

New Tissue Bank (TB) 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) Partnership Agreement
 - (2) Practice Management Assistance Agreement
 - (3) 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# of 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”
- 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

* Forms found at

<http://www.cdph.ca.gov/pubsforms/forms/Pages/RegulatedLaboratories.aspx>

Please mail all required documents to:

**Laboratory Field Services
Tissue Bank Program
850 Marina Bay Parkway
Building P, 1st Floor
Richmond, CA 94804-6403**