Principal Investigator Compliance Assessment (PICA)

Below is a list of questions that may be asked as a part of the Principal Investigator Compliance Assessment (PICA). This list is a tool for teams to understand which questions are included in this REDCap survey. Answers to all questions are in a "Yes/No/N/A" format, with explanations required for N/A responses. Teams should complete the following survey in full to officially submit their PICA forms to OCR Compliance.

Facilities, Equipment and Staff

- Are the facilities and equipment adequate to conduct the study?
- Is there current documentation of PI delegation of research responsibilities i.e., Delegation of Authority Log (DoA Log)?
- Are all study staff only performing tasks for which they are qualified and trained?
- Is protocol training of all personnel properly documented?

Consent/HIPAA Authorization

- Is there documentation that all subjects have provided informed consent and HIPAA authorization prior to start of study procedures?

Study Enrollment/Conduct

- Is there source documentation (EPIC, paper records, etc.) to verify inclusion/exclusion criteria?
- Are all subject eligible for this study?
- Has eligibility been reviewed and documented appropriately by the PI or appropriate designee?
- Are all study procedures being performed per protocol and within the allotted window?
- Are CRFs consistent with source documentation and complete according to GCP guidelines?

Regulatory Binder

- Are all safety reports and any other safety-related study information (i.e. new package insert, label, IB, etc.) filed and submitted to the IRB per IRB policy?
- Are approvals from the IRB, Sponsor or other reviewing entities (i.e. CAMRIS, CTRC, etc.), IDS or others current and on file?
- Are all approved versions of the following study documents on file as applicable? (Protocol and amendments, protocol signature page/investigator's agreement/FDA 1572, HIPAA/ICF and amendments, study approvals, CRF clean copy and completion guidelines, lab manual/IP administration manual, etc.)
- Are all tracking logs complete, accurate and filed with the essential documents?

Investigational Product/Investigational Device (if applicable)

- Is there documentation that the IP has been accounted for according to the following criteria: receipt, dispensation, return, and destruction (including date, amount and batch # for each of these criteria)?
- Are all IP supplies stored in a separate, secured location?
- Is the IP being stored per protocol (i.e. room temperature/refrigerator/freezer)?
- Is there enough IP on hand to sustain study procedures?
- Are certificates of analysis for all IP batches on file?
- Is there documentation that the device has been accounted for according to the following criteria: receipt, use and return (including date, amount and batch # for each of these criteria?
- Are all device supplies stored in a separate, secured location?

- Is the device being stored per protocol (i.e. room temperature/refrigerator/freezer)?
- Are the enough device supplies on hand to sustain study procedures?
- Has the device been maintained/calibrated as required per protocol and manufacturer?

Laboratory/Biological Samples (if applicable)

- Are normal ranges and laboratory certification (CLIA/CAP) current and on file?
- Are there enough lab supplies (i.e. lab tubes) n hand to sustain study procedures?
- Is a specimen log current and on file?
- Are the samples being stored per protocol (i.e. use of refrigerator/freezer)?
- Is there a receipt for each corresponding shipment on file?

Safety Review

- Has every adverse event been assessed and has this assessment been properly documented?
- Have all unexpected problems and adverse events been properly followed-up by the PI or qualified sub-investigator?
- Have all adverse events been reported to the sponsor as per protocol in a timely manner?
- Have all serious and non-serious adverse events that were unexpected AND probably or definitely related been reported to the IRB within 10 business days?
- Has any death occurred on the study that was consider unexpected AND probably or definitely related?
- Were any adverse events classified as possibly, probably or definitely related?
- If so, were these adverse events summarized at continuing review?

Privacy

- Is electronic PHI stored securely?
- Is paper documentation stored securely?
- Is PHI/identifiable data shared securely?

Clinicaltrials.gov (if applicable)

- Is the study an Applicable Clinical Trial (ACT)? If so, the following questions will be asked.
- Has the study been registered on clinicaltrials.gov and updated as necessary?
- When was the record on clinicaltrials.gov last updated?
- Is this trial required to post results in compliance with FDAAA 801?
- Does the study team have a plan to post the results?