

### Regulatory Binder Self-Assessment

Study Title:  
 PI Name:  
 Person Completing:  
 Date of self-assessment:

Depending on the type of study and sponsor, different regulatory documents are required. These sections are consistent with Good Clinical Practice guidelines and FDA regulations. Review your study’s regulatory documentation to complete this section.

#### 1. STUDY DOCUMENTATION FOR ALL STUDIES

|   |   | YES                      | NO                       |
|---|---|--------------------------|--------------------------|
| I.  | Are the most recent versions of the approved protocol, ICF and HIPAA Authorization form on file?  | <input type="checkbox"/> | <input type="checkbox"/> |
|   | Are there previous approved versions of the protocol, ICF or HIPAA?   | <input type="checkbox"/> | <input type="checkbox"/> |
|   | If yes, are they on file?   | <input type="checkbox"/> | <input type="checkbox"/> |
|   | Are the current protocol, ICF and HIPAA Authorization form versions filed separately from retired or approval-pending version(s) of these forms?          | <input type="checkbox"/> | <input type="checkbox"/> |
| II.   | Are there subject screening and/or enrollment logs? (If no, prepare these logs and file.)   | <input type="checkbox"/> | <input type="checkbox"/> |
|   | If yes, are these subject logs up to date?  | <input type="checkbox"/> | <input type="checkbox"/> |
| III.  | Are SOPs applicable to this study on file? (If no, obtain them and file.)   | <input type="checkbox"/> | <input type="checkbox"/> |
|   | Are general SOPs applicable to this study on file? (If no, is there explanation for where these documents are filed?)                                     | <input type="checkbox"/> | <input type="checkbox"/> |
| IV.   | Are there CVs of PI/Co-I and all study staff on file? (If no, obtain and file.)   | <input type="checkbox"/> | <input type="checkbox"/> |
|   | Are CVs reviewed each year and updated when necessary?  | <input type="checkbox"/> | <input type="checkbox"/> |
|   | Are CVs signed and dated to indicate such review and/or updating?   | <input type="checkbox"/> | <input type="checkbox"/> |
|   | Is current licensure for PI/Co-investigators and applicable study staff on file? (If no, obtain and file.)  | <input type="checkbox"/> | <input type="checkbox"/> |
|   | Are current HSP/HIPAA training certificates on file for PI, Co-investigators and all study staff?   | <input type="checkbox"/> | <input type="checkbox"/> |
|   | If CVs, licensure, and training certificates are not on file in this study’s Regulatory Binder, is there explanation for where these documents are filed? | <input type="checkbox"/> | <input type="checkbox"/> |
|   | Are financial disclosure forms (FDA 3454) on file for all applicable study staff?   | <input type="checkbox"/> | <input type="checkbox"/> |
| V.  | Is there a staff signature log? (If no, prepare this log and file.)   | <input type="checkbox"/> | <input type="checkbox"/> |
|   | If yes, is staff signature log up to date?  | <input type="checkbox"/> | <input type="checkbox"/> |
|   | Does the staff signature log include delegation of responsibility?  | <input type="checkbox"/> | <input type="checkbox"/> |
| Please use this space for additional explanation/comments |   |                          |                          |

**2. CORRESPONDENCE FOR ALL STUDIES**

|   |  | YES                      | NO                       |
|---|--|--------------------------|--------------------------|
| I.  | Is <u>all</u> correspondence to and from the IRB on file? (The original submission and all approval letters are particularly important documents.) | <input type="checkbox"/> | <input type="checkbox"/> |
|   | Is all correspondence to and from any Sponsor on file?   | <input type="checkbox"/> | <input type="checkbox"/> |
|   | Is all correspondence to and from any other institutional or regulatory reviewing body on file?  | <input type="checkbox"/> | <input type="checkbox"/> |
|   | Is all relevant correspondence between/among study staff on file?  | <input type="checkbox"/> | <input type="checkbox"/> |
| II.   | Is all correspondence filed in an easily retrievable manner (i.e. in either chronological or reverse-chronological order)?                         | <input type="checkbox"/> | <input type="checkbox"/> |
| III.  | Are all grant or merit review applications and updates on file?  | <input type="checkbox"/> | <input type="checkbox"/> |
| Please use this space for additional explanation/comments |  |                          |                          |

