SIV CHECKLIST

|  |  |  |  |
| --- | --- | --- | --- |
| **TASK:** | **LOCATION:** | **Yes** | **No** |
| 1572 Completed/Filed\*Please do not punch holes. Place in Plastic Sleeve  | Signed by PI/Given to you in start-up packet |  ⧠ |  ⧠ |
| Financial Disclosure Forms for everyone listed on 1572 Completed and Filed\*Please do not punch holes. Place in Plastic Sleeve | Signed by PI and Sub-I/Given to you in start-up packet |   ⧠ |   ⧠ |
| Current Approved Protocol Printed and Filed with Signed Protocol Signature Page | Signed by PI/ Regulatory Binder Protocol Section |   ⧠ |   ⧠ |
| Current Approve Investigator Brochure Printed and Filed with Signed IB AOR (Acknowledgement of Receipt)  | Signed by PI/ Regulatory Binder IB Section |   ⧠ |   ⧠ |
| Delegation Log Draft | Regulatory Binder |   ⧠ |   ⧠ |
| Study Specific CV templates Filed | Give to you in your start-up packet |   ⧠ |   ⧠ |
| Note To File Stating where to locate GCP/CV/Medical License Information | Qualifications Binder |   ⧠ |   ⧠ |
| Note to File Stating where to locate Lab CAP/CLIA/Medical License of Lab Director/CV of Lab Director/Normal Ranges(note if you had normal ranges provided to you in the start-up packet, these need to go in your reg binder. Leave this off the NTF) | Qualifications Binder |    ⧠ |    ⧠ |
| Study Specific Training for all Staff | Certificates from portals |   ⧠ |   ⧠ |
| IRB Initial Approval/Submission/Consent Filed | eIRB |   ⧠ |   ⧠ |
| IRB Roster | G:Drive:IRB Folder |   ⧠ |   ⧠ |
| IRB Statement of Compliance | G:Drive:IRB Folder |   ⧠ |   ⧠ |
| IRB OHRP Registration | G:Drive:IRB Folder |   ⧠ |   ⧠ |
| IRB Statement on Electronic Signatures | G:Drive:IRB Folder |   ⧠ |   ⧠ |
| IRB Statement on SAE Reporting | G:Drive:IRB Folder |   ⧠ |   ⧠ |
| Email Correspondence about study Printed/Filed | Your Email or provided to you by Manag./Supv. |   ⧠ |   ⧠ |
| Pre Study Visit Confirmation Letter/Follow up Letter Signed by PI/Filed | Forwarded to you by Manag./Supv. |   ⧠ |   ⧠ |
| SIV Confirmation Letter Signed by PI/Filed | Your Email or Forwarded by Manag./Supv. |   ⧠ |   ⧠ |
| Notify Relevant Physician Staff at least 2 days prior to SIV. Remind again the day of |  |   ⧠ |   ⧠ |
| Make a list of received supplies-Alternatively, have all your packing slips filed in the binder and available |  |   ⧠ |   ⧠ |
| Note to File explaining any missing sections even if they are simply Not Applicable Signed/Filed by You |  |   ⧠ |   ⧠ |
| Begin Working On Source Documents for Study | Save to G:Drive |   ⧠ |   ⧠ |