Site Checklist for NCCAM Initiation Visit

Scheduling/Logistics
- ❑ Query PI and relevant study staff regarding the monitor's proposed visit dates
- ❑ Confirm mutually-agreeable visit date with the monitor and study staff
- ❑ Reserve meeting room, computer, projector, screen, and teleconference line, as needed
- ❑ Reserve work space for the monitor
- ❑ Provide logistics information to the monitor for first visit day: directions to site/room, time to meet, emergency contact/backup number as requested
  Notes:

Preparing the Agenda
- ❑ Review the draft initiation visit agenda provided by the monitor, and make necessary modifications to reflect the specifics of the protocol and study team
- ❑ Identify and confirm which staff will be presenters and/or facilitators during the meeting
- ❑ Determine a due date for presenters to submit slides, talking points, or handouts, as applicable
- ❑ Finalize the agenda and all presentation materials prior to the visit date
  Notes:

Meeting Materials
- ❑ Identify if meeting materials will be needed for the initiation visit. For example, would meeting participants benefit from a copy of the final protocol, final CRFs, other study-related documents, and/or copies of slides from presenters during the discussion?
- ❑ Determine if meeting materials will be distributed in hardcopy or electronically, and when
- ❑ Prepare and distribute meeting materials per plan
  Notes:

Regulatory/Essential Documents
- ❑ NCCAM approval of protocol, CRFs, ICF, and DSMP
- ❑ File visit confirmation letter in the regulatory binder that was received from the monitor
- ❑ Per the NCCAM regulatory summary sheet and checklist at nccam.nih.gov/grants/toolbox/resources, all required IRB and NCCAM approvals, documents of staff qualification and training, lab certifications, tracking and other logs are complete, up to date, and organized for review
  Notes:

Study Data
- ❑ Confirm that source documents, CRFs, and database are finalized and available for review and discussion
  Notes:

Post-Visit Followup

- ❑ Return completed Action Item – Site Response Form to the monitor within 30 days of receipt, recording resolution of Action Item or plan for resolution if pending
- ❑ File visit report(s) received from the monitor and completed Action Item – Site Response Form in the regulatory binder

Notes: