The President's Emergency Plan for AIDS Relief

FY 2010

PUBLIC HEALTH EVALUATION (PHE) CONCEPT SUBMISSION GUIDANCE

FY10 GUIDANCE FOR PHE CONCEPTS

As outlined in the Five-Year Strategy released in December 2009 (www.pepfar.gov/strategy), the realization of the goals of the second phase of PEPFAR will focus on defining and supporting a sustainable, integrated, and country-led response to HIV/AIDS. Given the magnitude of the challenge faced at its creation, PEPFAR's initial emergency approach was critically needed, but its focus on establishing services took precedence over prolonged engagement with country governments to support existing national structures or plans. PEPFAR Phase II emphasizes country ownership, capacity building and sustainable responses, while continuing support for existing and emerging prevention, care and treatment needs. To accomplish these goals, PEPFAR must move forward using evidence-based programs and practices established through rigorous evaluations of existing and new PEPFAR programs. Such evaluations can accurately gauge program effectiveness, efficiency and cost-effectiveness. Evaluation is and must remain integral to all aspects of PEPFAR. Its scope ranges from basic monitoring and evaluation of PEPFAR programs to the more complex research of public health evaluations (PHEs). While this guidance pertains only to the latter, basic program evaluation of all PEPFAR programs is strongly encouraged and should be reflected in each country's COP.

The PHE Program was established to support studies in PEPFAR Phase I to guide program and policy development, to inform the global community by providing information and building knowledge applicable across the range of PEPFAR-funded sites, as well as to assess the impact of PEPFAR programs on those at risk for and those infected or affected by HIV at community and national levels. Despite this focus, the need for an "emergency" response required that decisions be made even with imperfect data. Therefore, it is important in Phase II to strengthen the focus on evaluating interventions with established efficacy but undetermined field effectiveness. In addition to effectiveness, it is also critical to evaluate the efficiency of delivering effective programs at scale, so that quality and cost are optimized.

As PEPFAR Phase II implements scientific advances on a large scale through its programs, PHE II will focus on examining strategies to increase the program efficiency and impact. The intention is to ensure the dissemination and use of evidence in decision making and the adoption of best practices across PEPFAR programs. To support this objective, study proposals submitted in response to the FY2010 PHE call for concepts are encouraged to focus on bringing evidence into practice to improve service delivery and outcomes.

At this time, the PHE Program is undergoing a transition intended to result in changes to the program that will broaden the scope of high-quality evaluations of PEPFAR-funded programs. This transition will also better allow PEPFAR evaluations to support the broader goals of country ownership, capacity building and sustainability outlined in the Five-Year Strategy. To that end, PEPFAR country teams will now be asked to demonstrate country ownership and research-capacity building as these pertain to their research agenda. In 2011, more detailed guidance will be provided to ensure that research concepts align directly with each country's national research priorities including consideration of the capacity building necessary to enable in-country investigators and institutions to lead both initiation and implementation of strategically relevant studies. In addition, PHEs in 2011 will shift towards implementation science (a scientific framework to guide health-program implementation and scale-up that focuses on effectiveness, efficiency and cost-effectiveness) in order to build the evidence base necessary to inform the best approaches to achieve sustainable prevention, care and treatment programs. Future

guidance will also provide details on the need for PEPFAR investigators to work with governments, universities and NGOs to develop a national HIV/AIDS research-needs assessment and plan, a plan for research-capacity building, and a plan for utilizing research to better inform policies and programs.

IDENTIFYING PUBLIC HEALTH EVALUATIONS

In PEPFAR Phase II, PHEs will continue to guide policy and program development, inform the global community, and identify areas where further evaluation and research may be needed. PHEs are meant to assess the effectiveness, efficiency and impact of PEPFAR programs; to compare evidence-based program models in complex health, social and economic contexts; and to address operational questions related to program implementation and efficiency within existing and developing health systems infrastructures (i.e., research aimed at strengthening health systems and their components for optimal implementation). The goal for PHEs increasingly emphasizes studies that examine real-world effectiveness and cost effectiveness, and optimize efficiency (e.g., comparative-efficiency studies). These types of more analytic studies specifically permit attribution of 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. We are encouraging investigators to think "big" and become involved in government and PEPFAR programs on the ground, and to actively seek opportunities to compare roll-out strategies without materially slowing down scale up.

