QA/QI Self-Assessment Tool

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study Title: |  | IRB#: |  | |
| PI Name: |  | Review Date: | |  |

Please use this QA/QI Self-Assessment Tool as a starting point for a Good Clinical Practice (GCP) self-review of your study files. Consider customizing this format so that it is study specific.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **General - Binder Formatting/Set-up** | | | | | |
|  | | **Yes** | **No** | **N/A** | **Comments** |
| Does the study file include appropriate identification such as: study site, PI name, study location(s), Protocol Number and title, etc. | |  |  |  |  |
| Are the documents maintained in a secure location? | |  |  |  |  |
| Has access to the documentation been limited to IRB approved study personnel? | |  |  |  |  |
| **Current Protocol and/or Amendments** | | | | | |
|  | | **Yes** | **No** | **N/A** | **Comments** |
| A current and IRB-approved copy of the Protocol is on file. | |  |  |  |  |
| All previous versions of the Protocol are on file. | |  |  |  |  |
| Signed versions of the protocol signature page are available for each version of the Protocol. | |  |  |  |  |
| **Current Investigator Brochure/Package Insert** | | | | | |
|  | | **Yes** | **No** | **N/A** | **Comments** |
| A current and IRB approved copy of the IB is on file. | |  |  |  |  |
| All previous versions of the IB are on file. | |  |  |  |  |
| A current and IRB approved copy of the Packaging Insert is on file. | |  |  |  |  |
| All previous versions of the packaging insert are on file. | |  |  |  |  |
| **IND Safety Reports** | | | | | |
|  | | **Yes** | **No** | **N/A** | **Comments** |
| The IRB AE Policy/Reporting guideline is available. | |  |  |  |  |
| An IND safety report log is included in the file. | |  |  |  |  |
| Is the log maintained/current? | |  |  |  |  |
| Are copies of all IND Safety Reports are present? | |  |  |  |  |
| Have IND safety reports been reviewed by the PI? | |  |  |  |  |
| Are completed Memo to Investigator/safety reports available? | |  |  |  |  |
| Have non-prompt safety reports been reported to the IRB as required? | |  |  |  |  |
| Have prompt safety reports been reported to the IRB as required? | |  |  |  |  |
| **Data Safety Monitoring** | | | | | |
|  | | **Yes** | **No** | **N/A** | **Comments** |
| Is the study reviewed by a Data Safety Monitoring Board (DSMB)? | |  |  |  |  |
| Are (DSMB) reports available and current? | |  |  |  |  |
| **Sponsor Regulatory Packet** | | | | | |
|  | | **Yes** | **No** | **N/A** | **Comments** |
| A current Investigator of Record Agreement (IOR) or a 1572 (for IND studies) is present and complete. | |  |  |  |  |
| All previous versions of the IOR or 1572 are on file. | |  |  |  |  |
| All versions of the affiliation page are on file. (if applicable) | |  |  |  |  |
| A CV, Med Lic log is on file. | |  |  |  |  |
| Is the log maintained/current? | |  |  |  |  |
| Current signed/dated CVs are present for the Principal Investigator and all sub-investigators listed on the IOR/1572.  Basic requirements of the CV include current work address, professional title, degrees, and current relevant licensure. | |  |  |  |  |
| Appropriate licenses (medical, nursing etc.) are present and current for Principal Investigator and all sub-investigators listed on the 1572/IOR. | |  |  |  |  |
| Current signed/dated CVs are present for all other IRB approved study personnel. | |  |  |  |  |
| Appropriate licenses (medical, nursing etc.) are present and current for all other IRB approved study personnel. | |  |  |  |  |
| Financial disclosure forms for all study team members are available (if applicable). | |  |  |  |  |
| Documentation of Human Subjects Protection (HSP) Training for all study personnel is on file. | |  |  |  |  |
| Documentation of Good Clinical Practice (GCP) Training for all study personnel is on file. | |  |  |  |  |
| **IRB Approved Combined Consent and Authorization Forms** | | | | | |
|  | | **Yes** | **No** | **N/A** | **Comments** |
