# University of Rochester Research Site Quality Management Plan (QMP) Reference Guide

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Abstract: The use of this program, written by University of Rochester (UR) Study Coordinators, is to guide research staff in identifying improvement opportunities at the research site through building and implementing a Quality Management Plans (QMP). A QMP is a detailed strategy outlining how errors will be identified and assessed during the conduct of a study.\(^1,2\) In summary, this includes approaches to:

- **Plan**: creating the QMP
- **Do**: executing the QMP
- **Check**: addressing findings
- **Act**: implementing corrective and preventative action plans

University of Rochester Research Site Quality Management Plan (QMP) Reference Guide

Purpose Statement: The UR Quality Management Plan Guide’s central goal is to provide resources that encourage, guide, integrate, and enhance continuous quality improvement for a research site, research program, or department/division. The guide focuses on and is intended to aid investigators and research staff in QMP set-up, implementation, and evaluation and to prioritize areas of potential risk to target.

Quality management within a study protocol includes all of the following: (1) a well-designed study protocol; (2) appropriately trained (and dedicated) study team; (3) appropriately delegated tasks; (4) study (and site) feasibility; (5) sufficient monitoring of subject safety, and (6) adequate data monitoring and management.\(^1,2,4,5,6\)

Additional information is available through the Clinical Trials Transformation Initiative’s (CTTI) Quality by Design Project\(^4\) and their ‘Critical to Quality Factors Principles Document’.\(^3\) Local resources pertaining to study design, protocol development, feasibility assessment, study team training, etc. are available through the Office for Human Subject Protection and the Clinical & Translational Science Institute.

I. What is a QMP?

In its most basic form, ‘quality’ in the conduct of human subject research is defined by the absence of errors. Therefore, a Quality Management Plans (QMP) is a detailed strategy outlining how errors will be identified and assessed during the conduct of a study.\(^1,2\) It is important to remember when developing a QMP that errors range in severity and their potential to introduce risk to subjects (e.g., minor documentation errors versus enrolling subjects without Institutional Review Board [IRB] approval). The goal of a QMP is to assist in conducting high quality research, which is research that protects subjects, is conducted in a compliant manner, and produces ‘good’ data with reliable conclusions.\(^3\)

Traditionally, assessing quality has been reactive; errors are identified and addressed after the fact. The ideal method of quality management is proactive, which involves the study team implementing a process to continuously assess the quality of the research operation by building quality measures into a study during the development stage.

II. Why have a QMP?

The increasing complexity of study protocols drives levels of site burden higher and, while causality has not been demonstrated, may adversely affect site performance.\(^7\) Compounding this notion with data demonstrating that common deficiencies identified by the FDA during site inspections have remained
unchanged over the past several years [6] further drives the need to put proactive QMP procedures into place.

As study protocols become increasingly complex and the requirement for single-IRB review becomes more common, study teams must be vigilant about maintaining the integrity of the study, protecting subjects and ensuring the quality of the data. [3, 5, 6] Neglecting to identify and address errors may compromise study data, put subjects at undue risk, prevent the ability to meet protocol objectives, and put both the Investigator and the institution at risk with federal regulators (OHRP and FDA) and sponsors.

Implementing a QMP may help a study team to successfully achieve study objectives, while:

- Protecting the health, safety, and welfare of subjects.
- Conducting research compliant with federal and state regulations, institutional policy, ethical principles and standards appropriate for the Principal Investigator’s (PI) discipline (e.g., Good Clinical Practice), and the study protocol.
- Ensuring data accuracy and validity.
- Improving site performance.
- Mitigating risk to the Investigator, study team, and institution.
- Preparing for external quality-related reviews (e.g., FDA inspections or sponsor audits). [3, 4, 6]

III. How to Implement a QMP?

Developing and implementing a QMP can be daunting. The decision to do so should be well thought out and planned in advance. Before diving into the process, consider the following:

Commitment and Resources
Implementing a QMP will take dedication, time, and resources (resources that may not have originally been budgeted for), but it may ultimately save time and resources by identifying and potentially preventing troubling incidents of non-compliance. The discussion and decision-making to create and implement a QMP should include Investigators, coordinators, and other leadership within the department/division, as appropriate. Determining the level of leadership support is crucial in the development of a QMP and will guide the scope of the QMP.

QMP Scope
A QMP can be developed and implemented for a single study, a group of studies similar in nature, or an entire department/division. Similarly, the review elements and the timing of the review can vary. For example: for a single study, you may decide to review signed consent forms semi-annually; as a department, you may decide to review a random selection of subject files quarterly; or vice versa.

Ultimately, the nature and scope of the QMP(s) you choose to implement will vary based upon needs and resources. If you are new to this process, or have limited resources, try starting with something simple. As the process becomes more familiar and routine, the QMP can be expanded. Keep in mind, to be effective the nature of the QMP must be realistic and work for the study team. Note that additional examples of QMPS are available in the appendices for your consideration.
**QMP Process**

Regardless of the nature and scope of your QMP, following the PDCA Cycle (also known as the Deming Cycle) will assist study teams in successful and effective implementation of a QMP. The PDCA Cycle is a model for continuous process improvements consisting of four repetitive steps:

- **PLAN:**
  - What to review?
  - When to conduct the review?
  - How to conduct the review?
  - Who should conduct the review?

- **DO:**
  - Execute the plan.

- **CHECK:**
  - How to address findings?

- **ACT:**
  - Implement corrective and preventative action plans.

**PLAN – DO – CHECK – ACT**

This section will discuss what to review, when to conduct reviews, how to conduct a review, and who should conduct the review. As quality is a continuous cycle, consider this when determining your approach:

A. **PLAN - What to review?**
   a. It is important to define the scope of what to review:
      - Do you want to target compliance areas within or across several studies or conduct study-specific audits?
      - What regulations and policies are you held to for the specific study?
      - Do you want to consider incorporating continuous monitoring into your day-to-day practice?
   
   See Appendix A for Quality Management Plan Examples
b. A risk assessment\(^{[8,9]}\) is a systematic process of evaluating the potential risks that may be involved in a projected activity or undertaking. Conducting a risk assessment in the context of the research will help to define what to review within your site or study-specific QMP. Consider the following for each study to create your QMP:

- Where will quality matter the most or have the greatest impact, especially when considering limited time and resources? Example – if your study includes a study drug, dosing compliance and accountability of the study drug
- What specific problems have occurred previously? Example – if you have errors in obtaining consent
- Where is the risk to the subject, the study staff, the institution, and/or data quality and integrity? Example – collection of adverse events in a high risk study or if you've neglected to adhere to a study protocol in the past

See Appendix B for Risk Assessment Examples

c. Elements to Review: For funded trials where an external monitor will be reviewing all of the above elements, a modified review of the following may be adequate. Do not assume external monitors assess and validate every risk area that is important to your site and your subjects; in particular, external monitors are not aware of specific institutional policies.\(^{[8]}\) Prospectively identify specific issues within the approved protocol or through study implementation in which compliance may be problematic; put controls in place to assist you to mitigate problems and errors. Based on your risk assessment, identify specific areas to consider:

- Informed Consent Process: was appropriate consent obtained
- Eligibility
- Protocol Adherence, for example, a major deficiency would be failure to assess adverse events. Minor deficiencies include missing initials on a data collection form as directed by the protocol.
- Data and Safety Monitoring Plan (DSMP), including adverse event identification, collection, reporting, and any other protocol-defined events of clinical interest. For example, a major deficiency would be failure to follow the approved DSMP. If applicable, consider:
  i. Disease outcomes/responses and/or long-term follow-up
  ii. Verification of response or progression for a treatment/intervention.
- Regulatory Expectations:
  i. Appropriate/continued delegation of tasks
  ii. Investigational drugs/devices accountability and related regulatory reporting requirements
  iii. General Data Quality: The fundamental elements of data integrity to consider:
      Is the data attributable, legible, contemporaneous and complete, original, and accurate?\(^{[10]}\)

d. Consider repeating your risk assessment during the trial as unexpected events may occur. Be sure to disseminate the risk assessment results to the study team and discuss potential QMP adjustments.

See Appendix C for a QMP Brainstorming Worksheet

e. Additional Points:

- Verification of Data: A process that checks for accuracy and inconsistencies after data collection is done. A best practice may involve a second person verifying the entry(ies).
- Good Documentation Practice:
  i. Use of controls/processes to prevent the inadvertent use of outdated documents
ii. Clear, legible, indelible handwriting  
iii. No entry space left empty (empty = not done)  
iv. Page numbering; version dates  
v. Consistent time and date formatting (i.e. military time and date)  

- Regulatory Documentation: Written or electronic documents which demonstrate adherence to IRB approved protocol/amendment(s), IRB requirements, Good Clinical Practice, institutional policy, in accordance with applicable federal regulations, the Food and Drug Administration (FDA), and under the University’s Federal Wide Assurance (45 CFR 46). Necessary documentation items are detailed in the Research Study Regulatory File Contents document:  


B. PLAN - When to conduct QMP Reviews?  
Deciding the frequency of conducting your audits is dependent on several things: identified risks, findings from previous audits, staff turnover, significant changes in regulations, policies, or processes, availability of resources, and breadth and complexity of the protocol/study. Resources should be allocated specifically naming who is responsible for what with a due date assigned. \(^{[8, 11]}\)

After some experience with your QMP, you’ll get a feel for which areas of your operation are prone to problems and would benefit from more frequent audits. The flipside, of course, is that there may be processes in your department that run smoothly and won’t derive a benefit from frequent audits. The audit schedule can be revised as your process develops, but be aware when your QMP plan is contained in the protocol, a revision may require a protocol amendment.

Ongoing application of your QMP and audit follow-up:  
- For non-compliance and internal control deficiencies, monitor timely completion of corrective action.  
- For audits that identified major issues, schedule follow-up re-review at a specific point in time (e.g., 6 months after audit).  
- Routine monitoring: Include research-related audits on your annual audit plan.  
- If you have ‘an event’ of significant non-compliance, conduct a root cause analysis and revisit your QMP.  
- Schedule an annual review of your QMP to review prior year results to determine the upcoming year’s QMP.

Examples for when to conduct reviews:

<table>
<thead>
<tr>
<th>Research Risk Area</th>
<th>Examples of Strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consenting</td>
<td>Review the signed consent, eligibility, and adverse events in the first enrolled subject and subsequently every fifth enrolled subject</td>
</tr>
<tr>
<td>Eligibility</td>
<td>OR Two subject charts per month</td>
</tr>
<tr>
<td></td>
<td>OR Review every signed consent plus eligibility plus adverse events (80% review)</td>
</tr>
<tr>
<td>Adverse Events</td>
<td></td>
</tr>
<tr>
<td>Protocol Adherence</td>
<td>Review the data and safety monitoring plan annually or quarterly dependent on timing defined in approved plan OR Review a specific component of the protocol after each subject is enrolled (i.e. height, weight, blood pressure collected)</td>
</tr>
<tr>
<td>-------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Regulatory Documentation</td>
<td>Review all regulatory documentation prior to enrolling the first subject and annually (perhaps with Continuing Review) OR Use a checklist to confirm proper filing of regulatory documents with each amendment</td>
</tr>
<tr>
<td>Other</td>
<td>Determine site or study specific needs.</td>
</tr>
</tbody>
</table>

C. **DO - How to conduct QMP Reviews?**
Once you’ve decided what to review and when to conduct reviews:

- Create site or study-specific documents and/or tools. What you decide to review will determine what you use, e.g. Microsoft Word, Excel spreadsheet, Access database, or a RedCap data collection form. There are some self-audit tools available: [https://www.rochester.edu/ohsp/quality/studySelfAuditTools.html](https://www.rochester.edu/ohsp/quality/studySelfAuditTools.html)
- Discuss the site-specific QMP with the study team; provide education as needed
- Allocate a specific time on the calendar at regular intervals to conduct the audits
- Have resources available, e.g. study protocol, regulations, policies
- Select a sample population to audit specific compliance components (i.e. square root + 1)
- **Execute the plan:** conduct the audit(s)

D. **DO - Who Should Conduct QMP Reviews?**
To be effective, QMP reviews need to be objective and therefore, it may be best for someone independent from the study team to conduct the review when possible (or at least, as independent as possible). Options include:

- Partnering with another investigator or coordinator within your department/division to conduct each other’s reviews
- Partnering with another investigator or coordinator external to your department/division to conduct each other’s reviews (see note below)
- Having senior level or back-up coordinator conduct reviews
- Who are findings reported to?
  - i. Have an understanding in place prior to the review to address what the escalation process is for findings.
  - ii. **Always** report findings to the Principal Investigator and the primary Study Coordinator.
  - iii. In some cases, it may be necessary to report findings to Research/Department Administrator or Supervisor/Manager if there are safety concerns or serious deficiencies noted.