The following is a list of generic PHE implementation science analytic or effectiveness questions that may be relevant for this call for concepts:

- What is the most efficient way to deliver effective interventions 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 outcomes (e.g., treatment success) and related behavioral measures (e.g., adherence and program retention)?

- What is the comparative effectiveness and cost effectiveness of one strategy for service provision compared with another?

- What is the optimal mix of multiple interventions to maximize effectiveness and efficiency while mitigating potential unforeseen adverse events (e.g., behavioral disinhibition in a prevention program; loss to follow-up in a care program)?

PHE utilizes rigorous, scientifically sound research methodology (quantitative or qualitative) of varying complexity and may include (but is not limited to) comparison groups, randomization, advanced statistical techniques or modeling. PHE does *not* extend to basic or investigational clinical research activities. PHE should prioritize local-investigator participation and research-capacity building and should reflect country priorities, particularly the priorities of host-country governments.

PHE is situated towards the end of the monitoring-evaluation-research continuum. In contrast to PHE, 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 also use scientifically sound evaluation methodology but tend to be methodologically simpler than PHE studies. For example, BPE studies tend not to seek generalizability beyond the people served in the program and do not compare program models or use a randomized design. Instead BPE studies tend to include needs assessments, formative and process evaluations, and some limited outcome evaluations. Formative evaluation produces local information that helps form and refine a program during implementation. Process evaluations describe what PEPFAR programs are offering, what is required and/or invested to implement programs (e.g., time, expertise, human and financial resources, infrastructure), how programs are being utilized by target populations, how programs are being implemented (e.g., whether programs are being implemented according to their theoretical or operational intent), and what factors help or hinder the success of a program. A basic program evaluation of outcomes could describe the effect of a program on the local population receiving or utilizing its resources. In the area of training, basic program evaluation can describe whether or not training and education programs utilize appropriate materials to meet the needs of the target audience, if the materials are being taught or otherwise applied as intended, and if those trained and hired are meeting expected standards and following approved protocols. **BPEs are critical to effective program implementation and should be funded through the COPs.**

There may be particular activities in which the boundaries of PHE, basic program evaluation or surveillance are not evident, and factors of size, scope, cost or methodological complexity may be relevant. Where there is significant doubt as to whether a proposed activity should be considered PHE or not, country PHE liaisons should contact OGAC PHE advisors or the appropriate Evaluation Team Lead in advance of submission to discuss the proper categorization. **All PHE concepts and protocols *must* receive technical review and be approved.** PHEs cannot be funded from country program funds and should not be subsumed under other programmatic activity areas. PHE studies that are mistakenly submitted as basic program evaluations in COPs will need to go through the PHE submission process for consideration the following year. For further guidance on PHE determination, see Appendix I.

FY2010 PHE Call for Concepts

This year's call for new PHE concepts will focus on bridging research and practice in PEPFAR settings. These studies should contribute to the knowledge base about how interventions are implemented effectively and efficiently in real-world practice settings. **PEPFAR USG country teams may submit concepts, which are due on July 15, 2010.**

Similar to PHE 2009, the PHE request for concepts for FY10 emphasizes the submission of **country-driven concept proposals that answer questions of specific interest and priority to the country.** Country priorities may align with those priorities outlined in the FY2009 COP guidance, but is not required. PHE concepts that are based on country needs, in particular needs identified and proposed by the MOH, will be prioritized as will concepts that involve local institutional and local-investigator participation and research-capacity building, including work with local government, universities, indigenous community organizations or not-for-profits.

