2016). <https://www.whitehouse.gov/wp-content/uploads/2017/11/M-18-04-Final.pdf>

<sup>44</sup> United States Agency for International Development, ADS 203. P. 10.

<sup>45</sup> OECD DAC, 1991. Principles for Evaluation of Development Assistance. P. 6.

<sup>46</sup> OECD DAC, Quality Standards for Development Evaluation. P. 11

**EXTERNAL EVALUATION:** An evaluation conducted externally by an independent consulting firm, research institute, or independent oversight agency such as GAO or an agency's Inspector General. The importance of an evaluator's independence from program management provides greater credibility of the evaluation findings and report.<sup>47</sup>

**IMPACT:** "The long-term, cumulative effect of programs/interventions over time on what they ultimately aim to change, such as a change in HIV infection and AIDS-related morbidity and mortality. Note: Impacts at a population-level are rarely attributable to a single program/intervention, but a specific program/intervention may, together with other programs/interventions, contribute to impacts on a population."<sup>48</sup>

**IMPACT EVALUATION:** Measures the change in an outcome that is attributable to a defined intervention by comparing actual impact to what would have happened in the absence of the intervention (the counterfactual scenario). IEs are based on models of cause and effect and require a rigorously defined counterfactual to control for factors other than the intervention that might account for the observed change. There are a range of accepted approaches to applying a counterfactual analysis, though IEs in which comparisons are made between beneficiaries that are randomly assigned to either an intervention or a control group provide the strongest evidence of a relationship between the intervention under study and the outcome measured.<sup>49</sup>

**INTERNAL EVALUATION:** Evaluations aimed at identifying program improvement and are conducted by a program office or an agency unit that specializes in program analysis and evaluation.<sup>50</sup> Internal evaluations include those led by or made up entirely of implementing agency staff (HQ or field), those implemented by partners of their own efforts, or those commissioned by implementing partners using external consultants.

**MONITORING:** "Monitoring provides an indication of progress against goals and indicators of performance, reveals whether desired results are occurring, and confirms whether implementation is on track. In general the results measured are the direct and near term consequences of program activities."<sup>54</sup>

**OUTCOME:** "Short-term or medium-term effect of an intervention's outputs, such as a change in knowledge, attitudes, beliefs, and behaviors."<sup>56</sup>

**OUTCOME EVALUATION:** "A type of evaluation that determines if and by how much, intervention activities or services achieved their intended outcomes." It focuses on "outputs and outcomes (including unintended effects) to judge program effectiveness, but may also assess program process to understand how outcomes are produced."<sup>51</sup>

**OUTPUTS:** "The results of program/intervention activities; the direct products or deliverables of program/intervention activities, such as the number of HIV counseling sessions completed, the number of people served, and the number of condoms distributed."<sup>52</sup>

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<sup>47</sup> GAO, 2012. Designing Evaluations, 2012 Revisions. P. 5

<sup>48</sup> UNAIDS, 2010, Basic Terminology and Frameworks for Monitoring and Evaluation, *op. cit.*, P. 62.

<sup>49</sup> PEPFAR 2014 Country Operational Guidance, and PEPFAR 2012 Supplemental Guidance on Implementation Science/Impact Evaluation.

<sup>50</sup> GAO, 2012, *op. cit.* P. 5 <sup>54</sup>

*Ibid.*

<sup>51</sup> Government Accountability Office (GAO), Performance Measurement and Evaluation: Definitions and Relationships, May 2011.

<sup>52</sup> *Ibid.*, P. 65.

**PROCESS EVALUATION:** “This form of evaluation assesses the extent to which a program is operating as it was intended.<sup>53</sup> This type of evaluation that focuses on program or intervention implementation, including, but not limited to access to services, whether services reach the intended population, how services are delivered, client satisfaction and perceptions about needs and services, and management practices. In addition, a process evaluation might provide an understanding of cultural, socio-political, legal, and economic context that affect implementation of the program or intervention.”<sup>54</sup>

**PROGRAM:** “An overarching national or sub-national response to a disease. A program generally includes a set of interventions marshaled to attain specific global, regional, country, or subnational objectives; involves multiple activities that may cut across sectors, themes and/or geographic areas.”<sup>55</sup>

**PROJECT:** “An intervention designed to achieve specific objectives within specified resources and implementation schedules, often within the framework of a broader program.”<sup>56</sup>

**PROTOCOL:** “A study protocol is a document that describes, in detail, the plan for conducting the [‘clinical’ – in the original] study. The study protocol explains the purpose and function of the study as well as how to carry it out. Some specific things included in the protocol are the reason for the study, the number of participants, eligibility and exclusion criteria, details of the intervention or therapy the participants will receive (such as frequency and dosages), what data will be gathered, what demographic information about the participants will be gathered, steps for clinical caregivers to carry out, and the study endpoints. A single standard protocol must be used without deviation to ensure that the resulting data will be significant and reliable”.<sup>57</sup> Use of the term ‘protocol’ in ESOP 3.1.2 refers to evaluation rather than clinical research studies.

**STATEMENT OF WORK/SCOPE OF WORK:** “A formal document that captures and defines the work activities, deliverables, and timeline a vendor must execute in performance of specified work for a client. The SOW usually includes detailed requirements and pricing, with standard regulatory and governance terms and conditions. “A Statement of Work is typically used when the task is well-known and can be described in specific terms. SOWs provide explicit statements of direction for the contractor to follow.”<sup>58</sup>

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<sup>53</sup> Government Accountability Office (GAO), Performance Measurement and Evaluation: Definitions and Relationships, May 2011. <https://www.gao.gov/assets/80/77277.pdf>

<sup>54</sup> *Ibid.*, P. 66.

