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HLA Testing Guidelines

The purpose of this document is to establish guidelines pursuant to Chapter 355 of the Acts of 2000. These guidelines are being established to ensure that human leukocyte antigen testing or histocompatibility locus antigen (HLA) testing for the purpose of establishing bone marrow/stem cell transplant donor suitability conforms to specific medical eligibility, informed consent, and laboratory licensing and accreditation requirements.

Facilities that conduct HLA testing or their designees must meet the following requirements:

Medical Eligibility Criteria

- Prior to having blood drawn, each potential donor must be screened for medical eligibility using criteria established by the National Marrow Donor Program (NMDP) or equivalent criteria established by a member of the World Marrow Donor Association (WMDA).

Informed Consent

- Prior to having blood drawn, each potential donor must provide informed consent in writing. At a minimum, the informed consent must include:
  - An explanation of the medical eligibility criteria for potential stem cell donors.
  - A statement regarding the purpose of stem cell donation and the understanding that the purpose of HLA typing is to facilitate unrelated donor bone marrow or peripheral blood stem cell (PBSC) transplantation.
  - An explanation of the types of stem cell donation and the methods for collecting the stem cells, including any physical or psychological effects which may result.
  - A statement of the confidentiality of all potential donor information.
  - An explanation of the risks of venipuncture.
  - An explanation of eligibility for mandated third-party insurer coverage of HLA testing for the purposes of determining stem cell transplant donor suitability, as well as any charges for HLA typing in the absence of insurance coverage. A statement permitting the donor center to submit a claim to the insurance company must be included on this consent form or on a separate insurance form.
  - A statement that donors will not be paid for their donation.
  - Permission to register with the NMDP or with any member of the WMDA.

Laboratories that conduct HLA typing must meet the following requirements:

- Clinical Laboratory Improvement Amendments (CLIA) certification.
- Accreditation for molecular typing by the American Society for Histocompatibility and Immunogenetics (ASHI).