Written Standard Operating Procedures and Required Records for Reproductive HCT/Ps

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Standard Operating Procedures (SOP) Under 21 CFR 1271

Subpart C

21 CFR 1271.47- Donor Eligibility

- SOPs for ***all steps that you perform*** in testing, screening, determining donor eligibility and complying with all other requirements. Establish and maintain means define, document, and implement; then follow, review, and as needed revise on an ongoing basis. **21 CFR 1271.47(a)**
- Review and approval by a responsible person **21 CFR 1271.47(b)**
- Availability to personnel **21 CFR 1271.47(c)**
- Adopted SOPs must be verified to meet regulations and are “appropriate for your operation” **21 CFR 1271.47(e)**

Standard Operating Procedures (SOP) Under 21 CFR 1271

Subpart C

21 CFR 1271.65(a) Ineligible Donor Storage

- If you are the establishment that stores the HCT/P, you must store or identify HCT/Ps from donors who have been determined to be ineligible in a physically separate area clearly identified for such use, ***or*** follow other procedures, that are adequate to prevent improper release until destruction or other disposition of the HCT/P.

21 CFR 1271.75(e) Abbreviated Screening Procedure for Repeat Donors

- Abbreviated procedure must determine and document any changes in the donor's medical history since the previous donation that would make the donor ineligible, including relevant social behavior.

21 CFR 1271.85(b) Reactive for CMV

- You must establish & maintain procedures governing the release of an HCT/P from a donor whose specimen tests reactive to CMV.

Required Records Under 21 CFR 1271

21 CFR 1271. 3(s)- What is a Relevant Medical Record?

Document(s) that include…

- a current donor medical history interview
- a current report of the physical assessment of a cadaveric donor or the physical examination of a living donor
- laboratory test results
- other medical records
- coroner and autopsy reports for cadaveric donors (not applicable to reproductive donors)
- records or information received from any source pertaining to risk factors for relevant communicable disease (e.g., social behavior, clinical signs and symptoms and treatments related to medical conditions suggestive of risk for relevant communicable disease).

Required Records Under 21 CFR 1271

Donor Eligibility Determination

Accompanying Records- **21 CFR 1271.55(a)**

- A distinct identification code affixed to the HCT/P
- A statement, based on screening and testing, the donor is eligible or ineligible
- A summary of the records used to make the donor-eligibility determination

Summary of Records- **21 CFR 1271.55(b)**

- A statement that communicable disease testing was performed by a CLIA, or equivalent, lab.
- A listing and interpretation of all communicable disease testing results
- The name and address of the establishment that made the donor eligibility determination
- In the case of an ineligible HCT/P donor based on screening, a statement noting the reason for ineligibility

Required Records Under 21 CFR 1271

Donor Eligibility Records

- Accompanying records must not contain the donors name or other personal information that might identify the donor- **21CFR 1271.55(c)**
- You must maintain documentation of results and interpretation for relevant communicable disease testing. The name and address of the testing laboratory. The name of the responsible person who made the determination and the date of the determination. **21CFR 1271.55(d)(1)**
- Records must be accurate, indelible, legible and in English- **21CFR 1271.55(d)(2)**
- Make required records available for authorized FDA inspections. Records that can be readily retrieved from another location by electronic means are considered "retained"- **21CFR 1271.55(d)(3)**
- For how long? At least 10 years after the date of administration, or if the date of administration is not known, then at least 10 years after the date of the HCT/P's distribution, disposition, or expiration, whichever is latest- **21CFR 1271.55(d)(4)**

Required Records Under 21 CFR 1271

Other Record Requirements

Departure from Procedures- 21 CFR 1271.47(d)

- You must record and justify any departure from a procedure relevant to preventing risks of communicable disease transmission at the time of its occurrence.

Shipping of HCT/Ps in quarantine- 21 CFR 1271.60(c)

- If you ship an HCT/P before completion of the donor-eligibility determination, you must keep it in quarantine during shipment. The HCT/P must be accompanied by records:
  - Identifying the donor (e.g., by a distinct identification code affixed to the HCT/P container)
  - Stating that the donor-eligibility determination has not been completed (must be clearly identified as in quarantine 1271.60(b))
  - Stating that the product must not be implanted, transplanted, infused, or transferred until completion of the donor-eligibility determination.

Required Records Under 21 CFR 1271

Subpart D CGTP Record Requirements

21 CFR 1271.155

Exemption Request and Approvals – 21CFR1271.155(f)

- If you operate under the terms of an exemption or alternative, you must maintain documentation of:
  - FDA's grant of the exemption or alternative, and
  - The date on which you began operating under the terms of the exemption or alternative

Summary

Standard Operating Procedures (SOP) for:

- All steps that you perform in testing, screening, determining donor eligibility and complying with all other requirements in subpart C "Donor Eligibility"
- Ineligible donor storage
- Abbreviated screening
- Reactive CMV results

Required Records include:

- Accompanying records
- Summary of records
- Donor eligibility records
- Departure from procedures
- Shipping HCT/Ps in quarantine
- Approvals of exemption request


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