Section 6.3 - Implementation Science and Impact Evaluations

Implementation Science

As PEPFAR implements scientific advances on a large scale through its programs, it has shifted towards an Implementation Science (IS) model, a scientific framework to guide program implementation and scale-up that focuses on effectiveness and efficiency in order to build the evidence base necessary to inform the best approaches to achieve sustainable prevention, care and treatment programs. This framework is intended to broaden the scope of high-quality evaluations of PEPFAR-funded programs from basic program evaluations to impact evaluations in order to ensure the dissemination and use of evidence in decision-making and the adoption of best practices across PEPFAR programs. PEPFAR-funded research through IS should continue to guide policy and program development, inform the global community, identify areas where further evaluation and research may be needed, and assess the impact of PEPFAR programs on those at risk for and those infected or affected by HIV at community and national levels in order to determine the best methods for implementation at scale.

Impact Evaluations (to be submitted with COP)

For country-driven rigorous study evaluations, we have implemented the Impact Evaluation (IE) mechanism. As PEPFAR programs move to strengthen the evidence-base for interventions funded within their operating plans, we recognize the unmet demand for more rigorous impact evaluations (IE) than those allowed under current guidance on operations research or monitoring and evaluation (M&E). Whereas outcomes monitored through M&E examine whether targets have been achieved and whether trends in outcomes are promising, IEs examine impact compared to the counterfactual or what would have happened in the absence of the program.

To address the need for this type of field-driven evaluation under PEPFAR, the IE process was created last year to allow for IE concept submissions from PEPFAR programs. This revised process allows funding of IEs of increased rigor for existing or new PEPFAR programs through the COP process. A key goal of the process is to ensure the quality and rigor of the evaluations while creating efficiencies in the application and review process, and to streamline funding mechanism issues so these evaluations can move forward rapidly in line with implementation of the program being evaluated.

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For guidance on how to submit country-driven IE concept proposals in the FY 2013 COP, please see Supplemental FY 2013 Impact Evaluation Guidance.

**Implementation Science Awards**

In 2011/2012, OGAC, in collaboration with CDC, NIH, and USAID issued a series of PEPFAR Implementation Science requests for applications (RFA). Managed through each of the respective agencies, solicitations were open to a broad range of investigators in order to create more direct linkages to researchers and institutions in countries receiving PEPFAR support.

Proposals awarded in response to these IS RFAs will inform PEPFAR on effective and efficient approaches to HIV prevention, care and treatment, with a focus on bringing evidence into practice to improve PEPFAR service delivery and outcomes. These studies will yield crucial knowledge on optimizing the delivery of HIV/AIDS services and identifying high-efficiency service delivery models, and are a critical component of PEPFAR’s focus on using scientific evidence for decision-making across programs.

For a list of PEPFAR funded IS evaluations or to find out current funding opportunities, please see PEPFAR Plan B or contact PEPFAR_ORS@state.gov.

**Ongoing/Closed Public Health Evaluations (PHE)**

As noted in last year’s COP guidance, the PHE mechanism has ended. For prior year PHEs with concepts approved between 2007–2010 and that are ongoing, please continue to follow the existing process for PHE protocol review and annual progress reporting, which is separate from the COP and detailed below.

As in prior years, all ongoing PHEs are required to submit an annual progress report. Progress reports for previously approved PHE activities continuing into FY 2013 will be due on **August 23, 2013**. For all PHE activities that were completed or that ended in the previous year, closeout reports should be provided. Please see the PHE Progress Report Guidance on for additional information.

As a reminder, PHE studies which were in protocol development or revision in the previous progress reporting round will be expected to have made substantial progress (e.g. protocol submission, PHE protocol approval, or study initiation) in this year’s progress reporting round. Studies failing to demonstrate such progress will be considered for termination. Studies with delayed or halted implementation will also be considered for termination unless a clear plan for resolution is provided.
The following PHE Guidance documents and additional information can be found at: https://www.pepfarplanb.org/2013phesub

- PHE Protocol Submission Guidance
- PHE Progress Report Guidance
- FY 2013 Budget Template for PHE Progress Reports

**Contact**
For PHE-related questions, please email PHEProtocols@state.gov.

**Basic Program Evaluation**

In general, evaluation should remain integral to all aspects of PEPFAR, including basic monitoring and evaluation of PEPFAR programs. Basic program evaluation (BPE) refers to studies that guide PEPFAR in program and policy development but are more locally focused on how a program is implemented and the direct effect of a program on the populations using or benefiting from the program resources. BPE studies tend to include needs assessments, formative and process evaluations, and some limited outcome evaluations. As they are critical to effective program implementation, basic program evaluations are strongly encouraged and should continue to be implemented through the COPs.
Impact Evaluation

Impact Evaluations assess the real-world effectiveness, comparative efficiency and/or cost-effectiveness, and thus, the impact of PEPFAR programs. They compare different evidence-based program models in complex health, social and economic contexts. These comparisons address operational questions related to program implementation and efficiency within existing and developing health systems infrastructures (e.g., research aimed at defining optimal models to improve patient retention in ART programs). These types of evaluations specifically permit attribution of outcomes (including indicators such as coverage or quality of services) to particular aspects of program delivery in order to determine the best methods for implementation at scale.

Impact Evaluation Methods

Impact evaluations use experimental approaches (e.g. randomization) to establish a counterfactual (i.e. what would have happened in the absence of the project) or quasi-experimental methods (e.g. comparisons groups, advanced statistical and modeling techniques) when randomization is not feasible. As a result, they permit an accurate estimate of effectiveness through causal attribution of outcomes or impact to the program being evaluated as opposed to what would have happened in the absence of the program. IE hypotheses reflect these comparisons (the counterfactual). Note that randomization can often be achieved through “smart implementation” (i.e., rolling a program out in a randomized, controlled fashion) without the enormous costs and levels of monitoring necessary in a clinical randomized controlled trial to achieve regulatory approval of a new drug or to evaluate the efficacy of a new product.

Because, by definition, IEs focus on real world effectiveness, they must be linked to the evaluation of a PEPFAR program. Proof-of-concept efficacy trials (with precisely defined and narrow objectives) as well as basic or investigational clinical research activities will not be considered for funding as IEs. Unlike many efficacy studies, another hallmark of IEs is that they require interim analyses and permit mid-course corrections in the program while the evaluation is ongoing. Rigorous IEs also permit assessments to understand whether and how the program may be replicated in other settings. IEs should seek opportunities for local-investigator participation, research-capacity building, and should align with priorities.

Where there is doubt as to whether a proposed activity should be considered for this IE concept submission or not, PEPFAR country team members should contact the S/GAC Office of Research and Science at PEPFAR_ORS@state.gov and their CSTL in advance of

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submission to discuss the proper categorization. Further guidance on IE determination can be found in Appendix I: *Guidance on Differentiating Impact Evaluation, Basic Program Evaluation, and Operations Research.*

**What kinds of IE may be funded through the COP?**

Only evaluations having direct and immediate programmatic relevance to PEPFAR will be considered. Proposals for IE should be submitted by country and regional teams and connect directly to activities funded through the COP/ROP. Some examples of potential IEs of interest are: the impact on HIV outcomes of integrating services for family planning, maternal and child health, and HIV treatment; impact of human resources for health activities on total numbers of health-care workers; impact of comprehensive programs for special populations on HIV incidence within that population; impact of community-based economic strengthening activities on HIV-prevention related outcomes such as retention of girls in school and delay of marriage, as well as on indicators of household health and well-being. PEPFAR teams are encouraged to consider IE whenever they are designing new programs or activities, as IE is a fundamental component of ensuring that programs are having their desired effect.

**How do PEPFAR teams apply to fund an impact evaluation?**

PEPFAR country and regional teams who wish to fund an IE in their FY 2013 COP should submit a concept note with the COP, as a supplementary document. More information about the requirements for this concept note follows below. The concept sheet will be reviewed both by the COP programmatic review team, to evaluate the relevance and appropriateness of the proposal to the overall country portfolio, and by technical reviewers who will evaluate the scientific merit of the proposal and determine if the concept meets the standards for IE under this guidance. Country teams will be notified of approval of their concept sheets at the time of COP approval in 2013. Country teams should ensure that a planned procurement or an appropriate mechanism exists such that IE activities fit the partner scope of work and timeframe of the mechanism. Country teams should work with agencies to ensure appropriate mechanisms are in place. In some cases, USG agency headquarters have created central mechanisms to assist teams with IE.

**Note:** IE activities will be funded through the COPs. The review process, although rigorous, is not competitive. All concept notes that meet the checklist items as detailed in the review sheet (YES to all YES/NO questions and score of at least 40/50 points on technical review) will be approved. Please see Appendix II for the *Technical Review Form and Checklist for IE Concept Sheets.* While the requirement for an existing or soon-to-be awarded mechanism with appropriate scope and timeline may be challenging, we encourage country teams to work with PEPFAR agencies to put these conditions in place in order to participate so that some critical IE activities may begin in FY 2013. Country teams that are considering submitting a concept note this year are
encouraged to begin discussion early with PEPFAR headquarters and OGAC's Office of Research and Science through their Country Support Team Lead (CSTL).

In order to provide additional assistance and prepare for the review, we ask that country teams planning to submit a concept note **alert their CSTL via email by January 23, 2013, and copy PEPFAR_ORS@state.gov**. The email should indicate 1) the name and type of program to be evaluated; 2) the hypothesis to be tested; and 3) the implementing mechanism for funds. S/GAC will use this information to ensure we have adequate numbers and expertise for the technical review or to clarify any questions. **Concept notes will be due along with the COP on March 1, 2013.**

Once country teams receive notification of approval, they should rapidly prioritize development of a full protocol for the IE. Given the level of rigor in the review of the concepts, protocols will not be evaluated with the same level of detail as was the case for the former PHE process. Instead, S/GAC along with the implementing agencies will convene an inter-agency expedited review to verify that the protocol aligns with the original concept sheet and remains consistent with the conditions for IE under PEPFAR guidance. **The target for approved FY 2013 IEs is protocol submission to relevant agency, partner, and in-country IRBs by October 15, 2013.**

Once the concept is approved, the country team will work with S/GAC to identify a series of milestones to be met before the next COP. Approval for continued funding of an IE in each out year will be dependent on meeting these milestones, with the expectation that review of this progress would occur as part of the yearly COP review. **In order to proceed with the IE, a country team submitting a concept note in the FY 2013 COP must have an approved protocol by submission of the FY 2014 COP.** If a protocol is not approved and ready for implementation before the submission of the FY 2014 COP, the IE will be determined inactive and no additional funds will be approved for the IE.

**What funds may be used to pay for IE?**

Funds for this work should be drawn from country budgets, per country team prerogative. While there is no total annual budget ceiling, teams should assume they will budget for the IE each year, and that each year's budget should be appropriate for the work to be carried out in that timeframe; budgets for IE should NOT add to country pipelines beyond a normal 6 month factor. Teams should make a commitment to fund the IE through completion before applying, and ensure that this commitment is clearly articulated in their submitted concept sheet. In FY 2013 after concept approval, the major IE activity will be drafting protocols and obtaining appropriate institutional review board (IRB) approvals; therefore, levels of investment in this first year of the IE should be relatively low. This expectation would not rule out higher levels of funding for proposals that could proceed to implementation more rapidly.
Concept Submission Requirements

The FY 2013 IE concept submission process will be for activities with a planned or existing implementing mechanism identified by the time of submission.

A concept note is required for any proposed impact evaluation. The concept note should be no more than 10 pages plus appendices specified below and include the following components (suggested page lengths are in parentheses)

 ✓ Cover page (0.5 – 1 page):
   o Impact Evaluation Title
   o Name of program/intervention being evaluated
   o Principal investigator
   o Country team contact
   o Implementing agency
   o Implementing partner
   o Implementing mechanism for the program
   o Length of evaluation

 ✓ Specific Aims (0.5 – 1 page): What is/are the main evaluation question(s) to be addressed by the proposed study? What is the purpose and goal of this evaluation? What hypothesis will be tested? What are the primary and secondary outcomes of interest?

 ✓ Background (justification) (0.5-1 page): Why is this question significant to your country program? How will this IE add the evidence base for your existing or newly funded activities? How might findings affect program planning? Describe how the concepts, methods, technologies, treatments, services or prevention interventions that drive programs will be changed if the proposed aims are achieved. What work has been done on this topic to date? (Cite relevant work)

 ✓ Evaluation design: (5 pages)
   o Outline the main features of the proposed evaluation design. Evaluations must adhere to high-quality methodological standards for establishing cause and effect between the programmatic activities that are being investigated and proposed specified outcomes. Although we recognize that space and time preclude detailed attention to the following factors, evaluation designs must ultimately be capable of addressing hypotheses that compare observed outcomes and impact to what would have happened absent the intervention by addressing: a) description of
the program, how “programmatic exposure” will be measured and anticipated measurement challenges (if any); b) description of the outcome measures and anticipated challenges (if any); c) expected relationship between “program exposure and primary outcome measure; d) key confounding factors; e) selection bias; f) other sources of measurement error; g) spillover effects; h) contamination of comparison groups or inadequate programmatic exposure (e.g., effects of in and out migration between intervention and comparison area); and i) impact heterogeneity by intervention, beneficiary type and context. Include methods for data management (including data collection and quality assurance) as well as the overall analytic framework (including proposed interim analyses). Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.

✔ Appendices

- References: Identify relevant work or other background information cited.
- Budget: Detailed budget w/narrative: Cost per year and distribution of budget. Please specify the total duration of the study (1-3 years) and the cost for each year the project is anticipated to be underway.
- Timeline: Specify the timeline for protocol development, submission, start of data collection and study end date.
- Innovation (if applicable): Does the study challenge or seek to shift current programmatic, clinical practice, or evaluation paradigms? Does the study design include novel concepts, approaches or methodologies, instrumentation or intervention(s) to be developed or used? If so, describe them and explain any advantage over existing methodologies, instrumentation or intervention(s).

IE Submission through FACTS Info

To submit an Impact Evaluation concept with your COP, please go to the “Document Library” section of FACTS Info, select “Impact Evaluation” in the drop down menu, upload the concept sheet and the review form with country information completed, and upload the IE documents. Use the following naming convention:

IE_Country_Brief Title_Review Form
IE_Country_Brief Title_Concept

IE concepts will be due on March 1, 2013.
IE Approval Process

All concept sheets submitted by the deadline will be reviewed and approvals will be provided concurrent with overall COP approvals. This review will also include a checklist that addresses various technical, logistical, and administrative aspects of the proposal (scientific rigor, public health significance, alignment with PEPFAR priorities, feasibility of the timeline, etc.), and confirmation by the Agreement Officer’s Technical Representative (AOTR), Project Officer or equivalent that the activity is within the scope of the implementing mechanism and the mechanism timeframe is sufficient to complete the evaluation.

Concept Review Process and Criteria

The concept notes will be reviewed both by the COP review teams, who will determine whether they directly support activities within the COP, and by a committee of USG technical advisors, who will evaluate the scientific merit of the proposal. Reviewers will be selected to ensure appropriate scientific expertise as well as relevant programmatic experience. Technical reviewers will assess concept notes on the following criteria:

**Methods:** An evaluation activity may be classified as PEPFAR impact evaluation (IE) if it addresses all of the following questions: Is the evaluation hypothesis driven? Is there a valid counterfactual comparison? Can the question(s) proposed be answered through well-designed and conducted research? Do the methods permit attribution of outcomes to the program of interest? Does the study measure specific outcomes (impacts) of the intervention, preferably using validated and externally verifiable measures? Are there plans for interim analyses and the ability to provide feedback to the program while it is being evaluated?

**Significance:** Will the evaluation contribute significantly to the country knowledge-base related to implementation of HIV prevention, treatment or care programs? Is the proposal relevant to broader PEPFAR programs?

**Logistics (timeline and feasibility):** Is the research sufficiently aligned with in-country field programs? How feasible will it be to widely implement the results of the research study? Is the research logistically feasible, financially doable and likely to produce timely results?

**Experience and expertise:** Does the proposed research team have the appropriate expertise, experience and established collaborations to conduct the study?

**Relevance:** Will the results of the evaluation address significant questions about funding and programmatic priorities in that country context? Does the evaluation contribute to larger goals of country ownership and sustainability?
**IE Concept Timeline:**

<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
</tr>
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<tbody>
<tr>
<td>10/01/2012</td>
<td>FY 2013 IE Guidance and call for IE concepts released</td>
</tr>
<tr>
<td>1/23/2013</td>
<td>E-mails to CSTLs and <a href="mailto:PEPFAR_ORS@state.gov">PEPFAR_ORS@state.gov</a> notifying intent to submit due</td>
</tr>
<tr>
<td>03/01/2013</td>
<td>IE Concept submissions due through the COP</td>
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<tr>
<td>05/2013</td>
<td>Scientific and programmatic reviews of IE concept notes</td>
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<tr>
<td>07/2013</td>
<td>IE Decisions reported to country teams</td>
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**Decisions on Proposed Activities**

Summary statements of the IE reviews and final disposition of the review process will be sent to country teams. Funding approved for these activities will be allocated from country budgets.

For IE-related questions or assistance, please contact PEFAR_ORS@state.gov.
Appendix I
Guidance on Differentiating Impact Evaluation, Basic Program Evaluation, and Operations Research

Definitions

✓ **Basic Program Evaluation (BPE):** BPEs are part of standard monitoring and evaluation activities and focus on descriptive and normative questions: what a particular project or program has achieved (either at an intermediate point in execution or at the conclusion of an implementation period); how it is being implemented; how it is perceived and valued; unintended consequences whether positive or negative; whether expected performance benchmarks and process indicators are being met; and other questions that are pertinent to program design and monitoring, management and operational decision making. BPEs often incorporate before-after comparisons, but generally lack a rigorously defined counterfactual.

✓ **Operations Research (OR):** Operations research (OR) focuses specifically on program delivery and how to optimally allocate limited resources for the day-to-day activities or the “operations” of programs. OR uses OR-specific techniques such as simulation, mathematical optimization, and decision science, but also borrows methods from both M&E and IE in order to design, implement, and test solutions to improve program delivery.

✓ **Impact evaluations (IE):** IEs are also part of the monitoring and evaluation spectrum but are more analytic than descriptive. An IE is an evaluation that measures the change in an outcome that is attributable to a particular project or program. The distinctive feature of an IE is the use of a counterfactual to control for factors other than the intervention that might account for the observed change that would have happened absent the project or program. IEs generally use experimental (randomization) or quasi-experimental methods. While well-designed IEs can provide the most accurate estimate of program effects that can be attributed to an intervention, they may not always be possible. Another hallmark of IEs is that they require interim analyses and permit mid-course corrections in the program while the evaluation is on-going.

Note that randomized, controlled efficacy trials that evaluate the efficacy of a single or multiple drug regimen, medical device, or other similar type of pharmaceutical or medical intervention do not meet the criteria for either a BPE or IE.

An evaluation activity may be classified as PEPFAR impact evaluation (IE) if it addresses **all** of the following four questions:

✓ Does the study measure the effectiveness of a PEPFAR intervention, using verifiable measures such as biological, clinical or other outcomes that can be externally validated?
Is there a valid counterfactual comparison and related hypotheses?  
Do the methods of design and analyses permit attribution of outcomes to the program of interest?  
Are there plans for interim analyses and the ability to provide feedback to the program while it is being evaluated?

**Examples of IEs**

Studies that qualify as IEs may ask questions such as the following:

- What is the most efficient way to deliver services at scale? What are specific strategies to improve reach and quality?
- How much difference does a program for care or prevention make on specific, well defined clinical and behavioral outcomes? Does a prevention program promoting partner reduction lead to reductions in HIV incidence? Do community support groups for PLHIV lead to better retention in care and ART adherence?
- What is the comparative effectiveness and cost effectiveness of one strategy for service provision compared to another?
- What is the optimal mix of multiple interventions to maximize effectiveness and efficiency while mitigating potential unforeseen adverse events (e.g. behavioral dis-inhibition in a prevention program; loss to follow-up in a program of care)?

Because of the level of rigor involved, IEs should be submitted through the COP IE process as indicated in this guidance.

**Examples of BPEs and OR**

The following types of activities are generally considered non-IEs and are part of usual monitoring and evaluation or OR activities:

- **Surveillance activities**
  - HIV case reporting
  - TB surveillance
  - HIV drug resistance (HIV DR) threshold surveys to detect transmitted resistance in drug-naive populations
  - ANC sentinel surveillance
- **Routine ongoing program monitoring**
- **Routine cost studies** for purposes of routine monitoring, basic program evaluation, planning or accountability. Note: cost studies which are conducted to support a defined IE activity, such as to provide cost-effectiveness or utility analysis of alternative intervention approaches, are generally considered as IEs.
✓ Primary or secondary analysis or review of routinely collected program data (including financial data and service delivery data) conducted routinely or periodically for the purpose of planning future activities or evaluating the performance of a program, as measured by outputs and outcomes.

✓ Periodic program evaluations that do not include intervention comparison groups in a quasi-experimental or experimental design such as those undertaken to measure performance in terms of outputs or outcomes among the populations enrolled in the program or receiving the services.

✓ Periodic system evaluations that do not include intervention comparison groups in a quasi-experimental or experimental design, such as those undertaken to measure performance of a surveillance system, program monitoring system, or other information systems, e.g. electronic medical record systems (EMRs).

✓ Baseline needs assessments, formative evaluations or feasibility studies to determine the characteristics of a population or the basis for a future intervention.

✓ Data quality assessments.

✓ Optimal allocation of resources for pharmaceutical supply chain management or healthcare workforce development.

