



IQPP Community-Based Donor Standard

Version 4.0
Approved June 25, 2014



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 June 25, 2014. 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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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. Exceptions are made only for area college students, members of a local military installation, or approved donors who possess unique antibodies for special collection programs.

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 house, apartment, or condominium located within the established DRA

4.3. Unacceptable Addresses

A list kept at the plasma center that includes all known hotels, motels, missions, half-way houses and shelters within the DRA and which is updated at least once a year. This list should include any addresses, apartments, or facilities that are found to be or identified as being used to shelter individuals without a permanent address. Alternatively, if available, companies could use a defined on-line checking system that is described in a company SOP and which meets the requirements in this PPTA standard

4.4. Valid Photo Identification

An educational, employee or government-issued photo identification. Acceptable forms include, but may not be limited to, a student ID, military ID, driver's license, green card, passport, age of majority card, etc. Photo identification that has expired shall not be accepted

5. Requirements

5.1. DRA

Plasma centers shall only accept donors or applicants that can show proof of residency 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) to identify potential donors who reside within the DRA.

5.2. Proof of Identification and Residency

5.2.1. All individuals shall provide the plasma center with proof of identification and residency upon their initial donation. Acceptable forms of proof include, but may not be limited to:

- 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 residential address:* Acceptable forms of proof of local residency include a driver's license, utility bill, lease or rental agreement, etc.



5.2.2. Acceptable local residences are houses, apartments, condominiums, etc. Hotels, motels, missions, half-way houses and shelters shall not be accepted under any circumstances.

5.2.3. The plasma center shall verify the donor's address against the unacceptable address list on the initial visit and on an annual basis after that. Documentation verifying these checks shall be put into the Donor Record File.

NOTE: The Donor Record File could be electronic or hard copy.

5.2.4. Plasma centers shall keep a list of all known hotels, motels, missions and shelters within the DRA. This unacceptable address list shall be version controlled, and maintained current and complete. The pages should be numbered (in the "Page X of X" format) and the list approved and marked as approved in accordance with company policy. The list shall be updated each time a center becomes aware of an unacceptable address. There shall be a documented process for updating or verifying this list annually.

5.2.5. The following shall not be accepted:

- a) donors with addresses known to be homeless shelters, hotels, motels or missions; and
- b) donors who reside outside of the plasma center's DRA.

5.3. Exemptions

The following are exempted from this standard (except for the requirement for proof of identification in 5.2.1 a):

- a) Students at local colleges/universities or locally-stationed members of the military, and
- b) 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.