# Site Checklist for NCCIH Closeout Visit

## Scheduling/Logistics

 Query PI and relevant study staff (including 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 applicable

 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

 Local IRB has been informed of the study closure, or the timeline to do so in accordance with local IRB reporting requirements

 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

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

**Notes:**

## Study Data

 Provide a current list of enrolled participant ID numbers to the monitor upon request

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

 CRFs and/or database records are complete with all data queries resolved (or a timeline for resolution)

 Study data have been reviewed for QC per the QC plan

**Notes:**

## Pharmacy, if applicable

 All study agents are accounted for and pharmacy documentation is in order

 Remaining study agents are returned/destroyed as outlined in the protocol or agreement with supplier

**Notes:**

## Specimens, if applicable

 All study specimens are accounted for and documentation is in order

**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 in the regulatory binder

**Notes:**