In addition, while the current PHE study portfolio is largely comprised of PHEs targeting Care and Treatment, and PMTCT programs, we also encourage countries to submit concepts for the evaluation of other areas of importance to PEPFAR programming.

Notes on PHEs

Individual country studies – PHEs may be considered for implementation within an individual country provided there is demonstrated human resource capacity, expertise and infrastructure to support the study and evidence of adequate statistical power, scope and scientific rigor is provided to show generalizability from a single country setting. It is expected that most studies approved will be individual country studies.

Collaborative multi-country studies – These studies may continue to be considered when the comparison of findings across countries and the potential to aggregate data will strengthen the impact of study results, or when the incidence of primary outcomes requires large numbers to detect significant results. However, demonstration of the capacity and expertise to manage such a study while maintaining rigor is required. Multi-country studies require careful planning, coordination and committed country ownership and buy-in within a feasible timeline.

Finally, those active in PHE will be encouraged to develop a wider range of partnerships and collaborations within their country and with other PEPFAR country PHE liaisons and investigators. This should result in a greater range of expertise and strengthen the capacity to carry out significant evaluation activities. The Evaluation Team (which provides technical review of all PHE protocols prior to approval and implementation of the PHE activity) is an important resource to assist in considering the optimal approach to addressing a particular question and to identify opportunities for collaborative multi-country studies. Most important, the Evaluation Team should be considered an ongoing technical resource to assist as needed with concept development, protocol development and study implementation.

Concept Submission Requirements

The FY10 PHE concept submission process will be similar to those of the PHE program in previous years. A concept proposal is required for any proposed PHE activity. The concept proposal should be approximately 5 pages and include information in the following categories. The following components are required for each concept and suggested page lengths are in parentheses (*Please see the PHE page on PEPFAR.net for concept template and other relevant templates for submission*):

- ✓ Cover page – to include title, principal investigator, country team contact, and length of project.
- ✓ Specific Aim (WHAT?) – What is the overarching research objective(s)? What is the purpose and goal of this project? What hypothesi(e)s will be tested? (0.5 pages)
- ✓ Background (WHY?) – Why is this question significant, either to your country program or to the larger HIV/AIDS community? 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*) (0.5-1 page)

- ✓ Methods (HOW?) – How will you answer the question? Include study design, data management, definition of impact and exposure and how assessed, analytic techniques, and power/sample-size calculation, if appropriate. Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims. If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high-risk aspects of the proposed research. (3 pages)
    - (WHERE?) – Will it be undertaken in a single site, within a single program, or multiple sites, multiple countries and/or programs? Why at this/these sites? What is the capacity at involved sites to carry out the study?
    - (WHO?) – Who will participate – men, women, children, clinic patients, community group, health care providers, or other? Will the project utilize unidentified data only or require active subject participation? What partners will be involved? What is your and/or your partners' capacity to carry out all phases of this research? How will this contribute to developing local research capacity?
    - (WHEN?) – What is the length of the study? When is the project expected to be begin? How does the research timeline align with the service delivery activities in the field?
    - (Dissemination)- How will results be disseminated to stakeholders, investigators and the larger community to contribute to the local and global knowledge base?
- ✓ Country Ownership and Capacity Building (0.5 pages)
    - Describe how the proposal supports and strengthens country ownership. Does the proposal respond to a country priority or strategy, especially as identified by the MOH? What would be the potential programmatic impact? Is there a commitment or plan to make use of the findings?
    - Describe how the proposal will contribute to research-capacity building. Does the proposal involve and strengthen an in-country institution's research capacity? Does the proposal involve in-country investigator (e.g., co-PI) participation? Is there participation by local governments, universities or indigenous NGOs in a way that will strengthen their capacity to conduct and/or utilize research findings?
- ✓ Innovation (optional for an additional 0.5 pages) – Does the study challenge or seek to shift current research or clinical practice paradigms? Does the study design include novel theoretical 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).
- ✓ References* – Identify relevant work or other background information cited
- ✓ Budget* - Detailed budget w/justification: 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. The budget form will be posted on pepfar.net.

