DDM8 Good Documentation

Good Documentation Practice

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Purpose: To establish guidelines for clinical research documentation for various time points during a subject's participation in a clinical research protocol. All licensed practitioners are to document their subject encounters in the NIH medical record (CRIS). Medical record documentation is part of good documentation practices; other aspects include maintaining participant research records and a protocol specific regulatory file (see SOP REG-12). Note: Clinical Data Managers under contract to the CCR are not allowed to document in the medical record/CRIS.

General Principles

- All subject encounters are to be documented in a note in CRIS. This ensures compliance with State practice acts, good clinical practices, AND allows for source documentation to be available at the time of a data abstraction, monitoring visit or audit.
- Documentation should be attributable, legible, contemporaneous, original and accurate (ALCOA).
- Label CRIS Notes: Start a new document. In the left side panel, click on the "Document Info" tab and at the bottom is "Document Topic" box for the entry of a note title or label (e.g., Baseline, end of Cycle 2, Cycle 5 Day 15, Day 0, and Day 100 Post-transplant). Consistent labeling of documents, allows for easier sorting, modification, and searching.

  NOTE: Free text progress notes do not have this option. Labeling a note is a feature for structured progress notes.

- Subject and/or family/guardian education should be documented in CRIS when performed.
- Conflicting, discrepant, or missing documentation requires a note be written in the research file or CRIS. This note can be written by any licensed practitioner (MD, NP, RN, etc…). Examples of notable events include:
  - Fellow note, dictated note, and/or nursing note have differing adverse event start dates
  - Tumor measurements/response per radiology report differ from CRIS note
  - Missing performance status
- Per GCP guidelines, all source documents are to be maintained. Research source documents that are not able to be placed in the medical record (e.g., eligibility checklists, PK flow sheets, participant diaries, surveys or other participant completed forms) will need to be maintained in a research record created by the team. The Research Nurse is responsible for maintaining the research record.
- See Appendix A: *Research Note Checklist*
- For outside record, see SOP DDM-4 *How to Submit a Subject's Outside (Non-NIH) Record(s) to the Clinical Center Medical Record Department for Scanning and Viewing in CRIS*

Eligibility

- Teams should verify that all results (e.g., labs, pathology, protocol specific procedures) and clinical documentation (e.g., performance status, life expectancy, prior therapies) that are required to confirm eligibility are in the appropriate section of the medical record/CRIS.
- If the patient is not eligible, document the discussion as to why the patient is ineligible including results from test or procedures that may deem them ineligible.

Informed Consent Process

- Write a note using the CRIS structured "Progress Note –Documentation of Consent" template. See CCR SOP DDM-7.

NOTE: Once eligibility is confirmed and informed consent is obtained, remember to register the subject with the Central Registration Office per CCR SOP AD-4.

Past Medical History/Prior Therapies

- Summarize past history and prior therapies on initial visit. If subject returns back to NIH after receiving outside therapy, provide a summary of past history and other therapies that the subject received during that time period. ***NOTE:*** In addition to documentation written by CCR clinical staff, documentation of past medical history/prior therapy can be information from outside providers, NIH referring providers, and medical facilities.
- Outside records that confirm prior cancer therapies, pathology, etc. are to be filed in the medical record. See CCR SOP DDM-4.

Concomitant Medications/Measures and Baseline Symptoms

- Subject's concomitant medications such as prescription medications, over-the-counter medications, herbals, supplements, and any complementary and alternative medications and measures (e.g., oxygen therapy, transfusions, alternative therapy) all need to be captured and include the following data:
  - Date:
    - Start and Stop dates. Also, document the start date if dosage changes, if known.
    - For medications taken/started before study enrollment, document approximate month and year or the approximate number of years taken
    - Once on study, day, month, year is to be used to documented concomitant medications/measures.
  - Reason/indication – Examples to chart for use may be off labeled use, symptom management, etc...

  NOTE: This information is important due to off-labeled use of medications. Some medications are given for indications not approved by the FDA. Staff should not assume that the subject is taking the medication for the condition listed in the package insert.

  - Dosage/Amount in unit of measure (i.e. 5 mg, one tab)

    - Frequency (i.e. daily, one time dose)
- Baseline symptoms including abnormal physical exam findings or laboratory values are to be documented in CRIS. Include approximate start /stop dates (mm/yyyy), description, severity, and frequency. At each visit, review them with the subject and update in CRIS as needed.

