

International Quality Plasma Program Standard

for

Community-based Donors

**Implemented 1991
Revised 2009**

Version 3.0

Document #019442

IQPP Community-Based Donor Standard Implemented 1991 Revised January 2009

I. 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. 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 Donor Recruitment Area 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.

II. Definitions

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| Donor Recruitment Area – | an area that has been pre-determined in which a plasma center accepts donors. |
| Local Residence – | a house, apartment, or condominium located within the established Donor Recruitment Area; examples of acceptable forms of proof of local residency can include a driver's license or utility bill, rental agreement, lease, etc. |
| Unacceptable Addresses – | a list kept at the plasma center that includes all known hotels, motels, missions, half-way houses and shelters within the Donor |

Recruitment Area that is updated at least once a year.

Valid Photo Identification – an educational, employee or government-issued photo identification. Acceptable forms include a student ID, military ID, driver's license, green card, passport, age of majority card, etc. Photo identification that has expired cannot be accepted.

III. Standard

All individuals presenting themselves for donation must have a residence located within the defined Donor Recruitment Area. There must be documentation defining what the Donor Recruitment Area is for the plasma center including but not limited to the covered area or zip codes. The plasma center must have a system (such as a map or list of zip codes) to identify potential donors who reside within the Donor Recruitment Area.

All individuals must provide the plasma center with proof of identification and residency upon their initial donation. Acceptable forms of proof include:

1. Proof of identification – All acceptable forms of identification must have a photo. These include a military ID, student ID, driver's license, green card, passport, age of majority card, etc. Photo identification that has expired cannot be accepted.
2. Proof of local residential address – Acceptable forms of proof of local residency include a driver's license, utility bill, lease or rental agreement, etc.

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

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

Plasma centers must keep a list of all known hotels, motels, missions and shelters within the Donor Recruitment Area. The list must be dated, 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. There should be a documented process for updating or verifying this list annually.

IQPP-certified plasma centers accept only donors with proof of residency within the defined Donor Recruitment Area. Donors with addresses known to be homeless shelters, hotels, motels or missions are not accepted. In addition, donors who reside outside of the defined Donor Recruitment Area in which the plasma center is located will not be accepted. This does not include students at local colleges/universities or locally-stationed members of the military. Other specialty donors who are intentionally transported for specialty programs are exempt from this Standard as well. These include the collection of source material for:

- non-coagulation concentrate products,
- hyperimmune products,
- diagnostic specialties, and
- other specialty programs.

IV. Inspection 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.

IQPP COMMUNITY-BASED DONOR STANDARD

Revision History

Date	History
1991	Standard implemented through IQPP Audit Report Form
1/2004	Added in requirement to check for photo identification.
1/2004	Added requirement to verify address against unacceptable address list annually.
1/2005	Changed 125-mile radius to Donor Recruitment Area.
1/2006	Separated Audit Report Form into Corporate Audit Checklist and Plasma Center Audit Checklist
1/2006	Eliminated question regarding checking donors for legal status within the United States.
1/2006	Eliminated question regarding donors incarceration history.
January 2009	Standard put into written format. "Permanent" residence changed to "local" residence.