

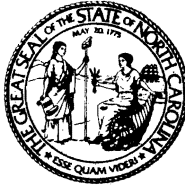
1975 REPORTS

LEGISLATIVE RESEARCH COMMISSION

HUMAN TISSUE DONATIONS



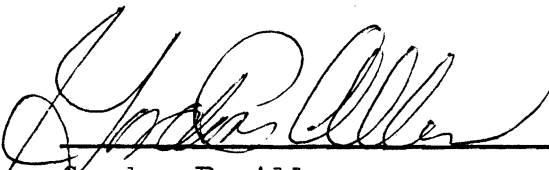
STATE OF NORTH CAROLINA
LEGISLATIVE RESEARCH COMMISSION
STATE LEGISLATIVE BUILDING
RALEIGH 27611

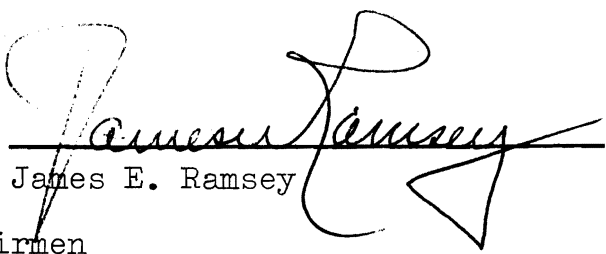


TO THE MEMBERS OF THE GENERAL ASSEMBLY:

The Legislative Research Commission herewith reports to the 1975 General Assembly, the findings and recommendations of its Committee on Human Tissue Donations, which study was authorized by Resolution 177 of the 1973 General Assembly (Second Session, 1974).

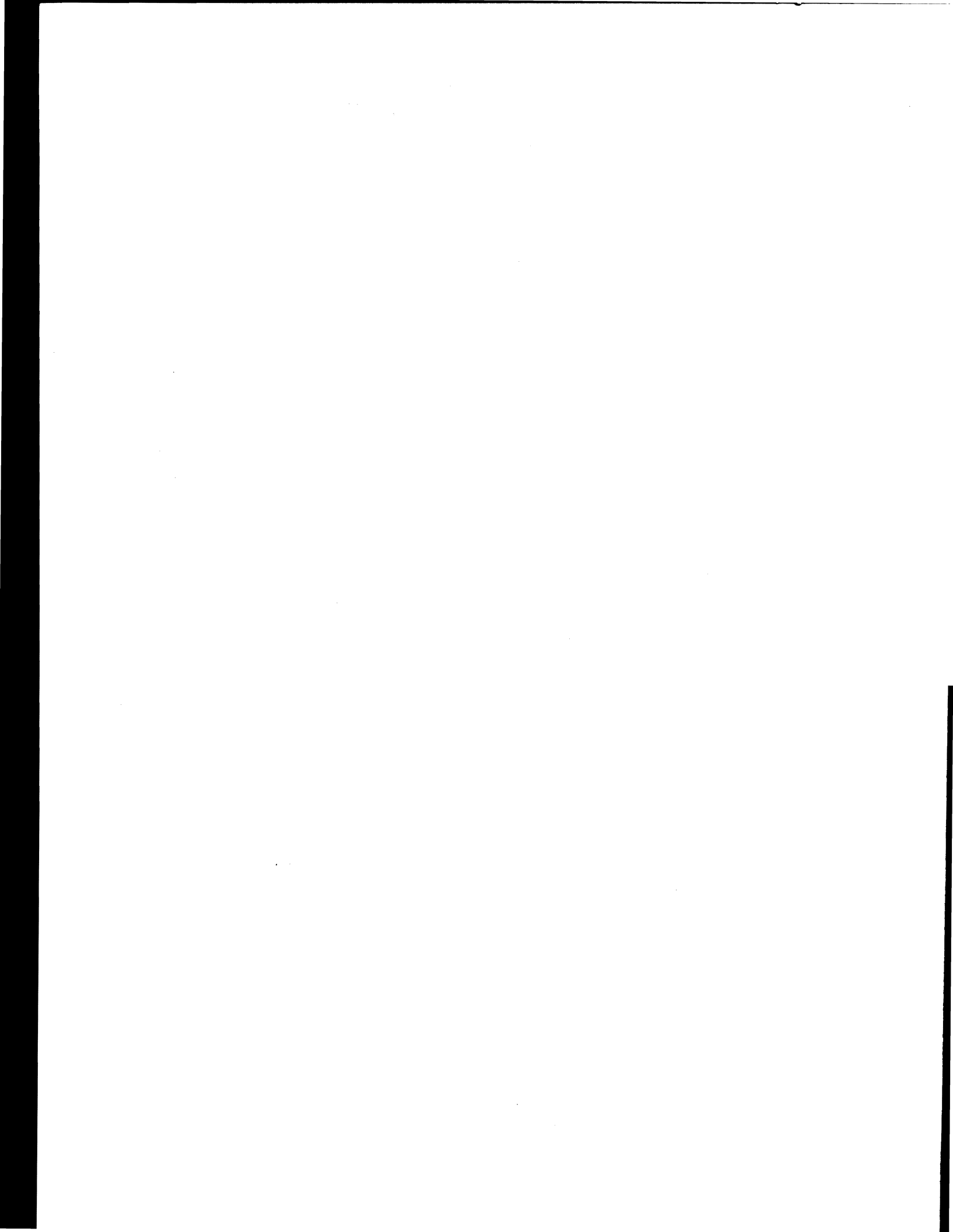
Respectively submitted,


Gordon P. Allen


James E. Ramsey

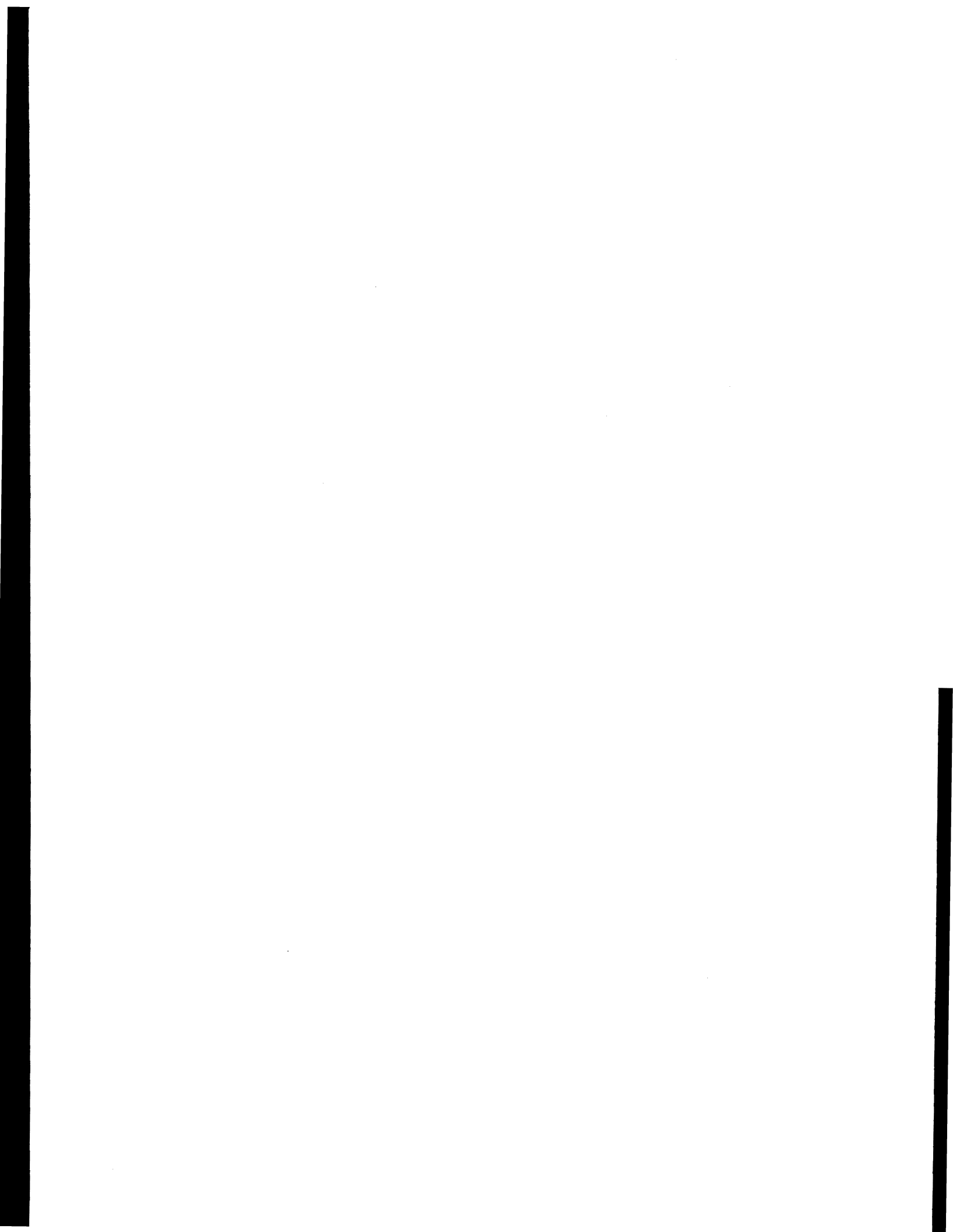
Co-Chairmen

Legislative Research Commission



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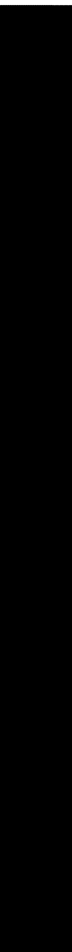


INTRODUCTION

The Legislative Research Commission, authorized by Article 6B of Chapter 120 of the General Statutes (G.S.), is a general-purpose study group consisting of legislators. Among the Commission's duties is that of making or causing to be made, upon the direction of the General Assembly, "such studies of and investigations into governmental agencies and institutions and matters of public policy as will aid the General Assembly in performing its duties in the most efficient and effective manner" (G.S. 120-30.17(1)). A list of the membership of the Legislative Research Commission will be found in Appendix I.

