

New Tissue Bank (TB) License Document Check Off List

- Application Fee enclosed (\$975.00 made payable to: CDPH/LFS Tissue Bank Program)
 - [Lab 172](#) (Tissue Bank Application)
 - [Lab 169](#) (Personnel Report)
 - [Lab 170](#) (ART Questionnaire, if applicable)
 - [Lab 184](#) (Contact Person Sheet)
 - Tissue Bank Site Lease Agreement; Business Permit; & Fictitious Name Permit
or
 Copy of hospital's California's 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. By-laws
 - c. List of Board of Directors and Officers
 - d. List of shareholders who own over 5%
 - e. Management Agreements
 - Employee & Director Resumes or CVs (BRN# on the personnel sheet for RN employees 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 [Advisory Note – STD Statement](#)
 - Copy of FDA Registration (if applicable)
 - List of all applicable commercial clients in California and/or all suppliers (name & address) with whom you conduct business (applicable to tissue)
 - Inventory list of all tissue types purchased, stored, distributed and/or used within the last 12 months. Include any recalls or adverse events.
 - Documents signed and dated. Call or e-mail for further assistance.
 - Alan.Ankerstar@cdph.ca.gov - 213-761-2689
 - Jan.Otey@cdph.ca.gov - 510-620-3816
 - Clint.Venable@cdph.ca.gov - 510-620-3829
- Please mail all required documents to:

Laboratory Field Services / Tissue Bank Program
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Richmond, CA 94804-6403