| A current and IRB-approved copy of the Consent Document is on file. | |  |  |  |  |
| All previous versions of the Consent Document are on file. | |  |  |  |  |
| Any lapses have been documented properly. | |  |  |  |  |
| Have expired versions of the consent/assent documents been obsoleted? | |  |  |  |  |
| **IRB Correspondence/Approvals** | | | | | |
|  | | **Yes** | **No** | **N/A** | **Comments** |
| A copy of the IRB statement of compliance is available. | |  |  |  |  |
| A copy of the IRB roster is available. | |  |  |  |  |
| For study personnel who are IRB members, is there a letter on file indicating they will abstain from voting on the study when it is reviewed? | |  |  |  |  |
| An IRB log is included in the file. | |  |  |  |  |
| Is the log maintained and current? | |  |  |  |  |
| Copies of all IRB submissions are included in the file | |  |  |  |  |
| Copies of all IRB approvals are included in the file. | |  |  |  |  |
| Any lapses have been documented properly. | |  |  |  |  |
| IRB correspondence is included in the file, when appropriate | |  |  |  |  |
| **Screening and Enrollment Logs** | | | | | |
|  | | **Yes** | **No** | **N/A** | **Comments** |
| A cross-reference for the location of the ID Code List is included in the file. | |  |  |  |  |
| **Study Personnel** | | | | | |
|  | | **Yes** | **No** | **N/A** | **Comments** |
| A Delegation of Authority Log is included in the file. | |  |  |  |  |
| Is the log maintained and current? | |  |  |  |  |
| Documentation of study-specific training for all relevant personnel is present and complete. | |  |  |  |  |
| **Notes to File** | | | | | |
|  | | **Yes** | **No** | **N/A** | **Comments** |
| Relevant study-specific notes to file/memos are included in the file. | |  |  |  |  |
| **Monitoring** | | | | | |
|  | | **Yes** | **No** | **N/A** | **Comments** |
| A monitoring log is included in the file. | |  |  |  |  |
| Is the log maintained and current? | |  |  |  |  |
| All monitoring reports/correspondence are on file. | |  |  |  |  |
| **Sponsor Correspondence** | | | | | |
|  | | **Yes** | **No** | **N/A** | **Comments** |
| Documentation of correspondence between the site and sponsor is present and current. | |  |  |  |  |
| **Clinical Laboratory** | | | | | |
|  | | **Yes** | **No** | **N/A** | **Comments** |
| This study includes lab tests. | |  |  |  |  |
| Normal Ranges for all protocol-required tests are available. | |  |  |  |  |
| A copy of the lab certification (CAP/CLIA) for each lab being used is on file. | |  |  |  |  |
| Are the certifications current? | |  |  |  |  |
| Are there certificates of qualification for collaborating labs on file? | |  |  |  |  |
| If there are no certificates of qualification, is a statement included explaining the reason and a description of the standard being used? | |  |  |  |  |
| Standard Operating Procedures (SOP’S) for study-specific procedures or the Manual of Procedures (MOP) are present and clearly identifiable as current or historical. | |  |  |  |  |
| Documentation of calibration is present, if applicable. | |  |  |  |  |
| **Investigational Product Accountability** | | | | | |
|  | | **Yes** | **No** | **N/A** | **Comments** |
| This study includes an investigational product | |  |  |  |  |
| This study uses the Investigational Drug Service (IDS) | |  |  |  |  |
| An investigational product accountability log is included in the file | |  |  |  |  |
| Is the log maintained and current? | |  |  |  |  |
| Instructions (protocol-specific MOP) for the storage, mixing, and handling of Investigational Product are present, or their location is specified and easily accessible. | |  |  |  |  |
| Shipping records for Investigational Product documenting the receipt date, quantity, and lot numbers of all test articles (if open-label study) are present and current. | |  |  |  |  |
| Randomization list and decoding procedures for Blinded Investigational Product are present. | |  |  |  |  |
| Investigational Product Temperature Logs are present, or their location is specified and easily accessible. | |  |  |  |  |