  NOTE: For treatment trials, baseline signs and symptoms are those that are present when the patient starts treatment (e.g., Cycle 1 Day 1 pre-dosing). These are not signs or symptoms that occurred and resolved between the time screening studies/exams/procedures are done and Day

Scheduled Study Visit

- All protocol related visits, procedures, exams, etc. need to be noted in CRIS. For intervention trials, this includes all visits that are part of active treatment, follow-up or any other clinically related problems.
- Date of visit, result or plan from the visit and any follow-up needed are documented.

  NOTE: This may be done through evidence of lab results or other procedures documented in CRIS or via an outside progress note/labs /tests.

- Protocol-specific activities including: biopsy obtained, surveys administered, diaries reviewed with subject should be documented by the individual conducting the activity in CRIS.

  NOTE: For protocol-specific activities that are carried out by the CC staff (e.g., PK or serial blood draws), ensure that these activities have been documented in CRIS.

  NOTE: For subject completed forms (e.g., surveys and diaries), a CRIS education note(s) is required and needs to include that the participant was given instructions and understands how to use the forms.

- Document any missed scheduled visit or study procedure/activity in CRIS and include the reason for the deviation and any applicable follow-up that needs to occur (e.g., Day 8 labs missed by subject and arrangements made to be drawn on Day 10 instead).

Study Drug Administration

- Most of the study drugs will be administered by the nurses in the Clinical Center Nursing and Subject Care Services.
- If administered by an NCI licensed practitioner, he/she is to record in CRIS:
    - Date, time, amount, route
    - For IV medications, start and stop times
- Subject self-administration of study drugs are to be documented in CRIS including:
    - Instructions for proper use/administration and storage of drug(s)
    - Date and amount dispensed/returned (to be done by the dispensing pharmacist and can be found in CRIS)
    - Subject's compliance with regimen
    - If using a diary, review diary with subject and document this review and the above information in CRIS

  NOTE: Ensuring that subjects are taking and storing their study drug appropriately is an ongoing process. All documentation related to teaching/reinforcement needs to be documented in CRIS.

Adverse Events

For all AEs, the following will be documented in one or a series of progress notes in CRIS:

- Date (and time) AE started.

  ***NOTE*:** May also need to document the time of the AE (e.g., allergic drug reaction, transfusion reactions).

- Description of AE so that a severity rating using CTCAE version described in the protocol can be determined.

  NOTE: Please make sure for subjective AEs that there is a description and not just a grade level.

- How AE was treated, if applicable.

  NOTE: This includes interruption or discontinuation of the study intervention(s).

- Attribution of the AE. The attribution is the best estimate as determined by the PI or designee of the causal relationship between the study intervention(s) and the adverse event. See below or Appendix B: *Adverse Event Attributions* for list of attributions.
- Date (and time) AE stopped.

  NOTE: An adverse event should be followed until it has resolved or, for an adverse event that might not ever resolve (e.g., neuropathy, alopecia), until it has stabilized. Include documentation of the resolved or stabilized date.

- Outcome of AE (e.g., recovered, died).

Adverse Events Attributes

Dichotomized Approach		5 Option Approach	
Attribution	**Definition**	**Attribution**	**Definition**
Related	Reasonable causal relationship between the AE and the intervention/research.	Definite	AE clearly related to the intervention/research.
		Probable	Likely related to the intervention/research.
		Possible	May be related to the intervention/research.

Unrelated	No reasonable causal relationship between the AE and the intervention/research.	Unlikely	Doubtfully related to the intervention/research.
		Unrelated	Clearly not related to the intervention/research.

Unscheduled Visits

- Unscheduled protocol visits usually occur as a result of a subject's complaint or adverse event. All unscheduled study visits, procedures, exams, etc. are to be documented in CRIS including reason for visit/procedure, any follow-up.

Off Treatment

- Enter a note in CRIS when a subject is taken off active treatment which should include:
  - Reason off treatment,
  - Off Treatment date (the date the Physician/Investigator decides no further therapy will be given).

NOTE: This may be the same as the date of a scan or the last dose of drug, but not always.This is not the same date as holding the research intervention to wait for resolving of adverse events.