The total amount of PHE support to a country will be capped at a level to equivalent of 1.5% of country program budget for combined amount of new and continuing activities; countries may apply for a cap waiver.

a. Total amount of central funding available for PHEs does not allow for every country to be funded at the maximum level. If there are enough well designed concepts in each country, the total would only cover equivalent of ~1.0% of country budget.
b. Former non-focus countries may not be held to same cap because of the limited size of program budgets.

√ Timeline – Specify the timeline for protocol development, submission, start of study and study end date.

**Items not counted as contributing to the overall page length.*

Five-page PHE concepts will be **due on July 15, 2010.**

Concept Review Process and Criteria

As in the previous review cycle, concept papers will be reviewed by independent USG technical experts who are not involved in the PHE process (i.e., not on a PHE team, the PHE Subcommittee, Scientific Steering Committee or otherwise directly involved in implementing studies). The reviewers will be selected to ensure appropriate scientific expertise as well as relevant programmatic experience. The review process will be competitive and the scores from the technical reviewers will be presented to the PHE Subcommittee. The PHE Subcommittee will make the final selections (subject to approval by the Scientific Steering Committee) based largely on the reviewer scores, in conjunction with country capacity, progress and completion of previous PHE studies in the country, and consideration of the distribution of study topics and countries. It is expected that the PHE funding allocation across program areas should be roughly proportional to the program area budget. Country distribution should fit within the 1.5% cap (subject to waiver).

The reviewer scores will be assigned to each concept based on the criteria described below:

Methods (40 points): Is the study hypothesis driven? 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?

Significance (25 points): Will answering the research question contribute significantly to the local and global knowledge base related to implementation of HIV prevention, treatment or care programs? Is the proposal relevant to the country program?

Logistics (timeline and feasibility; 15 points): Is the research sufficiently aligned with in-country field programs? How feasible will it be to rapidly and widely implement the results of the research study? Is the research logistically feasible, financially doable and likely to produce timely results?

Experience and expertise (5 points): Does the research team have the appropriate expertise, experience and established collaborations to conduct the study?

Country ownership and capacity building (15 points):** Does the proposal respond to a country priority or strategy, especially as identified by the MOH? What would be the potential 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 research capacity? Does the proposal involve in-country investigator (e.g., co-PI) participation? Is there participation by local governments, universities or indigenous NGOs in a way that will strengthen their capacity to conduct research and/or to utilize research findings?

**Country ownership and research-capacity building may be weighted more heavily in the FY2011 PHE Call for Concepts.

The PHE Subcommittee will also consider country progress on continuing studies in determining which study concepts will be approved.

Timeline

5/1/10	**7/15/10**	**8/1/10**	**9/15/10**
Guidance and call for FY10 concepts released	Concepts for new activities due on pepfar.net	Reviews of new concepts conducted	Decisions reported back to country for approval or non-approval

Decisions on Proposed Activities

Summary statements that address all of the criteria and the final disposition of the review process will be sent to country PHE liaisons. PHE activities that receive approval to proceed should reference the PHE tracking number cited in the approval communication. Funding for these activities is from a central budget and is in addition to the country's program allocation; this additional approved funding amount will be added to the country's total budget through the COP.

New Approach in FY 2010

Procedures for PHE submission in FY 2010 will provide a stronger emphasis on quality, and ensuring progress, with emphasis on country ownership, research-capacity building, and sharing of information to benefit countries and PEPFAR teams. Please remember as in prior years, in addition to concept approval, **all PHEs *must* receive technical review of the protocol.**

Protocol Development Funding

Upon concept approval in FY10, study groups should begin to develop a study protocol for submission, review and approval by the appropriate PHE Evaluation Team. All funding proposals should provide a narrative and budget indicating funds requested for protocol development, separate from those for protocol implementation. Agencies responsible for awarding PEPFAR PHE funds will be required to restrict implementation funds until protocols are fully approved by OGAC PHE and all institutional review boards. To support protocol development during the first 12 months, an itemized protocol development budget for up to

$50,000 funding should be included in the concept budget and will not be restricted by OGAC or agency headquarters. If a protocol has not been submitted to the PHE Team within 12 months from the date of the notice of funding award to the implementing partner, the study concept will be determined inactive and the agency will de-obligate the implementation funds.

