

FY09 PHE Guidance

DEFINITION of PUBLIC HEALTH EVALUATION

Public Health Evaluation (PHE) refers to studies that guide PEPFAR in program and policy development, inform the global community, and identify areas where further evaluation and research may be needed. These activities answer key questions, providing information and building knowledge applicable across the range of PEPFAR-funded sites, and assess the impact of PEPFAR programs on those at risk for, and those infected or affected by HIV, at community and global levels. As PEPFAR implements scientific advances on a large-scale through its programs, PHE assesses the effectiveness and impact of PEPFAR programs; compares evidence-based program models in complex health, social and economic contexts; and addresses operational questions related to program implementation within existing and developing health systems infrastructures. PHE utilizes rigorous, scientifically sound research methodology of varying complexity, and may include (but is not limited to) control groups, randomization, modeling or advanced statistical techniques. PHE does *not* extend to basic or investigational clinical research activities. PHE should prioritize local investigator participation and capacity-building and should reflect country priorities and the priorities of host country governments.

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 outcomes 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.

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 complexity of the methodology 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 of topics. **All PHEs must receive technical review and be approved for submission in the COP.** PHEs cannot be funded out of country program funds and should not be subsumed under other programmatic activity areas. PHE projects that are incorrectly submitted as basic program

evaluations in the COP will not be allowed to go forward and will be required to go through the PHE submission process for consideration the following year.

Some specific examples of what is PHE, what is not PHE?

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

- Comparative evaluations of interventions or program models
- In-depth studies beyond routine program evaluation
- Studies of community- or population-level effects or impact of an intervention
- Collection and analysis of patient-level data or interviews not part of routine patient assessment or regular program process evaluations
- ARV resistance monitoring of persons under care (N.B., surveillance of community-level background resistance is considered surveillance and *not* PHE)

The following types of studies are generally **not considered PHE** and **do not** need to be submitted as a separate PHE activity:

- Surveillance activities (*N.B., activities associated with ARV resistance monitoring of persons in treatment are considered PHE activities—see note above*);
- Routine ongoing program monitoring or routine periodic program evaluations, such as those undertaken to measure output or performance and not including comparison groups;
- Baseline needs assessments, formative evaluations or feasibility studies to determine the characteristics of a population or basis for a future intervention;
- Routine quality improvement/quality assessment activities, including L-STEP, HIV-QUAL, etc;
- Most focused outbreak investigations.
- In-country laboratory validation/calibration of accepted/proven laboratory techniques

Again, where there are doubts about whether a particular activity should be considered PHE or not, please have the PHE liaison contact OGAC PHE advisors or the relevant Evaluation Team lead to discuss the specific details of the proposed activity.

NEW APPROACH to PHE in FY 2009

Procedures for PHE submission in FY 2009 will provide a stronger emphasis on quality, quantity and ensuring progress, while continuing to support country ownership, capacity building, and sharing of information to benefit countries and PEPFAR teams.

NEW TIMELINE – separate PHE review process from COP review

8/7/08	9/1/08	9/12/08	10/15/08
Progress Reports on continuing activities due	Final review status reported back to country for decision on inclusion in COP (progress reports)	Concepts for new activities due	Final review status reported back to country for decision on inclusion in COP ()

* Approval is limited to scientific/technical evaluation only, final approval as part of overall country program activities during COP review will still be required.

Types of PHEs

PHE projects will be funded centrally and will support questions of global significance, as well as country-priority questions. Emphasis will be placed on questions of global significance.

- Globally Significant Projects – address questions of significance across borders, deals with larger issues of program management from a clinical or administrative perspective, may address questions that the large scale of PEPFAR is uniquely positioned to answer. See section below for additional information on globally significant projects.
- Country Specific Projects – address questions specific to the program, interests and environment of an individual country, and may focus on clinical and/or administrative perspective.

It is up to those submitting the proposal to make their case for why a project being proposed is of particular significance to their country program or is globally significant and offers the potential to inform PEPFAR programs or policy broadly.

Notes on Globally Significant Projects

Individual country projects – Globally significant projects may be considered for implementation within an individual country provided there is demonstrated human resource capacity, expertise, and infrastructure to support the project and evidence of suitable power, scope and scientific rigor is provided to show generalizability from a single country setting.

Collaborative projects – may be considered when the comparison of findings across countries and the potential to aggregate data will strengthen the impact of study results, or when looking at rare events would require a very large number to detect significant results.

- *Harmonized parallel studies* – may be considered if there is sufficient capacity in each country doing work on the topic for each study to stand alone with respect to size and scientific rigor; however, these studies are designed so that they share definitions, core variables, methods and/or other key aspects, allowing potential for subsequent comparison and aggregation of the data.
- *Single Protocol/Multi-country studies* – may be considered if a single country team does not have the capacity (either in eligible subjects or staffing resources) to undertake a project large enough to have the potential of reaching a level of significance in its findings (e.g., looking for rare occurrences), or where there may be benefit in utilizing a common protocol.

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 teams. This should result in a greater range of expertise and strengthen their capacity to carry out significant evaluation activities. The PHE Evaluation Teams are an important resource in considering which approach to addressing a particular question may be optimal and in identifying opportunities for collaborative projects across countries.

PHE Priorities

The priority setting process that took place in the last year has resulted in a list of eleven priority areas for PHE research of global significance. While the review committee will take into consideration quality projects that fall outside these priority areas, we expect that a majority of the monies set aside for globally significant projects will address these topics below:

1. What are the effects of available interventions (e.g., ART, male circumcision, behavior change communications) on incidence in serodiscordant couples?
2. What interventions reduce early mortality in patients (adults and children) initiating ART?
3. What are the effects of task-shifting for prevention, care, and treatment service delivery on quality, outcomes, cost effectiveness, etc?
4. Health systems impact of HIV-related services
 - a. What impact does provision of HIV-related services have on other services in a facility, and how does impact differ by models of service delivery?
 - b. What is the impact of provision of HIV-related services on the broader health system in a country (e.g., on healthcare personnel, services in non-HIV facilities, healthcare infrastructure, national health funding, etc)?
5. What are the optimal approaches to infant feeding and nutrition (e.g., feeding method, weaning strategy, ART and ARV prophylaxis for mother and child) among HIV-exposed children to maximize PMTCT and HIV-free survival?
6. How can barriers to national scale-up of PMTCT programs be overcome to maximize program impact (e.g., reduced transmission, improved health, prolonged life) while maintaining or improving overall maternal and child health (e.g., maternal mortality, infant mortality, immunization rates, reproductive health)?
7. Which models of routine HIV counseling and testing in clinical settings (i.e., provider-referral, provider-delivered, counselor-delivered) result in more people tested, higher percentage of HIV infected persons identified and linked to care, and a reduction in risk behaviors?
8. Can intensified behavioral interventions reduce HIV incidence among high-risk HIV-negative clients attending counseling and testing sites?
9. What are the effective individual and mass behavioral change communication models to reduce concurrent partnerships?

10. What are the most effective service delivery models to improve outcomes (e.g. retention in pre-ART, time to initiation of ART) among those receiving comprehensive pre-ART care?

11. What is the impact of wide-spread ART on prevalence/incidence on a population basis?

Submission Requirements:

New Concept Submission Requirements

A concept proposal will be required for any proposed PHE activity and the **concept must receive scientific/technical approval prior to being included in your COP**. If you are uncertain whether or not a concept you are considering for PHE really fits the definition, you are encouraged to discuss the proposed activity with the PHE coordinators at OGAC or with the relevant PHE Evaluation Team lead prior to submission.

A concept proposal should be *approximately* 5 pages and include information in the following categories (*Please see the PHE page on PEPFAR.net for a sample concept proposal, cover sheet and other relevant templates for submission*):

- √ Cover page – to include title, Principal Investigator, country team contact, length of project.
- √ Specific Aim (WHAT?) – what is question are you asking? What is the purpose and goal of this project?
- √ 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 What work has been done on this topic to date? (cite relevant work*)
- √ Methods (HOW?) – how will you answer the question? include study design, data management and statistical measures/approach, and power calculation if appropriate.
 - (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 project?
 - (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 capacity?
 - (WHEN?) – when is the project expected to be completed? What is the duration of evaluation activity and timeline?
- √ References – Identify relevant work or other background information cited.
- √ Budget - Detailed Budget w/justification: cost and distribution of budget – per year for each year the project is anticipated to be underway and total duration of project. The budget form will be posted to the PEPFAR extranet.

****PLEASE NOTE** When writing the concept paper, it is important to take into consideration the information listed below based on the type of PHE study you are proposing:**

INDIVIDUAL COUNTRY-SPECIFIC STUDIES: A program/country specific study should be identified as such and the background should include identifying the local support for this project as well as describe the rationale for such a project.

HARMONIZED PARALLEL STUDIES: A concept that has been pre-planned to harmonize with others doing similar work should be identified as such. Each country team will submit its own plan but will identify and reference the parallel activities proposed in other setting, in order to support their future goal of comparing findings or aggregating data.

