



Harvard Pilgrim Health Care, Inc.
Harvard Pilgrim Health Care Institute, LLC
Office of Sponsored Programs & Office of Research Integrity and Compliance

Policy and Procedure

TITLE: Quality Assurance Review for the Office of Sponsored Programs

PURPOSE:

The Harvard Pilgrim Health Care Institute, LLC (HPHCI) Quality Assurance/Quality Improvement (QA/QI) staff shall implement/maintain a Quality Assurance Review (QAR) process to monitor activities in the Office of Sponsored Programs (OSP) including federally funded awards to ensure sponsor requirements are met and to improve the quality of research for the purpose of protecting human subjects.

PERSONS AFFECTED:

This policy & procedure (P/P) applies to all Harvard Pilgrim Health Care (HPHC) and HPHCI (collectively, HPHC/I) personnel engaged in research, teaching, or research administration activities in support of the charitable and educational mission of HPHC.

POLICY:

Any active or closed award that has been funded through a federal department or agency and any related award records may be selected for a QAR. Periodically, the Office of Sponsored Programs (OSP) may also be selected for a QAR of departmental activities to ensure compliance with OSP Policies and Procedures.

DEFINITIONS:

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PROCEDURE:

I. General Guidelines for QAR

A. Award Selection

Any active or closed award that has been sponsored by a federal department or agency and its related award records may be selected for a QAR. Selection preference will be given to awards with known compliance issues.

B. Award Eligibility Determination

1. The Research Compliance QA/QI Specialist (QA/QI Specialist) will review the running list of sponsored awards, overseen by OSP, to ensure that the award meets the selection criteria and is accurately categorized.
2. The QA/QI Specialist shall create a folder in a shared folder with relevant material for the QAR which will document the following as applicable:
 - a. Relevant documents such as pre-award application and post-award material
 - b. QAR Checklist
 - c. Conflict of Interest Documentation
 - d. Visual Compliance Reports
 - e. Time and Effort Reports
 - f. Correspondence
 - g. Deliverables, if applicable

C. Grant/Contract Manager Notification

1. The Grant/Contract Manager (GM/CM) will be notified of award selection by email. The email will be documented in the appropriate QAR Folder on the J Drive. The GM/CM will be notified that their award has been chosen for a QAR. The initial notification email will include:
 - a. A description of what a QAR is;
 - b. The reason why and/or how the award was selected;
 - c. How the QAR will be conducted and by whom;
 - d. A request for access to grant materials through Cayuse and any other web-based platform as needed;
 - e. An attachment of the QAR checklist so the GM/CM understands what is being reviewed. This is the checklist that will be used to guide the review; and
 - f. A current version of the *Quality Assurance Review for the Office of Sponsored Programs* Policy and Procedure document.
2. The GM/CM will have 10 business days to respond to the notification email and request for additional information.
3. If a response is not received in ten business days, the GM/CM will be notified that the response is overdue and request and update on when the matter will be resolved.
4. If a response is not received in the required time frame, the GM/CM will be notified that the response is overdue and request an update on when the matter will be resolved.
5. Award eligibility will be confirmed by the GM/CM. An award will be deemed ineligible for the following reasons:
 - a. The award is not federally funded.
 - b. Other reasons determined by the Director, Research Integrity and Compliance Officer (DRICO) or the Director, Office of Sponsored Programs (DOSP).

II. Quality Assurance Review Process

A. Review of Award Files

1. The QA/QI Specialist will review the award files and database entries specific to the selected award. The information will be reviewed and documented in the QAR Checklist. The checklist, once completed, will be uploaded in the appropriate QAR folder on the J Drive.
 - a. The following information will be reviewed and documented on the QAR Checklist:
 - i. Pre-and post- award submission materials,
 - ii. Requested signatures on documents,
 - iii. Conflicts of interest,
 - iv. Visual Compliance reports,
 - v. Budget reconciliations (monthly financials) and cost transfers,
 - vi. Time and Effort reports,
 - vii. Deliverables (for contracts),
 - viii. Financial Federal Reports (FFR) for closed awards, and
 - ix. And any other issues found in previous reviews.

