Instructions for completing the NIDA-CTN Interim Monitoring Report

This report should be completed for each interim monitoring visit performed during the course of a trial to document activities performed and findings during the visit, as well as issues discussed and any corrective action required. Upon completion, copies should be distributed to the Site PI, Node PI, the Lead Node, and NIDA.

Note: This report has been formatted into a Form design for ease of electronic completion. This will allow for check boxes to be chosen as well as for text fields to automatically expand and to wrap text.

Page Header - *insert the following information*

Protocol No.: insert the NIDA-CTN-#### protocol number (i.e. NIDA-CTN-0001)

Report Date: MM-DD-YYYY (for example 04-12-2002)

Site Visit Information —*insert the following information*

NIDA-CTN-: insert the remaining 4 digits of the protocol number
Protocol Title: include the full title as listed on the protocol

Node Name: List the full name of the Node
Site ID: List the 6 digit number consisting of the 2 digit node number and the 4 digit site number, ex 130101. List the site name following the site code number.
Visit Date(s): List the date(s) of the visit. ***Note:*** *In the event you are unable to complete all the intended activities of your visit in one day and you choose to complete these activities the next day, you should record the dates appropriately (e.g., April 12-14, 2002). However, if the visit must be extended over long periods of time or if they are non-consecutive business days, they should be treated as separate visits and therefore a separate report should be completed*.

Node PI: List the name of the PI of the Node for which the CTP belongs
Node Protocol PI: List the name of the protocol PI of the node for which the CTP belongs.

Site Monitor: List the name of the Monitor conducting the visit (your name)

Site PI: List the name of the PI, for this protocol, at the CTP for which the visit is being conducted.
Node Protocol Coordinator: List the name of the person who is coordinating the study activities, for this protocol, within the Node the CTP belongs.

Study Type:

The lead node will specify the type of protocol.

Purpose of Monitoring Visit:

Check all sections on the list that apply.

Site Visit Attendees:

List the **name** (and any appropriate degree) of each person who participated in the monitoring visit and their protocol/node role.

Study Status at this Visit:

Check the appropriate box(es).

Completed means that all participants have completed all follow-ups.

In progress means that there are still active participants.

Discontinued means that a site s recruitment was halted before enrollment goals were reached for whatever reason.

*If more than one box is checked or if discontinued is checked, explain in summary.

Participant Enrollment Status:

This is a cumulative listing and should reflect numbers current as of the conclusion of the visit. Listed below are the definitions consistent with the DMAS committee determinations. Since each protocol may not fit within these guidelines, modifications may be required per protocol.

Consented: total number of persons who have signed the consent to be considered for participation

Screened: total number of subjects who have undergone screening to determine their eligibility to participate in the study.

Randomized: total number of eligible (successfully screened) subjects who have gone through the randomization process and have been assigned to receive one of the study interventions.

Active: total number of randomized subjects who are currently receiving the study intervention/treatment for which they were randomized (study medication/placebo or behavior therapy)

F/U: total number of subjects who have completed the active treatment/phase and are currently in or eligible for follow-up assessments.

Completed: total number of subjects who have completed both the treatment phase and follow-up assessments without early withdrawal.

Withdrawn: total number of subjects who discontinue participation after randomization and prior to completing follow-up(s). This section requires two numbers. The first number should indicate the number of subject initiated withdrawals. The second number should indicate the number of investigator initiated withdrawals. Please provide any other details in the summary at the end of the report.

Changes since the last visit:

This section is to capture if there have been any changes in the site address, study team members or their contact numbers. If there are any changes since the last visit, provide the new information in the space provided. Otherwise, select No Changes

Follow up on issues from the previous visit(s):

This section is to record all unresolved issues identified at the last visit. If there were none, select No Issues. Otherwise, record the following for each issue (be sure to number each line sequential for ease of reference):

Issue: provide the description as identified in the last visit report

Date Identified: provide the date of the visit in which this issue was noted

Action to be taken: provide the action to be taken as indicated in a previous report

Resolved?: **Check Yes** , if the issue has been resolved since the last visit. **Check No ,** if the issue is still outstanding. **Note:** *All No /unresolved issues should be noted in the comment sections along with an explanation, next plan of action and expected timeline for resolution.*

Complete the following checklist indicating one of the following choices for each item:

Yes All versions of the following essential documents are present and up-to-date

No All versions are not present — provide explanation in the comments section and any action to be taken

N/A Not Applicable - *this is based on study instructions and will be pre-defined per protocol*

N/R Not Reviewed — *provide explanation in the comments section and indicate when it will be performed*

*Please note that the examples that are included are not an exhaustive list.

