PLASMA PROTEIN
THERAPEUTICS
ASSOCIATION

INTERNATIONAL
QUALITY PLASMA
PROGRAM

Use of the National Donor Deferral Registry Standard

implemented 1993
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Version 3.1

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Background

The IQPP Use of the National Donor Deferral Registry Standard is part of a series of standards that comprise the Plasma Protein Therapeutics Association (PPTA) IQPP Standards Program. PPTA's Voluntary Standards Program provides global leadership for the plasma protein industry's goal of continuous improvement with a focus on safety and quality from the donor to the patient.

This voluntary IQPP Standard was developed by the PPTA IQPP Standards Working Group and was approved by the PPTA Source Board of Directors on May 19, 2025. The current version of this standard supersedes version 3.0 in its entirety.

For questions about this PPTA Voluntary Standard contact IQPP@pptaglobal.org. For more information about the IQPP Standards Program or PPTA, visit www.pptaglobal.org.

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Use of the National Donor Deferral Registry Standard

1. 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 or locally administered 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.

2. 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

3. 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) or, in jurisdictions where the NDDR is not allowed by law, an in-house or locally administered deferral registry, or SOP to determine whether or not that donor is listed. . The following requirements for use of the NDDR apply to centers operating in jurisdictions where the NDDR is allowed by law.

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, INS, Border Crossing Card ID, or ITIN 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).

4. Removal of Donors from NDDR

To remove a donor from the NDDR, participating companies must establish a procedure requiring the donor to successfully complete re-entry requirements set by the respective national regulatory authority. This process must be documented in the company's SOP.

5. Inspection and Compliance Verification

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