

TISSUE BANK FREQUENTLY ASKED QUESTIONS (FAQ)

1. What exactly defines “human tissue”?

Human tissue is defined by statute as any human cell, group of cells, tissue or organ including the cornea, sclera, or vitreous humor and other segments of, or the whole eye, bones, skin, arteries, sperm, blood, other fluids, and any other portion of a human body.

In more general terms, human tissue can be separated into several different categories:

1. reproductive tissue such as sperm, ova, and embryos
2. bone marrow
3. musculoskeletal
4. cardiovascular
5. eye
6. skin
7. human milk
8. adipose
9. stem cells
10. umbilical cord tissue
11. amniotic membrane

2. How do I know if I need to apply for a tissue bank license?

A “tissue bank” is any place, establishment, or institution that collects, processes, stores, or distributes tissue for purposes of transplantation into human beings.

You will need to apply for a tissue bank license if you perform any or all of the four functions, namely collection, processing, storage, or distribution of human tissue for purposes of transplantation.

3. What if I work with human tissue but only in a research capacity, e.g., not for purposes of transplantation?

You need not apply for a tissue bank license if your purpose is other than for human transplantation. For instance, if you are involved in tissue banking for purposes of autopsy, biopsy, training and education, or for other medical or scientific research of investigation where transplantation of the tissue is not intended or reasonably foreseeable, you are exempt from this chapter of law.

4. What if I am an individual physician in reproductive medicine, and I want to perform only IUI's? Do I still need a tissue bank license?

As long as you qualify as an individual physician and you only process and store semen for your own patients, then the law is not applicable to you. But first you should ask yourself some important questions:

- 1) Do I employ any other physicians in my practice, or do I have any other physician partners in my practice?
If you answer yes to either of these questions then under the law you do NOT own and operate an individual physician practice and you must be licensed as a tissue bank.
- 2) Do I accept referred work such as sperm washing?
If you accept ANY referred work, regardless of your status as an independent operator, you must apply for a tissue bank license. A physician who accepts referred work no longer meets the definition, under law, of treating ONLY his or her own patients.
- 3) Do I perform other services as a reproductive specialist such as IVF, ZIFT, GIFT, ICSI, etc?
The inapplicability of law holds only for physicians who qualify as individual physicians treating only their own patients and who do not process or store any other type of reproductive tissue other than semen. If your practice includes the processing and/or storage of ova or embryos, then you must apply for a tissue bank license.

5. I'm an Andrology specialist, and I'm not really sure how my practice would be seen in accordance with question set #4 above. I want to be in compliance with the law, but how can I know for sure that I am operating in compliance with all applicable laws?

That's easy: just call the Department for a consultation. We are happy to discuss the specifics of your practice and then advise if you are eligible for exemption from the law.

6. Are facilities that collect, process, store, or distribute whole organs exempt from the need for a tissue bank license?

OPO's or Organ Procurement Organizations as defined in law (42 Code of Federal Regulations, section 485.302) are exempt from the need for a tissue bank license. For more specific legal references, consult the California Health and Safety Code, Section 1635.1 (b) (5).

7. Is it true that a general, acute care hospital has a special exemption from the law requiring a tissue bank license when storing certain types of bone?

A general acute care hospital is exempt from law if it stores ONLY prepackaged, freeze-dried bone.

8. Do dentists have any exemptions?

Yes, dentists have an exemption from licensure for the storage of freeze-dried bone and dermis by any licensed dentist practicing in a lawful practice setting, providing that the freeze-dried bone and dermis has been obtained from a licensed tissue bank and is stored in strict accordance with package insert of the kit and any other manufacturer instructions and guidelines and is used for the express purpose of implantation into a patient.

9. How much does it cost to file a tissue bank licensing application?

The fee, which must be submitted with your application, may vary in any given fiscal year, but the current fee is \$975.00. This fee is paid at the time of application and must be paid annually with renewal at least 30 days prior to expiration of the license.

10. What kinds of attachments are required when I file my first application?

When you file your first application, we want you to include several items that tell us about your business from an administrative as well as from a technical perspective. We request that you include a copy of your "dba" permit (also known as a fictitious name permit) if you are operating under the name of a fictitious business, and also a copy of your lease agreement to confirm your permanent address location. If you are incorporated we want a copy of your corporate transcript and a list of your board of directors. Copies of other pertinent business permits may also be requested.

You also need to submit an STD policy statement that affirms that specified testing has been performed and found nonreactive for any implanted tissue. See our [advisory note](#) and [check-off list](#) sent with new application packets. (Note: refer to California Health & Safety Code 1644.5(c) and (d) for exceptions allowed under specific conditions)

As far as technical policies and procedures, we will require a complete set of your daily operating procedures. It is required by law that you submit these policies and procedures with your initial application. Please contact the tissue bank section for our Tissue Bank Application e-packet.

11. My daily operating policies and procedures are proprietary. I don't want my competitors to have access to these items.

We consider all submitted policies and procedures as proprietary and will NOT release them under The Public Records Act. The only time a policy or procedure is ever released is upon demand via a lawful subpoena. In that case, we will notify you that the Department has been served with such a request.

12. If I operate a tissue bank in California, do I also need to have a federal CLIA certificate?

You only need a federal CLIA certificate if you intend to perform tests in your facility that meet the definition of clinical laboratory tests. This question usually comes up in conjunction with the performance of a complete semen analysis by a practice involved in the treatment of reproductive problems. Physicians who wish to perform complete semen analysis or hormone testing as part of their on-site practice will need to make application for a CLIA certificate and a California facility clinical laboratory license.

13. How do I know if I need a CLIA certificate and state laboratory licensure? Where can I go to obtain an application?

Contact the Department at LFSTissue@cdph.ca.gov if you are in doubt about your need for a certificate. You can obtain an application by visiting the California laboratory licensing website at <http://www.cdph.ca.gov/programs/lfs/Pages/ClinicalLaboratoryfacilities.aspx>.

14. What if I need the actual license number of a certain tissue bank or want to know if a particular facility is licensed? How can I obtain this information?

Contact the Department at LFSTissue@cdph.ca.gov. We will verify a license for you or provide the exact license number as issued by the Department. Contact the tissue bank directly to request a copy of their tissue bank license.

15. What should I do if I want to file a complaint about a tissue bank?

You should call the Department and briefly describe the nature of your complaint. An examiner will try to obtain as much information about the problem as possible and will want to know if you want your name omitted in any follow-up activities by the Department. You will be asked to submit a written complaint on a special form available from the Department at <http://www.cdph.ca.gov/pubsforms/forms/CtrlForms/lab163.pdf>.

16. If I file a complaint and prefer to remain anonymous, will the Department give me 100% assurance that my name will never be used?

No, unfortunately the Department cannot give you this assurance. The Department will do everything in its power to protect your anonymity, but in the case of certain types of litigation or in the special case when the court orders the Department to reveal certain proprietary information, your anonymity cannot be guaranteed.

17. I'm looking for a facility where I can have assisted reproductive technology performed. Could you give me some recommendations as to what you consider your best services?

The Department cannot ever endorse one facility over another. If a facility has some derogatory information in its files, we are able to share with you certain items of information. We cannot share information concerning litigation which is ongoing at the time of your request. We will not necessarily share details of past litigation unless you show us that it is necessary for you to have the information, e.g. the information is shown to be related or germane to your current situation.

18. What other states license tissue banks?

The States of New York, Florida, and Maryland have formal state laws that require the regulation of tissue banks. Additionally, other states have or are in the process of developing tissue bank oversight and regulation.

19. When does a hospital need a tissue bank license regarding human milk?

Whenever a hospital stores donor human milk, a tissue bank license is required.

20. When does a facility in California need a tissue bank license to store allograft tissue?

Whenever a facility stores allograft tissue as part of its inventory, unless the storage is specifically exempted by law, the facility requires a tissue bank license. If the facility orders a frozen or cryopreserved allograft for a specific patient and holds it in the unopened, validated, temperature-controlled shipping container no longer than the validation expiration date and time specified by the shipper before implanting, returning, or discarding the tissue, the facility does not need a tissue bank license. The temporary storage of the allograft tissue in the unopened, validated, temperature-controlled shipping container is covered by the California tissue bank license of the facility that ships the tissue. The temporary storage of room temperature or refrigerated allografts ordered for a specific patient is covered by the shipping facility's California tissue bank license until implanted in that patient or returned to the shipping facility. If the receiving facility stores the tissue as part of available allograft inventory, the facility needs a California tissue bank license.

21. How long does it take to renew my tissue bank license?

Processing your renewal application packet takes approximately 30 days. Your tissue bank license is forfeit on the day it expires. Please send your renewal 30-60 days before expiration to avoid being out of compliance and possibly having to complete a new tissue bank license application.

22. Do I need a tissue bank if I use only non-human tissue?

No, xenographic implant material is not regulated through CDPH Laboratory Field Services California Tissue Bank Program.