I Review of Study Binder/Regulatory Materials

Are current, fully executed versions of the following present in the Study Binder? Expectations of each are described below:

A. Protocol and protocol amendments with corresponding completed signature pages. A copy of the final protocol submitted to the sites IRB and any revised versions or/and amendments should be present. For each protocol and/or amendment a complete signature page should be present as well. The IRB approval letter of this must be included.

B. Protocol SOPs: Detailed written instructions for the protocol. This will include site specific and Lead Node provided SOPs. These may be physically located in separate places at the site, in which case, a notation should be made in the Study Binder as to the location.

C. Sample IRB approved consent forms with IRB date and stamp: Sample of all IRB approved informed Consent Form(s) must be present along with the IRB approval letter. Look for correct version dates and matching IRB approval dates.

D. Sample copies of all protocol CRFs: One complete blank copy of all Case Report Form pages should be kept. If different versions of the same form are used in the study, all versions should be retained, with a notation on any outdated forms indicating that revisions were made.

E. List of CRFs used as Source Documents: A listing indicating which data collections form/fields will be used as source (i.e., the form is used as the recording source of the data).. The lead node should provide a list of which CRF s may be used as source. The site should modify this list for their local requirements.

F. Curriculum vitae / statement of qualifications for protocol staff: A current (i.e. within two years) Curriculum Vitae or other statement of qualifications for protocol staff should be present for all key protocol staff (i.e. for any staff that are listed on your staff log). This should reflect their current affiliation.

G. Copies of licenses / certifications for protocol staff: Copies of current licenses and/or certifications (e.g. M.D., R.N., MSW.) for professional staff involved with the protocol should be on file. Expired licenses should remain in the binder to show currency.

H. Documentation of required CTN training for protocol staff: Evidence of CTN required training should be present for all protocol staff as related to their responsibilities on the project. For example all staff should have GRP and protocol training. Those providing ASI should have ASI documentation, etc.

I. Investigator s Brochure for all investigational products:
*Applicable to pharmaceutical trials only — Investigator Brochure (for investigational products) or the package insert (for approved products) should be present. Assure that the most current copy is present. Outdated copies must also be retained.

J. FDA 1572 / Statement of Investigator Obligations: A completed current copy of the Form FDA 1572 should be on file (if conducted under an IND). A copy of the completed, signed FDA Form should be kept in the Study Binder. As updates are made, copies should be retained to provide an audit trail of changes. Behavioral studies and pharmaceutical studies not conducted under an IND only require a protocol signature page.

K. Documentation of IRB approval of any study related materials: This section should initially contain the Study Approval Letter, also approving the ICF. A copy of the approved advertisements and/or patient materials should be kept in this section. If local IRB requires approval stamp, please verify if present.

L. Appropriate lab certifications and normal ranges: Laboratory Certification and Normal Ranges should be on file as appropriate for protocol requirements for Laboratory Values (to be collected in the specific protocol). As certificates are renewed or normal ranges are updated, notification of out dated information should be indicated and retained along with new copies. Panic values should be defined as well as the procedures for how to handle them.
Note: CLIA Certification as required should be included.

M. IRB Assurance and IRB membership: A copy of the sites assurance must be present - FWA (Federal Wide Assurance) or MPA (Multiple Project Assurance) or CPA (Cooperative Project Assurance). Along with the membership list or appropriate membership composition/documentation.

N. DEA certification: (Applicable for pharmaceutical trials involving a controlled substance.) A copy of a current DEA License should be present. Note: each state may have unique requirements which must be complied with (e.g. a Research DEA License may be required in addition to a regular DEA License). The address of the certification needs to match the address of the drug shipment. Expired licenses should also be present.

II Site/Other

A. Are all required items/documents present? This refers to both CTN, Node and protocol-required items/documents. Refer to the Study Binder Table of Contents and Protocol Readiness Assessment checklist for a review of these.

Yes If all documents required to be present at the site are present. The answer would still be Yes if there was a change in these items/documents, if there is documentation accompanying whatever items have been changed as to the reason, date, and who authorized the change.

