# Site Checklist for NCCIH Interim Visit

## Scheduling/Logistics

* Query principal investigator (PI), study coordinator, and other relevant study staff (e.g., pharmacist, if applicable) regarding the monitor’s proposed visit dates.
* Confirm mutually agreeable visit dates with the monitor and study staff.
* Confirm pharmacy appointment date and time and communicate to the monitor.
* Provide the current protocol and list of enrolled participant ID numbers to the monitor upon request.

**For on-site visits**:

* Reserve workspace with internet access for the site monitor.
* Obtain local access to necessary electronic records for the site monitor. If local access to electronic health records or databases is unavailable, consult with the site monitor about printing records requested.
* Provide logistics information to the site monitor: directions to site/room, time to meet, emergency contact/backup number as requested.

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

* Instructions and guidance for remote monitoring, sharing of Protected Health Information (PHI), and creating certified copies will be provided by the site monitor.
* Obtain Institutional Review Board (IRB) approval/acknowledgment for remote monitoring, or provide a copy of a previous approval, to allow access to the electronic health records, database(s), electronic system(s), or web-based portal(s) containing institutional research records and provide it to the site monitor.
* Create or update the site’s standard operating procedure (SOP) for remote monitoring and creating certified copies, which should also specify if the site is allowed to share PHI remotely and provide it to the site monitor.
* If scanning/uploading multiple documents, plan to start about 2–3 days before the scheduled visit date. Reminder: Scanned documents are copies and should be certified by the authorized site staff member making the copy, per the site’s procedures for creating certified copies.
* Notify the site monitor if any research records are not available for remote review.
* Ensure the instructions for accessing the electronic systems, portals, and video conferencing to be utilized are available for all authorized staff and the site monitor.

**Notes:**

## Regulatory/Essential Documents

* All essential documents for the study. Per Good Clinical Practice (GCP) and NCCIH Guidance for Marinating Regulatory Documents ([nccih.nih.gov/grants/toolbox](https://www.nccih.nih.gov/grants/toolbox)), all required 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) are complete, up to date, and organized for review.
* File/save the visit confirmation letter received from the site monitor with regulatory documents.
* All ICFs signed to date are complete and on file, and the informed consent process is documented appropriately in participant records.

**Notes:**

## Participant Record and Study Data

* Ensure the records for the selected participant ID numbers on the confirmation letter are available/provided.
	+ Completed source documents, case report forms (CRFs), and database(s).
	+ Adverse Event (AE), Serious Adverse Event (SAE), and Unanticipated Problems (UP) documentation.
	+ Protocol deviations.
	+ If data entry is not up to date, inform the site monitor prior to visit.
* Study data have been reviewed for quality control (QC) per the QC plan.
* Cumulative protocol deviation and AE/UP Logs noted during study conduct or upon QC review have been reported to the IRB, Data and Safety Monitoring Board (DSMB), and NCCIH, per institutional requirements

**Notes:**

## Pharmacy or Study Agent Management Facility, if Applicable

* Confirm visit logistics with the pharmacist, authorized staff, and site monitor, including informing the site monitor if the pharmacy records requested are not available for any reason.
	+ Staff training records
	+ Pharmacy plan or study agent management SOP
	+ Storage and temperature monitoring
	+ Shipping invoices that correspond to starting balances for each study agent
	+ Updated paper or electronic accountability logs for each study agent, corresponding to the balance remaining after dispensation.
	+ QC and quality assurance (QA) plan and QA/QC logs, including documented issues with storage and dispensing and corrective and preventive action, as applicable
	+ Pharmacy/staff correspondence
	+ Physical inventory

**For remote visits**:

* There are limitations for verifying the physical inventory, but modified remote pharmacy monitoring visits will be considered.

**Notes:**

## Laboratory and Specimen Management, if Applicable

* Laboratory plan or specimen management SOP
* Staff training records
* Specimen tracking log(s) indicating collection, processing, and storage are managed according to protocol
* Refrigerator/freezer temperature logs and equipment maintenance records

**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 action item or 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 resolution of all action items.

**Notes:**