



## New York State Tissue Resources Program

Policy – Distribution of certain birth tissues requires documentation from FDA

Effective date – January 21, 2022

Valid until – Regulatory or policy change supersedes this policy

In 2017, the FDA published guidance on the minimal manipulation and homologous use of tissues and tissue products<sup>1</sup>, collectively human cells, tissues and cellular and tissue-based products (HCT/Ps). With few exceptions, HCT/Ps are also regulated by the Department's Tissue Resources Program (TRP) under 10 NYCRR Part 52 and/or Part 58-5. As such, distribution of most HCT/Ps to New York State, and clinical use of HCT/Ps in New York State, requires a Department-issued tissue bank license.

FDA regulates HCT/Ps under Title 21 of the Code of Federal Regulations (CFR) Part 1271, and either solely under section 361 of the Public Health Service Act (PHS Act), or under both sections 361 and 351 of the PHS Act and/or the Federal Food, Drug, and Cosmetic Act. HCT/Ps regulated under section 351 require FDA's premarket approval, or an FDA-allowed Investigational New Drug (IND) application to test the product in clinical trials.

The FDA's 2017 guidance document, updated most recently in 2020, describes situations in which the use of amniotic membrane is allowed under section 361, and situations in which it would also be regulated under section 351. Similarly, communication from FDA indicates uses of umbilical cord tissue that are allowed under section 361, specifically, "serving as a conduit," and uses that would render it subject to section 351 regulation.

FDA offers several options to assist tissue banks that manufacture these products in determining whether or not a product requires premarket approval prior to distribution, including both binding designations and non-binding recommendations as to the appropriate framework.

Historically, the TRP categorized umbilical cord tissue products<sup>2</sup> and amniotic membrane products together under the tissue type "amniotic membrane." Following the publication of the guidance document in 2017 and subsequent statements from FDA, most recently the letter to patients and consumers that FDA published on June 3, 2021<sup>3</sup>, TRP reconsidered its approach to the regulation of umbilical cord tissue and amniotic membrane products in New York State.

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<sup>1</sup> "Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use", available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/regulatory-considerations-human-cells-tissues-and-cellular-and-tissue-based-products-minimal>.

<sup>2</sup> Hematopoietic progenitor cells (HPCs) isolated from the umbilical cord are not considered umbilical cord tissue. These HPCs are explicitly regulated by the Department under 10 NYCRR Part 58-5, and their banking and transplantation is allowable with appropriate licensure.

<sup>3</sup> "Important Patient and Consumer Information About Regenerative Medicine Therapies", available at <https://www.fda.gov/vaccines-blood-biologics/consumers-biologics/important-patient-and-consumer-information-about-regenerative-medicine-therapies>.

Henceforth, any tissue bank, including transplantation facilities, whose license does not specifically list umbilical cord as an approved tissue type may not distribute or transplant umbilical cord tissue in New York State without first applying to the Department for a license, or to amend an existing tissue bank license, and receiving the new or amended license.

Furthermore, the Department will not approve a license for the distribution or transplantation of umbilical cord tissue without documentation that:

- FDA has approved its use;
- An IND is in effect to test the umbilical product in clinical trials;
- FDA has determined or recommended that the product is regulated solely under section 361; or
- FDA amends its guidance or regulations.

Additionally, amniotic membrane products in formats other than a sheet of tissue may not be distributed or transplanted in NYS without the same documentation from FDA.