

PPTA: IQPP

**NATIONAL DONOR DEFERRAL REGISTRY
DATA ENTRY SITE STANDARDS & CHECKLIST**

July 2004

An audit, like any other formal procedure, can be optimized with good preparation and sound organizational skills. The performance of this audit may be conducted separately or in conjunction with another IQPP audit. This document is intended to be used in conjunction with other IQPP documents.

I. Pre-visit Preparation

Prior to the visit:

- Initiate contact with the NDDR data entry site to coordinate/inform of visit.
- Review training materials related to the operation of the NDDR if needed.
- Schedule travel arrangements.
- Review the testing facilities past three (3) to four (4) months of NDDR transactions. These can be requested from PPTA. Note any modifications where the donor ID was deleted/modified.
- Review the past six (6) months of the Matching Donor Data Element Reports put out by NDDR staff. Note the progress the testing lab is making in reducing the number of matching donor data element records.
- Document the NDDR checklist with any relevant information discovered during pre-visit record review.
- Contact the facility for operational hours and the name of the individual responsible for the various NDDR functions to ensure you have staff doing NDDR updates during audit.

II. Opening session at the NDDR Data Entry Site (e.g. testing lab)

Explain the purpose of audit: *To evaluate the NDDR related processes to provide management with an independent audit of the quality and compliance of the NDDR Data Entry Site.*

- Areas to be evaluated during the audit:
 - 1) Organization and Personnel, as related to NDDR
 - 2) Data Entry and NDDR Maintenance
 - 3) NDDR File Donor Updating
 - 4) Center Notification
 - 5) Maintenance of NDDR File(s)
 - 6) Data Maintenance Tools, if appropriate
 - 7) Records Management

- Documentation to be reviewed:
 - 1) Documentation of designee responsible for updating the NDDR
 - 2) Training records, relating to NDDR
 - 3) Job descriptions
 - 4) Center notification records, relating to NDDR
 - 5) Center notification letters, relating to NDDR
 - 6) Center notification log, relating to NDDR
 - Testing/tracking log
 - Departmental error/accident reports, relating to NDDR
 - Log documenting the load and update of the NDDR
 - 7) Daily repeat reactive/reactive reports

- 8) Transaction verification reports/steps
- 9) Case files for the resolution data maintenance activities reports, if appropriate
- 10) Procedure manuals

III. Audit

The audit should take approximately 1/2 day. If there are problems getting the requested documentation or if the documentation is not well organized or not complete, it may not be possible to complete the assessment in one half day. Contact PPTA for direction if you feel the audit cannot be completed in the NDDR data entry site during the scheduled time.

Following are the general steps that will occur:

- Immediately after the opening session request that previously selected records be made available at the scheduled audit period.
- Meet with the relevant staff at the NDDR Data Entry Site (e.g., testing lab) to develop an understanding of how the various staff/departments interact to complete all the functions involved in the NDDR.
- Review the NDDR related procedure manuals to get an understanding of the operations and answer any procedural question you can.
- Observe NDDR operations. If possible, data entry of a batch of reactive test results and the resolution of issues should be observed.
- Audit records identified in II. Document any deficiencies identified in your record review.
- Complete the interview process.
- Complete and sign the audit findings record.
- Hold the close out meeting with appropriate site staff.

IV. Post-review

Auditor will submit audit findings record to PPTA. PPTA will follow up with corporate office.

V. Donor Deferral Registry Standard & Checklist Questions

A. ORGANIZATION AND PERSONNEL

1) Is either the NDDR responsible person, or designee, identified in the local operating procedures as accountable for the entire local function and daily maintenance of the NDDR? Do local procedures identify who is responsible for the NDDR and who is responsible for performing the various functions?

All actions and people accountable for those actions associated with the NDDR process should be identified in local operating procedures. The Lab or Facility Director is responsible for the NDDR, unless the director delegates this function to a designee. If the DIRECTOR has a designee, the designation should be in a written format that includes the title or name of the designee and must be signed by the DIRECTOR. Local procedures should also identify who is responsible for the NDDR and who is responsible for performing the various functions. Also check the availability and activity of the designee to insure that management is actively involved in NDDR issues.

2) Do signed confidentiality statements exist for each individual who has access to donor and NDDR information?

Confidentiality statements should to be signed for all individuals that have access to donor and NDDR information. This may be handled in various ways. Confidentiality statements may be signed during employee orientation or as a part of the employment contract. The confidentiality statements may be kept in either the individual department records or in the personnel department.

3) Are there training requirements and procedures for appropriate new and incumbent staff for the NDDR?