No If any items are missing and such documentation is not present.

N/R If this was not reviewed during this visit.

B. Are all equipment / supplies vital to the conduct of the protocol being maintained appropriately?

The guidelines for answering this are the same as in A. Please comment on equipment and procedures that relate to the protocol, such as temperature monitoring, locking of equipment, maintenance of medical devices, etc.

C. Are Site Visit and Monitor Logs being utilized?

Yes If to the best of your knowledge, any non-site CTN staff visiting the site who have contact with participant records or study materials have signed the log using the correct date of visit and any other required fields.

No If there is evidence (For example, reports by site visitors or any other documentation) that indicates that non-site CTN personnel were at the site and had contact with Participant records or study materials but said individual did not fill in the log.
Also answer No if log was only partially completed, e.g. any fields pertaining to a particular visit were not completed (some examples would be an entry with a signature but no date no times in and out, etc.).

N/R If this was not reviewed during this visit.

D. Are the investigator and his/her staff maintaining records of correspondence related to the conduct of this study?

Yes If there are copies of documentation on site from the IRB approving all renewals or amendments to the protocol. Answer yes if there is documentation of approval from the Lead Investigator to begin implementation of the study at this site. Answer Yes if copies of all site-related correspondence between the Lead Investigator and his/her staff are on file at the site. If copies of site-related correspondences with NIDA monitors are on file. If copies of correspondences to and/or from the Node IRB are on file.

No If any of the above are absent.

N/R If this was not reviewed at this visit.

Report information regarding communication related to SAEs in Section V-H
Report information regarding communication of protocol violations in Section VII.

III Informed Consents / Enrollment

A. Are signed original and current IRB approved informed consents on file for all participants?
Review Informed Consent forms to ensure the original current version of the IRB approved form has been signed and dated.

Yes If the informed consent form was signed after the date approved stamped on the last page or before the expiration date , and it is the original form (not a copy). Check Yes if the informed consent has been executed and documented according to local IRB requirements (ie. initials on each page, witnessed as required, passed informed consent quiz if applicable, etc.).

No If there is a deficiency in any of the above and note in comments section. If reconsent is necessary, then follow the same guidelines and retain all signed original informed consents.

B. Are Screening Logs being maintained?

Yes If the Screening Log is present in the location specified in the study binder, is legible, and includes information on all subjects who were screened for study participation and is up-to-date.

No If there is a deficiency in any of the above and note in comments section.

N/R You did not review the log during this visit.

C. Are Master Enrollment Logs being maintained?

Yes if the Master Enrollment Log is present and up to date in the location specified in the study binder and links the subject name with the subject ID#. All study participants should be listed here and there should not be any erasures or white out used.

No If any study subjects are not listed in the Master enrollment log, or if subject information has been erased or whiteout was used. Check NO if there is a deficiency in any of the above and note in comments section.

IV Review of Study Drugs and Drug Accountability Records

This section is applicable to any study in which a medication is being supplied/administered. The medication may be over-the-counter (OTC), prescription, or investigational (under an IND).

A. Are drug supplies properly stored in a secured area?
Proper storage of medications is in part protocol specific. Investigational drugs require stricter storage requirements than OTC medications.

Yes Indicates that medications are stored as required by the protocol or labeling requirement

No Indicates that supplies are not stored as required. *Explain in comments.*

N/A Indicates that there are no medications being supplied as part of the study OR that all study medication supplies have been returned but participants are still in the follow-up phase of the study.

N/R Indicates that you did not monitor drug supply storage at this visit. *Indicate in comments when this will be monitored.*

B. Have all drug supplies been dispensed by appropriate persons?
Is proper dispensing of medications as per protocol and in accordance with local and state dispensing regulations?

Yes Indicates that only properly authorized individuals have given the medications to the participant.

No Indicates that someone who is not authorized to provide medications to the participant has done so. *Explain in comments the circumstances surrounding the improper dispensing of medications and what action(s) will be taken to prevent a re-occurrence.*

N/A Indicates that there are no medications being supplied as part of the study OR that all study medication supplies have been returned but participants are still in the follow-up phase of the study.

N/R Not Reviewed. Indicate that you did not monitor drug dispensing records at this visit. *Indicate in comments when this will be monitored.*

C. Are copies of drug shipment records current and accurate/dated and signed?

Yes Indicates that all drug shipment records have been reviewed, are current, have been reconciled (i.e., what is listed as shipped was actually received) and signed as required, by appropriate personnel (e.g., pharmacist if supplies need to be stored in a pharmacy).

No Indicates that there is a deficiency in any of the above
OR if drugs have been returned, documentation is not up to date, etc. *Explain in comments.*

N/A Indicates that there are no medications being supplied as part of the study OR that no study medication supplies have been received yet OR that all study medication supplies have been returned and previous monitoring had been performed and no problems or discrepancies had been noted.

N/R Indicate that you did not monitor drug shipment records at this visit. *Indicate in comments when this will be monitored.*

D. Are drug dispensing and accountability records for supplied medications correct and up to date?

For studies in which orders are issued for medications in case the subject requires them (e.g., if participant develops diarrhea, then provide Imodium), there should be clear procedures in place to help distinguish between orders filled and orders not filled.

Yes Indicates that comparison of subject s research chart with source documents are current and in agreement. All medications are accounted for.

No Failure to meet above standard, Or participant has failed to return unused medication as required by protocol. Explain in comments.

N/A Indicates that there are no medications being supplied as part of the study OR that all study medication supplies have been returned but participants are still in the follow-up phase of the study.

N/R Indicate that you did not monitor drug dispensing at this visit. *Indicate in comments when this will be monitored.*

E. Is drug being dispensed according to protocol?

Yes Indicates that medications are being dispensed to the correct patient, at the correct dose, at the appropriate schedule, with the correct medication. In addition appropriate orders are on file. Also, all ancillary medications are prescribed for their intended purpose as listed in the protocol. In addition, no prohibited concomitant medications were dispensed by study personnel.

No Failure to meet above standard. *Explain in comments. Also indicate what action(s) will be taken to prevent future re-occurrences of this problem.*

N/A Indicates that there are no medications being supplied as part of the study OR that all study medication supplies have been returned but participants are still in the follow-up phase of the study.

N/R Indicate that you did not monitor drug dispensing records at this visit. *Indicate in comments when this will be monitored.*

F. Have outdated/expired supplies been returned?

Yes Indicates that all expired or outdated medications have been packaged, reconciled (i.e., what is listed as needing to be shipped was actually shipped) and signed as required, by appropriate personnel (e.g., pharmacist if supplies were stored in a pharmacy).

No Indicates that expired supplies are still present at the site or other pharmacy issues need to be resolved. *Explain in comments.*

N/A Indicates that there are no medications being supplied as part of the study OR that no study medication supplies are outdated/expired OR that information on returning outdated/expired supplies has not yet been given to the site.

N/R Indicate that you did not monitor drug shipment/receipt records at this visit. *Indicate in comments when this will be monitored.*

G. Are drug supplies and randomization envelopes adequate?

Yes Indicates that there are sufficient quantities of the study medications for dispensing and enough randomization envelopes to assign to eligible participants.
Note: *When determining if quantities are sufficient, take into account how long it will take to replenish supplies and the number of participants who are eligible (or will be eligible) to receive the medication supplies.*

No Indicates that medications or randomization envelopes are running low. This can be for the study intervention medication and/or ancillary or concomitant medication supplies. *Explain in comments. Also indicate if supplies have been ordered and/or any problems in receiving the supplies (e.g., lost in shipment, etc.).*

N/A Indicates that there are no medications being supplied as part of the study OR that all study medication supplies (including extra randomization envelopes) have been returned but participants are still in the follow-up phase of the study.

N/R Indicate that you did not monitor drug supply or randomization envelopes at this visit. *Indicate in comments when this will be monitored.*

H. Has the blind been maintained?

Yes Indicates that all blinded labels and envelopes are intact. Also, Yes would indicate that the blind did not require breaking on any subject for emergency medical care.

No Indicates that the blind has been broken for at least 1 subject at the site. There are usually protocol specific instructions for when it is okay to break the blind for an individual subject. Even if the protocol procedures are followed, if the blind is broken, then No should be checked. *Explain in comments the reason for breaking the blind. This may need to be reported to the IRB(s).*

N/A Indicates that there are no medications being supplied as part of the study OR that all study medication supplies (including extra randomization envelopes) have been returned but participants are still in the follow-up phase of the study or the study is an open label design.