| **Other UK Regulatory Committees** | | | | | |
|  | | **Yes** | **No** | **N/A** | **Comments** |
| VA IRB review/approval was completed, is current and on file. | |  |  |  |  |
| Institutional Biosafety Committee (IBC) review/approval was completed, is current and on file. | |  |  |  |  |
| Markey Cancer Center (MCC) Protocol Review Committee (PRC) review/approval was completed, is current and on file. | |  |  |  |  |
| Non-Indemnification Committee (NIC) review was completed, the approval is on file. | |  |  |  |  |
| Insurance analysis review/approval was completed, is current and on file. | |  |  |  |  |
| Any additional local, state, and/or special authorizations related to the protocol are maintained and up-to-date. | |  |  |  |  |
| **Plan code** | | | | | |
|  | | **Yes** | **No** | **N/A** | **Comments** |
| A plan code is needed for this study. | |  |  |  |  |
| A plan code has been requested and received for this study. | |  |  |  |  |
| **Clinical Trials Registration** | | | | | |
|  | | **Yes** | **No** | **N/A** | **Comments** |
| This study qualifies for registration on clintrials.gov | |  |  |  |  |
| The study has been registered on Clintrials.gov | |  |  |  |  |
| Documentation that the study is exempt from clinicaltrials.gov registration is included in the study file. | |  |  |  |  |
| **Certificate of Confidentiality** | | | | | |
|  | | **Yes** | **No** | **N/A** | **Comments** |
| This study qualifies for a certificate of confidentiality | |  |  |  |  |
| The certificate is current and on file | |  |  |  |  |
| **Study Enrollment -Participant recruitment** | | | | | |
|  | | **Yes** | **No** | **N/A** | **Comments** |
| Are potential participants identified using the procedures as described in the IRB approved protocol? (i.e. , checklist) | |  |  |  |  |
| Is initial contact made with potential participants according to the IRB approved procedures? | |  |  |  |  |
| Are the original and all revisions of recruitment materials submitted to the IRB on file?  (i.e., advertisements, flyers, web posting, letters, other) | |  |  |  |  |
| **Study Enrollment - Participant ID Code List** | | | | | |
|  | | **Yes** | **No** | **N/A** | **Comments** |
| The Participant Code List for the study is present. | |  |  |  |  |
| Is the list maintained and current? | |  |  |  |  |
| Has the Code list been maintained in a secure location? | |  |  |  |  |
| Is this location separate from where source documents and participant identifiers are maintained? | |  |  |  |  |
| Has access to the list been limited to IRB approved study personnel? | |  |  |  |  |
| **Study Enrollment – Informed Consent/Assent Form(s) and Process** | | | | | |
|  | | **Yes** | **No** | **N/A** | **Comments** |
| Informed consent/assent was obtained from each participant according to the IRB approved protocol. | |  |  |  |  |
| A consenting checklist was used. | |  |  |  |  |
| A complete, original, fully signed and dated consent/assent form is on file for each participant consented. | |  |  |  |  |
| Yes/No or tiering options on the consent form are complete or correctly marked for all participants (if applicable). | |  |  |  |  |
| Was the consent/assent form signed and dated prior to implementation of screening/protocol-specific procedures? | |  |  |  |  |
| The study team member consenting the participant has been IRB approved to consent participants. | |  |  |  |  |
| The dates for the participant, witness and the investigator (when required) who signed the consent form are consistent. | |  |  |  |  |
| In the case of non-English speaking participants, was an IRB approved consent form provided in the participant’s native language? | |  |  |  |  |
| In the case of Illiterate participant(s), was the Informed consent provided orally to the participant, parent/guardian and/or legally authorized representative? (if applicable) | |  |  |  |  |
| Was a witness present for the oral presentation? | |  |  |  |  |
| Has this process been documented in the study file? | |  |  |  |  |
| A consenting note was included in the file. | |  |  |  |  |
