Human Research Protections Program (HRPP)
Tip of the Month
April 2025

UNIVERSITY of MARYLAND BALTIMORE

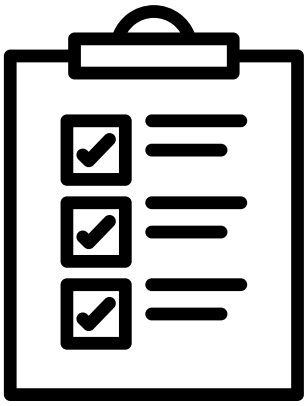
TIPS FOR PREPARING A REGULATORY BINDER

- Regulatory binders are required for all human subject research protocols approved by the Institutional Review Board (IRB), regardless of the risk level.

- Principal investigators (PI) are responsible for maintaining regulatory binder essential documents.

- Per the UMB Investigator Manual and Good Clinical Practice (GCP) (E6) sections 8.1, 8.2, 8.3, 8.4, regulatory binder essential documents demonstrate the compliance of standards of GCP and with all applicable regulatory requirements.

The regulatory binder houses your essential documentation, and includes information such as:



- IRB reviewed materials and approvals
- CVs & Medical Licenses
- Screening and Enrollment Logs
- Delegation Logs
- Study team training documentation
- Study communications
- Agreements
- Eligibility Checklists
- DSMB (Data and Safety Monitoring) and Adverse Events
    - Ensure compliance with the documents required by your sponsor/monitor.

Regulatory binders can be in the form of paper or electronic versions, like Veeva SiteVault https://sites.veeva.com/solutions/eisf/

620 W. LEXINGTON STREET SECOND FLOOR BALTIMORE, MD 21201

620 W. Lexington Street
Second Floor
Baltimore, MD 21201

P 410-706-5037

www.umaryland.edu/hrp/