**3. OTHER IRB DOCUMENTATION FOR ALL STUDIES**

|  | Continuing Review   | Date submitted | Date approved | IRB approval letter on file |                          |
|--|---|----------------|---------------|-----------------------------|--------------------------|
|  |   |                |               | YES                         | NO                       |
|  | Number of Continuing Reviews (CR)?  |                |               | <input type="checkbox"/>    | <input type="checkbox"/> |
|  | (If study has not undergone CR to date, you have completed the Regulatory Binder review.)               |                |               | <input type="checkbox"/>    | <input type="checkbox"/> |
|  |   |                |               | <input type="checkbox"/>    | <input type="checkbox"/> |
|  |   |                |               | <input type="checkbox"/>    | <input type="checkbox"/> |
|  |   |                |               | <input type="checkbox"/>    | <input type="checkbox"/> |
|  |   |                |               | YES                         | NO                       |
|  | Was each CR submitted on time? (45 days prior to expiration)  |                |               | <input type="checkbox"/>    | <input type="checkbox"/> |
|  | Was there any lapsed period(s) between expiration date and CR approval date?                            |                |               | <input type="checkbox"/>    | <input type="checkbox"/> |
|  | Was any subject enrolled during this lapse period?  |                |               | <input type="checkbox"/>    | <input type="checkbox"/> |
|  | If yes, was a protocol violation submitted to the IRB?  |                |               | <input type="checkbox"/>    | <input type="checkbox"/> |
|  | Were any study procedures done during the lapse period?   |                |               | <input type="checkbox"/>    | <input type="checkbox"/> |
|  | If yes, were they approved by an IRB Chair?   |                |               | <input type="checkbox"/>    | <input type="checkbox"/> |
|  | Have there been any changes to the study?   |                |               | <input type="checkbox"/>    | <input type="checkbox"/> |
|  | If there have been changes to the study, were the amendments approved by the IRB before implementation? |                |               | <input type="checkbox"/>    | <input type="checkbox"/> |

| Amendments  | Date submitted | Date approved | What was amended? | IRB approval letter on file |                          |
|---|----------------|---------------|-------------------|-----------------------------|--------------------------|
|   |                |               |                   | YES                         | NO                       |
| Number of Amendments: _____                               |                |               |                   | <input type="checkbox"/>    | <input type="checkbox"/> |
|   |                |               |                   | <input type="checkbox"/>    | <input type="checkbox"/> |
|   |                |               |                   | <input type="checkbox"/>    | <input type="checkbox"/> |
|   |                |               |                   | <input type="checkbox"/>    | <input type="checkbox"/> |
|   |                |               |                   | <input type="checkbox"/>    | <input type="checkbox"/> |
|   |                |               |                   | <input type="checkbox"/>    | <input type="checkbox"/> |
| Please use this space for additional explanation/comments |                |               |                   |                             |                          |

**4. FOR CLINICAL STUDIES**

|      |   | YES                      | NO                       |
|------|---|--------------------------|--------------------------|
| I.   | Is this an FDA regulated study? (If no, go to II.)  | <input type="checkbox"/> | <input type="checkbox"/> |
|      | If yes, is there a signed FDA 1572 on file?   | <input type="checkbox"/> | <input type="checkbox"/> |
|      | Is the Clinical Investigator Financial Disclosure form on file for each investigator?                           | <input type="checkbox"/> | <input type="checkbox"/> |
| II.  | Is PI sponsor-investigator (i.e. IND/IDE holder)? (If no, go to III.)   | <input type="checkbox"/> | <input type="checkbox"/> |
|      | If yes, is there a signed FDA 1571 on file (IND only)?  | <input type="checkbox"/> | <input type="checkbox"/> |
|      | If yes, are there 1571s on file for the following:  | <input type="checkbox"/> | <input type="checkbox"/> |
|      | Original application  | <input type="checkbox"/> | <input type="checkbox"/> |
|      | All amendments  | <input type="checkbox"/> | <input type="checkbox"/> |
|      | Annual Reports  | <input type="checkbox"/> | <input type="checkbox"/> |
|      | Who is listed as the monitor in section 14 of the 1571?   | <input type="checkbox"/> | <input type="checkbox"/> |
| III. | Is this an investigational drug or device study? (If no, go to IV.)   | <input type="checkbox"/> | <input type="checkbox"/> |
|      | If yes, are all versions of the Investigator Brochure or Device Manual on file?                                 | <input type="checkbox"/> | <input type="checkbox"/> |
|      | Is there a package insert/product information on file?  | <input type="checkbox"/> | <input type="checkbox"/> |
| IV.  | Is this a drug or device study? (If no, go to V.)   | <input type="checkbox"/> | <input type="checkbox"/> |
|      | Are drug or device shipment, receipt, return, dispensing, and/or destruction records filed?                     | <input type="checkbox"/> | <input type="checkbox"/> |
| V.   | Is there a data safety monitoring plan (DSMP) for this study? (If no, do you have an IRB waiver for this plan?) | <input type="checkbox"/> | <input type="checkbox"/> |
|      | Is indication of DSMP compliance on file?   | <input type="checkbox"/> | <input type="checkbox"/> |
| VI.  | Is there a data safety monitoring board (DSMB) for this study? (If no, go to VII.)                              | <input type="checkbox"/> | <input type="checkbox"/> |
|      | Has the DSMB met in accordance with the IRB approved Protocol?  | <input type="checkbox"/> | <input type="checkbox"/> |