| Is the consent/assent form free of any changes or handwritten corrections? | |  |  |  |  |
| Informed Consent deviations have been appropriately documented, reported and filed. (if applicable) | |  |  |  |  |
| **Eligibility Criteria – Inclusion/Exclusion Criteria** | | | | | |
|  | | **Yes** | **No** | **N/A** | **Comments** |
| Documentation of eligibility criteria review (inclusion/exclusion checklist, chart note) has been included in the participant files. | |  |  |  |  |
| Does the checklist/chart note include the statement that the participant meets the criteria? | |  |  |  |  |
| Has the chart note or eligibility checklist been completed and signed by the person obtaining the information | |  |  |  |  |
| The eligibility checklist is free of any changes or handwritten corrections. | |  |  |  |  |
| **Eligibility Criteria -Screen Failure** | | | | | |
|  | | **Yes** | **No** | **N/A** | **Comments** |
| A participant screening log is included in the study file | |  |  |  |  |
| Is the log maintained and current? | |  |  |  |  |
| If participant was a screen failure, or did not participate in/complete study, has it been properly documented? (log, NTF, etc.) | |  |  |  |  |
| **Study Enrollment** | | | | | |
|  | | **Yes** | **No** | **N/A** | **Comments** |
| A participant enrollment log is included in the study file | |  |  |  |  |
| Is the log maintained and current? | |  |  |  |  |
| If a participant withdrew, or did not participate in/complete study, has it been properly documented (log, NTF, etc.) and included in the participant’s study file? | |  |  |  |  |
| Has the total number of participants enrolled exceeded the approved estimate for number of participants to be enrolled by completion of the study? | |  |  |  |  |
| **Investigational Product - Concomitant Medication** | | | | | |
|  | | **Yes** | **No** | **N/A** | **Comments** |
| Are Concomitant medications documented? | |  |  |  |  |
| Is documentation complete with start/stop times and consistent with protocol? | |  |  |  |  |
| Is the participant taking any prohibited medications? | |  |  |  |  |
| If yes, was this finding documented and the PI notified? | |  |  |  |  |
| **Investigational Product - Receipt/Storage** | | | | | |
|  | | **Yes** | **No** | **N/A** | **Comments** |
| This study includes administration of an investigational product. | |  |  |  |  |
| The Investigational Drug Service (IDS) is being used for investigational product dispensing. | |  |  |  |  |
| A sample investigational product label is on file. | |  |  |  |  |
| A log of all investigational product shipping and receiving records is included in the study files. *Note: log should include receipt date, quantity and lot numbers* | |  |  |  |  |
| Is the log maintained and current? | |  |  |  |  |
| Do the accountability records agree with the actual inventory on hand? | |  |  |  |  |
| There are guidelines in place for drug/device storage in accordance with applicable regulatory requirements. | |  |  |  |  |
| Investigational product temperature logs are available. | |  |  |  |  |
| Instructions (i.e., protocol-specific MOP) for the storage, mixing, and handling of investigational product are easily accessible and on file. | |  |  |  |  |
| Disposition of used and unused study product is captured on the accountability logs? | |  |  |  |  |
| Drug return or drug destruction is documented and on file. | |  |  |  |  |
| **Study Product - Administration and Documentation** | | | | | |
|  | | **Yes** | **No** | **N/A** | **Comments** |
| There is a log for dispensing and retrieving the investigational product (IP) to and from each participant | |  |  |  |  |
| Is the log maintained and current? | |  |  |  |  |
| Documentation is present describing the IP administration (according to the current version of the protocol and MOP). | |  |  |  |  |
| The IP administrator is IRB approved. | |  |  |  |  |
| IP administration start and stop times have been recorded at appropriate timeframes with appropriate follow-up and documentation? (if applicable) | |  |  |  |  |
