# Site Checklist for NCCIH Closeout Visit

## Scheduling/Logistics

* Query principal investigator (PI), study coordinator, and other relevant study staff (e.g., pharmacist, if applicable) regarding the site monitor’s proposed visit dates.
* Confirm mutually agreeable visit date with the site monitor and study staff.
* Notify the site monitor if study staff are planning to resign or tasked with working on other projects before the scheduled date. It is recommended that site staff begin filing closeout documents if not planning to be available for the closeout visit.
* Confirm pharmacy appointment date and time and communicate to the site monitor.
* Provide the current protocol and final list of enrolled participant ID numbers to the site monitor upon request.
* The site monitor may request additional days to conduct a combined interim/closeout visit if there is a significant amount of research records pending review.
* Provide monitor the address where the visit will be conducted. Site staff will provide the monitor with physical location/address for the offices where the visit will be conducted (location of research records).

**For on-site visits:**

* Reserve workspace with internet access for the site monitor.
* Obtain local access to necessary electronic health records or databases for the site monitor, or consult with the site monitor about providing printed records if direct access is not available.
* 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 to allow access to the electronic health records, database(s), electronic system(s), and/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 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 Maintaining Regulatory Documents ([nccih.nih.gov/grants/toolbox](https://www.nccih.nih.gov/grants/toolbox)), all required IRB and NCCIH approvals, documents of staff qualification (e.g., curriculum vitae [CV]) and training), protocols, informed consent forms (ICFs), the Data Safety and Monitoring Plan (DSMP), lab certifications, and tracking and other logs (drug accountability, delegation log) must be complete, up to date, and organized for review.
* The PI or site staff will submit the closeout report to the IRB either before the closeout visit or shortly after and file the IRB acknowledgment.
* 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

* The site monitor will verify that the records/data for all participant ID numbers have been collected and entered in the database and request estimated date(s) for completing data cleanup activities.

 A progress note or checklist entry is included in each participant chart indicating that the end of study participation was communicated to each participant.

* Case report forms (CRFs) and/or database records are complete, with all data queries resolved (or a timeline for resolution).
* Cumulative Protocol Deviation and Adverse Event/Unexpected Problems logs noted during study conduct or upon quality control (QC) review have been reported to the IRB, Data and Safety Monitoring Board (DSMB), and NCCIH, per institutional requirements.
* Study data have been reviewed for QC per the QC plan.

**Notes:**

## Pharmacy, if Applicable

* Final disposition of study agents is accounted for, and pharmacy documentation is in order (e.g., all accountability and destruction logs, as applicable), and includes remaining physical inventory.
* Remaining study agents are returned/destroyed as outlined in the protocol or agreement with supplier.

**For remote visits:**

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

**Notes:**

## Laboratory and Specimen Managment, if Applicable

* Final disposition of study specimens is accounted for and documentation is in order (e.g., specimen tracking log, shipping and/or destruction records, plans for long-term storage).

**Notes:**

## Archiving Research Records

* File documentation of the physical address and point of contact for the location where research records will be archived (e.g., in PI office, with Iron Mountain).

**Notes:**

## Post-Visit Follow-up

 Return completed Action Item – Site Response Form to the monitor within 30 calendar days of receipt, recording resolution of the 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.
* File acceptance of the Action Item – Site Response Form received from the monitor and documentation supporting all action item resolution.

**Notes:**