§ 1271.45 What requirements does this subpart contain?

(a) General. This subpart sets out requirements for determining donor eligibility, including donor screening and testing. The requirements contained in this subpart are a component of current good tissue practice (CGTP) requirements. Other CGTP requirements are set out in subpart D of this part.

(b) Donor-eligibility determination required. A donor-eligibility determination, based on donor screening and testing for relevant communicable disease agents and diseases, is required for all donors of cells or tissue used in HCT/Ps, except as provided under §1271.90. In the case of an embryo or of cells derived from an embryo, a donor-eligibility determination is required for both the oocyte donor and the semen donor.

(c) Prohibition on use. An HCT/P must not be implanted, transplanted, infused, or transferred until the donor has been determined to be eligible, except as provided under §§1271.60(d), 1271.65(b), and 1271.90 of this subpart.

(d) Applicability of requirements. If you are an establishment that performs any function described in this subpart, you must comply with the requirements contained in this subpart that are applicable to that function.