| The randomization list and corresponding decoding procedures are included in the study file. | |  |  |  |  |
| Deviations (dosing, vaccination, administration or blinding) have been identified, documented on a Protocol Deviation Form and included in the participant file. | |  |  |  |  |
| **Adverse Event (AE) and Serious Adverse Event (SAE) Identification and Reporting** | | | | | |
|  | | **Yes** | **No** | **N/A** | **Comments** |
| An Adverse event reporting log has been included in the study files | |  |  |  |  |
| Is the log maintained and current? | |  |  |  |  |
| Are all adverse events and/or laboratory abnormalities found in the participant chart identified, recorded and reported per policy? | |  |  |  |  |
| Are all adverse events assessed for clinical significance and/or severity, and relationship to the study product and documented in the source documents? | |  |  |  |  |
| Were all adverse events identified in the protocol as critical to safety evaluations reported according to the protocol and/or MOP within the specific time periods? | |  |  |  |  |
| Were all serious adverse events reported to the local IRB/IEC, as required? | |  |  |  |  |
| Were all adverse events meeting the serious adverse event criteria (see IRB SAE Recording and Reporting Guidelines) reported within the IRB specified timelines of site awareness or as specified by the protocol? | |  |  |  |  |
| Are there any unreported AEs/SAEs ? | |  |  |  |  |
| **Deviations from Protocol - Missed Visits and Missed Tests/procedures** | | | | | |
|  | | **Yes** | **No** | **N/A** | **Comments** |
| Has the participant missed any visits? | |  |  |  |  |
| Were all missed visits and/or out of window visits identified? | |  |  |  |  |
| If yes or no, was the Protocol Deviation Form completed and submitted appropriately? | |  |  |  |  |
| Is there documentation of attempts to contact the participant noted? (i.e. phone call, certified mail, etc.) | |  |  |  |  |
| Was the deviation documented in the source documents? | |  |  |  |  |
| Were all protocol-specific tests and/or procedures completed? | |  |  |  |  |
| If no, have the missed tests/procedures been reported as Protocol Deviations? | |  |  |  |  |
| Was the deviation(s) documented in the source documents? | |  |  |  |  |
| Have all Protocol Deviations, Exceptions and Violations been reported to the IRB? | |  |  |  |  |
|  | |  |  |  |  |
| All Protocol Deviations are present, and all relevant deviations that have been reported to the IRB according to IRB requirements are present. | |  |  |  |  |
| **Endpoints** | | | | | |
|  | | **Yes** | **No** | **N/A** | **Comments** |
| Were applicable study-defined clinical and/or laboratory assessments/endpoints documented in the participant’s source documents and/or an endpoint-specific CRF/eCRF as required by the protocol? | |  |  |  |  |
| **Intervention/Study Discontinuation** | | | | | |
|  | | **Yes** | **No** | **N/A** | **Comments** |
| If the participant withdrew or discontinued study intervention, were protocol-required steps followed? | |  |  |  |  |
| **Documentation Standards - Participant Binder Formatting/Set-up** | | | | | |
|  | | **Yes** | **No** | **N/A** | **Comments** |
| Is a study file/binder available for each participant? | |  |  |  |  |
| Does the study file include appropriate identification such as: study site, PI name, Protocol Number and title, etc. | |  |  |  |  |
| Has the data collected been maintained in a secure location? | |  |  |  |  |
| Has access to the data been limited to IRB approved study personnel? | |  |  |  |  |
| **Documentation Standards - Source Documents** | | | | | |
|  | | **Yes** | **No** | **N/A** | **Comments** |
| Are all source documents labeled with participant ID? | |  |  |  |  |
| Are source documents complete and accurate? | |  |  |  |  |
| Are all entries signed and dated by the person obtaining the information for each participant? | |  |  |  |  |
| Are all handwritten chart notes legible and signed and dated by the responsible credentialed clinician? | |  |  |  |  |