The General Assembly of North Carolina by Resolution 177 of the 1973 Session Laws (Second Session, 1974), see Appendix II, authorized and directed the Legislative Research Commission to study "North Carolina's potential for human tissue donations and to propose a plan for facilitating the donation and effective utilization of such donations." The Co-Chairmen of the Commission appointed from the Commission's membership a Committee on Human Tissue Donations to study this area.

Senator Thomas E. Strickland was appointed Chairman of the Committee. Representative Nancy Chase was named Vice-Chairman. The other members appointed were Senator Willard J. Blanchard, Representative E. Lawrence Davis and Senator Harold W. Hardison. The Legislative Services Office provided staff assistance to the Commission for this study.



COMMITTEE PROCEEDINGS

The Legislative Research Commission's Committee on Human Tissue Donations (hereafter referred to as the Committee) held five meetings during the course of its deliberations. These meetings stretched over a six-month period - from May to October, 1974.

The Committee decided at its organizational meeting to hear from as many physicians, other health personnel, and individuals involved in the area of the acquisition, distribution and utilization of human tissue who cared to speak. With this view of obtaining as great as possible an inflow of information and reaction of the public concerning the work of the Committee, the Committee instructed its staff to notify the capitol press corps of its meetings.

During its investigation, the Committee heard from a total of 21 witnesses. These speakers included physicians, transplant surgeons, other health personnel, representatives of the North Carolina Medical Society, the North Carolina Hospital Association, transplant organizations, human tissue banks, the medical schools of this State, various State officials involved in this area, law enforcement units, and interested private citizens. A complete list of the individuals who appeared before the Committee and who these persons represent is attached as Appendix III.

From the witnesses, who appeared, and the statements and informational materials submitted to the membership, the Committee obtained an understanding of the forces and currents affecting the utilization of human tissue in this State.

The Committee decided to focus its attention primarily on the donation or the other acquisition, distribution and utilization of human tissue from cadavers.

Statutory Provisions and Principal Groups Concerned With Acquisition of Human Tissue in North Carolina

The Committee on Human Tissue Donation, as a necessary first step, reviewed the various statutory provisions and statewide groups which affect or which have an effect on the acquisition, distribution or utilization of human tissues.

Uniform Anatomical Gift Act

Foremost of all the provisions affecting this area is the Uniform Anatomical Gift Act, see Appendix IV. This act, codified as General Statutes 90-220.1 through 90-220.11, was adopted by the 1969 General Assembly to promulgate a uniform and simple procedure to facilitate the use of human tissue in North Carolina.

This statutory scheme allows any person of sound mind and of eighteen years of age or more to give all or part of his body upon his death. The Act also permits, at the time of an individual's death, the person's nearest available relative or his guardian to make such a gift (G.S. 90-220.2). The purposes for making such gifts, set out in G.S. 90-220.3, codify one of the competing interests in the dead body enunciated by the Commissioners on Uniform State Laws in their Prefatory Note to the Model Act. That interest is that of "the need of society for bodies, tissues and organs for medical education, research, therapy and transplantation." It is to this societal need that the Committee on Human Tissue Donations directed its inquiry.

The Uniform Anatomical Gift Act also provides for the methods of making, executing, amending and revoking anatomical gifts and sets forth the rights and duties of the interested parties in the donor's remains at the time of death.

Cadavers for Medical Schools

Article 14 of Chapter 90 of the General Statutes, see Appendix V, makes provision for the distribution of cadavers, required to be buried at public expense, to the medical schools of this State. G.S. 90-212 requires that all agents of the State or of any political subdivision and all undertakers doing business in North Carolina to offer and, upon request, deliver to the Department of Human Resources dead bodies which would, otherwise, be buried at public expense.

The Secretary of Human Resources must offer, in a proportion he decides upon, the bodies so obtained to the various medical schools in North Carolina for the purpose of "the advancement of science" (G.S. 90-214). The statute provides, in G.S. 90-215, that the expenses involved in obtaining such a cadaver will be borne by the medical school receiving it. The last section of this Article punishes as a misdemeanor any violation of this Article.

Until the 1973 legislation reorganizing State government, this Article was administered by the Board of Anatomy. Section 128 of Chapter 476 of the 1973 Session Laws (First Session, 1973) abolished the Board of Anatomy and placed its duties under the Department of Human Resources.

Chronic Renal Disease Control Program

This program is authorized by Article 27 of Chapter 130 of the General Statutes, see Appendix VI. The program was established in 1971 for the care and treatment of persons suffering from chronic renal disease and was to be administered by the State Board of Health (Chapter 1027 of the 1971 Session Laws). The functions and duties of this program were taken over by the Department of Human Resources under authority of 1973 legislation reorganizing State government.

Mr. Rodney Johnson, the project manager of the Chronic Renal Disease Program in the Department of Human Resources, outlined the work of his unit for the Committee, see Appendix VII. Mr. Johnson informed the Committee that for the first two years of the program's existence its emphasis was on providing assistance for patients on chronic hemodialysis, donor evaluation for relatives of patients sponsored by the program, and payment of the cost for procurement of cadaveric kidneys and for laboratory services for blood chemistries of dialysis patients awaiting transplantation and of post-transplant patients. The project manager reported that in 1973 the Chronic Renal Disease Program initiated the establishment of a statewide organ procurement network among the four hospitals in this State now performing kidney transplants - Duke, Chapel Hill, Charlotte and Winston-Salem. This nascent network is being implemented by purchase of standard preservation equipment for each of the hospitals, and of two transplant transportation vans, joinder of resource forces with the thirteen-state Southeastern Regional Organ

Procurement Foundation, and establishment of a nephrological nursing service.

To the structure outlined by the statutory provisions above must be added two non-governmental organizations to complete the basic blueprint in this State for the utilization of human tissue.

North Carolina Eye and Human Tissue Bank

The first organization engaged in promoting the utilization of tissue transplants is the North Carolina Eye and Human Tissue Bank, Incorporated of Winston-Salem. This non-profit corporation seeks donations of human tissues and aids in their distribution. Its importance to the total plan is inestimable because the Eye and Human Tissue Bank is not only the earliest organization which sought these tissues on a statewide basis but also the largest such organization in North Carolina both in terms of numbers of workers and in terms of the amount of cadaveric human tissue acquired.

Mr. John Googe, past president of the Eye and Human Tissue Bank, informed the Committee that his group was begun in 1951 with a modest budget and small staff. He recounted that in the mid-fifties the Lions Clubs of this State became interested in the work of the Eye and Human Tissue Bank, and lent the support of their 16,000 members to aid it in its work.

The organization's program now includes some 200 to 300 informational presentations before the civic groups in North Carolina which seek to alert the public to the need for anatomical gifts. The number of eyes passing through the North Carolina Eye and Human Tissue Bank has increased from the five or six a year obtained in the years preceding 1957, to the approximately 300 eyes acquired in 1973. The Eye and Human Tissue Bank also

maintains a file of about 110,000 organ donors who have registered their intent to make anatomical gifts through that organization. Among the organ donors are 6,000 kidney donors and 1,600 body donors.

North Carolina Kidney Foundation

The second organization engaged in the solicitation of donors of anatomical gifts is the North Carolina Kidney Foundation, headquartered in Chapel Hill. Local chapters of the Kidney Foundation are active in Mecklenburg, Buncombe and Forsyth counties. Although the Kidney Foundation, like the Eye and Human Tissue Bank, seeks to encourage donations of all types of human tissue through the use of donor cards, its particular mission is solicitation for donors of cadaveric kidneys for transplantation to victims of chronic renal disease.

Inadequacies in Segments of the Present System

The witnesses who testified before the Committee voiced their concern that the present system of acquisition and distribution of human tissues is inadequate in many instances for the vital work which can be done to relieve suffering and advance medical science with the use of these materials.

Dr. John McCain testified before the Committee in his capacity as the Chairman of the Committee on Public Relations of the North Carolina Medical Society. His complete statement is attached as Appendix VIII. With regard to the great need for donated eye tissue, he estimated that of the 400,000 blind persons in the United States, 30,000 could be helped through corneal surgery. Although Dr. McCain made no direct reference to the need in North Carolina for the donation of eyes, the number of donor eyes available falls below demand.

Dr. McCain informed the membership of the Committee that kidney disease is the nation's fourth leading killer, affecting eight million people and killing 60,000 people each year. He stated that many thousands could be saved through the technique of kidney transplantation. He added that although:

It is calculated that there are more than 100,000 potentially suitable cadaver donors in the U. S. each year, only about 500 were utilized in 1970, 800 in 1971 and 900 in 1972.