N/R Indicates that you did not monitor blinding information at this visit. *Indicate in comments when this will be monitored.*

I. Are blinded randomization envelopes accounted for and intact?

Yes Indicates that all unassigned envelopes/labels are accounted for and intact (still sealed/unopened) and that all assigned envelopes are accounted for.

No Indicates that *at least 1 label/envelope is missing. There are usually protocol specific instructions for when and how to randomize a subject using envelopes. Adherence to procedures is monitored in Part V, Section C. Explain in comments. This may need to be reported to the IRB(s).*

N/A Indicates that there are no blinded labels or envelopes being supplied as part of the study OR that all study medication supplies (including extra randomization envelopes) have been returned but participants are still in the follow-up phase of the study.

N/R Indicate that you did not monitor randomization envelopes/labels at this visit. *Indicate in comments when this will be monitored.*

V Protocol Compliance (for participant charts reviewed)

A. Were screening procedures followed correctly?

Yes If protocol specified instruments were used in the screening process, all assessments were performed and results were interpreted by appropriate individuals as defined by the protocol, and assessments were performed according to schedule. Indicate in comments if a release of information has been obtained prior to recording any of the measures. If clinic information is being used that the appropriate documents have been obtained according to local requirements (i.e. appropriate authorization has been obtained, consent to screen, etc.)

No If any of the screening measures were not collected, or if any of the procedures were not followed correctly. Include details in the comments section
N/A If screening is not required per protocol.
N/R If this has not been reviewed at the visit.

B. All participants meet inclusion/exclusion criteria?
Yes If all protocol specified inclusion/exclusion criteria are used to determine eligibility for participation, all criteria are met (no exceptions granted), and the determination for eligibility was made by appropriate individual(s) as defined by the protocol
No If any of the inclusion criteria are absent or exclusion criteria are present or participant was included without verification of eligibility by appropriate individual. Include details in the comments section
N/A Inclusion/exclusion criteria are not required by the protocol.
N/R If this has not been reviewed at the visit

C. Were randomization procedures followed correctly?
Yes If protocol specified randomization procedures were followed and participants did receive the assigned intervention by protocol approved staff
No If procedures were not followed according to protocol. Include details in the comments section
N/A If randomization is not a part of the study design.
N/R If this has not been reviewed at this visit.

D. Were AE s appropriately reported, documented, assessed and followed to resolution when applicable?
Yes If description of the AE is recorded in the progress notes, a study specific AE CRF was completed (this applies to protocols that report AEs, for example CTN001, 002, 003), the AE was assessed by appropriate individual(s) as defined by the protocol, that CTN, protocol, and node defined procedures were followed in documenting and reporting AEs, and that AE s were tracked to resolution.
No If documentation is incomplete without explanation or procedures were not followed
N/A If the study does not require AE reporting.
N/R If AEs were not reviewed at this visit

E. Participant visits and procedures follow protocol schedule
Yes If visits and procedures were in the proper sequence and within protocol accepted time frames
No If procedures were not followed according to protocol. Include details in the comments section
N/R If this was not reviewed at this visit.

F. Are missed visits and no-shows properly handled and documented?
Yes If documentation specifies the reason for a missed visit or a no-show (participant cancels, research staff unavailable), what attempts were made to contact the participant and the results of these attempts (reschedule, participant withdrew, unable to contact participant), what actions were taken, what repercussions if any were experienced by the participant due to a no-show, and that protocol specific procedures for missed visits/no-shows were followed.
No If documentation is not present or if procedures were not followed according to protocol. Include details in the comments section
N/A If there were no missed visits.
N/R If this was not reviewed at this visit.

G. Was study intervention delivered according to protocol? (behavioral trials)
Yes If documentation is present that intervention was delivered according to protocol.
No If any of the above is not true.
N/A If medication trial or Treatment As Usual (TAU) assignment.
N/R If this was not reviewed at this visit.

H. SAEs

A portion of this section is protocol specific. However, all SAEs are expected to be reported to NIDA and the Lead Node designated personnel within 24 hours of notification. There is a May 8, 2002 letter from NIDA advising on the proper procedure for notifying NIDA personnel.