Protocol Review Process

Upon submission of a study protocol, the appropriate PHE Evaluation Team will review the research methodology and other technical aspects, as well as conduct statistical and ethical reviews. PHE liaisons and study investigators will be contacted with the results and will be asked to submit responses to questions or comments highlighted by the Evaluation Team. The expectation is that the approval process will take three to four months to be completed. Further *Guidance for Protocol Submission* can also be found on PEPFAR.net.

New Concepts

Upon approval of a study protocol submitted within the required 12-month time frame, new studies for FY10 will receive funding requested and approved for the first year of the study.

Continuing Studies

OGAC PHE staff will contact study teams that are in the process of developing protocols for concepts approved prior to FY10 to determine an appropriate timeline for submission and/or protocol revisions. Submission of a protocol within the next 12-month period (or within the 12-month period following study award) is required.

Budget Requirements

Concept

Budgets and budget justifications submitted during the concept submission period should approximate as closely as possible the expected cost of the study. Budget templates to be used for concept submission are available at PEPFAR.net.

Protocol

If budget projections at the time of the protocol submission or projections based on protocol changes requested during the review process differ substantially (>15%) from the amount requested at the time of concept approval, a detailed budget with budget justification and explanation needs to be submitted to the Evaluation Team Lead and PHE Subcommittee for review and approval. Protocol budgets and budget justifications (with explanation) must use the budget templates available on PEPFAR.net.

IRB Requirements (New and Continuing)

The protocol approved by the PHE Evaluation Team is required to be approved by country IRBs and should meet agency IRB requirements. Protocols should be submitted to country and agency IRBs after the protocol has been approved by the PHE Evaluation Team. Should it be necessary to submit the protocol to an IRB concurrently or in advance of approval by the PHE Evaluation Team, an amended protocol will need to be submitted to the IRB following PHE Evaluation Team approval. Upon IRB approval, the final version of the study protocol including a copy of the IRB approval notification should be submitted to OGAC PHE staff for archival purposes.

