# Site Checklist for NCCIH Initiation Visit

## Scheduling/Logistics

* Query principal investigator (PI) and relevant study staff (e.g., lead study coordinator, pharmacist, and data manager) regarding the site monitor’s proposed visit dates.
* Confirm mutually agreeable visit date with the site monitor and study staff.

**For on-site visits:**

* Reserve meeting room, computer, projector, screen, and teleconference line, as needed.
* Reserve workspace for the site monitor.
* Confirm pharmacy appointment date and time and communicate to the monitor.
* Provide logistics information to the site monitor for first visit day: directions to site/room, time to meet, emergency contact/backup number as requested.
* Be prepared to provide information to the monitor on how source documents and data will be provided (certified copies, direct access to electronic medical records, etc.).

**For a remote visit:** (preparation time is increased if scanning/uploading documents)

* Confirm the approved web-based portals and communication systems to be utilized.
* Notify the site monitor if research records are not available for remote review.

**Notes:**

## Review and Finalize the Agenda

* Review the draft initiation visit agenda provided by the site monitor, and return suggestions for modifications to ensure specific information about the protocol is discussed with the responsible study staff members.
* Identify and confirm the study staff who will present and/or facilitate 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 case report forms (CRFs), other study-related documents, and/or copies of slides from presenters during the discussion?

 Determine if meeting materials will be available for attendees in hard copy (on-site visits only) or electronically, and when.

* Prepare and distribute meeting materials per plan.

**Notes:**

## Regulatory/Essential Documents

* All essential documents for study. Per Good Clinical Practice (GCP) and National Center for Complementary and Integrative Health (NCCIH) Guidance for Maintaining Regulatory Documents ([nccih.nih.gov/grants/toolbox](https://www.nccih.nih.gov/grants/toolbox)), all required Institutional Review Board (IRB) and NCCIH approvals, documents of staff qualification (i.e., curriculum vitae [CV]) and training), protocols, informed consent forms (ICFs), the Data and Safety Monitoring Plan (DSMP), lab certifications, and tracking and other logs (i.e., delegation) must be complete, up to date, and organized for review.
* File visit confirmation letter received from the site monitor with the regulatory/essential documents.

**Notes:**

## Study Data

* Confirm that the methods for maintaining and filing source documents, CRFs, and the database are finalized and available for review and discussion.
* List of CRFs and electronic case report forms (eCRFs) with data originators, explaining if direct data entry is planned.

**Notes:**

## Post-Visit Follow-up

* Return completed Action Item – Site Response Form to the site monitor within 30 calendar days of receipt, recording resolution of the action item or the plan for resolution if pending.
* File visit report(s) received from the site 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.
* File acceptance of the Action Item – Site Response Form received from the site monitor and documentation supporting all action item resolution.

**Notes:**