When determining who will conduct QMP reviews you may want to consider the reviewer’s level of experience in conducting research. While new study personnel should be exposed to the process, collaborating with experienced personnel will provide them more insight to the review process. Furthermore, if you are working within the scope of a department/division (versus within the scope of a specific study), it may also be helpful to designate a ‘QMP Leader’; someone whose responsibility could include leading the study team in developing the QMP and assigning QMP-
related tasks. Of course these individuals should always work with the Investigator and the research team to develop and execute the QMP.

If review by an independent individual or experienced personnel isn’t possible or there is no designated QMP Leader, don’t let that deter you from implementing a QMP. You will still benefit from conducting your own internal reviews – just be sure to seek advice when you need it!

**QMP Training**

If necessary, an essential step to take before implementing the plan is training the staff who will conduct reviews. As the study team should be involved in the development of the QMP, they should require minimal training. If using a QMP is unfamiliar for a study team, OHSP Division of Quality Improvement (OHSP-QI) is available for consultation. OHSP-QI will provide on-site consultation to research team members regarding implementing a QMP specific to their study.

**Proactive Strategies to consider:**
- Present and/or coordinate educational sessions
- Create and distribute tip sheets on how to avoid compliance issues
- Make tools and resources accessible to facilitate compliance
- Demonstrate compliance/audit function
- Be available for and willing to answer questions – serve as a resource
- Attend clinical staff and researcher lab meetings to reinforce plan and clarify any misconceptions
- Regular/routine audits: Make them a part of the day-to-day operations.

**Note:** As part of the University of Rochester’s Human Research Protection Program, staff is obligated to protect the rights, dignity, welfare, and privacy of research subjects by adhering to the highest ethical standards and to comply with applicable federal and state regulations, as well as institutional policies. As such, staff conducting QMP related reviews must be cognizant of protecting the privacy and confidentiality of the information reviewed, as well as reporting requirements required by the Office for Human Subject Protection. Study teams choosing to partner with staff in other departments should have frank discussions about the management of review findings, prior to entering into such a relationship. Additional information regarding the management of review findings is available in the section below.

**E. CHECK - How to address and manage QMP Review findings?**
- Discuss the findings with the Investigator and study team members
- Assess the scope and source of the problem
- Determine needed actions and develop a response

Consider the following: Is this a ‘minor’ or ‘major’ finding (see examples below)? Are vulnerable populations involved? Was the finding a one-time error or is it widespread? What is the source of the error? Is the error the result of a flaw in the process or was it due to lack of oversight? If it was widespread, are there trends in timing, across study personnel, or with a specific process?
<table>
<thead>
<tr>
<th>‘Minor’ Examples</th>
<th>‘Major’ Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Used pencil to sign consent</td>
<td>Issue that potentially impacts subject safety, e.g., failure to assess an adverse event</td>
</tr>
<tr>
<td>Did not correct a cross out</td>
<td>Missing documentation of consent</td>
</tr>
<tr>
<td>Misdated an event on a case report form</td>
<td>Enrolled an ineligible subject</td>
</tr>
<tr>
<td>Missing IRB approval documentation</td>
<td>Failed to complete study procedures, as defined by the protocol</td>
</tr>
<tr>
<td></td>
<td>Inadequate investigational product accountability</td>
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F. **ACT: Determine an Appropriate ‘Fix’**

Based on the scope and source of the error, develop an appropriate corrective and/or preventative action. At a minimum, all errors require a corrective action. Preventative actions should also be considered when there are systematic or process-related issues, multiple ‘minor’ errors that are similar in nature are identified, or a single but significant incident of non-compliance occurs.

