Site Checklist for NCCAM Interim Visit

Scheduling/Logistics

- ❑ Query PI and relevant study staff (include pharmacy if applicable) regarding the monitor's proposed visit dates
- ❑ Confirm mutually agreeable visit date with the monitor and study staff
- ❑ Confirm pharmacy appointment date and time and communicate to the monitor
- ❑ Reserve work space for the monitor
- ❑ Obtain access to necessary electronic records for the monitor
  ___ If access unavailable, consult with the monitor and print records as agreed
- ❑ Provide logistics information to the monitor for first visit day: directions to site/ room, time to meet, emergency contact/backup number as requested
  Notes:

Regulatory/Essential Documents

- ❑ NCCAM approval of protocol, CRFs, ICF, and DSMP
- ❑ File visit confirmation letter received from the monitor in the regulatory binder
- ❑ 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
- ❑ All ICFs signed to date are complete and on file, and the informed consent process is documented appropriately in participant records
  Notes:

Study Data

- ❑ Provide a current list of enrolled participant ID numbers to the monitor upon request
- ❑ Source documents, CRFs, and database records are complete, up to date, and organized for review
  ___ If entry is not up to date, inform the monitor prior to visit
- ❑ Study data have been reviewed for QC per the QC plan
- ❑ Protocol deviations noted during study conduct or upon QC review and have been logged and reported to the IRB per institutional requirements
  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: