**Research Self-Audit Tool**

# Section 1: Study Staff

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Yes** | **No** | **NA** | **Notes** |
| Are all people working on the study IRB-approved? | [ ]  | [ ]  | [ ]  |  |
| Are there CITI certifications for all members listed on the IRB on file? (Biomedical/Social Behavioral and Good Clinical Practice) | [ ]  | [ ]  | [ ]  |  |
| Are there signed and dated CVs of PI, Co-Is, and all study staff on file? | [ ]  | [ ]  | [ ]  |  |
| Are CVs updated within the past two years? | [ ]  | [ ]  | [ ]  |  |
| Is current valid medical/nursing/etc. licensure on file for all applicable IRB approved staff members for whom licensure is required? | [ ]  | [ ]  | [ ]  |  |
| Is there a delegation of authority log on file?  | [ ]  | [ ]  | [ ]  |  |
| Does the delegation of authority log reflect current and previous IRB-approved staff? | [ ]  | [ ]  | [ ]  |  |
| Is there documented protocol specific training on file for all study members? | [ ]  | [ ]  | [ ]  |  |

# Section 2: IRB Documentation

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Yes** | **No** | **NA** | **Notes** |
| Are all current and previous versions of the IRB-approved protocol on file? | [ ]  | [ ]  | [ ]  |  |
| Is the protocol signature page signed by the principal investigator? | [ ]  | [ ]  | [ ]  |  |
| Are all current and previous versions of the IRB-approved consents on file? | [ ]  | [ ]  | [ ]  |  |
| Are all IRB submissions on file? | [ ]  | [ ]  | [ ]  |  |
| Are all notifications of IRB required modification/deferral or disapproval on file? | [ ]  | [ ]  | [ ]  |  |
| Are all IRB notifications of approval on file? (initial and amendments) | [ ]  | [ ]  | [ ]  |  |
|  | **Yes** | **No** | **NA** | **Notes** |
| Are all adverse event submissions on file and reported appropriately to IRB and/or Sponsor? | [ ]  | [ ]  | [ ]  |  |
| Are all other event submissions on file and reported appropriately to IRB and/or Sponsor? (Protocol deviation, non-compliance, etc.) | [ ]  | [ ]  | [ ]  |  |
| Are there fewer enrolled subjects than the number approved by the IRB? | [ ]  | [ ]  | [ ]  |  |

# Section 3: Subject Recruitment Materials and Procedures

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Yes** | **No** | **NA** | **Notes** |
| Are recruitment methods described in the IRB approved protocol? (If no, skip to next section) | [ ]  | [ ]  | [ ]  |  |
| Is the approved recruitment method being adhered to? | [ ]  | [ ]  | [ ]  |  |
| Have all recruitment materials (e.g. ads and phone scripts) been approved by the IRB? Note: All recruitment materials must be re-approved at the time of continuing review. | [ ]  | [ ]  | [ ]  |  |
| Are all approved recruitment materials (original and all revisions) on file? | [ ]  | [ ]  | [ ]  |  |
| If changes were made to any recruitment materials, were these approved prior to implementation?  | [ ]  | [ ]  | [ ]  |  |

# Section 4: Investigational Products (If Applicable)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Yes** | **No** | **NA** | **Notes** |
| Is an IND being used for this study? | [ ]  | [ ]  | [ ]  |  |
| For IND studies, is there a signed FDA 1572 on file? | [ ]  | [ ]  | [ ]  |  |
| Is an IDE being used for this study? | [ ]  | [ ]  | [ ]  |  |
| For IDE studies, is an Investigator Statement on file for each investigator involved in the study? | [ ]  | [ ]  | [ ]  |  |
| Are all staff listed on the 1572 or who have signed an Investigator Agreement IRB approved? | [ ]  | [ ]  | [ ]  |  |
|  | **Yes** | **No** | **NA** | **Notes** |
| Is a Financial Disclosure form on file for each investigator listed on the 1572 or who have signed an Investigator Agreement?  | [ ]  | [ ]  | [ ]  |  |
| Are all correspondences to and from the sponsor on file? | [ ]  | [ ]  | [ ]  |  |
| Is there a copy of the Investigator Brochure or Device Manual on file? | [ ]  | [ ]  | [ ]  |  |
| If the product is already marketed, is there package insert/product information on file?  | [ ]  | [ ]  | [ ]  |  |
| Is the PI a sponsor-investigator (i.e. IND/IDE holder)? If yes complete Sponsor-Investigator section. | [ ]  | [ ]  | [ ]  |  |

# Section 5: Sponsor-Investigators (PI is IND/IDE Holder)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|   | **Yes** | **No** | **NA** | **Notes** |
| Is there a signed FDA 3674 – Certification of Registration to Clinicaltrials.gov on file (if applicable)?  | [ ]  | [ ]  | [ ]  |  |
| Is the complete IND/IDE application to the FDA on file? | [ ]  | [ ]  | [ ]  |  |
| IND: Is the FDA letter of no objection on file? Please note that the FDA does not always send a letter of no objection for IND studies. If no letter is received, the IND study may start 30 days after it is received by the FDA. | [ ]  | [ ]  | [ ]  |  |
| IDE: Is the FDA approval letter on file? | [ ]  | [ ]  | [ ]  |  |
| Are Amendments to the IND/IDE on file? | [ ]  | [ ]  | [ ]  |  |
| Are annual reports to the IND/IDE on file? | [ ]  | [ ]  | [ ]  |  |
| Are safety reports to the IND/IDE on file? | [ ]  | [ ]  | [ ]  |  |
| Are general correspondences with the FDA on file? | [ ]  | [ ]  | [ ]  |  |
| For IND studies, is there a FDA 1571 on file to accompany all of the above FDA correspondence? | [ ]  | [ ]  | [ ]  |  |
| Has the monitoring plan been followed?  | [ ]  | [ ]  | [ ]  |  |

# Section 6: Drug/Device Dispensing Accountability

|  |
| --- |
| Who is responsible for drug/device accountability?  [ ]  Study Team [ ] Research Pharmacy [ ]  Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [ ]  N/AIf study site is responsible for drug/device accountability, complete the section below. |
|  | **Yes** | **No** | **NA** | **Notes** |
| Is there documentation of investigational product receipt on file? | [ ]  | [ ]  | [ ]  |  |
| Is there documentation of drug/biologic/device use for each subject (e.g. drug accountability log, study file notation)? | [ ]  | [ ]  | [ ]  |  |
| Is there documentation for the return of drug/biologic/device from the subject back to the study site? | [ ]  | [ ]  | [ ]  |  |
| Is there documentation for the return (back to drug sponsor/manufacturing company) or destruction of drug/biologic/device? | [ ]  | [ ]  | [ ]  |  |
| Have there been any other events (e.g. drug/biologic dosing errors or device malfunctions to date? | [ ]  | [ ]  | [ ]  |  |
| Have these events been reported to the IRB as unanticipated problems? | [ ]  | [ ]  | [ ]  |  |

# Section 7: Data and Safety Monitoring

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Yes** | **No** | **NA** | **Notes** |
| Is there a Data Safety Monitoring Plan (DSMP) for this study?  | [ ]  | [ ]  | [ ]  |  |
| Has the DSMP been followed in accordance with the IRB approved protocol? | [ ]  | [ ]  | [ ]  |  |
| Is there a Data Safety Monitoring Board (DSMB) for this study? | [ ]  | [ ]  | [ ]  |  |
| Have all DSMB reports been submitted to the IRB? | [ ]  | [ ]  | [ ]  |  |

# Section 8: Screening

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Yes** | **No** | **NA** | **Notes** |
| Is there an eligibility checklist containing inclusion/exclusion criterion for all enrolled subjects?  | [ ]  | [ ]  | [ ]  |  |
| Is there source documentation to verify inclusion/exclusion criteria? | [ ]  | [ ]  | [ ]  |  |
| Does the eligibility criteria checklist for each subject include dated signature/initials of the person obtaining the information? | [ ]  | [ ]  | [ ]  |  |
| For any enrolled subjects that did not meet eligibility criteria, was a request for a protocol exception submitted to the IRB prior to enrollment? | [ ]  | [ ]  | [ ]  |  |
| Was identifiable information destroyed for screen-failures? Unless authorization obtained to keep the subject’s identifiable information. | [ ]  | [ ]  | [ ]  |  |

# Section 9: Informed Consent Process

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Yes** | **No** | **NA** | **Notes** |
| Was informed consent/assent/HIPAA obtained from each subject prior to the start of any study procedure(s), including screening procedures to determine eligibility? | [ ]  | [ ]  | [ ]  |  |
| Is there written documentation of the informed consent process for all enrolled subjects? (consent notes) | [ ]  | [ ]  | [ ]  |  |
| Were all optional sections of the consent completed? | [ ]  | [ ]  | [ ]  |  |
| If wards of the state enrolled, was appropriate process to obtained informed consent followed? | [ ]  | [ ]  | [ ]  |  |
| If non-English speaking subjects were enrolled, was the IRB-approved process for enrolling non-English subjects followed? (translated consent/short form) | [ ]  | [ ]  | [ ]  |  |
| Are the translated consents and/or short forms approved by the IRB?  | [ ]  | [ ]  | [ ]  |  |
|  | **Yes** | **No** | **NA** | **Notes** |
| Was the consent process conducted in adherence with the IRB-approved protocol? | [ ]  | [ ]  | [ ]  |  |
| Is the enrollment log updated to reflect consented subjects? | [ ]  | [ ]  | [ ]  |  |

# Section 10: Data Collection & Source Documents

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Yes** | **No** | **NA** | **Notes** |
| Is data collection complete/accurate for each subject (e.g. no blank fields/missing data)? | [ ]  | [ ]  | [ ]  |  |
| Is source documentation available to support data entry for each subject?  | [ ]  | [ ]  | [ ]  |  |
| Does the source documentation/CRF for each subject include dated signature/initials of the person obtaining the information for each subject? | [ ]  | [ ]  | [ ]  |  |
| Are changes/cross-outs, additional comments (if any) in subject files routinely initialed and dated? | [ ]  | [ ]  | [ ]  |  |
| For any changes/cross-outs being made, is the original entry still legible? Use of white-out or pencil erased entries is not acceptable | [ ]  | [ ]  | [ ]  |  |