<sup>55</sup> *Ibid.*, P. 66.

<sup>56</sup> *Ibid.*, P. 67.

<sup>57</sup> NIH. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5198475/>

<sup>58</sup> General Services Administration.

[https://www.gsa.gov/cdnstatic/SOW\\_Service.Platform.Infrastructure.Service.Interface.and.Integration.pdf](https://www.gsa.gov/cdnstatic/SOW_Service.Platform.Infrastructure.Service.Interface.and.Integration.pdf)

## Appendix B: Evaluation Report Components

An evaluation report is the primary ESoP-required vehicle to document evaluation methods, findings, recommendations and/or conclusions in order to disseminate results. Reports should clearly, succinctly, and impartially describe findings, recommendations and/or conclusions.

Evaluators must submit a final evaluation report which includes, at a minimum, the components and respective content outlined in the template below. Related documentation may be included as appendices in the report.

The order of report components can vary, but the report should be submitted as a single document. Agencies may have their own report formats, inclusive of the required material outlined below. Final PEPFAR evaluation reports and related project documentation that includes information on the required components will be posted on publicly accessible websites in accordance with agency and legislative requirements.

COMPONENTS	CONTENT	ESOP ADDRESSED
<b>1. Executive Summary (required)</b>	<ul style="list-style-type: none"> <li>Contains evaluation purpose, evaluation questions, brief description of project being evaluated, data collection methods, analytic methods, evaluation findings, limitations, and recommendations /conclusions.</li> </ul>	Standards 2, 3, 6, and 11
<b>2. Project Background (required)</b>	<ul style="list-style-type: none"> <li>Brief description of program/project to be evaluated including dates of project implementation, total cost, geographical location, and objectives</li> </ul>	Standards 2 and 5
<b>3. Evaluation Design, Methods, and Limitations (required)</b>	<ul style="list-style-type: none"> <li>Overall evaluation design (i.e. evaluation type, sampling strategy, data collection methods and rationale, data handling procedure, data analysis plan, evaluation limitations)</li> </ul>	Standards 3 and 6
	<ul style="list-style-type: none"> <li>Summary of stakeholder engagement</li> </ul>	Standard 1
	<ul style="list-style-type: none"> <li>Ethical considerations and assurances (e.g., non-research determination and/or IRB approval with dates; application of informed consent, <b>if appropriate</b>; procedures to ensure protection of human subjects)</li> </ul>	Standard 4
	<ul style="list-style-type: none"> <li>Deviations and adjustments (<b>if any</b>) from the approved SOW and/or protocol</li> </ul>	Standards 3 and 8
<b>4. Findings and Recommendations and/or Conclusions* (required)</b>	<ul style="list-style-type: none"> <li>Unexpected and key findings for program improvement in relation to evaluation questions</li> </ul>	Standards 9
	<ul style="list-style-type: none"> <li>Actionable, feasible, and specific recommendations aligned to key findings</li> </ul>	Standard 9 and 10

COMPONENTS	CONTENT	ESOP ADDRESSED
<b>5. Dissemination (required)</b>	• Dissemination procedures/plan	Standard 11
<b>6. References (required)</b>	• Reports or publications cited in the report	Standard 3
<b>7. Appendices (To be included where applicable and where information has not already been provided through requirements 1–6)</b>	• Approved Evaluation SOW and/or protocol	Standards 2, 3, and 6
	• Data collection instruments/tools	Standards 3 and 6
	• Informed Consent	Standard 4
	• Abridged bios of the evaluation team members including qualifications, experience, role on the team, and Ethical certifications	Standard 7
	• Conflict of interest statement	Standards 4 and 7
	• Evaluation costs	Standard 5
	• Project Results Framework or Logical Framework	Standards 9 and 10

\* Further, reports where notation of embargoed findings is present must be updated with the relevant findings and/or link to publication, once the findings are available in the public domain.

## Appendix C: Evaluation Resources

The below are evaluation resources and references for further information.

- The U.S. President's Emergency Plan for AIDS Relief, PEPFAR Evaluation Standards of Practice, <http://www.pepfar.gov/documents/organization/221324.pdf>
- PEPFAR Stewardship and Oversight Act of 2013 (S. 1545), <https://www.congress.gov/113/plaws/publ56/PLAW-113publ56.pdf>
- Department of State Program Evaluation Policy, <https://2009-2017.state.gov/s/d/rm/rls/fs/2011/163299.htm>
- USAID Evaluation Policy, Learning from Experience, [https://pdf.usaid.gov/pdf\\_docs/PNACG632.pdf](https://pdf.usaid.gov/pdf_docs/PNACG632.pdf)
- USAID, Automated Directives System 200, Assessing and Learning, <https://www.usaid.gov/who-we-are/agency-policy/series-200>
- CDC Evaluation Framework, <http://www.cdc.gov/eval/framework/index.htm>
- UNAIDS, 2010, Basic Terminology and Frameworks for Monitoring and Evaluation, [https://www.unaids.org/sites/default/files/sub\\_landing/files/7\\_1-Basic-Terminology-and-Frameworks-MEF.pdf](https://www.unaids.org/sites/default/files/sub_landing/files/7_1-Basic-Terminology-and-Frameworks-MEF.pdf)
- American Evaluation Association (AEA), Guiding Principles for Evaluators, <http://www.eval.org/p/cm/ld/fid=51>
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