UT Southwestern
Medical Center

Human Research Protection Program
Quality Assurance and Monitoring

HRPP Quality Assurance:
Essential Documentation Practices to Maintain Your Regulatory Binder

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Why is Regulatory Documentation Practice Important?

Importance

- To demonstrate compliance with the investigator and sponsor and monitor the standards of Good Clinical Practice while meeting all applicable regulatory requirements.
- It is crucial to note that non-compliance can lead to significant risks, including fines, reputation damage, or even study shutdown, underscoring the urgency and importance of our compliance efforts.
- The role of appropriate documentation is pivotal in safeguarding the organization from legal repercussions in a data breach.
- Help ensure the safety of the participants who have volunteered to participate in research studies here at UTSW.

During a scheduled Monitoring Visit from the Quality Assurance Team

- Our Monitoring Team reviews all essential documentation to ensure the study is compliant.
- This occurs for both minimal risk and studies that are greater than minimal risk.

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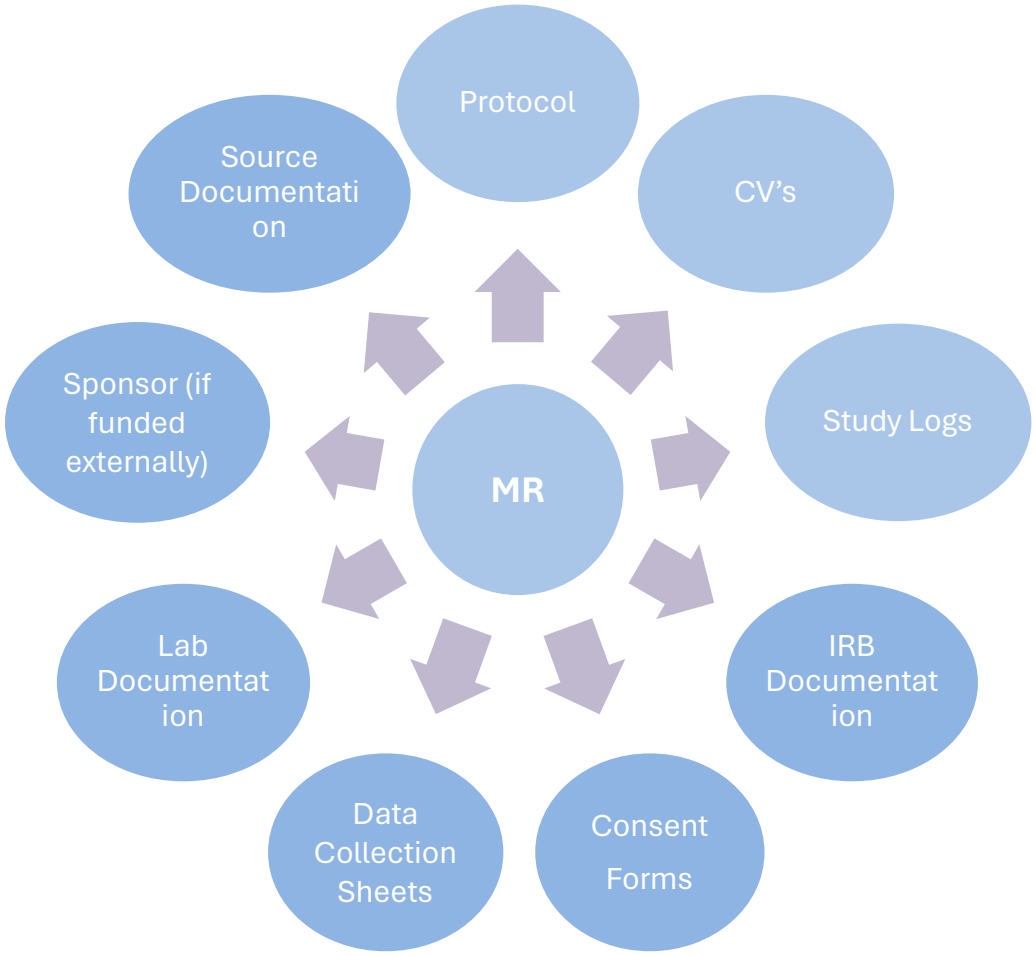
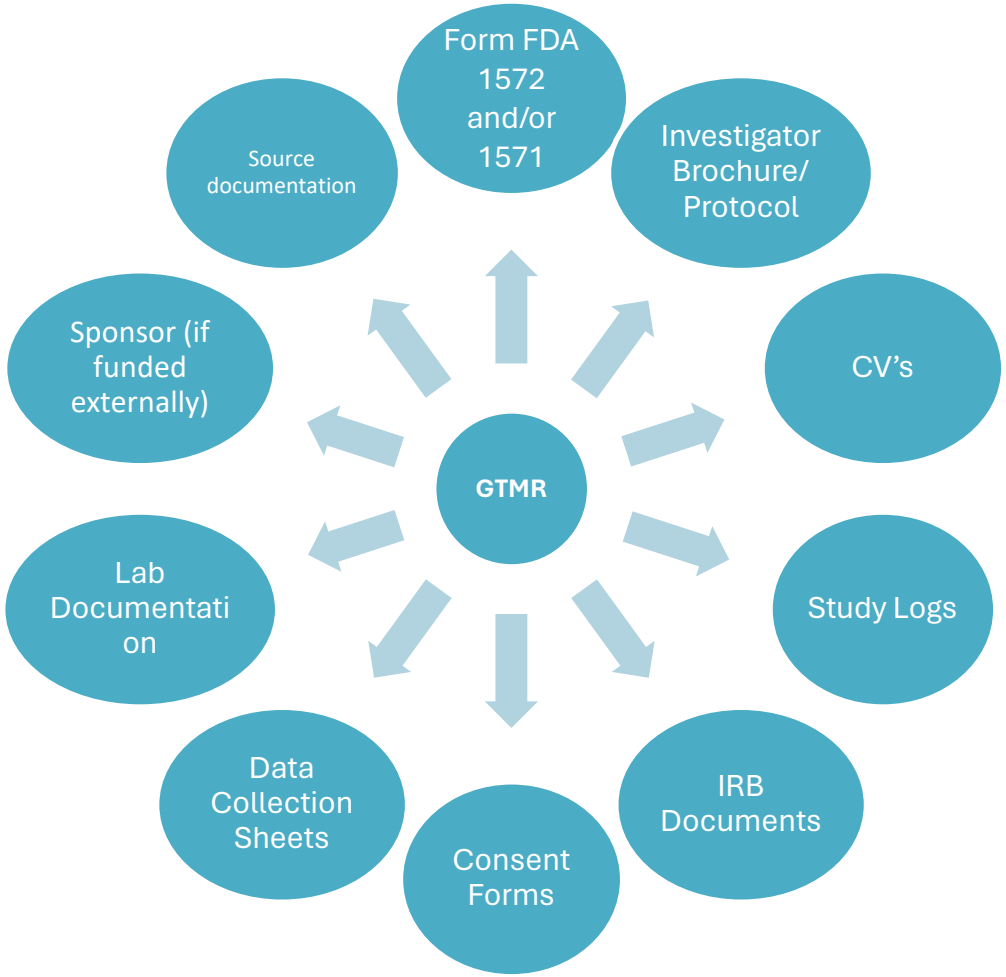
Regulatory Documentation Practice: Risk Determination

Minimal Risk Studies



Greater than Minimal Risk Studies



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Regulatory Documentation Practice: Organization Strategies

Identify key goals to guide the planning of your organization system for your essential documents.

Develop a process that works for your study team so you can adhere to appropriate maintenance of essential documents.

Meet regularly as a study team to discuss essential documents.

Take your time and be intentional with all essential documents.

Contact the QAM team if guidance or join office hours on Tuesday or Thursday to speak to a QAM representative.

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Regulatory Documentation Practice: Essential Documents Checklist

Minimal Risk Studies

I. Regulatory Binder	
Protocol	☐ Current IRB approved protocol and all previous versions
CVs	☐ Signed and dated CVs for all IRB approved study staff
Licensures	☐ Valid medical licenses and/or certifications that confirm staff eligibility to conduct study/perform delegated tasks
Logs	☐ Staff Signature and Delegation of Responsibility Log
	☐ Screening Log *(if pre-screening subjects to determine initial eligibility)*
	☐ Enrollment Log *(if enrolling and consenting subjects)*
	☐ Tissue Log *(if collecting, sharing and/or transferring tissue samples)*
	☐ Protocol Deviation/Exception/Violation Tracking Log
	☐ Adverse Event Log
IRB Documents	☐ Initial IRB Approval
	☐ Initial IRB Submission
	☐ IRB approval letters for all Modifications, Continuing Review and/or Reportable Events filed in the order of review
	☐ Wherever applicable - IRB approved study tools (e.g., survey/questionnaire/recruitment materials/Phone Script)
	☐ IRB notifications and investigator responses to the IRB
Consent Forms	☐ Current IRB approved consent/assent/HIPAA form(s)
	☐ All previous versions of IRB approved consent/assent/HIPAA form(s)
Data Collection Sheets	☐ Template forms used to collect study data (for example - demographic sheet, CRF etc.)
Lab *(if performing Lab procedures/tests)*	☐ Laboratory certification
	☐ Lab Director CV
	☐ Normal lab/reference values
Sponsor *(if funded by an external source)*	☐ Copies of significant correspondences with Sponsor
II. Patient/Subject Binder	
Source Documents	Examples of source documents include but are not limited to:
	☐ Eligibility Checklist *(if enrollment is based on inclusion/exclusion criteria)*
	☐ Signed and dated informed consent/assent/HIPAA form(s)
	☐ Documentation of informed consent process in Epic
	☐ Completed data collection sheets and/or case report forms
	☐ Wherever applicable - Progress Notes/Lab reports/Note to file/Logs/Checklists