Dr. Stanley Mandel, Associate Professor of Surgery and Chairman of the Kidney Procurement Committee of the Chronic Renal Disease Control Program, informed the Committee of the situation regarding renal disease patients in this State. He reported that the number of patients on kidney dialysis in North Carolina has grown from a handful in 1960 to 275 at the present time. These people are dialyzed at the four medical centers mentioned previously as well as at the patients' communities throughout the State. He estimated that of these 275 individuals there are over 200 who are awaiting transplantation. Dr. Mandel opined that the number of people on dialysis might well increase to 375 next year.

He apprised the Committee that the cost of dialyzing each patient for one year is approximately \$20,000. As one of the prime purposes of the Chronic Renal Disease Control Program is to:

extend financial assistance on the basis of need to persons suffering from chronic renal diseases in obtaining the medical, nursing, pharmaceutical, and technical services necessary in caring for such diseases, including the renting of home dialysis equipment (G.S. 130-238(4))

the State of North Carolina is in large measure subsidizing such renal care. Mr. William G. Gainey, Supervisor of the Medical Care Unit of the Chronic Disease Branch of the Department of

Human Resources, estimates that the Chronic Renal Disease Program is at present sponsoring the treatment of seventy percent of those patients in this State who require hemodialysis because of kidney disease.

Another area of concern related to the matter of human tissue donation concerns the continuing need for whole human cadavers in medical schools for the purposes of research and education. Dr. Charles W. Hooker, Professor of Anatomy at the University of North Carolina at Chapel Hill and last chairman of the North Carolina Board of Anatomy, outlined the problems of the medical schools in securing cadavers. His complete statement to the Committee is attached as Appendix IX.

Dr. Hooker stated that the study of human anatomy is "classically" the beginning of a medical education and is in many medical specialties a continuing activity. In the past the need for cadavers was met by unclaimed bodies, which must be buried at the expense of the public, he reported.

It is just such a case that is covered by General Statutes 90-211 through 90-216 concerning cadavers for medical schools. However, a variety of circumstances now conspire to defeat this statutory plan. Among them are the following: an increase in the number and extent of burial benefits available from the Veterans' Administration, Social Security Administration, and private pension and retirement plans, and ignorance of the provisions and of the penalty provided in the North Carolina statutes regulating the disposal of bodies which would be buried at public expense. Dr. Hooker illustrated this condition by noting that no such cadaver from Mecklenburg County, the state's most populous county, has gone to any medical school in the last

fifty years, and that the number of unclaimed bodies from the western half of the State has declined to two or three a year.

To offset the declining number of unclaimed bodies available for the medical schools, Dr. Hooker, informed the Committee, that there has been an increase in the number of bodies willed to medical schools. However, he stated that it would be some time before the medical schools of this State had the requisite inflow of cadavers for an adequate level of anatomical study. He pointed out that, at the end of May, 1974, the four medical schools of this State had on hand about one-half of the number of cadavers which would be needed at the beginning of August when anatomical studies begin.

Besides the need for eyes, kidneys and cadavers, witnesses testified to the continuing dearth of blood vessels, bone, bone marrow, cartilage, fascia, heart, intestines, liver, lung, pancreas, parathyroid, pituitary, thymus glands, thyroid, skin, spleen and teeth, among others for the use in transplantation, education and research.

The Legislative Research Commission's Committee on Human Tissue Donations had presented to it several proposals listing the current problems afflicting human tissue acquisition and distribution in this State and proposing remedies. See the enclosed statement of the North Carolina Medical Society and North Carolina Hospital Association, Appendix X; Dr. Paul M. James, Jr. of the Transplantation Service of the Bowman-Gray School of Medicine, Appendix XI; Drs. John L. Weinerth and Delford L. Stickel of the Duke Medical Center, Appendix XII; and the various letters of Dr. Charles W. Hooker, Appendix XIII.



FINDINGS

The Legislative Research Commission, after hearing the witnesses who appeared before it and after evaluating their statements and proposals concerning human tissue acquisition, distribution and utilization in North Carolina, makes the following findings:

1. All groups and individuals within this State involved in obtaining, transporting or transplanting human tissue for the purposes of relieving human suffering and advancing medical science have done and are doing an excellent job of acquiring and distributing human tissues in their respective fields of endeavor. The Legislative Research Commission particularly wishes to commend the work of the following organizations and people: the North Carolina Eye and Human Tissue Bank, the North Carolina Kidney Foundation, the personnel of the Chronic Renal Disease Program of the Department of Human Resources, the North Carolina Medical Society, the North Carolina Hospital Association, the medical schools, the physicians and other health professionals, and law enforcement personnel engaged in the transportation of human tissue.

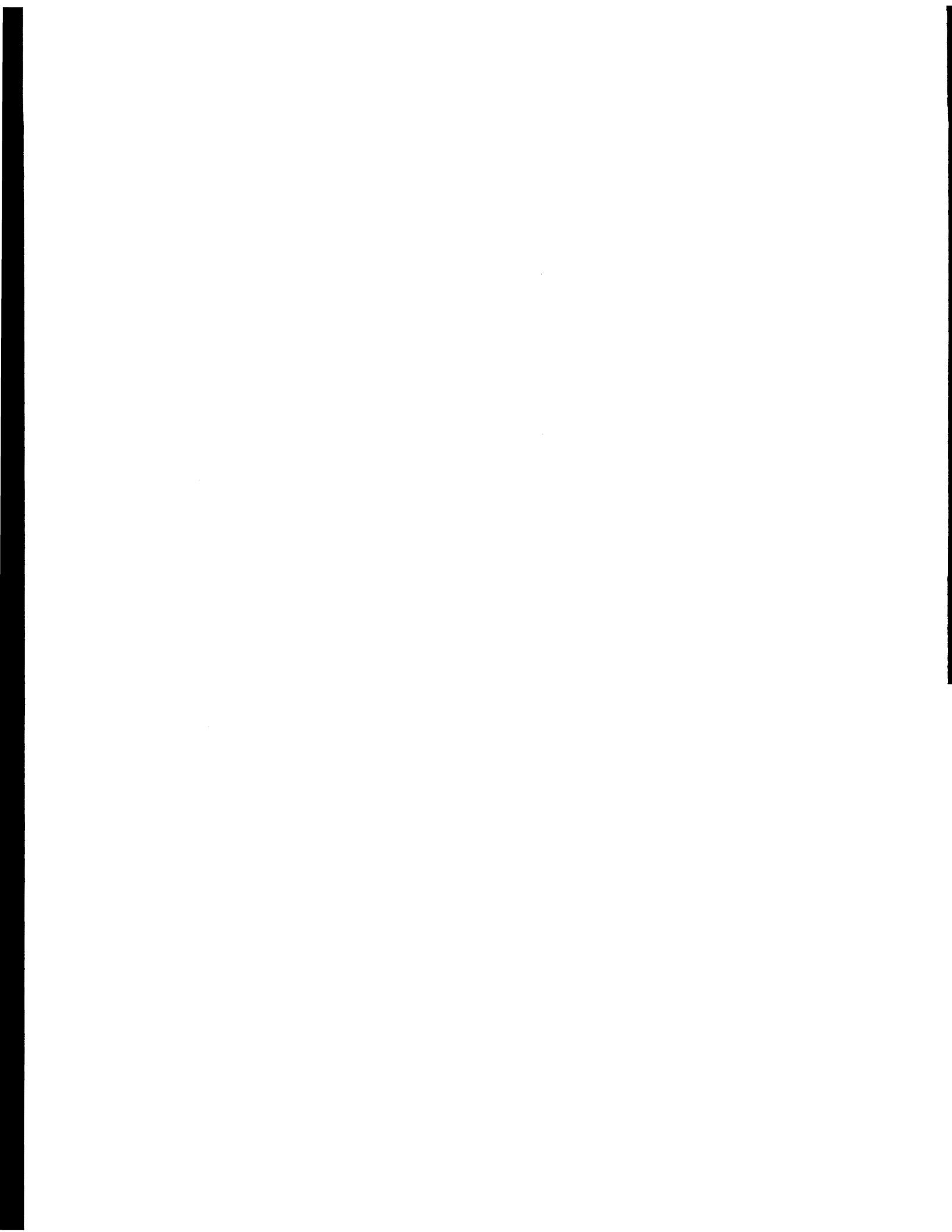
2. Despite the fine efforts of these groups, individuals, and agencies there is still a critical need within this State for more donations of human tissues. The shortage of these tissues spans the entire spectrum from individual organs such

as eyes and kidneys for transplantation to entire human cadavers for education and research in the medical schools and research laboratories of the State.

3. The need for such tissue has expanded and will continue to expand in the foreseeable future. This condition is due to the continuing discovery of new medical techniques allowing for the increased use of those organs and tissues now transplanted and for the transplantation of tissue in the future not now being used. It is also the result of the increasing enrollment in this State's medical schools which necessitates more cadavers for educational and for research purposes.

4. There has been little coordination of effort between the various groups interested in the area of human tissue acquisition, distribution and utilization. Such coordination between the human tissue groups in mutual programs could benefit each. The areas in which coordination could be of benefit would include: the publicizing of the need for such tissues, of the methods by which such donations can be made, the requirements of the present State law concerning the disposition of bodies which are to be buried at public expense; the exchanging of information on local and national problems and of their possible solutions between the parties which such information might benefit; and the speedy and precise transportation of human tissue for transplantation in emergency situations.