<table>
<thead>
<tr>
<th>‘Immediate Fix’ (Corrective Action)</th>
<th>‘Big-Picture Fix’ (Preventative Action)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correct the immediate problem</td>
<td>Prevent re-occurrence of the problem</td>
</tr>
<tr>
<td>Document what the finding was, what caused the error and what was done to resolve the issue (e.g., documentation, notification to PI/subject/study team, data corrections)</td>
<td>Document the solution that will be used to address the source of the problem. Be specific; use a simple, sustainable, and measurable solution (e.g., process change, re-training, protocol/CRF revisions. Note that while re-training may be helpful in some cases, it is not always effective as a standalone measure.)</td>
</tr>
<tr>
<td>Example: A note to file was created, signed and dated to clarify that the SF-36 measure was not completed during Study Visit 2, as the subject refused.</td>
<td>Example: A secondary study coordinator will cross-check regulatory files annually, at the time of continuing review.</td>
</tr>
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G. **ACT: Determine When to Report to the IRB**

Does the finding involve increased risk to subjects or others (serious, related and unanticipated)?

- If yes, report the event to the RSRB within 10 calendar days
- If no, report the event in summary at the time of continuing review

Note: This reporting information is based on [OHSP Policy 801 Reporting Research Events](#) and the associated [Guideline for Reporting Research Events](#). If the study was reviewed and approved by another Reviewing IRB (e.g., Western IRB, another commercial IRB, or institutional IRB), reporting should be based on their specific requirements.

H. **ACT: Implement the corrective and preventative action plan as agreed upon for your division/department.**
I. ACT and PLAN: Re-Evaluate the Preventative Action Measures

If a preventative action measure was implemented, re-evaluate the measure to determine whether it’s been effective at addressing the original error.

a. Identify the specific strengths and weaknesses in current practice. Note what is working and what needs to be addressed.

b. Additional considerations
   - Create a database of findings either in excel spreadsheet or RedCap.
   - Maintain a yearly departmental summary of findings for leadership and resources to aid in compliance for each finding.
   - Use the data to feed into protocol design and to monitor quality.

c. ‘When things go wrong which they will do on occasion’...use the resources available including your IRB Specialist, OHSP Policy 801 ‘Reporting Research Events’, the University integrity hotline (585-756-8888), other monitoring bodies, e.g. sponsor.

IV. Advice from the Front Line

- Start small and basic, build on your QMP when/if you can.
- Get advice from OHSP-QI when you need it; no question is too small.
- Consider compiling findings into a database (i.e. Access, Excel, RedCap) to look for trends/issues in a study or department.
- Be sure the entire study team is aware of the process and expectation. For example, if a newly hired coordinator’s study is always reviewed within a set amount of time, make sure the expectation is known upon hire/during orientation.
- Consider scheduling a time with the study team for everyone to conduct reviews. If everyone has QA meeting on their calendar once a month, then everyone has a designated time to complete their reviews.
- Meet with the entire study team to review the QMP (annually or quarterly).

Keys to Success of your QMP:
- Investigator and study team commitment.
- Senior leadership commitment.
- Allow the QMP to evolve as needed to reflect internal and external changes; continuous review of the QMP is important in relation to organizational/departmental changes.
- Have a vision for a ‘quality culture’ by working together to encourage honest communication, increase knowledge, correct problems and learn from mistakes.
REFERENCES/RESOURCES


Appendix A

Quality Management Plan Examples

Below are examples or ‘food for thought’ to stimulate ideas and direction for individual site QMP development. Keep in mind, these examples are not all-inclusive. You may, at any time, review any or all subjects and/or all data collection forms for protocol compliance.

Scenario #1 – Greater than Minimal Risk Behavioral Research:

Brief Protocol Summary: An Investigator-initiated, randomized, multi-center study of cognitive therapy with or without mindfulness training in adults (age 18 and older) with depression and history of suicidal ideation. Subjects are to be meditation-naïve for the previous six months per subject report. All enrolled subjects attend one study visit each week for four weeks, followed by every other week (+/- three business days) for 20 weeks. Each study visit includes a standard cognitive therapy session and questionnaire completion (including depression, suicidal ideation, and quality of life measures); duration of each study visit is expected to be one hour. Subjects randomized to receive mindfulness training complete additional training for the first eight weeks (duration of the additional training is 30 minutes each week); they will also maintain and submit mediation online diaries weekly. Approximately 100 subjects (randomized 1:1) are expected to enroll. All adverse events, depression, and suicidal ideation scales will be monitored by the Investigator at the time of each study visit. The Data and Safety Monitoring Committee will review comprehensive adverse event data annually.

