A. Study Documents	
Tab label	**Documents to include in binder**
1. Protocol and Amendments	Include all versions and amendments
2. Notice of Award	The Notice of Award (NoA) is the official grant award document notifying the grantee and others that a grant has been made.
3. Investigator's Brochure	Include all versions
4. FDA Form 1572	Include a copy of the 1572 form (keep document updated)
5. Statement of Investigator's or Investigator Agreements (Device study only)	This a brief agreement provided by the Sponsor
6. Investigational Product Information Form (Device study only)	Summary document describing the investigational product under study
7. Laboratory documents	Include the CV of the Laboratory Director; CAP and CLIA certificates; the Laboratory license and of the Laboratory Reference Ranges (include updates)
8. Financial Disclosure Forms(s)	Include all signed Financial Disclosure Forms of the Principal Investigator and the Co-investigator
B. Committee Documentation	
1. IRB Approval with Informed Consent and Assent documents (including all amendment)	Include all IRB approval letter(s), informed consent and the assent documents with amendments (if apply)
2. IBC Approval (including all amendment)	Include all IBC approval letters
3. IACUC Approval	Include all IACUC approval letters
C. Study Tracking Logs	
1. Subject Logs:	

• Screening Log	Screening log tracks all potential subjects screened
• Enrollment Log	Enrollment log tracks the progress of each screened subject including ID, date of enrolled, date was consent, date of the first study visit, date of the last study visit
2. Adverse Event Tracking log	Track all reports of adverse events and serious adverse events for site participants sent to the IRB
3. Monitoring Log	This document record all internal and external visits
4. IRB Submission Log	Track all IRB submissions
D. Correspondence	
1. Sponsor	Include all communication with sponsor, such as letters fax, telephone calls, emails, etc.
2. General	Include all communication on study-specific issues with clinical personnel, pharmacy, etc.
E. Study Personnel	
1.Biographical Sketch (Bio Sketch) of Principal Investigator (PI) and Co-Investigator (Co-PI)	Include Biographical sketch for all PI and Co-PI (must be updated) http://grants.nih.gov/grants/forms/biosketch.htm
2. Certifications	Include copy of all your study staff of the Protection of Human Subjects in Research certificate, HIPAA certificate and Good Clinical Practice certificate. Biosafety training certificates and IACUC certificates if applicable (must be updated)
3. Personnel Log	Include task delegated to specific study staff
4. Students' Log	Include task delegated to students' in you study staff
F. If the PI holds an Investigational New Drug (IND) or Investigational Device Exemption (IDE), then additional documentation is required (if applicable)	
1. Form 1571 (IND)	Maintain all versions
2. IND and/or IDE Application	Include application

3. FDA Annual Reports	Maintain copy of all reports sent to FDA
4. IND Safety Reports	Include all safety reports from sponsor. Keep documentation of receipt from the IRB
5. FDA Correspondence	Include communication with FDA