Beth Israel Lahey Health
Lahey Hospital & Medical Center | **Research Administration**

Guidance Document: QA Monitoring Activities

This guidance outlines the three primary QA monitoring activities that can be performed by the Research Quality staff. These activities support regulatory compliance, early issue detection, continuous quality improvement, and high-quality human subject's research.

Consent Documentation Review

Purpose: To ensure informed consent processes and documentation comply with Institutional Policies and SOPs, and applicable regulatory requirements.

When Performed: Upon receipt or access to executed consent forms.

Steps:

1. **Verify the correct documents were used**
   o Confirm the correct IRB-approved ICF version was signed within the valid timeframe.
   o For Cooperative Group studies, verify HIPAA Authorization (if required).
2. **Confirm authorization of personnel**
   o Ensure the individual obtaining consent was IRB-approved
   o Confirm delegation on the DOA log for consent-related tasks.
3. **Evaluate documentation quality**
   o All required fields completed correctly.
   o Appropriate progress note entered.
   o Proper linkage in systems (if applicable).
4. **Document issues & follow-up**
   o Log findings in the **ICF & Linking Tracking Log** (e.g., list of log fields: *Study ID, PI, CRC, ICF issue#1, ICF issue #2, if deviation noted*, etc.).
   o Notify CRC and/or PI promptly.
   o Request deviation submission or corrective action as needed.
   o Apply corrective action guidance.

Quarterly Review
- Total consents reviewed.
- Total findings (overall and by category).
   o Tally total number of consents reviewed (n=)
   o Tally total number of noncompliance findings (n=) and (%)
   o Tally total number of HemOnc HIPAA Auth issues (n=) and (%)
   o Tally total number of noted consent issues by category (n=) and (%) of each
   o Tally total number of deviations required. (n=) and (%)

Outcome: Identify compliance gaps, training needs, and operational risks.

Monitor Visit Report (MVR) Review

Purpose: To ensure findings from monitoring visits are reviewed, tracked, and addressed to maintain compliance and support continuous improvement.

When Performed: Upon receipt of Monitor Visit Report (MVR) from study coordinators, per Monitoring Visits Policy and SOP.

Steps

1. **Review the MVR**
   - Identify unresolved issues or repeated findings.
   - Note trends and potential systemic problems.
2. **Assess deviations**
   - Confirm deviations noted in the MVR were submitted.
   - Document each report in the **MVR Assessment Tracking Log** (*e.g., list of log fields: Study ID, PI, CRC, Sponsor, when it was received by QA, findings noted- missing docs, expired docs, etc., and overall assessment -and then follow until resolved*).
3. **Quality Assessment**
   - Assign Quality Assessment score using defined criteria.
   - Determine appropriate QA actions:
     - Provide tools or templates.
     - Offer suggestions or direct assistance.
     - Provide re-education.
   - File a copy of the report in a MVR folder sorted by project ID or PI.

4. **Communicate follow-up requirements**
   - If action is needed from the study team, notify them of QA assessment and required corrective actions.
   - File a copy of the notice in the study's MVR folder and any additional correspondence.
5. **Track & trend**
   - Enter results and follow-up items in the MVR Assessment Tracking Log.
   - Review quarterly for patterns.

Quarterly Review

- Total MVRs received.
- Receipt timeliness (<1 week, 1–4 weeks, >4 weeks).
- Quality assessments by category.
- Findings and required follow-up by category.

Outcome: Ensures timely resolution, prevents recurring issues, and enhances study team compliance.

Minor Deviation Review

Purpose: To assess reported protocol deviations for accuracy, completeness, preventability, and required corrective actions.

When Performed: Upon submission of minor or major deviations. Evaluate separately.

Steps

1. **Review the deviation in full**
   - Check all fields (attribution, avoidability, severity) for correctness.
   - Request additional details when needed.
2. **Tracking:**
   - Enter the details in a **tracking log** or generate a report *(e.g., of log fields: Study ID, PI, CRC, date of report, whether it was received in proper timeframe, deviation type, deviation cause, deviation attribution, impact and deviation CAPA)*.
3. **Evaluate trends**
   - Assess for repeated issues from the same study or staff.
   - Review appropriateness of corrective actions.
4. **Analyze avoidable deviations**
   - Calculate the most frequent types and causes.
   - Identify patterns needing intervention.
5. **Apply trigger thresholds**
   - Determine whether a study meets "trigger" criteria (>50% avoidable deviations, severity >2, etc.).
   - Document in summary reporting.
6. **File each report** in a Deviation Report folder sorted by study ID or PI.
7. **Summarize and trend**
   - Enter quarterly summary data into the tracking log.
   - Compare across prior quarters or years.

Quarterly Review

- Total deviations.
- Number of studies.
- Deviation types and percentages.
- Avoidable deviations and percentages.
- Root causes and percentages.
- Attribution to CRC/PI (overall and avoidable only).
- Mean severity score of avoidable deviations.
- Number of triggered deviations.

Outcome: Identifies systemic risks, informs targeted training, and drives preventive and corrective action.

Summary: How These Activities Work Together

These three QA monitoring activities provide a comprehensive quality oversight framework:

- **Consent Review** protects participant rights and documentation integrity.
- **Monitor Visit Report Review** supports ongoing study oversight and timely resolution of issues.
- **Deviation Review** strengthens compliance, root-cause analysis, and prevention strategies.

Together, they create a **continuous QA/QI loop** that improves research quality, regulatory compliance, operational consistency, and participant safety.