



National Donor Deferral Registry Data Entry Site Standard

Revised 2004

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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

- 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 (e.g., testing lab).*

- 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. The 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:

1. Immediately after the opening session request that previously selected records be made available at the scheduled audit period.
2. 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.
3. Review the NDDR related procedure manuals to get an understanding of the operations and answer any procedural question you can.
4. Observe NDDR operations. If possible, data entry of a batch of reactive test results and the resolution of issues should be observed.
5. Audit records identified in II. Document any deficiencies identified in your record review.
6. Complete the interview process.
7. Complete and sign the audit findings record.
8. Hold the close out meeting with appropriate site staff.

IV. Post-Audit Review

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

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Revision History

Date	Version	History
January 2013		Document format change ONLY