# Site Checklist for NCCIH 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

 NCCIH approval of protocol, CRFs, ICF, and DSMP

 File visit confirmation letter received from the monitor in the regulatory binder

 Per the NCCIH regulatory summary sheet and checklist at [nccih.nih.gov/grants/toolbox/resources](http://nccih.nih.gov/grants/toolbox/resources), all required IRB and NCCIH 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 Follow-up

 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, completed Action Item Site Response Form, and documentation supporting Action Item resolution in the regulatory binder for follow-up at the next monitoring visit

**Notes:**