



INTERNATIONAL QUALITY
PLASMA PROGRAM

IQPP Cross Donation Management Standard

Version 3.0



Background

The IQPP Cross Donation Management 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 Committee, and was approved by the PPTA Source Board of Directors on April 14, 2016. The current version of this standard supersedes version 2.0 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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1. Introduction

The ability to manufacture and provide life-saving plasma protein therapies is dependent on having a steady supply of quality plasma from committed, healthy plasma donors. The health and safety of donors is of the highest importance. Regulations and standards have been developed to screen donors prior to donation, to monitor their health periodically during their donation tenure and to limit the volume of plasma at each donation as well as the number of donations in a given period of time.

A donor may not fully understand the reasons for limiting the number of donations and attempt to donate more often than regulations allow. This standard was developed to protect donor safety by minimizing the risk of a donor donating in excess of the allowable limits.

This Standard is part of a series of standards that comprise the PPTA IQPP Voluntary Standards Program. For more information about the program, visit www.pptaglobal.org.

2. Scope

This IQPP standard applies to facilities that collect Source Plasma.

3. Terms and Definitions

3.1. Cross Donation

A donation pattern in which a donor exceeds the maximum allowable donation frequency by donating at more than one plasma center

3.2. Donor Recruitment Area (DRA)

An area that has been pre-determined within which a plasma center accepts donors.

3.3. Cross Donation Check System (CDCS)

Electronic database used to identify donors or potential donors who may be at risk for cross donation or who may be cross donating

3.4. Donor Check Form

Form used between companies in the event that the CDCS is unavailable

3.5. PPTA ID Number

Unique number assigned by the PPTA to a collection center or corporate headquarters

3.6. Social Insurance Number (SIN)

Nine-digit number that you need to work in Canada or to have access to government programs and benefits (Service Canada, <http://www.servicecanada.gc.ca>)



3.7. Social Security Number (SSN)

(In the United States) a nine-digit number in the format 000-00-0000, unique for each individual, used to track Social Security benefits and for other identification purposes. (Oxford Dictionaries, 2015. www.oxforddictionaries.com)

3.8. Border Crossing ID

In the United States, a document that allows limited entry into the US by visitors

4. Requirements

4.1. Information to be Provided to the Database

4.1.1. No later than the end of a center's operating day, the center shall enter into the CDCS the following information from each individual who requested to donate and for whom a needle stick was performed:

- a) First name, middle initial (if applicable), last name
- b) Date of birth
- c) Type of donor identification (SSN, SIN, border crossing ID)
- d) Five-digit identifier (last 5 digits of SSN, etc.)
- e) Gender
- f) Date of donation
- g) PPTA ID # for the center entering the donor information

4.1.2. Companies shall have a notification process in place to inform all known plasma centers within a center's DRA of the opening of a new center and provide all required information to the CDCS no later than 30 days prior to the scheduled opening date.

Centers shall enter into the CDCS the PPTA ID numbers of all centers within their DRA.

4.1.3. Each center shall provide the following information to the CDCS:

- a) center scheduled operating days, including holidays and unexpected closures; and
- b) centers that fall within the center's DRA.

The center shall update this information within one full operating day of a change.

4.2. Database Queries

When an individual presents at a center for donation, and prior to a donation being obtained, the center shall query the CDCS to determine if the individual is listed.

Where the CDCS is not permissible by law, an alternative national or regional registry, if available, shall be used among centers to determine if a donor is active in more than



one center and is exceeding the allowable limit for donations. Where no alternate deferral registry is available, an intra-company process shall be used.

4.3. Disposition of Donors

4.3.1. A company shall have a procedure in place stating how it will prevent an individual from donating more often than allowed by regulation.

4.3.2. If an individual is found to be listed in the CDCS, the center shall determine whether the individual is knowingly attempting to violate the donation frequency allowed by regulation.

4.3.3. An individual who is found to be knowingly attempting to donate more often than regulation allows shall be permanently deferred.

4.3.4 An individual who is found to be listed in the CDCS but not knowingly attempting to donate more often than regulation allows shall be informed about the health risks of exceeding the allowable limits and the reasons for the center's concerns for the individual's health and safety should cross donation occur.

4.3.5 An individual who is found to have cross donated shall be permanently deferred.

4.4. Backup Process

4.4.1. If, for any reason a center will not open for collections on a regularly scheduled opening day, it shall, as soon as possible, change its schedule in the CDCS to "closed" for that day, or send data to the System indicating that zero donations occurred at the center for the day.

4.4.2. In the event that the CDCS is not available to a center for longer than one full operating day, or if a center learns that another center within its DRA has not provided information to the CDCS within the past full operating day of its scheduled operating time, affected centers shall revert to a manual system for checking donors, as follows.

4.4.3. The manual system shall require checking only A1 and AR1 Donors. Each center shall complete a Donor Check Form or equivalent system, listing all A1 and AR1 Donors that presented for donation in the center that day, and submit to all centers within its Donor Recruitment Area no later than the end of each day of center operation.

4.4.4. The form shall include the following:

- a) Receiving and sending center name, address and PPTA ID number,
- b) First Name, middle Initial (if applicable), last name
- c) Date of birth



- d) Type of donor identification (SSN, SIN, border crossing ID#)
- e) Five-digit identifier (last 5 digits of SSN, etc.)
- f) Gender
- g) Donor's last two known donation dates in the previous seven days at the center (this includes, where available, dates at other centers under the same corporate ownership; to be completed by the receiving center)

4.4.5. The form or equivalent system shall be submitted to all centers within the DRA such that the receiving center should receive the information on the same calendar day that the sending center transmits it.

4.4.6. Response shall be returned by the receiving center(s) as soon as possible but no more than one operating day after receipt of the Donor Check form.

4.4.7. Forms prepared and received by centers in the DRA shall be retained in accordance with company SOPs.

4.4.8. Procedures for review of forms and follow-up actions shall be incorporated into a company's quality system and subject to internal quality audits.

4.4.9. When the CDCS becomes available again, centers shall

- a) inform the other centers within its DRA, as soon as reasonably practicable, that the center is able to access the System again; and
- b) upload to the CDCS the data in accordance with subclause 4.1.1 that were collected during the time that the CDCS was not available. The data shall be uploaded, by no later than the center's normal Close of Business on the day that the CDCS became available again.

4.5. Records

Centers shall keep objective evidence of the use of the System in accordance with the requirements in this Standard.

4.6. Other

This Standard shall not be interpreted in such a way that it dissuades centers from adopting more stringent requirements. Where applicable, a fingernail dye identification (using fluorescent dye), or similar system, can be used as a method to help avoid cross-donation.



5. Inspection and Compliance Verification

During the IQPP Corporate Audit, auditors shall request the company's SOPs that relate to the Cross Donation Management Standard. They shall then review the procedures for compliance with the Standard. The auditor shall confirm that procedures for review of forms and follow-up actions are incorporated into a company's quality system and subject to internal quality audits.

During the IQPP Plasma Center Audit, auditors shall review records that relate to the Cross Donation Management Standard as well as track through the documentation of several donors for compliance to the Standard. Irregularities in conducting donor checks, sharing donor information or actions required in accordance with the Standard may result in issue-driven IQPP audits at each of the centers in the DRA.