1. **All SAEs reported and documented according to procedure and available information**
   - **Yes** Indicates that all procedures were followed, including:
     a) notification of all applicable parties
     b) notification within appropriate timeframes
     c) requests for additional information
     d) documentation of all actions and their results
   - **No** Indicates that at least one item was not performed according to protocol. *Explain in comments.*
   - **N/A** Indicates that:
     a) no new SAEs had been identified since the last visit
     b) that there were no continuing SAEs from the last visit
     c) there were no unreported SAEs detected at this visit

2. **Copies of SAE follow-up reports on file**
   - **Yes** Indicates that all SAE follow-up reports are on file in the regulatory binder and in the subject s file.
   - **No** Indicates either that a report is missing. *Explain in comments.*
     Note: *There may be a follow-up SAE report submitted to meet timelines, but information may still be outstanding (e.g., awaiting an autopsy report or hospital records). This would* ***not*** *be a reason to check NO. However, a comment should be written to continue to check for an additional report once information becomes available.*
   - **N/A** Indicates that this site does not have any SAEs.

3. **Do any SAEs still require follow-up?**
   - **Yes** Indicates that an SAE still needs to be followed. For example, if a participant was in a car accident and is in a coma, you will need to follow this event beyond the 14-day timeframe for submitting a final, written report to NIDA in order to determine final resolution death, recovery, recovery with sequelae, etc. If you are awaiting hospital records or autopsy results, this would also be reason for checking Yes. *Explain in comments.*
   - **No** Indicates that all SAEs have been followed to resolution and that follow-up reports have been submitted and are on file.
     Note: *There may be a follow-up SAE report submitted to meet timelines, but information may still be outstanding (e.g., awaiting an autopsy report or hospital records). This* ***would*** *be a reason to check YES.*
   - **N/A** Indicates that the site does not have any SAEs.

4. **SAEs reported to IRB**
   - **Yes** Indicates that all SAEs were reported to the IRB as required, including those from other sites if required.
   - **No** Indicates that at least 1 SAE from this site was not reported or that other SAEs had not been reported as required. *Explain in comments, including any plans to prevent a re-occurrence of this problem.*
   - **N/A** Indicates that this site has no SAEs and that they were not required to have submitted other sites SAEs to their IRB(s).

   Note: If submitted late, check YES but indicate in a comment that the IRB notification was delayed and the reason for the delay. Also indicate what action(s) will be taken in the future to prevent a delay in IRB submission.

5. Any unreported SAEs detected

Yes Indicates that a review of all subject records found at least 1 incident/event that should have been reported as a serious AE (e.g., hospitalization within 30 days of the end of active treatment). *Explain in comments. Also indicate what action(s) will be taken in the future to prevent a delay in IRB submission.*

No Indicates that a review of all subjects records found no events that should have been reported as a serous AE.
Note: *If only a subset of participants were examined, it is OK to mark NO, but note in the comments which subjects were reviewed and when you will monitor the remaining subjects.*

N/A Indicates that all participants are past 30 days post-active treatment phase (delivery of study intervention) and that all participants had been previously monitored up to and including 30 days post active treatment and no unreported SAEs have been detected.

VI Case Report Forms/Source Documentation

A. Are CRFs/corresponding source documents available for review?

Yes Indicates that all materials including Case Report Forms and source documentation are available for the monitor to conduct a complete review.

No If all CRFs and source documents are not available and provide comments.

N/R If the monitor did not intend to review CRFs and source documents during the current visit.

B. Do source documents allow for CRF verification?

Yes If source documents are adequate to perform CRF verification.

No Indicates that source documentation is not adequate to perform this task (ie., source documents are incomplete or missing). For CRFs that serve as source documents, check for current completeness.

N/R If the monitor did not intend to review CRFs and source documents during the current visit

C. Are CRFs complete, legible and accurate?

Yes Indicates that after the monitor has reviewed and appropriate research staff have made corrections, the CRFs are in a condition (complete, legible and accurate) to be submitted for data entry.

No If the CRFs are not in this condition, or corrections on reviewed CRFs have not been completed during the current visit and provide comments. If CRFs are outstanding, note this in the issues/comments section. During the next visit, write the resolution, or note that the item is still outstanding.

N/R If the monitor did not intend to review CRFs and source documents during the current visit.

D. Have CRFs been submitted in a timely manner?

Yes Check yes if CRFs have been completed and submitted (to data entry, etc.) according to the CTN SOPs or the protocol operations manual.

No If the CRFs have not been completed and submitted on time, check no and provide comments.

N/A If the CRFs are entered via electronic, direct entry.