5. The classification of individuals now permitted under the statutes to enucleate eyes is too restrictive. The Uniform Anatomical Gift Act allows only physicians and certain certified embalmers to perform this function (See G.S. 90-220.4(d) in Appendix IV). This restriction when joined with the continuing limitations on a physician's time and with an increase the number of eye enucleations to be made in all areas of North Carolina may result in delayed or missed opportunities to save the sight of some citizens through the surgical technique of corneal transplantation. See the statement of the Executive Council of the North Carolina Medical Society in Appendix XX.



RECOMMENDATIONS

After a complete review of the informational material collected and, in view of the findings which it has made, the Legislative Research Commission in accordance with the direction of the authorizing resolution recommends the following courses of action to the 1975 General Assembly:

1. The General Assembly ought to statutorily direct the Department of Human Resources to establish a Coordinated Human Tissue Donation Program. The Legislative Research Commission recommends the adoption by the General Assembly of Legislative Proposal A in Appendix XIV. The placement of the Proposed Coordinated program will be in the Department of Human Resources (See the chart, position paper and estimated cost in Appendix XV).

The Coordinated Program will seek to harmonize the efforts of all the agencies, institutions, groups and individuals in this State interested in this field to better facilitate the acquisition and distribution of human tissue. The Department of Human Resources shall have the responsibility to establish a program to accomplish and to aid the presently existing human tissue groups in accomplishing the following necessary functions:

- A. Publicizing the need for human tissue donations and the methods by which these donations are made. The

Legislative Research Commission recommends that the Department of Human Resources investigate all the means for disseminating the knowledge of the need for human tissues and the methods by which this need may be filled. The Commission specifically directs the attention of the Secretary to the following possible methods:

i. the maximum use of voluntary efforts in the advertising media and person-to-person communications.

ii. devotion of part of high school health classes to instruction on these matters. The Department of Public Instruction has already expressed its willingness to cooperate in this regard, see Appendix XVI.

iii. the distribution of human tissue donor cards, conforming to the Uniform Anatomical Gift Act, at the time of renewal of driver's license, together with a sticker which may be attached to the driver's license itself indicating that the licensee has made an anatomical gift. The Department of Transportation and Highway Safety has expressed its willingness to work with the Coordinated Program on this scheme. See the letter and the example of a driver's license sticker from Mr. J. T. Baker, Jr. of the Driver License Division in Appendix XVII.

iv. establishment of a standard donor form and of a standard identification card for donors. See Appendix XVIII for suggested forms from the North Carolina Kidney Foundation and the North Carolina Eye and Human Tissue Bank.

B. Dissemination to physicians, nurses, emergency medical services personnel, and other health personnel, hospital administrators, embalmers, funeral directors, lawyers, county directors of social services and other individuals vital to an effective human tissue program, information on the techniques of human tissue retrieval, the legalities involved in making anatomical gifts, and the individuals' legal responsibilities under Article 14 of Chapter 90 of the General Statutes which deals with cadavers for medical schools.

C. Study of the problems surrounding the acquisition and distribution of all human tissues, including cadavers, in this State and making suggestions as to their solution. The Department should include in its study the usefulness of a central registry for organ donors in this State.

D. Making itself aware of the existing programs of human tissue transplantation and of medical research and education employing human tissue both within and without this State and funneling of information of useful developments in the area of employment of human tissue to groups and individuals which such information might benefit. Among the existing programs to which

the attention of the Secretary of Human Resources is directed are the following:

- i. National Transplant Communication Network,
- ii. Southeastern Organ Procurement Foundation,
- iii. Duke Endowment's national program to computerize data on all hospital patients,
- iv. North Carolina Eye and Human Tissue Bank,
- v. National Eye Bank Network,
- vi. North Carolina Association for the Blind,
- vii. Eye Bank Association of America,
- viii. North Carolina Kidney Foundation,
- ix. National Kidney Foundation.

E. Arranging for speed and precision in the transportation of donated human tissue in emergency transplant situations utilizing, where needed, State and local law enforcement resources. Colonel E. W. Jones, Commander, expressed to the Committee the continued willingness of the Highway Patrol to cooperate in this part of the Coordinated Program, see Appendix XIX. Representatives of the North Carolina Sheriffs' Association, the North Carolina Police Executives' Association, and the Office of Emergency Medical Services all stated that their groups would join in aiding the vital transportation function.

Section 2 of Legislative Proposal A provides for an appropriation of \$72,840 to run the Coordinated Program for its

first year. The breakdown of this figure into types of expenses is found in the table in Appendix XV(C), which was prepared by the Department of Human Resources. The appropriation proposed in the recommended bill is based upon the passage of an annual State budget. If the legislature decides to adopt a biennial budget it will be necessary to amend the appropriation section to appropriate \$143,105 for the fiscal years 1975 through 1977. Appendix XV(C) also shows the Department of Human Resources' estimate as to the breakdown of expenses for conducting the proposed Coordinated Program for the next two fiscal years.

2. The General Assembly of North Carolina should establish a Human Tissue Advisory Council which would consist of representatives of agencies and groups in this State concerned and involved with the acquisition and distribution of human tissues. This Council would have as its duty conferring with and advising the Department of Human Resources on the establishment and conduct of the Coordinated Program for Human Tissue Donations. The Secretary of Human Resources is directed to give consideration to coordinating the proposed program with the present Chronic Renal Disease Control Program. This recommendation is included as §130-235.3 of Section 1 of Legislative Proposal A found in Appendix XIV .

3. The 1975 General Assembly should provide statutorily that all departments and agencies of the State and county and municipal law enforcement agencies shall cooperate, as much as possible and not inconsistent with existing law, in the

Coordinated Program instituted by the Department of Human Resources. The purpose of this statutory provision would be to assure the cooperation of these governmental agencies in such aspects of the Coordinated Program as the speedy transportation of tissue in emergency situations, the distribution of donor information at the time of renewal of the driver's license, and the education of high school students in the need for and method of making human tissue donations, as well as those parts of the Coordinated Program which will be developed. See Legislative Proposal B in Appendix XIV for the Legislative Research Commission's recommended bill.

4. The General Assembly ought to amend the Uniform Anatomical Gift Act to permit other qualified individuals, than physicians and certified embalmers now permitted to perform this function, also to enucleate eyes after death to effect an anatomical gift.

There is a need now for an increase in the number of people qualified to enucleate eyes. The Legislative Research Commission recommends that the group now qualified under Article 15A of Chapter 90 of the General Statutes be expanded to include physicians' assistants approved by and registered with the Board of Medical Examiners pursuant to General Statutes 90-18(13), registered and licensed practical nurses certified by the Board of Nursing pursuant to Article 9 of Chapter 90 of the General Statutes, and third and fourth-year medical students who are enrolled in medical schools in this State.

The Legislative Research Commission's statutory proposal, which is found in Appendix XIV (B), incorporates three safeguards to both the donor and the donee in an eye enucleation. First, the proposed bill keeps the requirement of the present G.S. 90-220.1(9) that certified embalmers must have completed a course in eye enucleation and have been certified as competent to enucleate eyes by a school of medicine in North Carolina and extends this requirement to the classifications of health personnel who would be permitted to enucleate eyes under this proposal. Secondly, this bill if enacted would retain the present requirement that a certification of death would have to be obtained before the surgical procedure was done by any of the qualified persons. The last safeguard found in the proposal is taken from G.S. 90-220.7(b) which forbids the physician certifying the death of the donor from participating in the procedures for removing or transplanting a part. The proposed bill would permit eye enucleation by any of the mentioned qualified individuals only after the express direction of a physician, other than the one certifying death. The elimination of this potential conflict of interest was the purpose of the General Assembly in enacting G.S. 90-220.7(b). Without this safety device, a physician who, himself, would be unable to remove an eye because of G.S. 90-220.7(b) would be able to direct one of the persons qualified under this proposal to perform this procedure.



A P P E N D I C E S

LEGISLATIVE RESEARCH COMMISSION MEMBERS

1974

<u>Name</u>	<u>Business Address</u>	<u>Phone</u>
Sen. Gordon P. Allen Co-Chairman	P.O. Box 100 Roxboro, N. C. 27573	(919) 599-2175
Speaker James E. Ramsey	P.O. Box 601 Roxboro, N. C. 27573	(919) 599-3193
Sen. Willard J. Blanchard	P. O. Box 99 Salemberg, N. C. 28385	(919) 525-4144
Sen. Harold W. Hardison	P. O. Box 128 Deep Run, N. C. 28525	(919) 568-4660
Sen. Marshall Rauch	P. O. Box 609 Gastonia, N. C. 28052	(704) 867-5333
Sen. McNeill Smith	P. O. Box G Greensboro, N. C. 27402	(919) 273-8263
Sen. Thomas E. Strickland	P.O. Box 2002 Goldsboro, N. C. 27530	(919) 736-7280
Rep. Norwood Bryan, Jr.	P.O. Box 1269 Fayetteville, N. C. 28302	(919) 484-1817
Rep. Nancy Chase	P.O. Box 226 Eureka, N.C. 27830	(919) 242-5633
Rep. E. Lawrence Davis	P.O. Drawer 84 Winston-Salem, N.C. 27102	(919) 725-1311
Rep. John R. Gamble, Jr.	P.O. Box 250 Lincolnton, N. C. 28092	(704) 735-3023
Rep. Thomas J. Harrelson	P.O. Box 128 Southport, N. C. 28461	(919) 457-5454

GENERAL ASSEMBLY OF NORTH CAROLINA
1973 SESSION (2nd SESSION, 1974)
RATIFIED BILL

RESOLUTION 177

HOUSE JOINT RESOLUTION 2014

A JOINT RESOLUTION AUTHORIZING AND DIRECTING THE LEGISLATIVE RESEARCH COMMISSION TO STUDY NORTH CAROLINA'S POTENTIAL FOR HUMAN TISSUE DONATIONS AND TO PROPOSE A PLAN FOR FACILITATING THE DONATION AND EFFECTIVE UTILIZATION OF SUCH DONATIONS.

