Federal and state regulations, institutional policies, and good clinical and research practices require investigators to keep documents related to human subjects research. The ICH GCP guidelines define Essential Documents as those documents which individually and collectively permit evaluation of the conduct of a research study and the quality of data produced. These documents serve to demonstrate compliance with standards of Good Clinical Practice and with all applicable regulatory requirements.

These documents are stored in what is most commonly referred to as the Regulatory Binder. The term "Regulatory Binder" refers to the place where regulatory documentation related to your study is stored and updated. This place is not necessarily one location or even one "binder". It is important to document the location of these records because the Regulatory Binder is often the first item reviewed during audits and inspections.

This tool was developed to assist investigators and research teams in organizing their documents. It details what documents may be stored in each section of a study specific regulatory binder. As documents are revised or updated, it is important to note that all IRB approved versions must be filed and maintained. Examples of documents with more than one version include the protocol, investigational drug brochure/investigator brochure, consent forms, and recruitment material. It is recommended to store documents in reverse chronological order, with the most current documents first.

This tool is to be used as guidance; research teams are not required to follow the exact grouping or sequence of document. Some of the sections, or documents, are not applicable to all studies. Additionally, investigators may choose to store certain documents in places other than the regulatory binder. Finally, some sponsors, CROs, or federal agencies may require that investigators keep additional documents that are not specifically referenced in this guidance.

Regulatory Binder Section	Regulatory Binder Contents	Applicable Guidance and Regulations
Study Personnel	• Study Team Contact Information • Delegation/Signature Log • Current Curricula vitae (CVs) or Biosketches • Medical Licenses (if applicable) • Documentation of Human Subjects Protection, HIPAA, and GCP training • Form FDA 1572 (If applicable) • Investigator Agreement(s) • Financial Disclosure Information/Forms • Conflict of Interest Management Plans *(if applicable)* • Protocol Training Documentation/Log	*ICH GCP E6 2.7, 2.8, 3.1.2, 4.1.1, 4.1.3, 4.1.5, 4.2.4, 4.9.4, 5.6.3, 5.18.4(b), 5.18.4, 6.1.4 - 6.1.7, 8.2.10, 8.3.5, 8.3.24* *21 CFR 54.4 (b), 312.23, 312.50, 312.53, 312.57(b), 312.64(d), 812.25, 812.40, 812.43, 812.110(d), 812.140(b)(3), 812.150(b)(4)* *45 CFR 164.530(b)(1)* *UW Conflict of Interest Policy* *UW-Madison HIPAA Training* *HRPP Education and Training Policy, HRPP Engagement in Human Participants Research Policy* *HS-IRB KB Doc ID: 18852, HS-IRB KB Doc ID: 19232, HS-IRB KB Doc ID: 19529 ,HS-IRB KB Doc ID: 22595* *UW-Madison Policy 9.1 HIPAA Privacy and Security Training*

Regulatory Binder Section	Regulatory Binder Contents	Applicable Guidance and Regulations
IRB Approvals and Correspondence	• IRB submission and accompanying documents (protocol amendments, continuing reviews, revised consent forms) submitted for approval. • Protocol Version History Log • Study protocol • Study protocol amendments (including protocol clarification letters) • Protocol (or amendment) signature pages • IRB approval/acknowledgement letters (initial review, change of protocol, continuing review submissions, and study closure) • IRB Correspondence (IRB notification of reportable events, responses to reportable events. • Recruitment materials • Case Report Form (CRF) documents or data collection forms • IRB Roster or Compliance Statement • Federal Wide Assurance (FWA) information • Protocol closure report	*ICH GCP E6 1.5, 1.45, 2.6, 3.1.2, 3.1.4, 3.3.6, 3.3.7, 3.3.8(d), 4.4.1, 4.4.3, 4.5.1, 4.5.4, 4.9.4, 4.10.1, 4.10.2, 4.11.1, 4.13, 5.11.1(c), 5.11.2, 5.11.3, 5.17.1, 5.17.2, 5.18.4, 8.2.1, 8.2.2, 8.2.3, 8.2.7, 8.2.8, 8.2.11, 8.2.17, 8.2.19, 8.3.2, 8.3.3, 8.3.4, 8.4.5, 8.4.7* *21 CFR 56.103, 56.107, 56.109 (e&f), 312.23(a)(iv), 312.30, 312.53(c), 312.62(b), 312.64(c), 312.66, 812.35(a), 812.60, 812.140, 812.150* *45 CFR 46.102(g&h), 46.103, 46.107, 46.109(e)* *BIMO Manual Part III C.5, E.2* *HHS Guidance on Continuing Review Section H* *FDA Guidance: IRB Continuing Review after Clinical Investigation Application Section H.1.* *HRPP Engagement in Human Participants Research Policy*
Informed Consent/HIPAA Authorization Forms	• Informed Consent/HIPAA Authorization Version History Log • Approved Informed Consent Document(s) and HIPAA Authorization(s) Subject instructions, subject diaries, and/or information sheets	*ICH GCP 3.1.2, 4.4.1, 4.8.1, 4.8.2, 4.8.5, 4.9.4, 5.11.1(c), 5.18.4(p), 8.2.2, 8.2.3, 8.2.7, 8.3.2, 8.3.3* *21 CFR 56.109* *HS-IRB KB Doc ID: 18671* *UW HIPAA Research Guidance*
Food and Drug Administration (FDA)	• IND/IDE/BLA Application/Submission (including letter of acknowledgment/approval and related FDA correspondence) • IND/IDE/BLA Amendment(s) • IND/IDE/BLA Safety Report(s) • IND/IDE/BLA Annual Report(s) • Correspondence (confirmation letters, inspection correspondence)	*ICH GCP E6 4.10.1, 5.10, 5.11.1(c), 5.17.1, 5.17.2, 5.18.4(l), 8.2.9, 8.3.4, 8.4.7* *21 CFR 312.20(a), 312.22(d), 312.23, 312.30, 312.31, 312.32,312.33, 312.40, 312.53, 312.64, 812.20, 812.35(a), 812.42, 812.150* *BIMO Manual Part III C.2, L* *HS-IRB KB Doc ID: 18324*