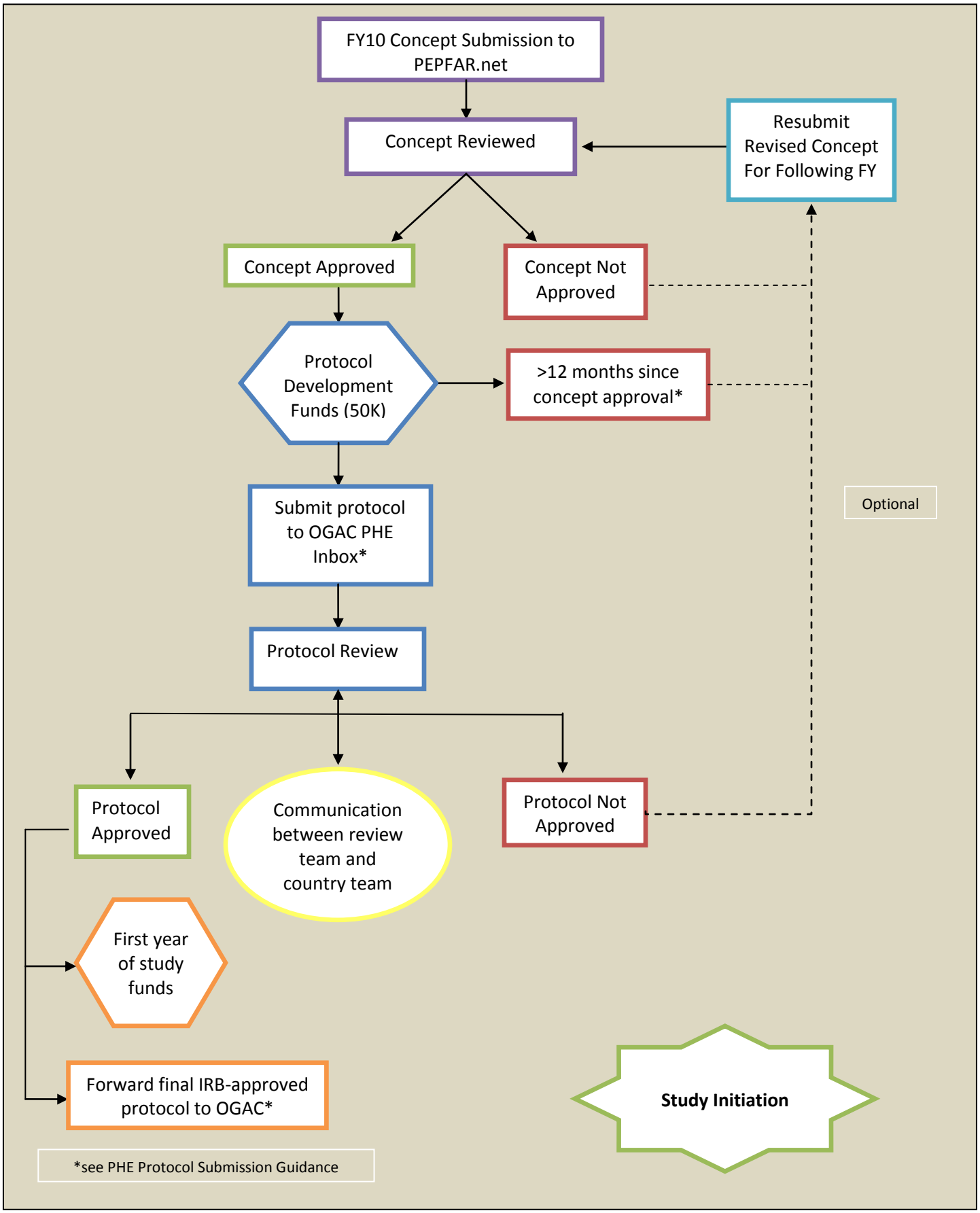
Please see Figures 1 and 2: FY10 Concept / Protocol Submission Process and Timeline.

Progress and Closeout Reports

As in prior years, all continuing PHEs will be required to submit an annual progress report. For all PHE activities that were completed or ended in the previous year, closeout reports should be provided. Further *Guidance for Progress and Closeout Reports* can be found on pepfar.net.

For questions related to this guidance or any other PHE activities, please contact PHEProtocols@state.gov.

