

## REGULATORY BINDER TABLE OF CONTENTS

(All dated items should be sorted in descending order, with most recent on top.)

### **1. Protocol [date]**

- Protocol Signature Page

### **2. IB [date]**

- IB Signature Page(s)
- Investigator's Brochure

### **3. Contract/Financial**

- Clinical Trial Agreement (CTA)
- Confidentiality Agreement (CDA)
- Feasibility Questionnaire

### **4. Statement of Investigator/1572 [date signed]**

- Statement of Investigator (Form 1572)

### **5. Primary Investigator [Primary Investigator Name]**

- CV (signed and dated)
- Financial Disclosure
- Medical License(s)
- DEA License (*if applicable*)

### **6. Sub-Investigator(s): [Sub-Investigator(s) Name]**

- CV (signed and dated)
- Financial Disclosure
- Medical License(s)
- DEA License (*if applicable*)

*\*Each individual listed on the 1572 should have a tab under this section*

### **7. Investigation Drug Services (IDS)/Pharmacy**

- Request for Services
- Intensity Worksheet
- Letter of Approval
- Hospital DEA License (if applicable)
- **[IDS Manager]**
  - CV (signed and dated)
  - Financial Disclosure (*if listed on the 1572*)
  - Pharmacy License

### **8. Laboratory (UNC)**

- **[Laboratory Name]**
  - CLIA Certificate
  - CAP Certificate
  - Relevant Lab Normal Ranges

- **[Director of Laboratory]**
  - CV (signed and dated)
  - Financial Disclosure (*if listed on the 1572*)
  - Medical License
- **[Study Laboratory Name] (*if applicable*)**
  - CLIA Certificate
  - CAP Certificate
  - **[Director of Study Laboratory]**
    - CV (signed and dated)
    - Medical License