



INTERNATIONAL QUALITY
PLASMA PROGRAM

IQPP Community-based Donor Standard

Version 5.0



Background

The IQPP Community-based Donor 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 May 5, 2020 for implementation on July 1, 2020. The current version of this standard supersedes version 4.0 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

People around the world depend on therapeutics derived from human plasma proteins to treat conditions such as hemophilia, immune disorders and other diseases or injuries. The ultimate safety of these therapeutics is critically dependent upon the quality of the source material from which they are derived.

IQPP-certified plasma centers accept only donors who live within the plasma center's defined Donor Recruitment Area (DRA). Donors must provide valid photo identification and proof of a local residence. Donors with addresses known to be half-way houses, hotels, motels, homeless shelters or missions are not accepted. In addition, donors who reside outside of the defined DRA in which the plasma center is located will not be accepted. Certain exceptions may apply as defined in the Requirements below.

The Community-based Donor Standard was created as another layer of safety for donors as well as patient groups who rely on plasma-based therapies. By maintaining a level of control over the donor population, a plasma center can help to ensure a steady and reliable donor population and supply of quality plasma. In addition, when positive test results are received the plasma center is able to contact the donor and provide them with this important information.

This IQPP 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 standard applies to facilities that collect Source Plasma.

3. Purpose

The purpose of this standard is to establish requirements for acceptable residency within the DRA and identification for donors at Source Plasma centers.

4. Terms and Definitions

4.1. Donor Recruitment Area (DRA)

A predetermined geographical area from which a plasma center accepts donors

4.2. Local Residence

A residence such as a house, apartment, or condominium located within the established DRA

4.3. Unacceptable Address

A known hotel, motel, mission, half-way house or shelter within the DRA. This includes any



address, apartment, or facility that is found to be or identified as being used to shelter individuals without a permanent address.

5. Requirements

5.1. DRA

Plasma centers shall only accept donors or applicants that can show proof of Local Residence within the DRA. There shall be documentation defining what the DRA is for the plasma center including but not limited to the covered area or postal codes. The plasma center shall have a system (such as a map or list of postal codes or other defined areas) to identify acceptable areas for potential donors who reside within the DRA.

5.2. Individuals who are found to reside at an Unacceptable Address, or whose address is found to be an Unacceptable Address, shall not be accepted.

5.3. Proof of Identification and Residency

5.3.1. All individuals shall provide the plasma center with proof of identification prior to the initial donation and proof of Local Residence prior to the second donation.

a) *Proof of identification:* All acceptable forms of identification shall have a photo. Acceptable forms include a military ID, student ID, driver's license, green card, passport, age of majority card, etc. Photo identification that has expired shall not be accepted.

b) *Proof of Local Residence:* Acceptable forms of proof of Local Residence include a valid driver's license, utility bill dated within the last 60 days, valid lease or rental agreement, mail dated within the past 60 days, etc.

5.3.2. Plasma centers shall verify the suitability of a donor's address using one of the following methods.

- a) Centers shall keep a list of Unacceptable Addresses.
 - i. The list shall be updated each time a plasma center becomes aware of a new Unacceptable Address or when the status of a previously known Unacceptable Address changes.
 - ii. The list shall be version controlled and maintained current and complete.
 - iii. When the list is not maintained electronically, the pages shall be numbered (in the "Page X of Y" format) and the list approved and marked as approved in accordance with company policy.
 - iv. There shall be a documented process for verifying this list annually;

or

- b) Centers shall use an online search engine to verify that a donor's given address is not an Unacceptable Address.



5.3.3. The plasma center shall verify the suitability of a donor's given address on the initial visit, at least annually, and anytime the donor's address changes. Documentation of this verification shall be maintained.

5.4. Exemptions

The following are exempted from this standard (except for the requirement for proof of identification in 5.3.1 a):

- a) Students at local colleges/universities or locally-stationed members of the military;
- b) Qualified Donors who have an established approved local residence within a company's Blood Establishment Computer Software ("BECS") and available donation history may donate at other locations within the same company utilizing the same set of Standard Operating Procedures.

In such circumstances, the company must have a documented process to verify that the individual continues to have an acceptable residence at the location where they became a Qualified Donor; and

- c) Donors who are intentionally transported for specialty programs. Specialty programs include the collection of source material for:
 - i. hyperimmune products,
 - ii. diagnostic specialties, and
 - iii. other specialty programs.

6. Audit and Compliance Verification

During the IQPP Corporate Audit, auditors shall request the company's SOPs that relate to the Community-based Donor Standard. They shall then review the procedures for compliance to the Standard.

During the IQPP Plasma Center Audit, auditors shall review records that relate to the Community-based Donor Standard as well as track through the documentation of several donors for compliance to the Standard.