# Site Checklist for NCCIH 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

 NCCIH approval of protocol, CRFs, ICF, and DSMP

 File visit confirmation letter received from the monitor with the regulatory/essential documents

 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

**Notes:**

## Study Data

 Confirm that source documents, CRFs, and database are finalized and available for review and discussion

**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:**