A comprehensive training plan should be in place to address new and incumbent staff and supervisory training. The organization must have an overall plan; individual departments (as necessary) may have a more specific plan which may include a mechanism for ensuring individuals receive training for the functions they perform. Training for a function must occur prior the individual performing the function independently. Review the training records to ensure training documentation is available. Training records should be compared against the job descriptions. Training documentation should be consistent with the firm's procedure/policy on training.

4) Do written, detailed job descriptions exist and define responsibilities, authority levels and limitations, computer access, necessary qualifications, and reporting lines in relation to the NDDR?

Job descriptions should be available that list the major functions the individual is responsible for performing. These should include any backup functions for which they are responsible. The job descriptions must also include reporting lines and authority levels. Education and experience qualifications should be included.

5) Do procedures exist that document a mechanism for reporting and monitoring

the occurrence of errors /deviations/events in relation to the NDDR, particularly as related to investigation of failures?

All deviations that occur while performing the various NDDR related functions must be reported and documented according to SOP. As you read the procedures, look for instructions as to what actions should occur when either an error/deviation is found. Review a sampling of NDDR related deviation reports to ensure they are being handled appropriately.

6) Are appropriate NDDR procedures current and available in areas where related tasks are performed?

SOPs must be reviewed yearly by the department director or the quality unit and revised when necessary. They must be available in the areas where the related tasks are performed. Along with the SOPs, current User/Operator's manuals should be available when applicable. Audit to ensure that the most recent NDDR system related correspondence is incorporated into the SOP.

7) Are NDDR procedures followed?

Staff must follow procedures. Look for evidence during the performance of this checklist that the staff is following the procedures. If non-compliance is found and time permits, try to determine the scope of the problem, whether it was a single incident, or a consistent practice by one or all staff.

B. NDDR DATA ENTRY AND SCREENING

1) Are there procedures that hold individual staff members accountable for completing NDDR documents properly?

Documents referenced in this question are any forms that are completed by personnel. SOPs should identify the staff members who are responsible for completing the various documents. This question can be answered after reviewing several procedures that require forms to be filled out.

2) Are there procedures for correcting errors that are discovered on NDDR documents?

When errors are discovered on documents, steps should be taken to correct the errors. The various procedures should include the actions taken when errors are discovered. If the document is routed to another department for correction, check for a mechanism to ensure the document is returned to data entry for subsequent actions.

3) Do procedures exist for the entry of information from the center donor form into the NDDR computer system?

NDDR Data Entry Site (e.g. testing laboratory) procedures that describe the donor deferral data entry process should be available for staff. These procedures should address the data entry of the donor information from the collecting facility.

Review these procedures and then, if possible, observe data entry of several batches of donor records to assure that the procedures address all steps and are being followed.

4) Are there procedures for the entry of donor information from the collecting facility into the computer for updating donor demographics when reported or entered in error?

Note: The center currently must request a correction of any information that is associated with a donor deferral record. The entity (NDDR Data Entry Site) that enters the data is the entity that must correct it.

5) Is there documentation of the acceptable values for data input?

NDDR Data Entry Site procedures should include documentation of the information that is expected for each data entry field. The site should also have the edit requirements for each data entry field from the software developer. Review data entry procedures looking for input requirements.

6) Is there a procedure for tracking or logging donor information?

There should be a mechanism in place to document the records received from the collecting facility for data entry. This may be in the form of a log. Look at the mechanism the NDDR Data Entry Site uses to ensure that they can document when the information was received.

7) Is the information source for each document identified? [Traceability of entry to form to center.]

The purpose of this question is to be able to identify from where the information on documents was obtained so that if the information is in question the source can be queried. Within the various NDDR Data Entry Site (e.g. testing lab) specific procedures, the identity and source (i.e., the information on the collecting facility forms come from the donor and nursing personnel) of each document used to perform a task should be identified. Review several procedures to answer this question.

8) Are source documents reviewed for completeness and legibility upon receipt by data entry personnel?

9) Is the data entry person identified on each transaction/batch?

Each step in the manufacturing of plasma should be traceable to identify by whom and when each step was performed. The NDDR Data Entry Site (e.g. testing lab) should have a mechanism in place to identify who did the data entry of the source data. If you are questioning whether the system is adequate, give the users several reactive bleed/whole blood numbers and ask them to show you who did the data entry on those numbers.

10) Do procedures exist to ensure that the re-entry of error transactions is

authorized and that corrective actions are documented?

Error transactions are processes that were not completed correctly the first time. An example of an error transaction would be the correction of a data entry error that was identified during the verification process. NDDR Data Entry Site SOPs should include procedures for authorizing and documenting the re-entry of error transactions. The procedures should include steps utilized to verify that the error was properly corrected.