MULTI-COUNTRY STUDIES: A common concept paper should be developed collaboratively, in consultation with the relevant PHE Evaluation Team(s), or by the lead investigator, and the proposal may be identical with the exception that each country will need to include a section to define its own capacity to carry out their end. It is possible that some minor adjustments may be required to fit the study into different infrastructure, and this should be identified. Each country will also need to submit its own budget for their part in the collaborative work. Within the body of the concept, they should define that this is a multi-country project and list all participating countries/sites.

Ongoing Activities Progress Report Requirements

All continuing PHE activities from prior years must have a progress report filed annually. This report will reviewed and will factor into decisions regarding approval of continuing the specific project as well as approval of new projects. A progress report should be 1-2 pages and needs to include:

- √ WHAT/WHERE – what activities have taken place to carry out this project?
 - Is there a written protocol, and which review bodies have seen and approved it? If not approved, where is it in the process? If approved, has the project begun, are subjects enrolled or has data been collected – on what percent of targeted amount?
 - Are all sites at the same point in progress?
 - Have there been any changes to the original concept in terms of study population, sites, methodology?
 - If there have been unexpected obstacles, what are they, what has been done to overcome them, and have they been successfully cleared or has there been a plan developed to address them?
 - Do you still anticipate carrying out this activity – is it still considered active?
- √ WHO – has there been any significant change in investigators, partners, or personnel required to carry out the activity?
- √ WHEN – what is the current expected timeline to completion of the project?
- √ REFERENCES – Have there been any presentations or publications resulting from this work?
 - Is there new information available that is relevant to this project?
- √ Budget Justification – for the current year. Specify if there are any changes from prior budget expectations, and if funds are being carried forward from previous year.

Please see the PHE page on PEPFAR.net for a sample concept proposal, cover sheet and other relevant templates for submissions

REVIEW PROCESS

- *New activities* – Review and approval of new PHE activities will be based on scoring of technical merit and will take into consideration such factors as external review technical scores, geographic diversity, country capacity, and record of progress and completion of previously funded PHE studies.
- *Continuing activities* – will be factored into decision on funding new activities as well as continuing funding for ongoing projects. Renewal funding for continuing country-specific PHE activities, including those originally funded in FY 2008 or earlier, will limit the ability of programs with significant out-year commitments from undertaking new country-specific PHEs.

REVIEW CRITERIA

Funding of PHE activities in FY09 will be based on a competitive process. The following criteria will be considered in the review of each proposed concept:

Per Project

- 1) Does the project address one of the 11 identified priority topic?
- 2) If the project does not address a priority topic, has the applicant provided justification to support this project in terms of country or global importance? (for country priorities – info on MOH request, process for in-country prioritization, etc...)
- 3) Has the methodological approach been articulated; if so, is it sound?
- 4) Does the applicant demonstrate adequate capacity to carry out the project? If not,
 - a. Have they identified a source of technical assistance, if needed?
 - b. Have they recognized and requested a source of technical assistance? And if so, can the review group identify a source for providing that assistance (PHE Evaluation Team, TWG or local resource)?
- 5) Will this project provide new information or has the question already been addressed? (or are significant studies already underway?)
- 6) Will this project contribute to capacity building in the country?
- 7) Does the proposal indicate collaboration with in-country organizations?
- 8) If there is collaboration, do collaborating project submissions fit together?
 - a. Have each of the countries submitted a project indicating collaboration?
 - b. If a single protocol study, have they identified how protocol will be developed? Is the combined effort likely to reach a level of significance?
 - c. If harmonizing activities, have they demonstrated how or what critical elements they will harmonize? Does each country's study have the capacity to stand alone?
- 9) Does the proposal indicate efficient planning for use of resources and a likelihood of completion in a timely manner so that results can benefit PEPFAR programs in the near future?

Per Country

- 1) *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 waiver to this cap.*
 - 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. Non-focus countries may not be held to same cap because of the limited size of program budgets
- 2) Progress on continuing studies:
 - a. If 1-2 continuing activities have demonstrated no progress – maximum of 1-2 new activities can be funded for that country
 - b. If ≥ 3 continuing activities have demonstrated no progress – no new activities will be funded unless the continuing activities are discontinued.

Other HQ Considerations for funding

- 1) Distribution of funds will encourage capacity-building for country teams new to PHE/research arena
- 2) Distribution of funds will support diversity of PHEs to address questions across PEPFAR programmatic areas (e.g., care, treatment, and prevention for pediatric and adult populations)

DECISIONS ON PHE PROPOSED ACTIVITIES:

Summary statements on the outcome of the review process will be sent to country PHE liaisons with a final determination and comments. PHE activities that receive approval to proceed must be included in COP submissions and should reference the PHE activity 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 should also be included in the COP. Please see page 107 of the FY 2009 COP Guidance for further instructions on how to enter information into COPRS.