# Human Tissue Preservation

## Development of Regulations and Removal of Some Legal Barriers

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**• Human tissue must be obtained promptly postmortem if it is to be successfully preserved.**

**Legal assistance toward this goal has been established by the California Legislature.**

**To implement this legislation the State Board of Public Health has established regulations relating to human tissue preservation. These are the first such regulations in the nation.**

**Tissue preservation is not yet fully developed. Much research is in progress to overcome many problems.**

**The future may hold interesting developments. Present laws and regulations will implement them.**

THE STATE BOARD of Public Health[6] at its April 1959 meeting established regulations relating to the preservation of human tissues, as required to implement the provisions of the California Health and Safety and Probate Codes. These are the first regulations in the nation dealing exclusively with human tissues.

Blood preservation, a related activity, has been performed under regulation for many years, but this activity falls within a different category.

The preserving and transplanting of human tissues is a comparatively new development. Much investigation is still in progress. Ultimately there may be a whole system of spare parts for ailing human beings.[7,9] Before this goal is reached, however, there are still some knotty problems to unravel. At present, materials consist mostly of non-viable homografts and plastic prostheses.[1,2,10,11]

Hopeful progress is being reported.[8,9,12] The future holds the realization of these exciting prospects. For present activity and in anticipation of this interesting future, California has formulated a constructive legal background.

The state legislature in 1957 removed some of the legal obstacles from the way of persons who desire to bequeath their bodies or portions of them for use in therapeutics or in research. Section 7115 was added to the Health and Safety Code, and Section 7100 was amended.[4] Section 20 of the Probate Code was also amended.[5]

These additions and amendments provide for the immediate fulfillment of instructions in a will by which a decedent has directed that the whole or any portion of his remains be given for therapeutic use, for research or for teaching purposes.

These statutes state that regardless of the validity of the will in other respects, or of the fact that it may not be offered for probate until a later date, the persons entitled to control the remains shall faithfully and immediately carry out the instructions of the decedent.[4,5]

Such provisions make possible the procurement of valuable structures within the critical few hours following death during which they may be successfully preserved.

For future success in human tissue transplantation, adequate supplies of such tissues must be available. Development in this field may parallel the now established function of blood transfusion. Not so long ago the transfer of blood from one person to another was an exciting and spectacular surgical achievement. The donors were looked upon as heroes. Today the giving of blood is looked upon as a routine responsibility.

For other tissue transplantation to keep pace with growing scientific knowledge and therapeutic need, tissue donations will have to become routine and commonplace, and legal barriers reduced to a minimum. The recent actions of the State Legislature and the State Board of Public Health have opened the way to achieve these goals.

Physicians in their relationships with the public and with their patients have a responsibility and an opportunity to promote the popularity of developing these storehouses of human spare parts.

In the process of formulating the regulations, assistance was sought from other agencies, including the Federal Government, which presumably had some experience in this field. It was disappointing to discover that the legal situation in tissue donation is chaotic. Therefore, it is a source of satisfaction to realize that California has taken the first positive action to establish an orderly legal basis for this service.

Other communities are also taking action to improve their situations in this regard. For example there is at present a committee in Washington, D. C., whose purpose is to assist Congress in passing a bill known as "The District of Columbia Tissue Bank Act."[16,17]

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In developing the California tissue preservation regulations, the first procedure was a tour of known tissue banks. The directors of these services almost without exception welcomed the idea of legal[15] backing for their work. They assisted actively in the formulation of the regulations.

Since blood banking is well established in California, and the regulations[3] under which it functions have served successfully, the first draft of tissue preservation regulations was patterned after the blood banks. Since both procedures are similar in scope, the established blood bank regulations should have served properly as a prototype. This was not the case, however. Tissue preservation is not yet ready for regulations as precise and detailed as those in blood banking.[15] So after further consultation with persons with experience in preserving human tissues, it was decided to reword the proposed regulations into a very generalized form. This met with difficulty from another source. Attorneys stated that such generalized language was entirely unsatisfactory from a legal point of view. It was stated by them that some sort of criterion for making determinations would have to be established. The regulations as they now stand represent a compromise between detail and generalization.

It is of special interest to note that no one person professed knowledge of all types of tissue preservation. Those who work with arteries disclaim knowledge of bones or eyes, those who work with bones say they have no knowledge of arteries or eyes.

For the most part, structures transplanted at present are not living tissues.[11] Bones, for example, act as biological splints over which the tissues of the recipient grow as over a scaffolding, eventually surrounding and ultimately replacing the transplant. Arteries are used in much the same way. In fact, dacron, orlon, and other synthetics seem to work just as well as human artery transplants, and therefore, in this field human material as prepared at present may not be entirely essential.[10]

Organs as such cannot be transplanted successfully at this time, except in special instances such as from one identical twin to the other. This is due to some undescribed marker on the cells of each individual which proclaims them as belonging to himself.[9] Transplants of living tissues from place to place in the same person are successful because they are recognized in their new surroundings as belonging.

It should be emphasized that research is busily in progress toward overcoming these barriers to transplantation of living tissues from one person to another. Ferrabee and Thomas[9] have stated: "In this exciting realm of spare parts we have two newly recognized basic biologic phenomena with which to help ourselves. It is the recognition of these phenomena that has infused new life into the ancient and wistful field of organ transplantation."