A. A Limited Resources QMP example:
   1. Review the regulatory file for completeness once annually with Continuing Review.
   2. Review the signed consent for the first enrolled subject and subsequently for every fifth enrolled subject. Review consent forms for:
      i. Watermark and letterhead present
      ii. Account for all consent pages
      iii. Option section(s) completed
      iv. Signature dates congruent
      v. Original signatures in indelible ink
      vi. IRB-approved staff obtained consent
      vii. Watermark valid (not expired)
      viii. Version correct

B. A Comprehensive QMP example:
   1. Complete the above in A plus review eligibility, adverse events, and protocol adherence in the first enrolled subject and every fifth enrolled subject.
   2. Review the eligibility documentation for:
      • Adherence to the approved inclusion/exclusion criteria
      • Investigator signature and date, as applicable
      • Accuracy of eligibility decision, e.g. calculate date of birth for age range noted in protocol (age 18 and older), correct and documented diagnosis (depression and history of suicidal ideation), and meditation-naïve for previous six months.
3. Review documentation for the assessment of adverse events, signature of Investigator, and date, as applicable.
   - If present, are the events reviewed?
   - If reportable, have they been reported to the IRB per reporting policy?
   - What follow up was provided to the subject?
4. Protocol Adherence:
   - The Data and Safety Monitoring Committee annual meeting summary reports should be present in the regulatory file. Best practice: The Investigator signed and dated when reviewed.
   - Review 100% of the suicidal ideation measures for completion and ‘red flags’ requiring further follow-up.
Scenario #2 – Greater than Minimal Risk Biomedical Research:

Brief Protocol Summary: An Investigator-initiated, single-center, open-label study of DrugABC used in children age 14-17 with uncontrolled seizures (minimum of twice daily for previous four weeks). An Investigational New Drug (IND) application has been filed with the Food and Drug Administration (FDA) for this study; while DrugABC is FDA approved, it has not been approved for use in this population. Enrolled subjects are DrugABC-naïve, undergo a screening visit, and 13 additional monthly (+/- four business days) study visits that include a physical examination, vital signs, clinical labs, 24-hour EEG monitoring, and a pain assessment questionnaire. The Data and Safety Monitoring Plan includes: collecting information on all adverse events; reporting adverse events deemed serious to a Medical Monitor within 24 hours of notification, and Data and Safety Monitoring Committee (DSMC) reviews every six months. The subject’s signed informed consent will be scanned into the electronic health record. Registration with clinicaltrials.gov is expected. Approximately five subjects are expected to enroll.

A. A Limited Resources QMP example:

1. Review the regulatory file for completeness once annually with Continuing Review. Ensure registration is complete and up-to-date for clinicaltrials.gov.
2. Ensure the following items are maintained for the IND:
   - The original FDA IND safe-to-proceed letter receipt
   - Annual FDA reports
   - The original FDA IND application and submitted amendments
   - Safety reports, submitted and reviewed by the Investigator, as applicable
3. Review the signed consent for each enrolled subject. Review the consent forms for:
   i. Watermark and letterhead present
   ii. Account for all consent pages
   iii. Option section(s) completed
   iv. Signature dates congruent
   v. Original signatures in indelible ink
   vi. IRB-approved staff obtained consent
   vii. Watermark valid (not expired)
   viii. Version correct

B. A Comprehensive QMP example:

1. Complete the above items in A. plus review eligibility, adverse events, and protocol adherence for each enrolled subject:
2. Review the eligibility documentation for:
   - Adherence to the approved inclusion/exclusion criteria
   - Investigator signature and date, as applicable
   - Accuracy of eligibility decision, e.g. calculate date of birth for age range noted in protocol (age 14-17), correct and documented diagnosis (uncontrolled seizures minimum of twice daily for previous month), and DrugABC-naïve.
3. Review documentation for the assessment of adverse events, signature of Investigator, and date, as applicable.
   - If present, are the events reviewed by the Investigator?
   - If reportable, have they been reported per IRB policy?
• What follow up was provided to the subject?

4. **Protocol Adherence:**

• Review the 24-hour EEG monitoring for each enrolled subject i.e.: completion, time points, events/findings requiring follow-up, Investigator signature and date.

• Data and Safety Monitoring Committee meeting summary reports should be present in the regulatory file from the biannual review. Best practice: Investigator to sign and date when reviewed.