  - Subject education related to follow-up that needs to occur per protocol.
  - Drug accountability (i.e., return of drugs), if applicable.

Follow-up

- Review and document all protocol-specific activities that occur in the follow-up period as defined in the protocol. This may include survival alone or in combination with: adverse events (new and/or ongoing), concomitant medications or measures, tests/procedures conducted, disease /response and/or research labs.
- Document all attempts to contact/locate the subject, including but not limited to:
  - Contact referring physician
  - Contact emergency contact subject identified on admission
  - Check SSDI (Social Security Death Index)
  - Send certified, return receipt letter
  - Phone and/or e-mail

NOTE: Lost to follow up subjects need to be documented in CRIS along with information on what was done to attempt to contact the individual. If the investigator decides to take them off study, this information will need to be documented in CRIS.

Off study

- When the subject is taken off-study, a note needs to be entered in CRIS including why the subject was removed from the study and the date. For subjects who are lost to follow-up, before they can come off study, every attempt should be made to locate the individual as noted above (section 10).

NOTE: Once a participant is taken off study, remember to inform the Central Registration Office per CCR SOP AD-7.

Telephone Calls

- All telephone calls with subject, family, referring doctor, etc. need to be entered in CRIS including the reason for call (e.g. adverse event, general question, test result, etc.)
- Document outcome of call (e.g. instructed to have blood drawn the next day, how adverse event to be treated, etc.)

E-mail Correspondence Within NIH

- For e-mail communication among NIH staff about patients, secure email is required as these emails contain Personally Identifiable Information (PII).
  - To obtain secure email, submit an online request to NIH Center for Information Technology (CIT) at: http://itservicedesk.nih.gov/support/.
  - To use secure email, select "options" from the outlook menu, then select "encrypt". When you send the email, you will need to use your PIV card and password.
  - When selecting the email recipient, use the address from Global/GAL; ***DO NOT*** use Outlook's auto-populate feature as the recipient may not be able to open if they have changed their PIV password.

E-mail Correspondence with Provider/Patient

General: A patient or their legally authorized representative (LAR) may request to communicate with NIH health care providers or other authorized NIH staff via secure encrypted e-mail. Secure e-mail communication must be accomplished utilizing the Clinical Center's Medical Secure E-mail Service (https://medicalsecureemail.nih.gov/). E-mail communication with patients can begin only ***after*** the authorized NIH staff initiates the process. The NIH reserves the right to deny a patient's request to communicate with him/her via secure e-mail or to terminate a patient's access to secure e-mail at any time. Email sent and received through the secure encrypted process must not be stored on individual computers, servers, and/or databases.

- Obtain an updated Information Practices Authorization Form signed by the patient or LAR.
  - The Updated Information Practices Authorization Form (NIH-2753) can be found http://intranet.cc.nih.gov/medicalrecords/forms/forms-number.shtml.
  - Send completed form to the Medicolegal Section of the Medical Record Department - 10/1N205
- Provide the patient/LAR with the *Important Information about Provider/Patient Emai*l brochure prior to processing the patient's request. Brochure found in MAS policy noted below.

NOTE: If the patient's request to communicate via secure email is granted by the MRD, the patient will be required every time they use the system to acknowledge receipt of the *Important Information about Provider/Patient Email* brochure describing the risks of engaging in secure email communications with his/her providers and/or authorized NIH staff prior to engaging in secure email.

- To register to use Medical Secure e-mail service, send an email to CC-DCRI BDS Secure Comm Admins.

- MRD staff will update the patient's record in the Clinical Research Information System (CRIS) indicating that the patient has requested and been approved to communicate with NIH health care providers and other authorized staff via secure email.
- Summarize e-mail correspondence in CRIS.

Resources:

- Appendix A: *Research Note Checklist*
- Appendix B: *Adverse Event Attributions*
- Medical Administrative Series Policy: M09-3 Communicating Protected Health Information via Electronic Mail (Email) at the NIH Clinical Center http://cc-internal.cc.nih.gov/policies/PDF/M09-3.pdf
- A training tutorial provides an overview of the secure email process and is available at http://cris.cc.nih.gov/cristraining/documents/Secure_Email/secure_email.htm .