

# Research Tissue and California Tissue Banks

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When dealing with research tissue questions, remember:

- 1) YOU are experts- take advantage of each other's knowledge and experience whenever possible
- 2) "Responsibility" and "liability" in a given situation may end up being decided by the legal system- be careful!
- 3) DHS currently has no authority over research tissue

## DEFINITIONS

CH&SC 1635(d) defines a **tissue bank** as, "any place, establishment, or institution that collects, processes, stores, or distributes tissue for transplantation into human beings".

CH&SC 1635(c) defines **tissue** 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 the human body".

In 2002, there were approximately 800,000 human tissues for transplant distributed by U.S. tissue banks. The tissues include:

- **Skin** (fresh skin and skin substitutes of human origin)
- **Heart valves**
- **Bone** (fresh-frozen, freeze-dried, de-mineralized)
- **Veins** (saphenous)
- **Musculoskeletal** (tendons, ligaments, tendon-bone complexes)
- **Ocular** (corneas, sclera)
- **Placenta** ("band-aid" for eye repair)
- **Mother's milk** (CH&SC 1647)
- **Reproductive tissue** (semen, ova, embryos)

Tissues not included in the above list:

- **Blood** (Regulated by state and federal govt.)
- **Research Tissue** Exempt from tissue bank statutes, CH&SC §1635.1(b)(2): "The collection, processing, storage, or distribution of tissue for autopsy, biopsy, training,

education, or for other medical or scientific research or investigation, where transplantation of the tissue is not intended or reasonably foreseeable.”

- **Organs** (regulated by federal govt.)

### **Tissue Recovery:**

- Cadaveric tissue is recovered in morgues, tissue banks, hospitals, funeral homes, etc.
- Recovery teams include surgeons, surgical nurses, or specially trained employees of tissue banks

### **Tissue Processing:**

Some tissues are modified and then packaged for distribution; others are not modified after recovery.

#### Modified tissues:

Bone + tendon, bone dowels and screws

#### Unmodified tissues:

Fresh frozen bone, corneal implants, heart valves, skin

**Tissue Storage:** Any place that stores human tissue for transplant into humans (in California) is a tissue bank. (The FDA has a slightly different definition.) There are hospitals in California that store tissue (especially bone) for use in their surgery departments that are not licensed. (The storage of freeze-dried bone by a general acute care hospital is exempt from licensure.) DHS is working to identify unlicensed facilities and bring them into compliance with state law.

**Tissue Distribution:** Any place that provides human tissue for transplant into humans is a tissue distributor and subject to California tissue bank laws. (California Health and Safety Code § 1635)

## **Questions**

### **California Willed Body Consortium**

### **Spring 2003 ❖ Reno Hilton**

(Questions submitted by individual California WBP)

1. **Please provide an overview of Tissue Banking and explain how a non-profit vs for-profit bank works.**
  - *California has both non-profit and for-profit tissue banks. Although not a requirement, all tissue recovery in California is done by non-profits. Both non-profit and for-profit tissue banks process, store and distribute transplant tissue in California. Financially, non-profit tissue banks barely break even or lose money; for profit tissue banks, with a few exceptions, are also only marginally profitable, due to high overhead expenses involved in tissue banking.*

**2. Within the framework of tissue bank triage, how are decisions for matching donations with patients standardization work?**

- *There is enough tissue available to meet all patient's needs in California, so triage is really not an issue. If for some reason a specific tissue was locally in short supply, tissue banks "network" among themselves to ensure that patients' needs are met. Also, the American Association of Tissue Banks (AATB) has an emergency hotline to assist tissue banks in locating critically needed tissue, but this service has never been used (!).*

**3. What are the licensing requirements for tissue banks?**

- *Licensing requirements are defined in H&SC §1639. Again, any entity that recovers, processes, stores, or distributes human tissue for transplantation into other humans is required to have a license. Tissues are regulated to protect public health.*

**4. How many licensed tissue banks are there in California?**

- *Currently, there are approximately 340 tissue banks licensed by the state, and approximately 3 new tissue banks are licensed each month. Cadaveric transplant banks are about 60 - 70% of the banks licensed; the other 30 - 40 % are ART ("assisted reproductive technology" tissue banks, which are sperm banks and IVF clinics).*

