**Instructions**

* Use the checklist as guide for assessing the overall conduct of the study activities.
* Not all sections of the checklist may apply to your study.
* Use the Self-Assessment Review Tools in combination with this checklist to help you assess study compliance in the areas of consent documentation and process, inclusion/exclusion criteria adherence, and protocol adherence.
* If using this checklist shows that some deviation has occurred, then follow-up corrective actions will be necessary. Unreported deviations should be submitted to the IRB. Deviation submissions will require the creation of a Corrective Action and Preventative Action (CAPA) Plan to ensure the deviation is corrected and that procedures are in place to prevent it from occurring in the future.
* Once the Self-Assessment Review Checklist has been completed, it is a good idea to share the findings with your entire study team.
* It is important to keep these completed forms as documentation of on-going oversight of your monitoring of the conduct of the study.
* The UA Human Subjects Protection Program is available to discuss your checklist findings with you. Keep the checklist as evidence of your self-assessments which support the overall conduct of the study and the oversight of the PI and study team.
* For on-going tracking of certain study processes such as training of study staff, delegation of study tasks, tracking AEs, etc., you can use customizable forms and templates available on the HSPP website.

**General Information**

|  |  |
| --- | --- |
| **Study Title:** |  |
| **IRB Protocol #:** |  |
| **Initial IRB Approval Date:** |  |
| **Principal Investigator:** |  |
| **Staff Member Completing Self-Assessment:** |  |
| **Self-Assessment Date:** |  |

**Self-Assessment Review Detail**

1. **Research Team Roles and Responsibilities**

|  |  |
| --- | --- |
| Have all key personnel completed Human Subjects Protection training? | ☐ Yes  ☐ No  Comments: |
| Is there documentation of staff training? | ☐ Yes  ☐ No  Comments: |
| Is there documentation of delegation of authority to study staff? | ☐ Yes  ☐ No  Comments: |
| Have tasks been delegated to staff trained and qualified to perform the tasks and are staff doing ONLY the tasks that have been delegated to them? | ☐ Yes  ☐ No  Comments: |
| Do the study files include copies of the CVs for the PI, Co-PIs and study staff? | ☐ Yes  ☐ No  Comments: |
| Are the CVs up to date and signed? | ☐ Yes  ☐ No  Comments: |
| Does the file include copies of medical licenses for study staff (e.g., nurses, MDs, etc.?) | ☐ Yes  ☐ No  Comments: |

1. **Subject Recruiting: Process, Records, and Documentation\***

|  |  |
| --- | --- |
| Are recruitment activities conducted per protocol? | ☐ Yes  ☐ No  Comments: |
| Are screening/enrollment logs complete and up to date? | ☐ Yes  ☐ No  Comments: |
| Are subject withdrawals and dropouts documented? | ☐ Yes  ☐ No  Comments: |
| Are inclusion/exclusion criteria documented and eligibility confirmed prior to the start of study required procedures? | ☐ Yes  ☐ No  Comments: |

**\*To fully assess inclusion/exclusion adherence, please use the Inclusion/Exclusion Adherence Assessment Checklist.**

1. **Informed Consent: Process, Records, and Documentation\***

|  |  |
| --- | --- |
| Is the consent process being implemented per protocol? | ☐ Yes  ☐ No  Comments: |
| Are appropriate personnel conducting the consent process? | ☐ Yes  ☐ No  Comments: |
| Is the consent process adequately documented for each participant in the medical record/research chart? | ☐ Yes  ☐ No  Comments: |
| Is a signed/dated copy of the ICF on file for each person screened/enrolled? | ☐ Yes  ☐ No  Comments: |
| Is the correct ICF version being used for each subject? | ☐ Yes  ☐ No  Comments: |

**\*To fully assess informed consent adherence, please use the Consent Documentation and Process Adherence Assessment Checklist.**

1. **Protocol Adherence\***

|  |  |
| --- | --- |
| Are all study procedures being conducted according to the approved protocol? | ☐ Yes  ☐ No  Comments: |
| Are processes in place for handling protocol non-adherence? | ☐ Yes  ☐ No  Comments: |
| Have all AEs/UPSERS/protocol deviations been documented? | ☐ Yes  ☐ No  Comments: |

**\*To fully assess protocol adherence, please use the Protocol Adherence Assessment Checklist.**

1. **Record Retention and Data Storage**

|  |  |
| --- | --- |
| Is documentation on file for all persons screened/enrolled? | ☐ Yes  ☐ No  Comments: |
| Is access to on-site research records restricted to delegated and trained personnel? | ☐ Yes  ☐ No  Comments: |
| Is access to on-site electronic research data restricted as applicable, to delegated and trained personnel? | ☐ Yes  ☐ No  Comments: |
| Are research records and data used and stored accordingly to the protocol/IRB Application? | ☐ Yes  ☐ No  Comments: |

1. **IRB Post-Approval Communication**

|  |  |
| --- | --- |
| Did any research-specific activities occur prior to IRB approval or during a lapse in IRB approval? | ☐ Yes  ☐ No  Comments: |
| Were all modifications approved by the IRB prior to implementation? | ☐ Yes  ☐ No  Comments: |
| Were there any lapses in IRB approval? | ☐ Yes  ☐ No  Comments: |
| Are Renewals accurate and complete? | ☐ Yes  ☐ No  Comments: |
| Is there a process in place to capture and document all AEs as defined in the protocol? | ☐ Yes  ☐ No  Comments: |
| Were adverse event reports submitted to the IRB/sponsor/funding agency/FDA as required? | ☐ Yes  ☐ No  Comments: |
| If the study uses a DSMB or other independent monitor, have the monitoring reports been submitted to the IRB in a timely manner? | ☐ Yes  ☐ No  Comments: |

1. **Regulatory Files**

|  |  |
| --- | --- |
| Do the study files include copies of all versions of the IRB approved protocols? | ☐ Yes  ☐ No  Comments: |
| Do the study files include documentation on specific assignment of study-related duties to study staff who are qualified by training, experience and credentials to perform those activities (e.g., delegation log)? | ☐ Yes  ☐ No  Comments: |
| Do study files include documentation of specific training of study staff needed to perform the study-related tasks that have been assigned? | ☐ Yes  ☐ No  Comments: |
| Do study files include copies of all IRB correspondence (i.e., e-mail)? | ☐ Yes  ☐ No  Comments: |
| Do study files include all sponsor correspondence (as applicable)? | ☐ Yes  ☐ No  Comments: |
| Do study files include all FDA correspondence (as applicable)? | ☐ Yes  ☐ No  Comments: |
| Are drug/device accountability records complete (as applicable)? | ☐ Yes  ☐ No  Comments: |

1. **Self-Assessment Review Summary:**
2. **Recommendations:**
3. **Overall Summary:**

☐ Satisfactory

☐ Findings – may require reporting to IRB, changes to protocol, CAPA, etc.