

PEPFAR Publication Clearance Process

Overview

All written material intended for publication as part of a federal employee's official duties OR where the source of the written material is derived from resources provided by the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) must undergo **PEPFAR Publication Clearance** prior to submission. Applicable written materials include research articles, book chapters, and other permanent products intended for public consumption including "Letters to the Editor." Not applicable to this process are internal reports, conference abstracts, slide sets, presentations, and talking points. The PEPFAR publication clearance process is intended to provide a streamlined, administrative process for ensuring that materials reflect PEPFAR priorities, undergo technical and ethical review by publishers, and are added to a tracking database for written products. Following are the roles and responsibilities, review processes, and instructions for submitting written material for clearance.

Roles and Responsibilities

The roles and responsibilities for persons involved in the clearance process are outlined below.

Submitter. The lead or PEPFAR-affiliated author is responsible for submitting written material for review using the [PEPFAR Manuscript Clearance Form](#). The submitter will serve as the contact person for the material and receive notifications about the status of the clearance request.

Office of Research & Science. The ORS Director will monitor and track written materials submitted for clearance and identify **within one week of receipt** any appropriate S/GAC section staff to provide a technical review, as needed.

Submission Coordinator. The ORS Program Support Officer will manage the review process, track manuscripts assigned to reviewers, and serve as the clearance contact person. For questions or comments, please email SGAC_MSCL@state.gov.

Ad Hoc PEPFAR Technical Reviewers. Members of the SGAC community may be asked to volunteer on an *ad hoc* basis to serve as reviewers, particularly when subject matter expertise is necessary to inform clearance recommendations to the Ambassador. These *ad hoc* reviewers will be asked to **complete their reviews within one week**.

Final Approval by the Ambassador or designee. Final approval for publication on behalf of PEPFAR rests with the Ambassador or her/his designee. ORS staff will facilitate this approval process and alert submitters as soon as possible when clearance is secured.

SUBMISSION PROCESS

To submit written material for **PEPFAR Publication Clearance**, the submitting author must complete the **PEPFAR Clearance Form**, and submits the corresponding written material in MS-Word to SGAC_MSCL@state.gov. For tracking purposes, a new request is needed for each initial or revised submission.

Approval Process and Estimated Timeline:

Publication Clearance is expected to take **two - three** weeks, as depicted below:

- **Week 0:** Submitter completes [PEPFAR Manuscript Clearance Form](#), attaches the relevant written material, and emails them to SGAC_MSCL@state.gov. ORS pre-screens the submissions and assigns them to SGAC ad hoc reviewers **within 2 working days**.
- **Week 1:** Ad hoc reviewers acknowledge receipt and proceed to review materials. Completed review forms and comments to the ORS submission coordinator will be returned **within 5 working days** using the online [Reviewer Form](#).
- **Week 2 - 3:** ORS provides a clearance recommendation to the Ambassador, who returns a clearance decision **by end of week 2 or 3**.

In cases where submitted materials require modifications, clearance for resubmissions will be expedited to preserve the original timeline to the extent possible.

REVIEW PROCESS

Clearance Form Elements

Following are elements of the clearance form that will be completed by submitters, reviewers, and other SGAC team members. These include:

Submittal Information

1. Submission date (MM/DD/YY)
2. New or Revised submittal (N/R):
3. Submitter name (Last, First):
4. Submitter email:
5. Submitter phone number:
6. Type:
 - Journal
 - Chapter
 - Letter to Editor
 - Other
6. Title of Manuscript/Materials:
7. Author affiliation:
8. Intended Journal/Publisher:
9. Acknowledges PEPFAR support: (Y/N)

10. Includes standard disclaimer¹: (Y/N)
11. Are the data derived from human subjects research: (Y/N)
12. If so, was the study approved by an Institutional Review Board (IRB): (Y/N)
13. Name of approving IRB(s), if applicable:
14. Is your section chief or supervisor aware of, and approve of, the submission of the manuscript for clearance: (Y/N)
15. Has the manuscript been cleared, or is it in the process of being cleared by your home agency (i.e., CDC, DOD, HRSA, NIH, USAID, etc): (Y/N)
16. Name of agency, if applicable:

Review Criteria

Ethics/Human Subjects Protections

17. Is the written material based on a Clinical Study Protocol (Y/N):
18. IRB Approved (Y/N):
19. IRB Approving Entity (University/Agency IRB):

Science/Policy/Program

20. Scientifically Rigorous. Are there major concerns about the scientific methods used by the study, including sampling, methodological rigor, randomization, statistical conclusion validity, and discussion of limits to generalizability? (Y/N)
21. Relevance to PEPFAR priorities. Does the study align with PEPFAR's priorities for focusing on geographic areas and population groups with the greatest burden of HIV infection and unmet needs? (for list of programmatic priorities see the [2017 Report to Congress - 10-Point Plan for Epidemic Control](#))? (Y/N)
22. Acknowledgement. Does the project acknowledge PEPFAR support (e.g., "Funding, data, and/or technical expertise for this research were supported wholly or in part by the U.S. President's Emergency Plan for AIDS Relief (PEPFAR).")? (Y/N)
23. Policy/Program relevance. Are there important implications for policy or program? (Y/N)

Approvals

24. Approved by ORS Director & Date:
25. PEPFAR Clearance – major comments:
26. Front Office Approved: (Y/N)
27. Approval Date:

Contact Information

If you have any questions or comments about the Clearance process, please email SGAC_MSCL@state.gov.

¹ The findings and conclusions in this article are those of the author(s) and do not necessarily represent the official positions of the United States Government."