| Do all diagnostic tests ordered have corresponding results in the chart according to the protocol? | |  |  |  |  |
| Are all addenda signed or initialed and dated in present time by the person making the entry ?  Note: Do not alter past-dated addenda. chart notes, progress notes, etc. | |  |  |  |  |
| Are all error corrections clear with a single line drawn through the incorrect information, initialed, dated, and a reason for change (if necessary)?  Note: Never obliterate entries or destroy original documents that require correction. Never use whiteout or pencils. | |  |  |  |  |
| If a participant death was identified; has the incident been documented in the source documents by one of the following:  1. Obituary  2. Autopsy Report  3. Death Certificate  4. Verbal Communication Contact Report  Note: See IRB SAE Recording and Reporting Guidelines | |  |  |  |  |
| Are all documents received from outside facilities to be used as original source documents verified or certified, as indicated by signature and date, as an exact copy having all the same attributes and information as the original?  Note: Documents received via fax are not considered to be original, and must be certified. | |  |  |  |  |
| Are source documents maintained chronologically? | |  |  |  |  |
| **Case Report Form** |  |  |  |  |  |
|  | | **Yes** | **No** | **N/A** | **Comments** |
| If data are captured on paper CRFs, a blank copy of each approved version is present and easily identifiable as current or historical. | |  |  |  |  |
| Are all scheduled CRFs present? | |  |  |  |  |
| Does the data provided in the CRF match the data in the source document(s)? | |  |  |  |  |
| If data was identified as out of range or missing from the CRFs, were corrections made and the CRF resubmitted within the required time frame? | |  |  |  |  |
| Are all protocol-required parameters captured in the CRF/source documents for each participant? | |  |  |  |  |
| Are the CRFs/eCRFs used as source documents signed and dated? | |  |  |  |  |
| Is there documentation (i.e., initials, signature) to show that the data from the source document(s) was recorded in the Case Report Form(s) by IRB approved study personnel? | |  |  |  |  |
| **Laboratory Review - Specimen Collection and Results** | | | | | |
|  | | **Yes** | **No** | **N/A** | **Comments** |
| Does this study include specimen collection? | |  |  |  |  |
| Specimen Tracking Logs or Retention Records are present, or their location is specified and easily accessible. | |  |  |  |  |
| Is there a laboratory manual on file? | |  |  |  |  |
| Do the participant files include documentation that protocol-required specimens were drawn as well as the date of specimen collection. | |  |  |  |  |
| Was confirmation of fasting by the participant, as required by the protocol, documented in the source documents? | |  |  |  |  |
| Were specimens prepared, labeled, and transported properly per the International Air Transport Association (IATA) regulations? | |  |  |  |  |
| Has the person shipping specimens have a current IATA certificate on file? | |  |  |  |  |
| Are temperature logs for stored specimens maintained and current? | |  |  |  |  |
| Are specimen retention records on file? | |  |  |  |  |
| Are shipping documents available, accurate and complete? | |  |  |  |  |
| Are order forms/receipts for supplies available? | |  |  |  |  |
| **Calibration Process** | | | | | |
|  | | **Yes** | **No** | **N/A** | **Comments** |
| Is equipment requiring calibration used for this study? | |  |  |  |  |
| Is a calibration plan or schedule included in the study documents? | |  |  |  |  |
| Are calibration certificates available and current? | |  |  |  |  |
| **Participant Payment** | | | | | |
|  | | **Yes** | **No** | **N/A** | **Comments** |
| Are the participants receiving any rewards for this study? | |  |  |  |  |
| If yes, are there a documented procedures for handling payments to participants, or a payment log? | |  |  |  |  |
| Are the payment procedures adhered to? | |  |  |  |  |
|  |  |  |  |  |  |