Regulatory Binder Checklist

The purpose of a regulatory binder is to demonstrate compliance with Good Clinical Practice (GCP) and all applicable requirements by organizing study specific essential documents. The Regulatory Binder should be monitored throughout the study and is subject to audit. The storage location needs to be secure and accessible to study staff at all times.

*Use a separate 3-ring binder for the regulatory documents for each study. Use labeled dividers to organize documents by topic and file documents in reverse chronological order. Include only those sections pertinent to your protocol. As appropriate for the study, some documents may be stored electronically. Please include an explanation in the binder indicating where electronic documents can be located.

Tab Number	Title of Document	Purpose
1	Binder Cover to include the PI Name, Protocol Name/ Title, Protocol Number, IRB Number	To provide an introduction
2	Table of contents	To organize the binder so that documents can be found quickly.
3	Study team contact information including 24 hour contact person/number	To provide contact information for all study team members and the sponsor or CRO.
4	Form FDA 1572 for studies involving drugs, vaccines, and biologics. Investigator Agreement, and any updates, for studies involving devices.	To provide information to the sponsor and to obtain investigator's commitment to follow FDA regulations.
5	Delegation of authority (DOA) log	To identify study team members and their roles, responsibilities, signature/initial, and dates worked on the study. Sample available in the HRPP manual.
6	Curriculum vitae, licenses and/or other relevant documents evidencing qualifications of investigator. Minimally, include investigators listed on the 1572 or Investigator Agreement.	To document qualifications and eligibility to conduct trial and/or provide medical supervision of subjects.
7	Financial disclosure forms	To document for the sponsor and TTUHSC El Paso, potential conflicts of interest or lack thereof. If the sponsor or TTUHSC El Paso determines that a COI exists, a management plan must accompany the disclosure forms.
8	Training records • CITI training: Biomedical, COI, CRC • Training on the study and study related activities	To document that all people involved with the clinical trial are adequately trained and informed about the protocol, the investigational product (IP) and their trial-related functions.
9	IRB correspondence and approvals • Initial approval • Continuing review • Amendments • Reportable events • Final study report	To document that the trial has been approved by the IRB. Documents should be filed in reverse chronological order.
10	All versions of the following IRB-approved materials: • Protocol and any amendments • Investigator's brochure or device manual • Informed consent forms • HIPAA authorization • Advertisements • Any other written information that will be	To document that all study materials have been approved by the IRB. To identify the version number and date of document(s). To document that relevant and current scientific information about the IP has been provided to the investigator and IRB. Documents should be filed in reverse chronological order.

	provided to subjects	
11	IRB Membership Rosters	To document IRB compliance with applicable regulatory requirements.
12	Other TTUHSC EP ancillary approvals (e.g., IBC, RDBC, etc.) as well as any hospital approvals	To document required additional reviews, if applicable. To document approval to conduct the study at locations outside of TTUHSC El Paso.
13	Correspondence with the sponsor and contract research organization (CRO), if applicable	To document correspondence with the sponsor and CRO.
14	Sponsor and CRO written requirements and/or updates	To document receipt and review of sponsor requirements.
15	Subject enrollment log	To document chronological enrollment of subjects.
16	Blank case report forms (CRF)	To show all and complete CRF versions.
17	Instructions for handling the investigational product (IP) and trial related materials	To document instructions needed to ensure proper storage, packaging, dispensing, and disposition of the IP.
18	Investigational product accountability • IP shipping records • IP storage conditions • Dispensation to the subjects • Return from the subjects • Return to investigational pharmacy • IP destruction	To document receipt, handling, dispensation, and destruction of IP.
19	Record of retained body fluids/tissue sample, if applicable	To document that the investigator received instructions on how to obtain samples. To document samples obtained.
20	Decoding procedures for blinded study	To document how, in case of an emergency, identity of blinded investigational product can be revealed without breaking the blind for the remaining subjects' treatment
21	Each laboratory/medical/technical support facility documentation • Certifications (IATA/HazMat training) • Accreditation • Licenses • Laboratory Director CV and license	To document competence of facility to perform required test(s) and support reliability of results
22	Normal values range of medical/ laboratory/ technical procedures supporting the study	To document normal values and/or ranges of the tests.
23	External safety letters with documentation of review by the PI	To document receipt of and investigator's review of external adverse events.
24	Protocol deviation log	To document protocol deviations and associated reporting to IRB and/or sponsor.
25	Monitoring visit log and reports	To document site visits by, and findings of, the monitor.
26	Receipts for subject compensation	Reimbursement for study subjects for their time and inconvenience.
27	Note to File	A brief explanation/clarification of an administrative error, discrepancy, or process that has occurred and is being corrected; does not need to be reported as a deviation to the IRB.
28	Research team meeting minutes	To document pertinent discussions of trial related activity and oversight by the principal investigator.