C. NDDR DONOR UPDATES

Donors with reactive test results must be entered into the NDDR no more than five (5) business days from the time the test results are known. The center has no more than three (3) business days to respond to the laboratory with individual donor information.

1) Are there procedures for entering donors with reactive test results into the NDDR?

Information from donors with reactive test results must be entered into the NDDR by the end of the fifth (5th) working day of final test results (three working days of results being received at the center). How the donor information gets into NDDR file(s) is dependent upon the host computer system. Some systems will automatically update the NDDR file(s) when a reactive test result is received by the host computer. Other systems should produce a list of donors with reactive test result and enter the donor's information into the NDDR file(s).

2) Is there evidence on file documenting and justifying the adjustment of a deferred individual (i.e., the deletion of a deferred individual)? Review log or record of deletion.

3) Were quality procedures followed for exceptions (e.g. when donor centers do not respond to the laboratory)?

Provided the data entry site has followed quality procedures for obtaining the data, the data entry site would not be held responsible for the delay. IQPP would then look to the offending center's adherence to this standard.

D. CENTER NOTIFICATION

1) Are there procedures to notify the collecting facility that a donor should be entered into the NDDR ?

All collecting facilities with reactive donor samples must be notified of the need to enter the donor into the NDDR. The notification process must be initiated as soon as possible after receipt of the final test results.

2) Does the review of collecting facility's notification files indicate that the center was properly notified?

E. DATA MANAGEMENT

Procedures should be in place for the identification and resolution of duplicate, inconsistent, and invalid donor and deferral records.

1) Does documentation exist to support the resolution of matching donor data element, inconsistent, and invalid records?

The NDDR Data Entry Site (e.g. testing lab) should maintain documentation of the resolution of matching donor data element and inconsistent records. Review three (3) to four (4) donor records in detail. While reviewing the documentation note what caused the matching donor data element record to be created. When reviewing these donor records check to see if the site has notified the collecting facility for them to investigate the possibilities of the erroneous release of products.

2) Does the NDDR Data Entry Site document the investigation and correction of Matching Donor Data Element Reports?

The documentation of the investigation and correction of matching donor data element records should contain sufficient details to recreate the original process. This is essential because the person who did the initial investigation may not be available at a future review.

3) Does the NDDR Data Entry Site identify and document the cause of each occurrence of matching donor data element records?

Part of the investigation of matching donor data element records should be to identify the cause of the matching donor data element record. This will help in the prevention of future matching donor data elements.

4) Does the NDDR Data Entry Site evaluate the cause of Matching Donor Data Element Reports to determine whether system changes in any of the site's SOPs or software are necessary or appropriate?

Once the causes of matching donor data element records have been determined, the site can review them for trends. The site should look to see if procedures or processes can be changed to lessen the chance of introducing duplicate record.

F. RECORDS MANAGEMENT

1) Do procedures exist for governing the destruction of confidential information (i.e., data, reports)?

Much of the information associated with the NDDR is confidential. The NDDR Data Entry Site should have procedures that document the mechanism they use for the destruction of this information.

2) Is access to confidential information contained in NDDR records stored in a manner that limits them to authorized persons?

Access to confidential information contained in the NDDR records should be limited

to only those individuals who have been authorized by job functions. NDDR information should be available only on a need to know basis. To answer this question the auditor should observe that the NDDR-related records and reports are stored to assure their confidentiality. The auditor will ask questions to ascertain just who has access to NDDR category information that is stored in the computer files. Computer program access listings should be reviewed as well.

3) Are records recorded accurately, completely, indelibly, and legibly?

All records reviewed must be legible and indelible. If a record was changed, the record should reflect the date and person who changed the record.

4) Is documentation maintained according to established guidelines?

NDDR and donor notification records and reports must be maintained according to established regulatory guidelines. While reviewing procedures, the auditor should look for the retention periods of the various reports and then ask the personnel performing the task how long the reports are maintained.

G. ELECTRONIC SYSTEM MANAGEMENT

1) If using an electronic log to support entry of data into the NDDR, does the data entry site maintain and follow internal procedures for backing up data?

2) Does the data entry site maintain and follow internal procedures for NDDR password maintenance?

3) If the data entry site uses an electronic log to support entry of data into the NDDR and the NDDR Data Entry Process is managed by a computer interface with a laboratory test result management software system, has the interface been validated?

H. QUALITY ASSURANCE

1) Is there an audit of the NDDR Data Entry System and Records by QA or a 3rd party to ensure compliance with internal SOP and that entries are made according to internal SOP and IQPP Standards?