**5. Explain cooperatives between National and Statewide tissue banks?**

- *Some tissue banks in California are national organizations, such as TBI (Tissue Banks International) and ARC (American Red Cross). Some tissue banks operate only in California. My observation is that all tissue banks, whether "connected" to each other or independent, cooperate amongst themselves to ensure that patients get the tissue they need.*

**6. Do you foresee the possibility of State regulation of Willed Body Programs (WBP)? If so, under what jurisdiction would they most likely be placed?**

- *State Regulation of willed-body programs is possible. However, there would, at minimum, need to be a change to the CH&SC removing the exemption of research tissue. If that change to the law was made, then research tissue could be regulated through statute (laws made in Sacramento) or through regulations (laws adopted by a department).*
- *A sponsor introduces statutes into the legislature They are voted on and amended in the senate and assembly, and then respective versions are reconciled in conference committee. The reconciled bill is presented to the governor for signature, non-action, or veto.*
- *Regulations are developed by a department. The "Administrative Procedures Act" (APA) spells out how regulations are developed and adopted. Regulations have the force of law.*

**7. How do we sponsor legislation in Sacramento regarding WBP regulations?**

- *Find a legislator who is sympathetic to your cause*
- *Present them with a clear outline of your needs*
- *The Legislative Counsel will translate your list into statutory language (a bill)*
- *Legislator introduces the bill into the legislature*
- *(See “Legislative Process” below)*

**8. Is there any legislation that is being presented now that may impact WBP’s?**

- *Current bills can be found at <http://www.leginfo.ca.gov/bilinfo.html> Do a search with any term you are interested in, such as, “willed body program”, “tissue”, “cadaver”, “informed consent”, etc. Some bills that may be of interest to CFDA are detailed in the “Current Legislation” section of this handout.*

**9. There are times when a program is unable to provide a certain specimen and the physician or researcher goes to an outside source. Is there a way to determine if that source is authorized to provide specimens in California? (e.g. science care anatomical from Arizona)**

- *There is no way at present to evaluate a tissue source by the state, as there is neither the authority to do this, nor regulations or statutes setting standards. The combined expertise of the California’s WBP directors is invaluable. Find out if anyone you know has used them before, ask about them at conferences, etc. You have to do your homework. One might ask the supplier for references, especially WBP’s, or researchers at reputable institutions. (Such as a major university or research center.)*

**10. I’m hearing more and more about organizations having seminars in Hotel conference rooms utilizing "fresh" (Un-embalmed) tissues. We have, in fact, received requests for such materials, but have refused. What is the DHS perspective on these seminars?**

- *Fresh tissues (un-embalmed) at hotels for demonstrations are biohazardous materials, and should be treated as such. If one feels that a potentially dangerous (potential disease transmission) situation exists, prompt reporting is essential.*

**11. Is there a Department or section within DHS, which regulates research labs, specifically at colleges and universities?**

- *I am not aware of any “program” in DHS that monitors research labs, either at colleges or universities. If a research lab is in or affiliated with a hospital, then there may be state or federal oversight of some sort that is connected with patient care, through Medi-Cal or Medicare. There may also be some sort of oversight associated with research grants (NIH, etc.), and the university’s IRB.*

**12. How do we determine what Tissue bank is legitimate?**

- *Legitimate tissue banks (tissue for transplantation) are licensed by the State of California. Call me at any time to inquire about a bank. Tissue for research is not regulated. You are literally “on your own” with these. I think that doing everything in your power to determine whether or not a research tissue supplier is legitimate is up to you.*

**13. How much responsibility do Willled Body Programs bear when a university researcher obtains human anatomical material from an outside source unknown to the program?**

- *I am not aware of any specific regulations or statutes that address this issue. Your institution's legal counsel should advise you on the legal responsibilities of this issue.*

**14. How can Willled Body Programs be assured that shared human anatomical material has been acquired by appropriate consent, permission for multiple uses has been approved by the donor and the material obtained has been biotested?**

- *WBP's must assure themselves that shared material has been acquired properly. Ask to see documents, such as infectious disease testing, consent forms (keep HIPAA in mind when you do this), and very importantly, talk to your colleagues. WBP directors know more than anyone in California about research tissue, WBP's, etc. Talk to each other!*

**15. Does failure by a program to gain appropriate consent make a recipient of the material legally liable?**

- *Liability may have to be determined by the legal system. (That's the bottom line!) Keep in mind that whether or not your program is "legally liable", to have your WBP in the press and on the radio because someone you did business with turns out to have been doing unethical or illegal activities could have adverse consequences for your program.*

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