

International Quality Plasma Program Standard

for

Donor Education

**Implemented 1991
Revised 2009**

Version 2.0

Document #019443

IQPP Donor Education 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.

PPTA Source IQPP-certified plasma centers must initiate education and screening programs to exclude donors who may be at increased risk of possible infections.

The Donor Education Standard was first introduced in 1991 and was known as the Elimination of Donors at Increased Risk for HIV. Since its inception, the Standard has evolved to focus on educating donors not only on high-risk behavior but also on other aspects of general well-being.

II. Definitions

High-Risk Behavior - Activities that increase an individual's risk of contracting an infectious disease.

High-Risk Disease State - Positive test results for HIV, HCV, HBV or other possible infectious diseases.

Donor Well-being - A state of good health.

III. Standard

Each IQPP-certified plasma center has developed educational materials to help donors recognize and avoid behavior that is believed to lead to an increased risk of possible infections. Donor comprehension is tested about the information in order to assure their understanding of high-risk activities. Companies must address activities related to the possible transmission of infectious disease in their educational materials. The comprehension assessment methods may be determined by individual company.

The plasma center must have an electronic, paper or video-based system in place to educate and assess a donor's comprehension of the education for high-risk behavior that could potentially lead to a high-risk disease state.

Each company should create educational materials of their choosing to provide to their plasma centers to educate donors, on their initial visit, on general well-being practices for plasma donation (eg, staying hydrated, eating low-fat foods, staying well-rested, smoking cessation, etc.). Donor's comprehension of these well-being practices does not need to be tested.

IV. Inspection and Compliance Verification

During the IQPP Corporate Audit, auditors shall request the company's SOPs that relate to the Donor Education 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 Donor Education Standard to ensure the plasma center is following the company SOPs.

IQPP EDUCATION OF DONORS AT RISK FOR INFECTIOUS DISEASE CRITERIA STANDARD

Revision History

| Date | History |
|--------------|---|
| 1991 | Standard implemented through IQPP Audit Report Form |
| 2005 | Removed requirement to include assessment in the Donor Record File |
| 2005 | Name changed from "Exclusion of Donors at Increased Risk for HIV" |
| January 2009 | Standard put into written format. |
| January 2009 | Name changed from "Education of Donors at Increased Risk for Infectious Disease." |
| January 2009 | Requirement for donor education on general well-being added. |