PPTA
Plasma Protein Therapeutics Association

National Donor Deferral Registry Data Entry Site Audit

Report Form and Checklist

Version 1.1

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National Donor Deferral Registry (NDDR) Data Entry Site
Audit Report Form

Auditor _____

Facility _____

Address _____

_____

Government Authority Identification _____

_____

Telephone _____ Telefax _____

Manager _____

Medically Qualified Person _____

Person Responsible for Quality Assurance _____

Date of audit _____ Start Time _____

(approx.) End Time _____

Auditor notes unrelated to standards _____

_____

_____

_____

Auditor Recommendation: [ ] For Certification/Recertification

[ ] For Certification/Recertification, pending resolution of issues listed on report form,

Section(s)Page(s) _____

[ ] Significant issues listed on report form,

Section(s)/Page(s) _____

[ ] Recommend Re-audit within _____ days.

PPTA National Office Review _____ **Date Reviewed** _____

Auditor's Statement

As an Auditor for the International Quality Plasma Program (IQPP), I shall not, either directly or indirectly, for myself or for the benefit of or in conjunction with any other person, corporation, partnership, association, agency, department, or other legal entity, use, communicate or otherwise disclose, or permit to be disclosed, any Confidential Information relating to this audit or facility without prior written consent of such facility; provided, however, Auditor may, only to the extent reasonably necessary or appropriate to the performance of Auditor's duties, disclose such Confidential Information to PPTA or an employee of PPTA for use in the IQPP Certification or a person to whom disclosure is otherwise required by applicable state or federal law or regulation.

All information obtained during audit will be forwarded to PPTA to be made a part of the facility's permanent IQPP certification file.

As a consultant appointed by PPTA to perform this facility's IQPP audit, I hereby attest that to the best of my knowledge no conflict of interest exists between my current clients and the audited facility and/or PPTA.

As a consultant for the purposes of performing the IQPP audit of said facility, I certify that the attached audit findings and comments are true and accurate findings based on my observations and record review during the audit.

Auditor Signature _____ Date _____

POST AUDIT REVIEW

I acknowledge that the Auditor has reviewed the observations listed in this report. My signature does not constitute concurrence or denial of any of the observations made by the Auditor.

Company Representative _____ Date _____

Title _____ Center Name/Location _____

National Donor Deferral Registry (NDDR) Data Entry Site Audit Report Form

SECTION A – Organization and Personnel	Yes	No
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?		
2. Do signed confidentiality statements exist for each individual who has access to donor and NDDR information?		
3. Are there training requirements and procedures for appropriate new and incumbent staff for the NDDR?		
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?		
5. Do procedures exist that document a mechanism for reporting and monitoring the occurrence of errors/deviations/events in relations to the NDDR, particularly as related to investigation of failures?		
6. Are appropriate NDDR procedures current and available in areas where related tasks are performed?		
7. Are NDDR procedures followed?		
SECTION B – NDDR Data Entry and Screening	**Yes**	**No**
1. Are there procedures that hold individual staff members accountable for completing NDDR documents properly?		
2. Are there procedures for correcting errors that are discovered on NDDR documents?		
3. Do procedures exist for the entry of information from the center donor form into the NDDR computer system?		
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?		
5. Is there documentation of the acceptable values for data input?		
6. Is there a procedure for tracking or logging donor information?		
7. Is the information source for each document identified? [Traceability of entry to form to center.]		
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?		
10. Do procedures exist to ensure that the re-entry of error transactions is authorized and that corrective actions are documented?		

SECTION C – NDDR Donor Updates	Yes	No
1. Are there procedures for entering donors with reactive test results into the NDDR?		
2. Is there evidence on file documenting and justifying the adjustment of a deferred individual (i.e., the deletion of a deferred individual)? Review the log or record of deletion.		
3. Were quality procedures followed for exceptions (e.g. when donor centers do not respond to the laboratory)?		

Audit Comments Observation/explanation of deficiency Recommendations

Section/Item #

SECTION D – Center Notification	Yes	No
1. Are there procedures to notify the collecting facility that a donor should be entered into the NDDR?		
2. Does the review of collecting facility's notification files indicate that the center was properly notified?		

Audit Comments Observation/explanation of deficiency Recommendations

Section/Item #

SECTION E – Data Management	Yes	No
1. Does documentation exist to support the resolution of matching donor data element, inconsistent, and invalid donor and deferral records?		
2. Does the NDDR Data Entry Site document the investigation and correction of Matching Donor Data Reports?		
3. Does the NDDR Data Entry Site identify and document the cause of each occurrence of matching donor data element records?		
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?		

Audit Comments Observation/explanation of deficiency Recommendations

Section/Item #

SECTION F – Records Management	Yes	No
1. Do procedures exist for governing the destruction of confidential information (i.e., data, reports)?		
2. Is access to confidential information contained in NDDR records stored in a manner that limits them to authorized persons?		
3. Are records recorded accurately, completely, indelibly, and legibly?		
4. Is documentation maintained according to established guidelines?		

Audit Comments Observation/explanation of deficiency Recommendations

Section/Item #

SECTION G – Electronic System Management	Yes	No
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 results management software system, has the interface been validated?		

Audit Comments Observation/explanation of deficiency Recommendations

Section/Item #

SECTION H – Quality Assurance	Yes	No
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?		

Audit Comments Observation/explanation of deficiency Recommendations

Section/Item #