Whereas, while science and medicine today have developed methods for approved matching and acceptance of transplanted human tissue; and

Whereas, the Legislature has already recognized the importance of human tissue transplants by passing the Uniform Anatomical Gift Act in 1969; and

Whereas, any further development of the implementation of that act and related efforts to attract human tissue donors offers great promise for the improvement of the human condition and alleviation of human suffering;

Now, therefore, be it resolved by the House of Representatives, the Senate concurring:

Section 1. The Legislative Research Commission is hereby authorized and directed to study the potential and utilization programs for human tissue donations.

Sec. 2. The Commission shall make a broad and in-depth study of the status of the current kinds and numbers of tissue transplants and the coordination involved by statewide health care personnel. It shall analyze the problem of getting the human tissue needed to the person who needs it. It shall seek to

suggest methods by which a coordinated statewide program might be established in conjunction with the efforts of the North Carolina Medical Society and the North Carolina Hospital Association.

Sec. 3. The Legislative Research Commission shall report its findings and recommendations to the 1975 General Assembly.

Sec. 4. This resolution shall become effective upon ratification.

In the General Assembly read three times and ratified, this the 12th day of April, 1974.

JAMES B. HUNT, JR.

James B. Hunt, Jr.

President of the Senate

JAMES E. RAMSEY.

James E. Ramsey

Speaker of the House of Representatives

Witnesses Appearing Before the
Legislative Research Commission

Mr. Steve Acai
Transportation Specialist
Office of Emergency Medical Services

Mr. Danny Allen

Mrs. Jo Ann Brickell, President
North Carolina Kidney Foundation

Mr. William G. Gainey, Supervisor
Medical Care Unit
Chronic Disease Branch
Division of Health Services
Department of Human Resources

Mr. John Googe, Past President
North Carolina Eye and Human Tissue Bank

Dr. L. B. Holt, Past President
North Carolina Eye and Human Tissue Bank

Dr. Charles W. Hooker
Professor of Anatomy
School of Medicine
University of North Carolina at Chapel Hill

Dr. Paul M. James
Transplantation Services
Bowman-Gray School of Medicine

Mr. Rodney Johnson
Project Manager
Chronic Renal Disease Control Program
Division of Health Services
Department of Human Resources

Col. E. W. Jones, Commander
Highway Patrol
Department of Transportation and Highway Safety

Mr. Charles Lee, Administrator
Kidney Project
North Carolina Regional Medical Program

WITNESSES - Continued

Dr. John McCain, Chairman
Public Relations Committee
North Carolina Medical Society

Dr. Stanley R. Mandel
Department of Surgery
North Carolina Memorial Hospital
Chapel Hill, North Carolina

Mr. Stephen C. Morrisette
Director of Governmental Affairs
North Carolina Medical Society

Mr. W. J. O'Brien, President
North Carolina Eye and Human Tissue Bank

Sheriff Robert Pleasants of Wake County
North Carolina Sheriffs' Association

Mr. Dan L. Shackelford, President
North Carolina Funeral Directors Association

Mr. Haywood Starling
Vice President
Police Executives' Association

Dr. Delford Stickel
Professor of Surgery
Duke University Medical Center

Mr. Edward H. Wade, Director
Driver License Division
Department of Transportation and Highway Safety

Dr. J. L. Weinerth
Assistant Professor of Urology
Duke University Medical Center

ARTICLE 15A.

Uniform Anatomical Gift Act.

§ 90-220.1. Definitions.—As used in this Article:

- (1) "Bank or storage facility" means a facility licensed, accredited, or approved under the laws of any state for storage or distribution of human bodies or parts thereof.
- (2) "Decedent" means a deceased individual and includes a stillborn infant or fetus.
- (3) "Donor" means an individual who makes a gift of all or part of his body.
- (4) "Hospital" means a hospital licensed, accredited, or approved under the laws of any state and a hospital operated by the United States government, a state, or a subdivision thereof, although not required to be licensed under state laws.
- (5) "Part" means organs, tissues, eyes, bones, arteries, blood, other fluids and any other portions of a human body.
- (6) "Person" means an individual, corporation, government or governmental subdivision or agency, business trust, estate, trust, partnership or association, or any other legal entity.
- (7) "Physician" or "surgeon" means a physician or surgeon licensed or authorized to practice medicine under the laws of any state.
- (8) "State" includes any state, district, commonwealth, territory, insular possession, and any other area subject to the legislative authority of the United States of America.
- (9) "Certified Embalmer" means an embalmer holding a valid license to practice in North Carolina who has completed a course in eye enucleation and has been certified as competent to enucleate eyes by an accredited school of medicine operating within the State of North Carolina. (1969, c. 84, s. 1; 1971, c. 873, s. 1.)

Editor's Note.—Session Laws 1969, c. 84, adding this Article, is effective Oct. 1, 1969. The 1971 amendment, effective Oct. 1, 1971, added subdivision (9).

§ 90-220.2. Persons who may execute an anatomical gift.—(a) Any individual of sound mind and 18 years of age or more may give all or any part of his body for any purpose specified in G.S. 90-220.3, the gift to take effect upon death.

(b) Any of the following persons, in order of priority stated, when persons in prior classes are not available at the time of death, and in the absence of actual notice of contrary indications by the decedent or actual notice of opposition by a member of the same or a prior class, may give all or any part of the decedent's body for any purpose specified in G.S. 90-220.3:

- (1) The spouse,
- (2) An adult son or daughter,
- (3) Either parent,
- (4) An adult brother or sister,
- (5) A guardian of the person of the decedent at the time of his death,
- (6) Any other person authorized or under obligation to dispose of the body.

The persons authorized by this subsection may make the gift after or immediately before death.

(c) If the donee has actual notice of contrary indications by the decedent or that a gift by a member of a class is opposed by a member of the same or a prior class, the donee shall not accept the gift.

(d) A gift of all or part of a body authorizes any examination necessary to assure medical acceptability of the gift for the purposes intended.

(e) The rights of the donee created by the gift are paramount to the rights of others except as provided by G.S. 90-220.7 (d). (1969, c. 84, s. 1.)

"Adult" Is Person 18 or Older. — See opinion of Attorney General to Lena S. Davis, 41 N.C.A.G. 489 (1971).

§ 90-220.3. Persons who may become donees; purposes for which anatomical gifts may be made.—The following persons may become donees of gifts of bodies or parts thereof for the purposes stated:

- (1) Any hospital, surgeon, or physician, for medical or dental education,

research, advancement of medical or dental science, therapy, or transplantation; or

- (2) Any accredited medical or dental school, college or university for education, research, advancement of medical or dental science, or therapy; or
- (3) Any bank or storage facility, for medical or dental education, research, advancement of medical or dental science, therapy, or transplantation; or
- (4) Any specified individual for therapy or transplantation needed by him. (1969, c. 84, s. 1.)

§ 90-220.4. Manner of executing anatomical gifts.—(a) A gift of all or part of the body under G.S. 90-220.2(a) may be made by will. The gift becomes effective upon the death of the testator without waiting for probate. If the will is not probated, or if it is declared invalid for testamentary purposes, the gift, to the extent that it has been acted upon in good faith, is nevertheless valid and effective.

(b) A gift of all or part of the body under G.S. 90-220.2(a) may also be made by document other than a will. The gift becomes effective upon the death of the donor. The document, which may be a card designed to be carried on the person, must be signed by the donor in the presence of two witnesses who must sign the document in his presence. If the donor cannot sign, the document may be signed for him at his direction and in his presence and the presence of two witnesses who must sign the document in his presence. Delivery of the document of gift during the donor's lifetime is not necessary to make the gift valid.

(c) The gift may be made to a specified donee or without specifying a donee. If the latter, the gift may be accepted by the attending physician as donee upon or following death. If the gift is made to a specified donee who is not available at the time and place of death, the attending physician upon or following death, in the absence of any expressed indication that the donor desired otherwise, may accept the gift as donee.

(d) The donor may designate in his will, card, or other document of gift the surgeon or physician to carry out the appropriate procedures, subject to the provisions of G.S. 90-220.7(b). In the absence of a designation or if the designee is not available, the donee or other person authorized to accept the gift may employ or authorize any surgeon or physician for the purpose. In respect to a gift of an eye, a certified embalmer, as defined in G.S. 90-220.1, may enucleate eyes for such gift after proper certification of death by a physician and compliance with the intent of such gift as defined within this chapter.

The enucleation of the eyes by a certified embalmer may be performed when permission has been granted by the next of kin.

(e) Any gift by a person designated in G.S. 90-220.2(b) shall be made by a document signed by him or made by his telegraphic, recorded telephonic, or other recorded message. (1969, c. 84, s. 1; 1971, c. 873, s. 2.)

Editor's Note.—The 1971 amendment, effective Oct. 1, 1971, added the last sentence of the first paragraph and added the second paragraph of subsection (d).