Recent success with living marrow transplants following radiation of the recipient illustrates these advances.[8,12] Work at the Naval Medical Center by Hyatt and his associates[13,14] with growth of human tissue in laboratory media further strengthens hope of an eventual living tissue transplantation program.

With these inspiring developments in progress and with an optimistic future ahead, it is believed that the California laws and regulations will remove legal obstacles and lubricate the administrative machinery for the bequesting of tissues by persons before they die, thus allowing opportunity to obtain them and to use them therapeutically and scientifically at the earliest possible moment. These regulations will also be an encouragement to new tissue preservation centers, both for therapeutic use and to advance the horizons of knowledge so that when greater use of human tissue is scientifically possible, the legal and administrative tools will be available with which to promote development in this exciting field.

The text of the regulations is appended.

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## REGULATIONS RELATING TO HUMAN TISSUE PRESERVATION

(Title 17, California Administrative Code, Chapter 2, Subchapter 1, Group 7, Article 1, Sections 1200-1205, inclusive.)

Statutory Authority: California Health and Safety Code, Division 7, Part 1, Chapter 3, Sections 7100 and 7115; and Section 20 of the Probate Code.

### ARTICLE I.

1200. DEFINITIONS. (a) As used in this Group, "person" includes teaching institution, university, college, legally licensed hospital, non-profit blood bank, artery bank, eye bank, or other therapeutic service operated by any agency approved by the State Director of Public Health.

(b) As used in this Group, "department" means State of California Department of Public Health.

1201. APPROVAL REQUIRED FOR TISSUE PRESERVATION. No person shall collect, process, store, or distribute human tissues obtained in accordance with Sections 7100 or 7115 of the Health and Safety Code, or Section 20 of the Probate Code, unless such person shall have received approval from the department.

1202. PROVISIONS FOR APPROVAL. (a) An application for approval shall be made to the department, which shall include the following items:

(1) Complete and detailed description of the methods, equipment, and technics used in relation to each tissue which is to be processed.

(2) The name and address of the person owning the place, establishment, or institution, in which the processing is to be carried on.

(3) The name and address of the director who shall be a duly licensed physician and surgeon in the State of California.

(4) Kinds of tissues to be processed.

(5) Such additional information as the department may require in order to determine compliance with these regulations.

(b) The operation of the tissue bank shall be under the direct supervision of a physician and surgeon duly licensed in this state.

(c) The person shall be prepared to begin operations at the time application for approval is submitted.

(d) Application will be approved only when establishment and the methods used are such that the tissues processed will not be contaminated, dangerous, or harmful.

(1) Representative samples shall be provided for the department of each lot of tissues, if requested by the department, for the purpose of checking sterility, quality, or other factor.

(2) Any duly authorized representative of the department shall have free access to the establishment and the records thereof at all reasonable hours for the purpose of ascertaining compliance with these regulations.

(e) Approval may be granted only for the processing of tissues for which there is scientific evidence of therapeutic value and for which methods of preservation have been developed.

(f) Renewal of Approval. (1) The department shall issue renewal notices annually prior to the end of each calendar year.

(2) Each person on applying for renewal shall review his activities in the field for the preceding year if requested to do so by the department.

(g) There is no fee required in connection with this approval, or with renewal of approval.

1203. EXEMPTIONS FROM APPROVAL. This Group does not apply to autogenous tissue grafting, or to homografts where tissues are obtained from living donors, or to other biologic products as defined in Section 1601 of the Health and Safety Code.

1204. RECORDS. (a) The director or supervisor of approved tissue processing programs shall keep records of all tissues processed.

(b) Records may be designated by number (instead of by name of donor) to conform with individual specimens or lots of tissue.

(c) Records shall contain the following data:

(1) Name and address of institution from which material was obtained, also name of physician responsible for procurement.

(2) Date and hour of death of donor.

(3) Cause of death, and age of donor, and when available, pathologic results including autopsy report.

(4) Date and hour of obtaining tissue. If more than 4 hours postmortem, state whether refrigeration was used and, if so, give length of time and temperature.

(5) Date and method of processing tissue, if applicable.

(6) Date final storage begins.

(7) Date and place of use.

(8) Results of tests for contamination and other examinations.

(9) Pertinent laboratory data, such as serologic tests for syphilis, from donor. Prospective donors with histories of hepatitis shall not be accepted.

(10) Information relating to consent or authorization.

(d) Unless otherwise required by other provisions of law, all records and information shall be retained for not less than two (2) years.

1205. LABELS. (a) A method which will positively identify each specimen during the period from procurement to the beginning of final storage shall be placed in effect by each person.

(b) The final label shall show:

(1) The name of the product, and method used in processing.

(2) A number which will identify the processing information related to the specimen.

(3) A date prior to which use must be made of the product, or prior to which use of the product is recommended, whichever is applicable.

(4) Name and address of the processor.

(5) If temperature is a factor in preservation, the temperature range within which deterioration is avoided shall be specified.

(6) Other data descriptive of the product may also be included in the label.

(7) Directions for reconstitution of the product, and preparation for its use may be included in the label or in an accompanying circular.

(8) Altered or supplementary labels shall not be used.