✓ Routine quality improvement or quality assessment activities (e.g., HIV-QUAL).

✓ In-country laboratory validation/calibration of accepted or proven laboratory techniques.

✓ Population-based surveys such as the Demographic and Health Survey (DHS) or the AIDS Indicator Survey (AIS).

✓ Knowledge, attitude, and practice (KAP) surveys conducted on specific populations, such as school age children, that are not associated with a quasi-experimental or experimental design to compare the effect of one program model, approach or intervention compared to another.

✓ Sample Vital Registration with Verbal Autopsy (SAVVY)—a sample population-based vital registration system to assess levels and cause of mortality.

✓ Mortality validation studies, which compare one source of mortality data to another to assess quality, accuracy, validity of available mortality data.

As BPEs and OR are critical to effective program implementation, they are strongly encouraged and should continue to be submitted and implemented through the COPs (separate from the COP IE process).
Appendix II
Technical Review Form and Checklist for IE Concept Sheets

To be completed by Country Team:

Country/Regional Program

__________________________________________________________________________

Primary Evaluation Contact

__________________________________________________________________________

PHE/IS Liaison in field office

__________________________________________________________________________

Technical Area

__________________________________________________________________________

Hypothesis_________________________________________________________________

__________________________________________________________________________

Program to be Evaluated (Provide clear linkage to PEPFAR Program and COP mechanism to be used)

__________________________________________________________________________

__________________________________________________________________________

Have relevant stakeholders been part of designing this concept? If so, who have you briefed within the MOH, the national HIV Council/Commission and other local stakeholders? YES/NO

Comments___________________________________________________________________

__________________________________________________________________________

Has the country team identified a planned or existing mechanism with sufficient funds and adequate length of agreement to complete the study?

__________________________________________________________________________
List IRBs or other relevant Ethical Review Panels that will be reviewing the protocol that emerges from this concept sheet:

_____________________________________________________________

Has the AOTR/Project Officer verified that the activities are within the scope of the agreement? YES/NO

Comments______________________________________________________

AOTR/Project Officer signature (if signoff confirmation, please attach email):

Signoff________________________________________________________

To be completed by IE Reviewer(s):

IE Submission Number (OGAC will assign)

____________________________________________________

IE Reviewer (OGAC will assign)

____________________________________________________

Does this concept sheet meet the definition of Impact Evaluation based on the PEPFAR Guidance for Impact Evaluation? YES/NO

Comments____________________________________________________

Is the scope realistic such that impact data will be available in less than 3 years from submission of concept? YES/NO

Comments____________________________________________________

Does the concept allow for interim data analysis and a plan to feedback results to inform program planning? YES/NO

Comments____________________________________________________

Is the study question related to a current knowledge gap? Is this an area of priority for PEPFAR? YES/NO

Comments____________________________________________________
Is the PEPFAR program submitting the concept well positioned to address this question? YES/NO

Comments__________________________

Is the budget consistent with the scope of the study and has the country team drawn on local information to provide realistic cost estimates for the total study? YES/NO

Comments__________________________

Technical Review

Methods (40 points): ________ points

Is the evaluation hypothesis driven? Is the study design rigorous and has there been adequate statistical/epidemiological inputs to ensure the sampling methodology and sample size are adequate to address the hypothesis? Is there a valid counterfactual comparison?

Can the question(s) proposed be answered through well-designed and conducted research? Do the methods permit attribution of outcomes to the program of interest? Does the study measure specific outcomes (impacts) of the intervention, preferably using validated and externally verifiable measures such as biological or clinical outcomes?

Are there plans for interim analyses and the ability to provide feedback to the program while it is being evaluated?

Comments__________________________

Country ownership and capacity building (10 points): ________ points

Does the proposal respond to a country priority or strategy, especially as identified by the MOH and/or National AIDS Council? What would be the programmatic impact? Is there a commitment or plan to make use of the findings?

Does the proposal involve and strengthen an in-country institution’s evaluation/research capacity? Does the proposal involve in-country investigator (e.g., co-PI) participation? Is there participation by local governments or indigenous NGOs in a way that will strengthen the research capacity or research utilization capacity of those organizations?
Additional Reviewer Comments or special considerations?

__________________________________________________________

The Primary Reviewer recommends this concept sheet be approved YES/NO

_______________________________________

Signature of Primary Reviewer

_______________________________________

The Secondary Reviewer recommends this concept sheet be approved YES/NO

_______________________________________

Signature of Secondary Reviewer