



TISSUE BANK LICENSE NEW APPLICATION CHECKLIST

*Go to our webpage to download the forms: cdph.ca.gov/TissueBank

- Form **LAB 172*** (*Tissue Bank Application*) (*Including question #3*)
- Form **LAB 169*** (*Personnel Report*)
- Form **LAB 170*** (*ART Questionnaire, if applicable*)
- Form **LAB 184*** (*Contact Person sheet*)

EITHER: Tissue Bank Site Lease Agreement; Business Permit; & Fictitious Name Permit

OR: Copy of hospital’s California State license from Licensing & Certification

Ownership Substantiation:

- 1) Corporate organization chart structure detailing parent and intermediary owners
- 2) Partnership Agreement
- 3) Practice Management Assistance Agreement
- 4) Corporation documents:
 - a. Articles of Incorporation
 - b. List of Board of Directors and Officers
 - c. List of shareholders who own 5% or more
 - d. Management Agreements

Employee & Director Resumes or CVs (*BRN# of RN employees on LAB 169 is sufficient*)

Copy of all Policies and Procedures pertaining to: receipt and/or collection of tissue; processing and/or storage of tissue; preparation of tissue prior to implantation; recall; QA; documentation of performed procedures

Copy of Patient Consent Form(s)

STD Screening Policy Statement on company letterhead (*See “STD Statement” from website*)

Copy of FDA Registration (*if applicable*)

Documents signed & dated

Operations Affirmation Letter (*see page 2*)

Application fee enclosed: • \$975

- Made payable to: “CDPH” or “Tissue Bank Fund”
- No license fee required for a tissue bank operated by the State, State agency, health care district, city, or county



Please mail your complete application to:

California Department of Public Health
Laboratory Field Services
Attention: Tissue Bank Program
850 Marina Bay Parkway Building P, 1st Floor
Richmond, CA 94804-6403



Operations Affirmation Letter

Dear Tissue Bank Director,

To ensure we have the most current and accurate information for your tissue bank, please complete this affirmation letter and return it with your initial packet.

Sincerely,

CDPH / Laboratory Field Services
Tissue Bank Licensing Program
LFSTissue@cdph.ca.gov

Tissue bank operations performed under my tissue bank license include:

Control of all operations as IND Sponsor: IND Number: _____

Donor qualification

Tissue collection / recovery (*This operation includes skull flap collection*)

Tissue processing (*This operation includes skull flap cleaning or sperm washing*)

Tissue distribution (*This operation includes transfer of tissue as well as sale*)

Tissue storage at my facility:

Room Temperature

Refrigerator (Temperature: _____ °F / °C)

Freezer (Temperature: _____ °F / °C)

Liquid Nitrogen

As the tissue bank director of:

Tissue Bank Name:

Tissue Bank License Number:

I affirm this information is correct.

(Signature of Tissue Bank Director)

(Printed Name)

(Date)

