

---

# Manual of Standard Operating Procedures and Policies

---

## Regulatory - Cellular, Tissue and Gene Therapies

### Procedures for Handling Requests for Exemptions and Alternative Procedures for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) Under 21 CFR Section 1271.155

SOPP 9151

Version #1

June 13, 2006

---

#### 1. Purpose

The purpose of this document is to describe the procedures the Office of Cellular, Tissue and Gene Therapies (OCTGT) staff should follow to address requests for exemptions and alternative procedures under 21 CFR 1271.155.

#### 2. Background

On November 24, 2004, the Food and Drug Administration published a final rule that includes requirements for requesting an exemption from or alternative procedure to any requirement in subpart C (Donor Eligibility) or D (Current Good Tissue Practices) of 21 CFR Part 1271. This rule was effective on May 25, 2005 for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P) procured on or after the effective date.

#### 3. Policy

This SOPP applies to all requests for exemptions from or alternative procedure to any requirement in 21 CFR 1271.155. Such requests can be made by phone or in writing.

#### 4. Responsibilities and Procedures

Responsibilities:

The Division of Human Tissues (DHT) in the Office of Cellular Tissue and Gene Therapies (OCTGT) is responsible for database management, filing, processing and drafting responses for the requests for these exemptions and alternative procedures. Appendix 1 lists all appropriate contacts in DHT.

Procedures:

- Exemptions and alternative procedure requests, addressed to the Center Director, CBER, are forwarded by CBER's Document Control Center to DHT at HFM- 775.
- The tissue establishment registration coordinator logs these requests into the DHT database on OCTGT'S shared network drive.
- The registration coordinator then forwards the requests to the DHT point of contact for coordination. A

letter template and all drafted correspondence will be kept in the DHT folder on OCTGT's shared network drive.

- o Depending on the nature of the request, DHT determines if expertise from other OCTGT divisions or FDA staff is needed to address the request. If additional expertise is needed, a meeting will be scheduled.
- o DHT staff will draft the response letter in cooperation with the appropriate experts.

Draft responses are discussed at a meeting of the Tissue Policy Team before finalizing the letter for the Center Director's signature. The members of the Tissue Policy Team are from CBER's Office of Cellular, Tissue and Gene Therapies, Office of Compliance and Biologics Quality, the Office of the Director and the FDA Office of Chief Counsel. Currently, these meetings are held twice monthly.

Sign-off for all responses is through the DHT Division Director, OCTGT Office Director, and the Center Director. Correspondence for the Center Director's signature is entered into the appropriate Agency/Center correspondence tracking system (currently AIMS). Once all signatures have been obtained, the signed response letter is sent back to the DHT tissue establishment registration coordinator to process, date and mail. This process includes any updates to the appropriate databases.

When the letter is signed and dated, copies are sent to OCBQ (HFM-650) to forward to the appropriate District Office. Copies of the final letter are filed in DHT's official registration and listing file for the establishment if the establishment has registered. If the product is under IND, the sponsor will be encouraged to forward the response to their IND file.

**5. Appendices**

[Appendix 1: List of OCTGT contacts](#)

**6. Effective date:**

June 13, 2006

**7. References**

[21 CFR 1271.155 \(PDF\)](#)

[Current Good Tissue Practice for Human Cell, Tissue, and Cellular and Tissue-based Product Establishments; Inspection and Enforcement; Final Rule, November 24, 2004.](#)

**8. History**

| <b>Written/Revised</b> | <b>Approved</b>          | <b>Approval Date</b> | <b>Version Number</b> | <b>Comment</b>    |
|------------------------|--------------------------|----------------------|-----------------------|-------------------|
| OCTGT/Wells            | Robert A. Yetter,<br>PhD | June 8, 2006         | 1                     | Original document |

Updated: June 13, 2006