Regulatory Binder Section	Regulatory Binder Contents	Applicable Guidance and Regulations
Investigational Product *(as applicable)*	• List of authorized pharmacists/prescribers • CVs of authorized pharmacists/prescribers • Process/procedures for unblinding • Master randomization list (or a description of how and where the list is maintained) • Product receipt/packing invoices • Device Accountability Log/Drug Accountability Log • Instructions for Handling or Use • Investigational Drug Brochure (IDB), Package Insert/Prescribing Information, and/or Investigator Brochure (IB) and/or Device manual (as applicable)	*ICH GCP E6 1.10, 1.48, 2.4, 4.6.3, 4.7, 4.9.1, 5.12.2, 5.13.1, 5.13.2, 5.13.4, 5.14.3, 5.18.4, 8.2.1, 8.2.14, 8.2.15, 8.2.17, 8.2.18, 8.3.1, 8.3.8, 8.3.23, 8.4.1, 8.4.3, 8.4.6* *21 CFR 312.23, 312.55, 312.57, 312.59, 312.60, 312.61, 312.62, 812.5, 812.100, 812.110, 812.140* *BIMO Manual Part III C.3.c, J.1*
Laboratory	• Lab Certifications (CAP & CLIA) • Laboratory normal ranges • CV for lab director (if applicable) • CV for pathologist (if applicable) • Lab kit inventory • Research sample/specimen sampling, handling, labeling, storing, and shipping procedure(s) • Research Sample/Specimen Tracking Log	*ICH GCP E6 4.9.4, 5.18.4(b), 8.2.11, 8.2.12, 8.3.6, 8.3.7, 8.3.25* *BIMO Manual Part III C.4* *UWHC website for lab accreditations* *UWHC Clinical Lab Test Directory*
Equipment	• Temperature Logs • Equipment maintenance and calibration records	*ICH GCP E6 4.2.3, 4.9.4, 5.18.4(b), 8.2.12, 8.3.7*
Communication and Correspondence	• Study related correspondence between the site, sponsor, CRO, etc. • Monitoring Log(s) • Correspondence to/from study monitor • Monitoring Reports (including Study Initiation, IMV and Close-Out) • External site visit/audit related correspondence (FDA, sponsor, third party) • DSMB/DSMC Letters/Reports • Other approvals (Biosafety Committee, Clinical Research Unit, etc) • Miscellaneous (CRF transmittal logs), etc. • Study Newsletters or Notification • Publications, presentations, manuscripts, etc.	*ICH GCP E6 4.1.4, 4.9.4., 5.2.2, 5.18.6, 5.19.3, 8.2.6, 8.2.19, 8.2.20, 8.3.10, 8.3.11, 8.3.17, 8.3.18, 8.4.4, 8.4.5* *21 CFR 312.55, 312.56, 312.64(b), 812.43, 812.140(a)(1), 812.140(b)(1)* *HRPP Review of Data and Safety Monitoring in Research Policy* *HS-IRB KB Doc ID: 19538*

Regulatory Binder Section	Regulatory Binder Contents	Applicable Guidance and Regulations
Study Conduct	• Manual of Procedures/Operations • SAE Reporting Form(s) and Instructions • Completed SAE Reports (or note where they are located) • Adverse Event Tracking Log • Log of unanticipated problems, new information, noncompliance (including protocol deviations, violations, or exceptions) and/or completed reports • Subject Identification Code List • Pre-screening Log • Subject Screening and Enrollment Log • Informed Consent Log • Clinicaltrials.gov and/or Clinical Trials Reporting Program (CTRP) Registration • Documentation of PI Oversight (weekly meeting agendas/sign-in sheets, etc.)	*ICH E2 III* *ICH GCP E6 1.44, 2.6, 3.3.8(c and d), 4.4.1, 4.4.2, 4.5, 4.7, 4.8.11, 4.9.4, 4.10.2, 4.11, 5.13.4, 5.16, 5.17, 5.18.4, 5.23.1, 8.2.17, 8.3.20, 8.3.21, 8.3.22, 8.4.3, 8.4.6* *21 CFR 56.108, 312.32, 312.50, 312.53(c)(1)(vi)(a), 312.60, 312.64(b),312.66, 812.40, 812.46(b), 812.100, 812.110, 812.140, 812.150* *45 CFR 46.103* *BIMO Manual Part III C.6, D.2, D.3, E.3, G* *HRPP Noncompliance Policy* *HRPP Unanticipated Problems Policy* *HRPP Support for Clinical Trials Registration & Results Reporting* *HS-IRB KB Doc ID: 18324* *HS-IRB KB Doc ID: 33303*