§ 90-220.5. Delivery of document of gift.—If the gift is made by the donor to a specified donee, the will, card, or other document, or an executed copy thereof, may be delivered to the donee at any time to expedite the appropriate procedures immediately after death. Delivery is not necessary to the validity of the gift. The will, card, or other document, or an executed copy thereof, may be deposited in any hospital, bank or storage facility, or registry office that accepts it for safekeeping or for facilitation of procedures after death. On request of any interested party upon or after the donor's death, the person in possession shall produce the document for examination. (1969, c. 84, s. 1.)

§ 90-220.6. Amendment or revocation of the gift.—(a) If the will, card, or other document or executed copy thereof, has been delivered to a specified donee, the donor may amend or revoke the gift by:

- (1) The execution and delivery to the donee of a signed statement, or
- (2) An oral statement made in the presence of two persons and communicated to the donee, or
- (3) A statement during a terminal illness or injury addressed to an attending physician and communicated to the donee, or
- (4) A signed card or document found on his person or in his effects, and made known to the donee.

(b) Any document of gift which has not been delivered to the donee may be revoked by the donor in the manner set out in subsection (a) or by destruction, cancellation, or mutilation of the document and all executed copies thereof.

(c) Any gift made by a will may also be amended or revoked in the manner provided for amendment or revocation of wills or as provided in subsection (a). (1969, c. 84, s. 1.)

§ 90-220.7. Rights and duties at death.—(a) The donee may accept or reject the gift. If the donee accepts a gift of the entire body, he shall, subject to the terms of the gift, authorize embalming and the use of the body in funeral services, upon request of the surviving spouse or other person listed in the order stated in G.S. 90-220.2 (b). If the gift is of a part of the body, the donee, upon the death of the donor and prior to embalming, shall, within 24 hours, cause the part to be removed without unnecessary mutilation. After removal of the part, custody of the remainder of the body vests in the surviving spouse, next of kin, or other persons under obligation to dispose of the body.

(b) The time of death shall be determined by a physician who attends the donor at his death, or, if none, the physician who certifies the death. Such physician shall not participate in the procedures for removing or transplanting a part.

(c) A person who acts with due care in accord with the terms of this article or the anatomical gift laws of another state is not liable for damages in any civil action or subject to prosecution in any criminal proceeding for his act.

(d) The provisions of this article are subject to the laws of this State prescribing powers and duties with respect to autopsies. (1969, c. 84, s. 1.)

§ 90-220.8. Uniformity of interpretation.—This article shall be so construed as to effectuate its general purpose to make uniform the law of those states which enact it. (1969, c. 84, s. 1.)

§ 90-220.9. Short title.—This article may be cited as the Uniform Anatomical Gift Act. (1969, c. 84, s. 1.)

§ 90-220.10. Use of tissue declared service; standard of care; burden of proof.—The procurement, processing, distribution or use of whole blood, plasma, blood products, blood derivatives and other human tissues such as corneas, bones or organs for the purpose of injecting, transfusing or transplanting any of them into the human body is declared to be, for all purposes, the rendition of a service by every person or institution participating therein and, whether or not any remuneration is paid therefor, is declared not to be a sale of such whole blood, plasma, blood products, blood derivatives or other human tissues, for any purpose. No person or institution shall be liable in warranty, express or implied, for the procurement, processing, distribution or use of said items but nothing herein shall alter or restrict the liability of such person or institution in negligence or tort in consequence of said service. (1971, c. 836.)

§ 90-220.11. Giving of blood by persons 18 years of age or more.—Any person who is 18 years of age or more may give or otherwise donate his blood to any individual, hospital, blood bank or blood collection center without the consent of the parent or parents or guardian of such donor. (1971, c. 10; c. 1093, s. 16.)

Editor's Note. — The 1971 amendment substituted "person" for "individual" near the beginning of the section and substituted "donor" for "individual" at the end of the section.

GENERAL STATUTES OF NORTH CAROLINA

ARTICLE 14.

Cadavers for Medical Schools.

§ 90-211: Repealed by Session Laws 1973, c. 476, s. 128, effective July 1, 1973.

§ 90-212. **What bodies to be furnished.**—All officers, agents or servants of the State of North Carolina, or of any county or town in said State, and all undertakers doing business within the State, having charge or control of a dead body required to be buried at public expense, or at the expense of any institution supported by State, county or town funds, shall be and hereby are required immediately to notify, and, upon the request of said Department of Human Resources or its authorized agent or agents, without fee or reward, deliver, at the end of a period not to exceed 36 hours after death, such body into the custody of the Department of Human Resources, and permit the Department of Human Resources or its agent or agents to take and remove all such bodies or otherwise dispose of them: Provided, that such body be not claimed within 36 hours after death to be disposed of without expense to the State, county or town, by any relative within the second degree of consanguinity, or by the husband or wife of such deceased person: Provided, further, that the 36-hour limit may be prolonged in cases within the jurisdiction of the coroner where retention for a longer time may be necessary: Provided, further, that the bodies of all such prisoners dying while in Central Prison or road camps of Wake County, whether death results from natural causes or otherwise, shall be equally distributed among the funeral homes in Raleigh; but only such funeral homes can qualify hereunder as at all times maintain a regular licensed embalmer: Provided, further, that nothing herein shall require the delivery of bodies of such prisoners to funeral directors of Wake County where the same are claimed by relatives or friends.

Whenever the dead body is that of an inmate of any State hospital, the State School for the Deaf, the State School for the Deaf, Dumb and Blind, or of any traveler or stranger, it may be embalmed and delivered to the Department of Human Resources, but it shall be surrendered to the husband or wife of the deceased person or any other person within the second degree of consanguinity upon demand at any time within 10 days after death upon the payment to said Department of Human Resources of the actual cost to it of embalming and preserving the body. (1903, c. 666, s. 2; Rev., s. 4288; 1911, c. 188; C. S., s. 6786; 1923, c. 110; 1937, c. 351; 1943, c. 100; 1969, c. 1279; 1973, c. 476, s. 128.)

Editor's Note.—

The 1969 amendment deleted the word "white" preceding "prisoners" and "funeral homes" in the third proviso and also deleted in that proviso a provision requiring distribution of the bodies of negro prisoners to negro funeral homes.

The 1973 amendment, effective July 1, 1973, substituted "Department of Human Resources" for "Board" in the first paragraph and near the end of the second paragraph and for "North Carolina Board of Anatomy" near the middle of the second paragraph.

§ 90-213. **Autopsies unlawful without consent of Secretary of Human Resources.**—It is hereby declared unlawful to hold an autopsy on any dead human body subject to the provisions of this Article without first having obtained the consent, in writing, of the Secretary of Human Resources or of his accredited agent: Provided, that nothing in this Article shall limit the coroner in the fulfillment of his duties: Provided, further, that nothing in G.S. 90-211 through 90-216, inclusive, shall prevent a person from making testamentary disposition of his or her body after death. Provided, that nothing in this Article shall restrict or limit the provisions of Article 21 [of Chapter 130] of the General Statutes, entitled "Post-mortem Medicolegal Examinations." (1903, c. 666, s. 3; Rev., s. 4289; 1911, c. 188; C. S., s. 6787; 1943, c. 100; 1955, c. 972, s. 5; 1967, c. 1154, s. 3; 1973, c. 476, s. 128.)

Editor's Note.—

The 1967 amendment, effective Jan. 1, 1968, rewrote the last proviso, which formerly related to article 30 of chapter 130 and now relates to article 21 of that chapter of the General Statutes.

The 1973 amendment, effective July 1, 1973, substituted "Secretary of Human Resources" for "chairman of the Board."

Section 90-211, referred to in this section, was repealed by Session Laws 1973, c. 476, s. 128, effective July 1, 1973.

§ 90-214. Bodies to be distributed to medical schools.—The bodies obtained under this Article shall be distributed, with due precautions to shield them from the public view, among the several medical schools in a proportion to be agreed upon by the Secretary of Human Resources, such bodies to be used within the State for the advancement of science. (1903, c. 666, s. 4; Rev., s. 4290; C. S., s. 6788; 1943, c. 100; 1973, c. 476, s. 128.)

Editor's Note.—

The 1973 amendment, effective July 1, 1973, substituted "by the Secretary of Human Resources" for "by a majority of the members of the North Carolina Board of Anatomy."

§ 90-215. How expenses paid. All expenses for the delivery, distribution and embalming of the dead bodies obtained under this Article upon the request of the Department of Human Resources, under such rules and regulations as the Commission for Health Services may provide shall be borne by the medical school receiving same, and in no case shall the State or any county or town be liable therefor. (1903, c. 666, s. 5; Rev., s. 4291; C. S., s. 6789; 1943, c. 100; 1973, c. 476, s. 128.)

Editor's Note.—

The 1973 amendment, effective July 1, 1973, substituted "Department of Human Resources" for "North Carolina Board of Anatomy" and "Commission for Health Services" for "Board."

§ 90-216. Violation of article misdemeanor.—Any person failing or refusing to perform any duty imposed by this article, or violating any of its provisions shall be guilty of a misdemeanor, punishable by a fine and/or imprisonment in the discretion of the court. (1903, c. 666, s. 6; Rev., s. 3567; C. S., s. 6790; 1943, c. 100.)

Editor's Note.—The 1948 amendment rewrote this section.

GENERAL STATUTES OF NORTH CAROLINA

ARTICLE 27.

Chronic Renal Disease Control Program.

