

Department of Health

KATHY HOCHUL Governor JAMES V. McDONALD, M.D., M.P.H. Commissioner JOHANNE E. MORNE, M.S. Acting Executive Deputy Commissioner

December 28, 2023

Michael J. Bauer, M.D., FACP, CTBS Medical Director and Tissue Bank Director California Cryobank LLC 201 W. North River Dr., Suite 100 Spokane, WA 99201 Fac. ID: 3045

Dear Colleague,

Please find enclosed the provisional license certificate for tissue bank operation at the following location:

California Cryobank LLC 201 W. North River Dr., Suite 100 Spokane, WA 99201

The certificate is effective until the date indicated, or the issuance of a full license following an onsite survey of your facility. The certificate must be posted conspicuously at the approved location. Your license is specific to this location; you must notify the Department of any changes in address.

You must submit a new application if you intend to expand your services or activities beyond those listed on this certificate. All tissue for clinical use must be procured, processed, stored, and distributed by tissue banks licensed by the Department for the relevant activities.

To remain in compliance with New York State regulations, you must also:

- Report any changes in director, medical director, and compliance officer within five days;
- Report any change in ownership of five percent or more within 30 days;
- Report any accidents in retrieval, testing, processing, storage, or distribution that may affect the safety of any product within seven calendar days of discovery.

Application forms, specifics of 10 NYCRR Part 52 and Subpart 58-5 regulations, and updated policies are available online at <u>https://www.wadsworth.org/regulatory/tissue-resources</u>. If you have any questions, please call (518) 485-5341, or e-mail <u>tissue@health.ny.gov</u>. Please reference the Facility ID number at the top of your license in any correspondence.

Sincerely,

Diane Sullivan

Diane Sullivan, B.S., M.T. Tissue Bank Consultant Tissue Resources Program

Enclosure

NEW YORK STATE DEPARTMENT OF HEALTH

PROVISIONAL LICENSE FOR TISSUE BANK OPERATION

Issued in accordance with and pursuant to section 4364 Public Health Law of New York State

Facility ID: 3045

Tissue Bank Director: Michael J. Bauer, M.D., FACP, CTBS Medical Director: Michael J. Bauer, M.D., FACP, CTBS

Owner: CooperSurgical, Inc.

California Cryobank LLC 201 W. North River Dr., Suite 100 Spokane, WA 99201

is hereby APPROVED as a Tissue Bank for the following categories of service:

Comprehensive Tissue Procurement Service Tissue Processing Facility Tissue Storage Facility Male reproductive tissue from anonymous donors Male reproductive tissue Male reproductive tissue

Issued: December 28, 2023

Expires: January 1, 2026

Property of the New York State Department of Health. Valid only at the address shown. Must be conspicuously posted.

DOH-3908 (04/2001)