



American Association of Tissue Banks® AATB TPG, LLC

September 7, 2021

Manufacturers Assistance and Technical Training Branch (MATTB)
Center for Biologics Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

In Re: Electronic Summary of Records for 361 HCT/Ps

Sent via e-mail to Industry.Biologics@fda.hhs.gov

Dear Madams and Sirs:

The American Association of Tissue Banks (AATB or Association) and the American Association of Tissue Bank's Tissue Policy Group, LLC (AATB TPG) submit a request to you for additional clarification regarding tissue bank requirements related to the summary of records for 361 human cells, tissues, and cellular and tissue-based products (HCT/Ps), as detailed in 21 CFR 1271.55. We appreciate the work of the Manufacturers Assistance and Technical Training Branch (MATTB) in providing timely, accurate and useful information to stakeholders, and we look forward to receiving your response, hopefully within five business days.

The American Association of Tissue Banks (AATB) is a professional, non-profit, scientific and educational organization. It is the only national tissue banking organization in the United States, and its membership totals approximately 120 accredited tissue banks and 2,000 individual members. These banks recover tissue from more than 58,000 donors and distribute in excess of 3.3 million allografts for more than 2.5 million tissue transplants performed annually in the U.S. The overwhelming majority of the human tissue distributed for these transplants comes from AATB-accredited tissue banks.

The AATB's Tissue Policy Group (TPG), LLC (AATB TPG or TPG) includes Chief Executive Officers and senior regulatory personnel from U.S. tissue banks that process donated human tissue. The purpose of the TPG is to drive public policy in furtherance of the adoption of laws and regulations that foster the safety, quality and availability of donated tissue. The TPG's membership is responsible for the vast majority of tissue available for transplantation within the U.S.

Specifically, the AATB and the TPG seek clarification as to whether a tissue bank would be in compliance with the summary of records (per 21 CFR 1271.55) and the instructions for use (IFU) requirement (per the labeling requirements contained within 21 CFR 1271.370) if the tissue bank ensures that the distinct identification code (i.e., alphanumeric code that relates the HCT/P to the donor and all records pertaining to the HCT/P, likely through the use of a QR or bar code) is affixed directly to the HCT/P, and then the instructions for use (IFU) and the donor eligibility and testing is electronically provided. **In light of the definitive patient safety benefit, the increased need for**

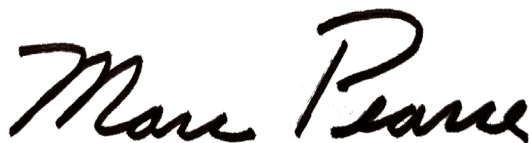
ensuring that key data are available to practitioners, and the value of an electronic exchange of information, the AATB and the AATB TPG strongly urge you to consider interpreting the regulations (e.g., clarifying the terms “accompanying records” and “accompany” in 21 CFR 1271.55 and the labeling requirements under §1271.370) to allow for an electronic summary of records and IFU.

This interpretation is consistent with current regulatory guidance. For instance, section III.G of the [Guidance for Industry, Eligibility Determination for Donors of HCT/Ps](#) states that “[e]lectronic access to accompanying records within a facility would satisfy the regulatory requirements under 1271.55(a), as long as they are in compliance with 1271.55(c) – deletion of personal information.” Therefore, the Agency has already clarified that electronic access to the records is acceptable “within a facility,” and it seems the concept could and should be applied for HCT/Ps being distributed from a facility. In addition, in the [Guidance for Industry, CGTP and Additional Requirements for Manufacturers of HCT/Ps](#), Section XXIII.B states “your labeling procedures should be designed to ensure that consignees can readily link the product to all required labeling and accompanying records, such as instructions for use.” This language appears to indicate that the intent of the requirements is to ensure that such linkage is possible, and electronic access would be consistent with that intent.

In addition, this interpretation will help ensure that the most up-to-date information (including the IFU, package insert, implant tracking cards, and summary of records) are up-to-date and readily available to both the clinician and the patient alike, while also ensuring harmony between the device and tissue regulations. In addition, this interpretation would lessen the risk of the summary of records and labeling information, including the IFU, being detached from the HCT/P (e.g., the hardcopy paper coming detached from the HCT/P) and thereby decreasing risk to the end-user. Finally, this interpretation is most consistent with the realities of tissue banking.

The AATB and the TPG stand ready and willing to assist the FDA with its deliberations in any way that the FDA deems appropriate.

Respectfully,



Marc Pearce, MBA
President & CEO
American Association of Tissue Banks



Joe Yaccarino
Chair
Tissue Policy Group