N/R If the CRFs were not reviewed at this visit.

E. Have data queries been completed and submitted appropriately?

Yes If ALL data queries to date have been completed by site research personnel and submitted to the appropriate persons for approval/data entry.

No If some or all data queries have not been completed, and explain under issues/comments section. During the next visit, write the resolution, or note that the item is still outstanding.

N/A If no data queries have been received by the CTP.

N/R If the CRFs were not reviewed at this visit.

VII Protocol Violation(s)

Have any protocol violation(s), not previously noted, been reviewed and appropriately documented?

A protocol violation is defined as any non-adherence to the protocol.
Appropriate actions have been taken according to local SOPs.

VIII Central Laboratory Procedures

A. Are samples being collected and stored according to the protocol specifications?
If the protocol identifies specific procedures for discarding specimens, are they being followed?

Yes If samples (i.e., blood, urine, etc.) are being collected stored and/or discarded if applicable according to the protocol.
No If there is a deficiency in any of the above.
N/A If no samples are being collected or stored for the study.
N/R If not reviewed at this visit.

B. Are shipment records and procedures documented appropriately?

Yes Indicates that sample shipment records and procedures have been monitored for completeness and that the protocol timelines and requirements for shipping are being followed.
No If records are inaccurate or incomplete or if protocol procedures for shipping are not being followed. Indicate date of last shipment on the appropriate line.
N/A If samples are not being shipped for the study.
N/R If not reviewed at this visit.

C. Clinical significance of laboratory data has been assessed and documented appropriately by medical personnel.

Yes If appropriate personnel have reviewed laboratory data for clinical significance, have documented the review, and appropriately addressed any abnormal findings. Initials and NCS (Not Clinically Significant) or the action taken must be noted if there are abnormal findings. Note: For abnormal values NCS is noted, or if clinically significant there is an indication of what action was taken.
No If this has not been done. Provide comments for follow-up required in the Issues Identified section.
N/A If no labs are being done for the study.
N/R If not reviewed at this visit.

IX Study Facilities/Recruitment

A. Do study site facilities remain suitable?

Yes If in your opinion you feel that the facility is suitable to carry out the protocol (i.e. adequate space, adequate equipment, climate controls, cleanliness, etc.).
No If any of the above are lacking, or if there is some reason why study staff or participants might not be safe in building (for example, if the building fails a fire safety inspection or has recently suffered severe structural damage that has not been repaired, or if space no longer allows for privacy).
N/R If this is not reviewed at this visit.

B. Does staff remain suitable?

Yes If current study staff meet CTN and protocol requirements in terms of educational background, experience, and if they have completed CTN and protocol-specific training.
No If study staff do not currently meet staff criteria set in protocol and/or if they have not completed CTN or protocol-specific training by appropriate personnel (i.e. licenses have expired, annual certifications have not been met, etc.).
N/A If there is not any study staff for the protocol.
N/R If this was not reviewed at this visit.

C. Is current participant recruitment plan adequate?

Yes If site is enrolling at or above protocol-specified rate. If this rate has changed to a lower number AND there is documentation that the Lead Investigator has approved the change, answer Yes.

No If the recruitment rate at the site is below the protocol-specified rate, there is no documentation that this has been approved by the Lead Investigator even if there is plan in place, there is no documentation that this has been approved and there is no documentation in place.
Note in Comments if this has been addressed with site study staff, PI(s), and Lead Investigator, if there was a plan of action, and if there is documentation that it is being implemented.

N/A: If there is no recruitment plan.

N/R If not reviewed at this visit.

X Status of the Site

Has anything changed at the site that impacts the conduct of the study?

Instructions: Observe whether there are any CTP characteristics that have changed in a way that would interfere with the conduct of the study.

Yes A change has occurred that impedes or effects the conduct of the study. For example, renovations of the clinic might mean that private office space is no longer available.

No No change has occurred.

N/R Not reviewed at this visit. (For example source document review performed off site or at an administrative office or pharmacy not located at the CTP).

XI Issues Identified

Please summarize any issues identified at this visit that require action, the action required and whether it was resolved at the visit.

Attachments

Summary

Narrative statement of the performance and condition of the site based on all items reviewed at this visit.

Next Visit Scheduled

List the date of the next visit if this has already been scheduled.

Signature(s)

I certify that the above information is, to the best of my knowledge, correct and accurate.