Figure 1. FY10 Concept / Protocol Submission Process



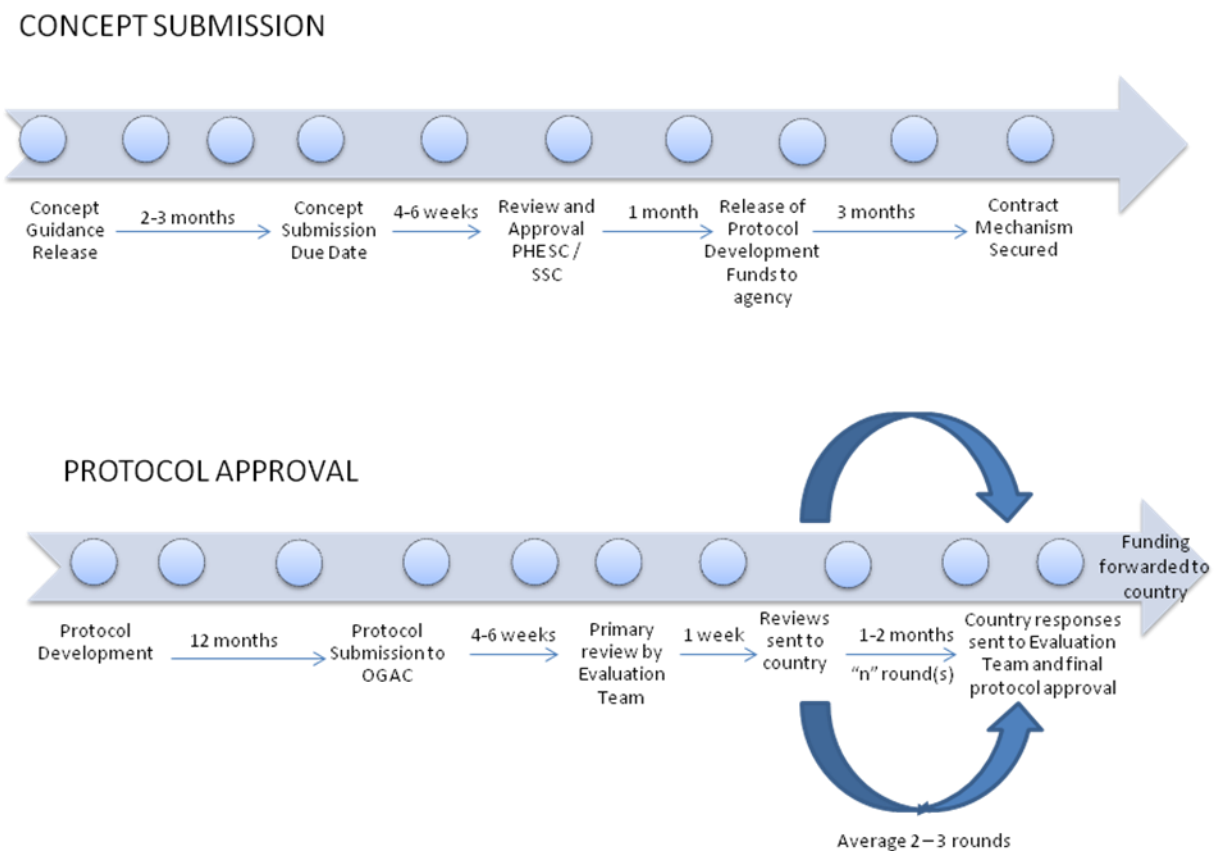


Figure 2. Concept and Protocol Submission Timeline

Appendix I

Guidance on Determination of Public Health Evaluation and Basic Program Evaluation

Determination of PEPFAR Public Health Evaluation

Definition

An evaluation activity may be classified as PEPFAR public health evaluation (PHE) if it meets any of the following three criteria: *(For specific examples of studies that qualify as PHE, see below)*

1. Intent of Evaluation Question
Projects that are hypothesis driven or are intended to determine the effectiveness or efficiency of one program model, approach or intervention compared to another in order to produce generalizable knowledge that can be applied more broadly to a country, geographic region, epidemic pattern, or globally for the scale-up or improvement of PEPFAR programs.

2. Methodology
Projects that *a)* use quasi-experimental or experimental designs—including but not limited to randomized, controlled designs–to compare the effect or efficiency of one program model approach or intervention relative to another; or that, *b)* prospectively observe or follow a sample of individuals in a population (*e.g.,* those enrolled in HIV care or treatment) and conduct interventions or monitoring (including patient interviews or laboratory testing) beyond what is considered standard of care or routine for the context.

3. Need for Support, Coordination, and Oversight
At times because of the great scale, scope, cost, importance, novelty or relevance to PEPFAR priorities, an evaluation question and its associated group of evaluation studies may be proposed to be coordinated and overseen through the management and administrative structures of PEPFAR PHE, including the Scientific Steering Committee (SSC), the Public Health Evaluation Subcommittee (PHE SC), and the PHE Evaluation Teams. Study questions or approaches that meet these criteria will be announced in the Concept Guidance when applicable.