Greater than Minimal Risk Studies

I. Regulatory Binder	
Protocol	☒ Current IRB approved protocol and all previous versions
Form FDA 1572 and/or 1571	☐ If under IND, a current signed FDA 1571 ☐ For sponsored studies, a current signed FDA 1572 (PI name should match the 1571/1572 and the protocol)
Investigator Brochure (IB)	☐ Current investigator's brochure and/or package insert and all previous versions
CVs	☒ Signed and dated CVs for all IRB approved study staff
Licensures	☒ Valid medical licenses and/or certifications that confirm staff eligibility to conduct study/perform delegated tasks
Logs	☒ Staff Signature and Delegation of Responsibility Log
	☐ Screening Log *(if pre-screening subjects to determine initial eligibility)*
	☐ Enrollment Log *(if enrolling and consenting subjects)*
	☐ Tissue Log *(if collecting, sharing and/or transferring tissue samples)*
	☒ Protocol Deviation/Exception/Violation Tracking Log
	☐ Adverse Event Log
	☐ Accountability Log for drug/device/combined drug and device studies
	☐ IP handling Log for shipment or transfer of IP/Chain of Custody Forms
IRB Documents	☒ Initial IRB Approval
	☒ Initial IRB Submission
	☒ IRB approval letters for all Modifications, Continuing Review and/or Reportable Events filed in the order of review
	☐ Wherever applicable - IRB approved study tools (e.g., survey/questionnaire/recruitment materials/Phone Script)
	☒ IRB notifications and investigator responses to the IRB
Consent Forms	☒ Current IRB approved consent/assent/HIPAA form(s)
	☒ All previous versions of IRB approved consent/assent/HIPAA form(s)
Data Collection Sheets	☐ Template forms used to collect study data (for example - demographic sheet, CRF etc.)
Lab *(if performing Lab procedures/tests)*	☐ Laboratory certification
	☐ Lab Director CV
	☐ Normal lab/reference values
Sponsor *(if funded by an external source)*	☐ Copies of significant correspondences with Sponsor
Oversight Committee (DSMB, DMC, Safety Officer, etc.)	☐ Progress reports/reviews/recommendations with meeting minutes if available. Any correspondence related to this section
II. Patient/Subject Binder	
Source Documents	Examples of source documents include but are not limited to:
	☐ Eligibility Checklist *(if enrollment is based on inclusion/exclusion criteria)*
	☐ Signed and dated informed consent/assent/HIPAA form(s)
	☐ Documentation of informed consent process in Epic
	☐ Completed data collection sheets and/or case report forms
	☐ Wherever applicable - Progress Notes/Lab reports/Note to file/Logs/Checklists

Regulatory Documentation Practice: eFlorence

According to the Florence regulatory Management System Requirements and Use SOP Revision 2.0.

Section 4.2.1 states “Studies determined to be a Clinical trial per the NIH/OHRP definition outlined in Section 3.0 are required to use the Florence eRegulatory Management System from January 1, 2023.

Sectiom 4.2.2 also states that qualifying studies are required to create and maintain a Study regulatory Folder within the Florence System. All regulatory documentation related to the study should be stored in the Florence eRegulatory Management System and follow the UT Southwestern-mandated Study Regulatory Folder Template as outlined in SOP-FLORENCE-003.

sop-florence-001.pdf (utsouthwestern.net)

Regulatory Documentation Practice: Conclusion

- Essential Documents are a vital piece to the research process.
- There are resources and strategies to help you become efficient in maintaining your regulatory documents.
- If you have questions, join HRPP Office Hours every Tuesday & Thursday from 10:00 a.m.-11:00 am; a representative from the QAM team will be happy to help.

Thank you!