§ 130-236. Department of Human Resources to establish program. — The Department of Human Resources, hereafter referred to as the Department, shall establish a program for the care and treatment of persons suffering from chronic renal diseases. This program shall assist persons suffering from chronic renal diseases who require lifesaving care and treatment for such renal diseases, but who are unable to pay for such services on a continuing basis. (1971, c. 1027, s. 1; 1973, c. 476, s. 128.)

Editor's Note. — The 1973 amendment for "State Board of Health" and "Department" substituted "Department of Human Resources" for "Board."

§ 130-237: Repealed by Session Laws 1973, c. 476, s. 128.

§ 130-238. Powers and duties of the Department. — The Department shall:

- (1) Develop standards for determining eligibility for care and treatment under this program;
- (2) Assist in the development and expansion of programs for the care and treatment of persons suffering from chronic renal diseases, including dialysis, renal transplantation and other medical procedures and techniques which will have a lifesaving effect in the care and treatment of persons suffering from these diseases;
- (3) Assist in the development of programs for the prevention of chronic renal diseases;
- (4) Extend financial assistance on the basis of need to persons suffering from chronic renal diseases in obtaining the medical, nursing, pharmaceutical, and technical services necessary in caring for such diseases, including the renting of home dialysis equipment;
- (5) Assist in equipping dialysis and transplantation centers; and
- (6) Institute and carry on an education program among physicians, hospitals, public health departments, and the public concerning chronic renal diseases, including the dissemination of information and the conducting of educational programs concerning the prevention of chronic renal diseases and the methods for the care and treatment of persons suffering from these diseases. (1971, c. 1027, s. 1; 1973, c. 476, s. 128.)

Editor's Note. — The 1973 amendment substituted "Department" for "Board" in the introductory language and deleted "With the advice of the Committee" at the beginning of subdivision (1).

§ 130-239. Renal Disease Fund. — There is hereby created a Renal Disease Fund. Contributions to the fund may be accepted in its behalf by the Secretary of Human Resources from any source including, but not limited to, insurance proceeds, the medical profession and the Veterans Administration. (1971, c. 1027, s. 1; 1973, c. 476, s. 128.)

Editor's Note. — The 1973 amendment substituted "Secretary of Human Resources" for "Director."

REPORT TO THE LEGISLATIVE RESEARCH COMMISSION'S
COMMITTEE ON HUMAN TISSUE DONATIONS

August 9, 1974

IN JULY OF 1971, THE NORTH CAROLINA GENERAL ASSEMBLY APPROPRIATED FUNDS FOR THE ESTABLISHMENT OF A STATEWIDE KIDNEY PROGRAM -- A PROGRAM THAT WOULD PROVIDE ASSISTANCE FOR THOSE PERSONS SUFFERING FROM KIDNEY FAILURE (CHRONIC RENAL DISEASE). THE LEGISLATION REQUIRED THE DIVISION OF HEALTH SERVICES TO ESTABLISH THE PROGRAM AND PROVIDED FOR THE APPOINTMENT OF A RENAL ADVISORY COMMITTEE TO ASSIST THE DIVISION OF HEALTH SERVICES IN ADMINISTERING THE KIDNEY PROGRAM. DURING THE FIRST YEAR, MAJOR EMPHASIS WAS PLACED UPON PROVIDING ASSISTANCE FOR PERSONS ON CHRONIC HEMODIALYSIS. DIALYSIS IS BOTH AN ALTERNATIVE METHOD OF PROVIDING LONG-TERM CARE FOR PATIENTS AND A NECESSARY TOOL TO MAINTAIN THE PATIENT ALIVE AND WELL UNTIL A KIDNEY BECOMES AVAILABLE FOR TRANSPLANTATION.

OTHER SERVICES ASSISTING TRANSPLANTED PATIENTS AND IMPLEMENTED DURING THOSE INITIAL TWO YEARS INCLUDED: DONOR EVALUATION FOR RELATIVES OF PATIENTS SPONSORED BY THE KIDNEY PROGRAM; PAYMENT OF THE COST FOR THE PROCUREMENT OF CADAVERIC KIDNEYS,

AND LABORATORY SERVICES FOR BLOOD CHEMISTRIES ON DIALYSIS PATIENTS AWAITING A TRANSPLANT AND POST-TRANSPLANTED PATIENTS.

IN 1973, THE KIDNEY PROGRAM SOUGHT TO ESTABLISH A STATEWIDE ORGAN PROCUREMENT NETWORK AMONG THE FOUR TRANSPLANT HOSPITALS IN NORTH CAROLINA. RENAL TRANSPLANTS WERE BEING PERFORMED AT DUKE, CHAPEL HILL, CHARLOTTE, AND WINSTON-SALEM. DR. STANLEY MANDEL, VASCULAR SURGEON AT THE UNIVERSITY OF NORTH CAROLINA MEDICAL SCHOOL WAS CALLED UPON TO DIRECT ORGAN PROCUREMENT ACTIVITIES IN OUR STATE. INITIAL EFFORTS TO IMPLEMENT THIS CONCEPT INCLUDED THE PURCHASE OF STANDARD PRESERVATION EQUIPMENT FOR EACH OF THE FOUR TRANSPLANT HOSPITALS. FUNDS WERE COORDINATED WITH THE NORTH CAROLINA REGIONAL MEDICAL PROGRAM FOR THE PURCHASE OF TWO VANS TO TRANSPORT THE PROCURED KIDNEYS THROUGHOUT THE STATE. ADDITIONALLY, THE KIDNEY PROGRAM CONTRACTED WITH THE FOUR TRANSPLANT CENTERS TO CONDUCT PROCUREMENT ACTIVITIES, NAMELY FOR SUPPLEMENTING THE SALARY OF PERFUSION TECHNICIANS AND PURCHASE OF BACK-UP PERFUSION SUPPLIES. REALIZING A GREATER NEED TO SHARE KIDNEYS ACROSS

STATE LINES, THE NORTH CAROLINA NETWORK JOINED FORCES WITH THE THIRTEEN-STATE SOUTHEASTERN REGIONAL ORGAN PROCUREMENT FOUNDATION IN ORDER TO OPEN MORE AVENUES FOR KIDNEY AVAILABILITY.

LAST YEAR, DR. MANDEL VISITED COMMUNITY HOSPITALS THROUGHOUT THE STATE IN AN EFFORT TO ENLIST THEIR SUPPORT IN IDENTIFYING POTENTIAL DONORS ADMITTED TO THEIR HOSPITALS. ALTHOUGH SEVERAL HOSPITALS RESPONDED FAVORABLY TO THE COMMUNITY HOSPITAL ORGAN DONOR PROGRAM, OTHERS RESPONDED WITH DOUBTFUL CONCERN WITH REGARD TO THE ISSUE OF BRAIN DEATH.

A NEPHROLOGY NURSING SERVICE WAS ALSO INITIATED DURING THE PAST YEAR FOR MONITORING THE PROGRESS OF TRANSPLANT PATIENTS, AS WELL AS ASSISTING DIALYSIS PATIENTS WITH HOME TREATMENT.

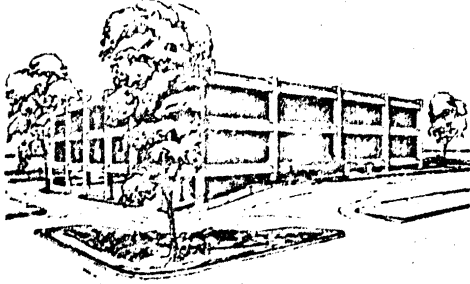
FOR THE COMING YEAR, THE KIDNEY PROGRAM HAS AGAIN CONTRACTED WITH THE FOUR TRANSPLANT HOSPITALS, MAKING AVAILABLE TO THEM FUNDS FOR BACK-UP PERFUSION SUPPLIES. DR. MANDEL WILL AGAIN DIRECT THE ORGAN PROCUREMENT NETWORK WITH MAJOR EMPHASIS ON

IMPLEMENTING THE COMMUNITY HOSPITAL ORGAN DONOR PROGRAM AND PRESENTING THE NEED FOR CADAVERIC KIDNEYS TO THE GENERAL PUBLIC. THE KIDNEY PROGRAM, IN RESPONSE TO REQUESTS MADE FROM ALL FOUR OF THE PARTICIPATING TRANSPLANT HOSPITALS, WILL MAKE FUNDS AVAILABLE FOR A TRANSPLANT COORDINATOR AT EACH MEDICAL COMPLEX. THE CONCEPT OF A TRANSPLANT COORDINATOR ORIGINATED AT CHARLOTTE MEMORIAL HOSPITAL. THE TRANSPLANT COORDINATOR IS AN INDIVIDUAL HIGHLY TRAINED IN THE AREA OF DIALYSIS AND KIDNEY PROCUREMENT. HIS RESPONSIBILITIES INCLUDE IDENTIFYING DONORS, COMMUNICATING WITH FAMILIES OF THE DONOR, AND ACTING AS THE FOCAL POINT FOR CONTACT DURING THE PRE- AND POST-TRANSPLANT PERIODS.