|   |   |                          |                          |
|---|---|--------------------------|--------------------------|
|   | Is DSMB report or indication of DSMB review and recommendations on file?  | <input type="checkbox"/> | <input type="checkbox"/> |
|   | Has DSMB report or review been submitted to the IRB?  | <input type="checkbox"/> | <input type="checkbox"/> |
| VII.  | Are CRFs provided for this study? (If no, go to VIII.)  | <input type="checkbox"/> | <input type="checkbox"/> |
|   | Are CRF samples on file?  | <input type="checkbox"/> | <input type="checkbox"/> |
|   | Is a CRF completion guide on file?  | <input type="checkbox"/> | <input type="checkbox"/> |
| VIII.   | Is study site monitored? (If no, go to IX.)   | <input type="checkbox"/> | <input type="checkbox"/> |
|   | If yes, is there a monitoring log?  | <input type="checkbox"/> | <input type="checkbox"/> |
|   | Is monitoring log up to date?   | <input type="checkbox"/> | <input type="checkbox"/> |
|   | How often is site monitored?  |                          |                          |
| IX.   | Are there adverse event and serious adverse event tracking logs? (If no, prepare these logs and file.)                                      | <input type="checkbox"/> | <input type="checkbox"/> |
|   | Are on-site AEs/SAEs separated from off-site AEs/SAEs? (If no, consideration may need to be given to separation.)                           | <input type="checkbox"/> | <input type="checkbox"/> |
|   | Are IND safety reports on file?   | <input type="checkbox"/> | <input type="checkbox"/> |
|   | Is documentation readily available showing the AE, SAE and/or IND reports have been sent to the IRB? To the Sponsor? Other entities?        | <input type="checkbox"/> | <input type="checkbox"/> |
| X.  | Are lab tests required? (If no, go to 5.)   | <input type="checkbox"/> | <input type="checkbox"/> |
|   | Is a copy of normal lab values on file?   | <input type="checkbox"/> | <input type="checkbox"/> |
|   | Is lab certification on file, (e.g. CLIA)? If this is an IND study, documentation for all laboratories listed on form 1572 must be on file. | <input type="checkbox"/> | <input type="checkbox"/> |
|   | Is the lab director's CV on file?   | <input type="checkbox"/> | <input type="checkbox"/> |
| Please use this space for additional explanation/comments |   |                          |                          |

**5. NON-REGULATORY BINDER ITEMS**

|   |   | YES                      | NO                       |
|---|---|--------------------------|--------------------------|
| I.  | Are there any study financial records in the Regulatory Binder?   | <input type="checkbox"/> | <input type="checkbox"/> |
| II.   | Are there any non-study related personnel records in the Regulatory Binder?   | <input type="checkbox"/> | <input type="checkbox"/> |
| III.  | Are there any auditing reports in the Regulatory Binder?  | <input type="checkbox"/> | <input type="checkbox"/> |
| IV.   | Are there any monitoring reports in the Regulatory Binder?  | <input type="checkbox"/> | <input type="checkbox"/> |
| V.  | Are there any records belonging to other studies in the Regulatory Binder?  | <input type="checkbox"/> | <input type="checkbox"/> |
| VI.   | If answer to any of the questions in section 5 is "yes", remove those items from the Regulatory Binder and file them in another location. |                          |                          |
| Please use this space for additional explanation/comments |   |                          |                          |