§ 1271.145 Prevention of the introduction, transmission, or spread of communicable diseases.

You must recover, process, store, label, package, and distribute HCT/Ps, and screen and test cell and tissue donors, in a way that prevents the introduction, transmission, or spread of communicable diseases.

§ 1271.150 Current good tissue practice requirements.

(a) General. This subpart D and subpart C of this part set forth current good tissue practice (CGTP) requirements. You must follow CGTP requirements to prevent the introduction, transmission, or spread of communicable diseases by HCT/Ps (e.g., by ensuring that the HCT/Ps do not contain communicable disease agents, that they are not contaminated, and that they do not become contaminated during manufacturing). Communicable diseases include, but are not limited to, those transmitted by viruses, bacteria, fungi, parasites, and transmissible spongiform encephalopathy agents. CGTP requirements govern the methods used in, and the facilities and controls used for, the manufacture of HCT/Ps, including but not limited to all steps in recovery, donor screening, donor testing, processing, storage, labeling, packaging, and distribution. The CGTP provisions specifically governing determinations of donor eligibility, including donor screening and testing, are set out separately in subpart C of this part.

(b) Core CGTP requirements. The following are core CGTP requirements:

1. Requirements relating to facilities in §1271.190(a) and (b);
2. Requirements relating to environmental control in §1271.195(a);
3. Requirements relating to equipment in §1271.200(a);
4. Requirements relating to supplies and reagents in §1271.210(a) and (b);
5. Requirements relating to recovery in §1271.215;
6. Requirements relating to processing and process controls in §1271.220;
7. Requirements relating to labeling controls in §1271.250(a) and (b);
8. Requirements relating to storage in §1271.260 (a) through (d); and
9. Requirements relating to receipt, predistribution shipment, and distribution of an HCT/P in §§1271.265(a) through (d); and
10. Requirements relating to donor eligibility determinations, donor screening, and donor testing in §§1271.50, 1271.75, 1271.80, and 1271.85.

(c) Compliance with applicable requirements—(1) Manufacturing arrangements

(i) If you are an establishment that engages in only some operations subject to the regulations in this subpart and subpart C of this part, and not others, then you need only comply with those requirements applicable to the operations that you perform.

(ii) If you engage another establishment (e.g., a laboratory to perform communicable disease testing, or an irradiation facility to perform terminal sterilization), under a contract, agreement, or other arrangement, to perform any step in manufacture for you, that establishment is responsible for complying with requirements applicable to that manufacturing step.

(iii) Before entering into a contract, agreement, or other arrangement with another establishment to perform any step in manufacture for you, you must ensure that the establishment complies
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§ 1271.155 Exemptions and alternatives.

(a) General. You may request an exemption from or alternative to any requirement in subpart C or D of this part.

(b) Request for exemption or alternative. Submit your request under this section to the Director of the appropriate Center (the Director), e.g., the Center for Biologics Evaluation and Research or the Center for Devices and Radiological Health. The request must be accompanied by supporting documentation, including all relevant valid scientific data, and must contain either:

(1) Information justifying the requested exemption from the requirement, or

(2) A description of a proposed alternative method of meeting the requirement.

(c) Criteria for granting an exemption or alternative. The Director may grant an exemption or alternative if he or she finds that such action is consistent with the goals of protecting the public health and/or preventing the introduction, transmission, or spread of communicable diseases and that:

(1) The information submitted justifies an exemption; or

(2) The proposed alternative satisfies the purpose of the requirement.

(d) Form of request. You must ordinarily make your request for an exemption or alternative in writing (hard copy or electronically). However, if circumstances make it difficult (e.g.,