Examples of PHE

The following types of studies are generally considered **PHE** and should be submitted for PHE review:

- Evaluations for which the intent (hypothesis-driven, seeking generalizability) or methodology (quasi-experimental or experimental design) is analyze the effectiveness or efficiency of a program or to compare the effectiveness or efficiency of one program model or intervention to another.
- Evaluations of community-level or population-level effects (especially of outcomes and impacts) of an intervention whose intent and methodology is to compare the effect of one program model or intervention to another (or to none) and go beyond the aggregation and analysis of available data sources

- Prospective (longitudinal) cohort studies that follow a sample of a population (*e.g.,* those enrolled in HIV care or treatment) and conduct interventions or monitoring (including patient interviews or laboratory testing) beyond what is considered standard of care or routine for the context.

Studies that qualify as PHE 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 (e.g. adherence and retention in a program)?
- 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)?

Examples of non-PHE

The following types of activities are generally considered **non-PHE**, do not need to be submitted for PHE review, and should be funded through the COP process:

- Surveillance activities
    - HIV case reporting
    - TB surveillance
    - HIV drug resistance (HIV DR) threshold surveys to detect transmitted resistance in drug-naïve populations, and surveillance of acquired HIV drug resistance in treated patients when using methods consistent with published WHO standards *(please refer to updated guidance on HIV DR activities on pepfar.net)*
    - ANC sentinel surveillance
- Routine ongoing program monitoring
- Routine cost studies for purposes of routine monitoring, basic program evaluation, planning or accountability. (Note: cost studies that are conducted in conjunction with or to support a defined PHE activity, such as to provide cost-effectiveness or -utility analysis of alternative intervention approaches, are generally considered as PHE).
- 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
- Data triangulation, which is the synthesis of various types of available surveillance, survey and program monitoring information to discern epidemic variability and generate hypotheses about possible population (*i.e.,* social, economic, behavioral) and programmatic factors associated with variability.
- Periodic program evaluations that do <u>not</u> include intervention comparison groups in a quasi-experimental or experimental design and do <u>not</u> include observational prospective cohort 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, a program monitoring system, or another type of information system, including 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 (including. I-RARE, PLACE)
- Data quality assessments
- Routine quality improvement or quality assessment activities (*e.g.,* HIV-QUAL)
- Most focused outbreak investigations
- 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), with or without biological testing (*e.g.,* HIV test)
- Specific population-based surveys on most-at-risk populations, with or without biological testing (*e.g.,* HIV test)
- 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

FY2010 Concept Submission Process

Any activity that meets the above PHE criteria or examples must be submitted during the **FY2010 Call for PHE Concepts**. PHEs cannot be funded out of country program funds and should not be subsumed under other programmatic activity areas. PHE projects that are mistakenly submitted as basic program evaluations in the COP will be asked to go through the PHE submission process for consideration the following year.

Activities that are submitted during the FY2010 Call for PHE Concepts and are determined to be non-PHE may be appropriately funded in a program area section or the strategic information section of the COP, depending on the nature of the activity. Surveillance activities, program evaluations and other strategic information activities should be described in sufficient detail to differentiate them from PHE and they will be reviewed during the normal course of COP review. Basic program evaluation of all PEPFAR programs are critical to effective program implementation, strongly encouraged, and thus should be should be reflected in each country's COP.

Where there is doubt as to whether a proposed activity should be considered a PHE or not, country PHE liaisons should contact OGAC PHE advisors or the appropriate Evaluation Review Committee lead in advance of submission to discuss the proper categorization of topics.

Please note: The following types of activities are generally not supported by PEPFAR funds, either as PHE or strategic information (SI) activities:
- Clinical trials to evaluate the efficacy of a single or multiple drug regimen, medical device, or other similar type of pharmaceutical or medical intervention compared to another