



Use of the National Donor Deferral Registry Standard

**Implemented 1993
Revised 2008**

Version 3.0

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I. Introduction

Government regulations require the testing of every unit of plasma. Plasma units that have positive test results for Hepatitis C (HCV), Hepatitis B (HBV) and Human Immunodeficiency (HIV) must be destroyed or diverted for non-therapeutic use except for the collection of such donors under a government-approved program. The donors must be permanently rejected from future donations. Each plasma center is required to keep a list of these permanently rejected donors.

In 1993, PPTA Source established the National Donor Deferral Registry (NDDR) in the United States as a means of notifying other plasma centers about a donor's reactive viral test status. The NDDR is a database of any donor who has had a first-time reactive test result for HIV, HCV or HBV at an IQPP-certified plasma center.

Donor identification information about permanently rejected donors is added to the NDDR at designated data entry sites. When an Applicant Donor arrives at an IQPP-certified plasma center, the NDDR is queried to determine whether or not that donor is listed in the NDDR.

In 2004 PPTA updated the NDDR to allow for online, internet-based access to the system. Additional standards were added at this time to recognize the changes to the internet-based NDDR system.

Where NDDR is not permissible by law, an in-house deferral registry must be used to share deferral information among plasma centers of the same corporate entity.

Use of the NDDR is required by IQPP in order to prevent inadvertent collection from a donor who has been permanently deferred. Such a system helps to ensure the quality and safety of the therapies created using Source Plasma.

II. Definitions

Applicant Donor – All individuals presenting themselves who have not been previously qualified as a donor within the past six (6) months.

Reactive Donor –	Any donor who receives a reactive (positive) test result for HIV, HCV and/or HBV. This individual will be permanently deferred from donating and will be placed into the NDDR.
Serology –	The initial test run on a donation or sample at the testing facility.
NAT –	Nucleic Acid Amplification Testing.
HCV –	Hepatitis C Virus
HBV –	Hepatitis B Virus
HIV –	Human Immunodeficiency Virus

III. Standard

All individuals processed as Applicant Donors in a plasma center must be checked to see if they are listed in the National Donor Deferral Registry (NDDR) to determine whether or not that donor has been listed in the NDDR.

Donors that are intentionally collected for anti-HIV, HBsAg or anti-HCV positive units under a government-approved collection program must be listed in the NDDR.

The response/verification code of the NDDR check must be recorded in the Donor Record File, either in hard-copy form or in a computerized donor management system.

Upon receipt of a positive test result from a lab, the plasma center must provide the donor's information to the NDDR Data Entry Site for listing in the NDDR within three (3) business days of receipt of those test results. This does not apply to companies using an integrated system shared by their centers and the NDDR Data Entry Site/Laboratory. Plasma centers that input information into the NDDR directly must input donor information into the NDDR within three (3) business days of receipt of positive test results from the lab.

The NDDR Data Entry Site is responsible for listing individuals with reactive test results within three (3) business days of receipt of the donor information. The NDDR listing includes the individual's donor ID, first and last name, middle initial, birthdate and gender. The donor's social security number or INS number may be used as their NDDR Donor ID.

All individuals who test positive for HIV, HCV and/or HBV will be listed in the NDDR upon receipt of a reactive test result. This includes samples collected as well as full donations.

There should be an individual staff member, noted by their job description, who is held accountable for all activities involving the NDDR. A back-up position may be assigned for those times when the primary contact is unavailable. This does not apply to companies using an integrated system shared by their centers and the NDDR Data Entry Site/Laboratory.

Each company should have written procedures to correct error(s) in the NDDR and in all other records, if data error(s) is/are discovered and is/are relevant to the NDDR (e.g. incorrect birth date, social security number).

IV. Inspection and Compliance Verification

During the Corporate Audit, auditors shall request all of the company's SOPs that relate to the NDDR. They shall then review the procedures for compliance to the Standard.

During the Plasma Center Audit, auditors shall review all records that relate to the NDDR as well as track through the documentation of several donors for compliance to the Standard.

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Revision History

Date	Version	History
1993		Standard implemented through IQPP Audit Report Form
July 2004		Changes made to incorporate the implementation of the internet-based system.
January 2006		Separated Audit Report Form into Corporate Audit Checklist and Plasma Center Audit Checklist.
January 2006		Combined questions for clarity.
April 2007		Standard put into written format and clarified.
February 2008	3.0	
January 2013	3.0	Document format change ONLY