• Electronic Health Record (EMR): Does the site have IRB-approval to include specific research study components in the EMR? Are the results of research testing, the signed consent form, documentation of study participation, or other approved items in the subject’s EMR?
Scenario #3 – Minimal Risk Research:

Brief Protocol Summary: An Investigator-initiated study examining sleep habits in medical residents. Upon enrollment, all subjects complete a demographic questionnaire, a functional magnetic resonance imaging (fMRI) scan, and undergo an overnight sleep study. Subjects will be notified via email every other month to complete questionnaires and cognitive testing online. Repeat overnight sleep studies will be completed every six months and a repeat fMRI scan will be completed annually. Any study related activity has a +/- 21-day window for completion. Subjects remain enrolled in the research for up to five years or until they complete their medical residency. Final results from the fMRI and overnight sleep studies are reviewed within two weeks by the Investigator; notable results are referred to the subject’s private physician, as appropriate. Approximately 90 subjects are expected to enroll.

A. A Limited Resources QMP example:
   1. Review the regulatory file for completeness once annually with Continuing Review.
   2. Review the signed consent in the first enrolled subject and subsequently every fifth enrolled subject. Review the consent forms for:
      i. Watermark and letterhead present
      ii. Account for all consent pages
      iii. Option section(s) completed
      iv. Signature dates congruent
      v. Original signatures in indelible ink
      vi. IRB-approved staff obtained consent
      vii. Watermark valid (not expired)
      viii. Version correct

B. A Comprehensive QMP example:
   Complete the above items in A, plus review protocol adherence for each enrolled subject.
   Protocol adherence: Review for completeness the demographic questionnaire at screening, the repeat overnight sleep studies every six months, and the repeat fMRI scans annually. Review to confirm the final results from the fMRI and overnight sleep studies are reviewed and any follow-up is initiated within two weeks by the Investigator; best practice, signed and dated by the Investigator/designee. Report adverse/research events and consenting issues to the IRB.
### Risk Assessment Information Graphic Example

<table>
<thead>
<tr>
<th>Issue</th>
<th>LOW RISK</th>
<th>MODERATE RISK</th>
<th>HIGH RISK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Informed Consent Process</td>
<td>The form used to consent the subject was not on letterhead.</td>
<td>A wrong version was used to consent subject(s); version differences are administrative (date change, added a Sub-Investigator name).</td>
<td>A wrong version was used to consent subject(s); multiple invasive procedures were added and blood samples will be saved for genetic testing.</td>
</tr>
<tr>
<td>Eligibility</td>
<td>The Investigator did not confirm eligibility (signed, dated).</td>
<td>The eligibility assessment not documented.</td>
<td>There is no evidence of eligibility assessment, the subject is found to be ineligible, and has taken study drug.</td>
</tr>
<tr>
<td>Protocol Adherence</td>
<td>Data and Safety Monitoring committee meeting minutes were kept electronically but not filed in paper regulatory binder.</td>
<td>Data and Safety Monitoring committee meetings were held; no documentation kept as follow-up.</td>
<td>Adverse Events were not assessed in a drug/device trial.</td>
</tr>
<tr>
<td>Regulatory Documentation example: Appropriate Delegation of Tasks</td>
<td>The Investigator did not date his/her signature when delegating tasks.</td>
<td>A staff member who is not IRB-approved and is trained in human subject protection training consented four subjects.</td>
<td>A staff member who is not IRB-approved and hasn’t taken human subject protection training consented a subject.</td>
</tr>
</tbody>
</table>
### QMP Brainstorming Worksheet

<table>
<thead>
<tr>
<th>Risk Identified</th>
<th>How to Check</th>
<th>What to Check/Review</th>
<th>Tools/Plan</th>
</tr>
</thead>
</table>
| Example: Informed Consent Forms  | • Review the OHSP Policy  
• Review consent form versions and changes in ROSS (i.e. ‘build a timeline’); review approval letters for expectations, including reconsent requirements |                                                                                     | Consider use of the self-audit tool(s) from the OHSP-QI website. |
| Example: Eligibility             | • Read Protocol  
• Extract specifics regarding inclusion and exclusion criteria             | Assess each enrolled subject related to each eligibility criteria.  
Was eligibility confirmed and dated by Study Personnel? Was eligibility reviewed with the Investigator? | Build a checklist/form to conduct this assessment    |