B. Follow-up Meeting

1. If the review documents any findings, the QA/QI Specialist will organize a meeting with the GM/CM and any other requested staff within two weeks (if possible) following the completion of the QAR checklist review.
2. The topics below, in addition to other issues necessary for the QAR, will be formally outlined and discussed with the GM/CM at the follow-up meeting. The meeting should last approximately 30 minutes to 1 hour and should include the following elements:
 - a. Explanation of the QAR Program. The GM/CM should be encouraged to ask questions at any point.
 - b. Address any points on the QAR checklist that require further discussion or clarification and document GM/CM's corresponding responses.
 - c. Verify appropriate documentation and signatures were collected in the pre- and post-award cycles.
 - d. Verify budgets and cost transfers are completed in a timely manner.
 - e. Verify time and effort reports are complete and accurate.
 - f. Discuss processes and organizational tools throughout the award life cycle.
 - g. Verify any required reporting by the sponsor is completed in a timely manner.
 - h. Discuss any observed abnormal delays in submissions of required reports or deliverables.
 - i. Ask about obstacles in the award process.
 - j. Check where award materials are stored.

- k. Provide an opportunity for the GM/CM to discuss ideas, concerns, opinions about the QA/QI program at HPHCI. Pertinent points will be documented in QAR checklist.
- l. Schedule a final meeting, if necessary, ideally within 2 weeks of the initial follow-up meeting.

C. Preliminary Report

1. Within two weeks of the meeting or review, a preliminary report will be drafted containing all the review findings and observations. Findings will be reported in the following categories:
 - a. Summary of findings – a summary of any issues uncovered during the QAR process will be included in the report. If these issues have been discussed with the GM/CM and resolved, that will be noted as well.
 - b. Issues Identified – summary of issues and discussion of overall organization and processes of the GM/CM and the sponsored award.
 - c. Required corrective action – observation requiring mandatory action as per federal, state, or industry regulations or HPHC/I policies. Corresponding regulation or policy will be cited for GM/CM reference immediately following each required action.
 - d. Recommended actions – observations not requiring mandatory action, but open to recommendations deemed as good practice based on other notable best practices and experiences of other awards.
2. The content of the preliminary report will be reviewed by the DRICO before the final review with the GM/CM.
3. The preliminary report will be sent to the GM/CM via email for their review, allowing for any necessary clarification or questions to be addressed. A meeting will be scheduled with the GM/CM, if needed, to review the preliminary report and note any clarifications given by the GM/CM.

D. QAR Final Report

The QAR Final Report will be issued following the follow-up meeting and/or email correspondence with the GM/CM and will include any updates/clarifications made to the preliminary report. The Final Report will be documented in the award's QAR folder in the J Drive. The notification of the published report will be emailed by the QA/QI Specialist to the GM/CM, DRICO, and DOSP.

III. Office of Sponsored Programs QAR

The Office of Sponsored Programs will be selected for a QAR periodically to evaluate departmental activities; emphasis will be given after an Internal Audit conducted by Point32Health, Inc. is completed. The process will mirror that of the federal awards process detailed above. The DOSP will be notified that a QAR is occurring and will meet with the

QA/QI Specialist to complete the OSP Department QAR Checklist. A preliminary report will be drafted for the DRICO and DOSP to comment on. A final report will be published in a QAR folder on the J Drive and shared, via email, to the DRICO, DOSP, VP Chief Compliance Officer of Point32Health, and Vice President of HPHCI.

REVISION HISTORY:

Department: Office of Research Integrity & Compliance	Title: Quality Assurance Review for the Office of Sponsored Programs
Effective Date: 12/9/24	Owner: Research Compliance QA/QI Specialist
Replaces P/P Dated: 03/29/24	
Related Documents: Policy and Procedures: <i>Quality Assurance and Quality Improvement Program</i> ; Grants Quality Assurance Review Checklist; OSP Department Quality Assurance Review Checklist	
References: 42 CFR Part 52 – Grants for Research Projects	