PPTA
Plasma Protein Therapeutics Association

Qualified Donor Standard

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IQPP Qualified Donor Standard

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IQPP Qualified Donor Standard

I. Background

The purpose of the standard is to take advantage of opportunities in the collection and processing of plasma for further manufacture into therapeutic plasma products to further reduce the risk of undetected infectious units of plasma being manufactured. The standard attempts to exclude from manufacture "window units" by requiring additional testing/donations to qualify "Applicant Donors."

II. Definitions

Applicant Donor - All individuals presenting themselves who have not been previously qualified as a donor within the past six (6) months.

Qualified Donor - All individuals who have been qualified for continued donations by successfully passing two donor medical history screenings and required viral testing.

III. Standard

Individuals will be considered Applicant Donors until they have successfully passed the following two-stage minimum donor screening process:

1. Persons presenting themselves for donation initially will be screened according to all applicable regulatory and IQPP screening and testing criteria. This applies whether a complete plasma unit or blood/plasma sample only is collected. At this stage the person will be considered an Applicant Donor. The initial screening required by IQPP of Applicant Donors include:

    a. Physical examination by a Physician or Physician Substitute;
    b. Check against the National Donor Deferral Registry (NDDR);
    c. Donor education and quiz on high-risk activities.

2. Reclassification of a person from Applicant Donor to Qualified Donor is achieved by passing the physical examination as required by regulations and:

    a. Subsequent donation of a complete unit and donor screening and testing based on all applicable regulatory and IQPP requirements noted above; or
    b. Subsequent donation of a sample only and donor screening and testing based on all applicable regulatory and IQPP requirements noted above.

The subsequent screening of Applicant Donors must occur no less than the minimum time interval allowed by applicable regulatory requirements and no greater than six (6) months.

Testing and donor screening to classify a person as a Qualified Donor must be administered by plasma centers operated by the same company.

No units of plasma from Applicant Donors will be acceptable for the manufacture of therapeutic plasma products until the person has become a Qualified Donor. Donations made by Applicant Donors who do not return to become Qualified Donors shall be clearly labeled in accordance with the requirements of the relevant health authority for non-injectable use only or destroyed.

IV. Inspection and Compliance Verification

Auditors shall request the plasma center's procedures or system for managing Applicant Donors. They shall then track through the documentation of several donors/units for compliance. The plasma center's owners, upon IQPP certification or recertification, must sign a statement that all donors will be processed in accordance with the definitions for Applicant and Qualified donors and the standard above.

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Appendix 1: Questions & Answers Related to IQPP Qualified Donor Standard

The questions and answers below are intended to help clarify the International Quality Plasma Program QUALIFIED DONOR STANDARD.

Q. Can you prescreen a donor without collecting a unit of plasma?

A. The Applicant Donor must undergo a complete donor testing and medical screening on the initial visit, whether a unit of plasma is collected or only a blood/plasma sample. This is not intended to preclude the practice of using a government approved infrequent donor program screening process (i.e., it does not necessarily require that a physician perform physical examination and screening unless regulations would require it).

Q. Can you collect a sample only subsequent to the initial visit and donor screening in order to qualify the donor or unit?

A. Following the initial Applicant Donor screening and testing, the donor must successfully pass all the donor health history screening interview questions and viral marker testing whether or not a unit of plasma is drawn. Since a complete unit is not being collected and this sample and screening only would be as a part of the IQPP Standard, it would not be necessary to perform the various donor vital signs screening tests such as hematocrit.

Q. Must you have completed the testing from the original Applicant Donor visit prior to accepting a subsequent donation?

A. No. But, it must be completed prior to acceptance of the unit for further manufacturing as required by regulatory authorities.

Q. What is the minimum and maximum time period between viral marker testing for Applicant Donors?

A. Donations or test samples and donor screening procedures must be done no more frequently than the minimum time interval between donations allowed by the applicable regulatory authority. Additionally, those individuals not appearing for donation for greater than six (6) months will be considered Applicant Donors and must be re-qualified to become classified as a Qualified Donor.

Q. Can a donor be reclassified as an Applicant donor at an interval of less than six months?

A. Companies are entitled to make the Qualified Donor Standard more rigorous by reclassifying donors as Applicants following an interdonation interval of less than six months. However, they must comply with the requirements of the Qualified Donor Standard and treat the donors and the units as Applicant and these policies must be reflected in the company's SOPs. In addition, when submitting viral marker data according to the Viral Marker Standard, the IQPP Qualified Donor Standard definitions of Applicant and Qualified must be adhered to.

Q. Can test results from previous or subsequent donations at other licensed collection facilities be used to qualify a donor?

A. No. However, if the test results and other required donor screening information is administered by a plasma center operated by the same company, it would be acceptable. This would not preclude the use of test results performed by a separate laboratory specifically for that plasma center (i.e., testing performed by the fractionator customer's laboratory for the plasma center).

Q. How is the status of Applicant Donors who have not yet returned to become Qualified Donors affected by a change in ownership of the plasma center and donor screening/test information?

A. It is not affected. Although technically the donor screening and testing information from the two donation visits necessary to qualify a donor would be administered and owned by two different legal entities, it is interpreted by IQPP as the consistent property of "the plasma center."

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Revision History

Date	Version	History
November 1997	1.0	Standard implemented.
May 2000	2.0	Added Appendix: Q&A
April 2006	3.0	
January 2013	3.0	Document format change ONLY