AS WAS REPEATEDLY STATED BY REPRESENTATIVES FROM ORGAN DONOR FOUNDATIONS AT THE JUNE 28 MEETING, THE AVAILABILITY OF HUMAN TISSUE FOR TRANSPLANTATION IS THE GREATEST SINGLE NEED IN THE TREATMENT OF NUMEROUS CHRONIC CONDITIONS. DR. HOOKER OF THE NORTH CAROLINA BOARD OF ANATOMY ALSO DIRECTED OUR ATTENTION TO A NEED JUST AS IMPORTANT IN THE LONG RUN- THAT OF PROCURING UNCLAIMED BODIES FOR ANATOMICAL STUDY AND TRAINING.

THE NORTH CAROLINA KIDNEY PROGRAM WOULD LIKE TO PARTICIPATE IN THE

IMPLEMENTATION OF ANY PLAN OF ACTION TAKEN HERE TO MEET THIS NEED.



NORTH CAROLINA MEDICAL SOCIETY

JOHN L. McCAIN, M.D., Chairman
 Committee on Public Relations
 Wilson Clinic
 Wilson, N. C. 27893

TO: The Health Committee
 Legislative Research Commission

DATE: June 28, 1974, 10:00 a.m.

PLACE: State Legislative Building
 Room 1118

BY: John McCain, M.D., Chairman
 Public Relations Committee
 North Carolina Medical Society

TOPIC: A Need for Comprehensive Coordinated Human Tissue Conservation
 Program in North Carolina

Before oil was discovered during the last century, this strange liquid was not considered a natural resource...with the technological advances that have been made during this period of time, oil is now one of our most precious resources.

Before the capability of utilizing human tissue from one to help another was developed, human tissues were not considered a natural resource. In contrast to fossil fuel of which the supply is finite and the utilization rate is high, available human tissues for recycle use are bountiful but the utilization rate is low.

Since the acceleration of the utilization rate of human tissues falls progressively more behind the acceleration rate of technical advances for utilization, the overall relative rate of underutilization progressively increases. This trend for progressive underutilization needs to be reversed.

Unfortunately, human tissue resources, unlike for the most part oil resources, are not commercially available and involve a personal commitment on the part of the donor...but the potential for continued use, if accepted by the recipient, is indefinite.

With blood conservation as the grandfather model from which to work in developing a retrieval and conservation program for human tissues, it is necessary that the contributor be well-informed, healthy and collection points be accessible and convenient to the donor. In contrast to blood tissue donation programs, other human tissues conservation efforts are more complicated, however...as they can usually be donated only once by the individual, they are usually given after death (with the legal and medical retrieval complications that ensue), and they are more expensive and complex to utilize.

It is estimated that in the United States today there are over 400,000 men, women and children who are blind. Of these, 30,000 may regain their vision by having corneal surgery. Whether they do greatly depends on a constant supply of corneal tissue, without which the surgeon is helpless. Eye donations are received from those people who have generously pledged their eyes to be used following death. At the current rate of receiving eye tissue, decades will pass before the supply meets the demand.

Kidney disease, the nation's fourth leading killer, affects 8 million people and kills 60,000 each year. Many thousands could be saved through kidney transplantation. However, the number of kidneys available from donors is in tragically low supply. Although it is calculated that there are more than 100,000 potentially suitable cadaver donors in the U. S. each year, only about 500 were utilized in 1970, 800 in 1971 and 900 in 1972. With the accumulation of new transplant candidates and the return of patients with transplant failures, the number of waiting, respective recipients has reached unmanageable proportions. It is clear that efforts to procure cadaver kidneys must be increased in order to prevent continued dissipation of this invaluable human resource. The rapid increase in the number of prospective cadaver recipients has resulted in an increase in the average waiting time of suitable transplant candidates. Since more than half of

The patients currently in the collaborative pool are high risk because they are presensitized, an active national kidney sharing program is essential. A National Transplant Communication Network has been initiated to achieve an increased utilization rate by encouraging the free exchange of kidneys between transplant centers.

In general, a cadaver donor is considered acceptable if he is under 50 years of age and had shown no signs of infection, cancer, hypertension or kidney disease. The most satisfactory donors are those who have sustained irreversible brain injury due to trauma, although some with the diagnosis of brain tumor or nontraumatic, intracranial bleeding are acceptable. Brain death or Cardiac arrest is the criteria of death that is determined by the donor's private physician. Removal of the kidney is preferably started no earlier than 5 minutes after cardiac arrest. The increasing numbers of kidney transplants reflect the increasing numbers of centers performing the procedure as well as the broadening criteria for patient selection. For example, children of all ages as well as many older patients, and patients whose kidney failure is due to diabetes or allergic conditions (lupus nephritis) are now considered as recipients for transplantation at a number of centers. The most critical need in the field of renal transplantation is to increase the inadequate supply of cadaver kidneys available. The number of patients awaiting kidney transplantation and the length of time they must spend on dialysis are both increasing. Kidney disease in North Carolina Regional Medical Program Chronic Uremia Program the number of beds in North Carolina has increased from 7 in 1972 to 22 in 1974. The North Carolina State Board of Health Kidney Program has been working with the Regional Medical Program in the provision of these services. An excellent booklet on the "Community Hospital Organ Donor

Program", has been prepared by the State of North Carolina Kidney Procurement Program, Department of Human Resources, N.C. Board of Health, but its utilization and implementation rate has been less than desirable.

One of the most important community developments in the field of renal transplantation was the signing into law Social Security HRI which provides for payment by Medicare of the major portion of the cost of dialysis and renal transplantation. All persons who have paid into the Social Security System are eligible for these benefits, as well as their dependents. There is a three-month waiting period from the time of diagnosis of renal failure until the benefits start. It is estimated that approximately 90% of the population will qualify legally for these benefits. By this, the expense accrued by dialysis and renal transplantation will be reimbursed with no economic or geographic limitations.

The closing of the gap between technological capability and financial feasibility has increased our need for kidney donors.

In addition to blood, eyes and kidneys, the following tissues are also now needed: blood vessels, bone, bone marrow, cartilage, fascia, heart, intestines, liver, lungs, pituitary glands, skin, spleen, teeth and thymus glands.

As a practicing internist, providing a great deal of primary care at the community level, good questions are being raised by the providers as well as consumers of health services.

- a. From the physicians vantage point, I have had a number of patients with chronic renal disease that could benefit from transplantation who are having to undergo chronic renal dialysis for a long period of time waiting to receive the kidney from a donor...these patients and relatives wonder why they have to wait so long...especially when we are aware of instances of non-use of excellent prospective donors in our own and other hospitals.

- b. From a hospital standpoint, the hospital recognizes that a community service it is desirable that they help retrieve potential human tissues for we are our "brother's keepers", however many legal obstacles are involved, such as obtaining permission from the patient and the family and then determination of death. Also, procedural obstacles have to be overcome such as who will retrieve the organs, who will pay for the service and how will the organs be stored and transplanted by whom and where.
- c. From the informed public standpoint, a willingness is being indicated to donate kidneys, eyes, body, etc., but the physician does not know which form to use, what the requirements are and how to go about it. The public is also asking the question, "When I die how will the doctor at the time carry out my wishes that I should donate part or whole of my body?" "What if I die in another state...will the attending physician know to remove the organs I have donated?"

From these questions frequently raised at the local level, it is apparent that a coordinated comprehensive approach toward conservation of all human tissue is desirable for North Carolina.

It was upon this background of information that Mrs. Margaret Macklin, of the North Carolina Eye and Human Tissue Bank approached the Public Relations Committee of the North Carolina Medical Society several years ago about this concern. Accordingly, the Statement of Policy on Donation of Human Tissue for Transplantation of the North Carolina Medical Society and the North Carolina Hospital Association was prepared and adopted in cooperation with the North Carolina Regional Medical Program, North Carolina Eye and Human Tissue Bank, Inc., The North Carolina Kidney Foundation, Human Growth Foundation and the North Carolina Anatomical Board.

Since we were aware that "what is everybody's business is nobody's business", it would be most appropriate for an independent legislative study group to have a

fresh look at the entire problem of human tissue conservation in North Carolina and make recommendations as to what should be done. We would hope that the development of a comprehensive coordinated program from the state would be one of the developments from this study. We would also hope that the eventual program would fully utilize the leadership of existing health agencies such as the North Carolina Eye and Human Tissue Bank and others in the implementation of any proposed program that develops.

We are so pleased that in the wisdom of the legislature they have accepted this responsibility by having some of North Carolina's most outstanding health legislators undertake the study. By reviewing the collective records of performance of the individual members of this Committee, I do believe that we will have a model human tissue conservation program for our state which will be an example for the rest of the country to follow.

We are fortunate in North Carolina to have many national leaders in specialty fields concerned with appropriate conservation of human tissues. I am pleased to learn, in the discussions to date of the intention of the Committee in its wisdom to take full advantage of this available expertise.

STATEMENT

Charles W. Hooker
Professor of Anatomy, University of North Carolina
Chairman, North Carolina Board of Anatomy

June 28, 1974

As I understand it, this meeting is concerned with problems inherent in implementation of the provisions of the Uniform Anatomical Gift Act adopted by the General Assembly in 1969. Although the Act is concerned primarily with donation of organs and tissues for transplantation, it also, and quite significantly, provides for bequeathal and donation of the entire body for anatomic study and instruction.

My only function is to remind you of the latter provision and to urge that in your concern for the obviously life-saving procedures and arrangements for transplantations you not overlook the problem of entire bodies for anatomic study. The problem I represent is recognized in the Statement of Policy of the Medical Society of the State of North Carolina, in the policy of the North Carolina Eye and Tissue Bank, in the thinking and probably the policy of the Kidney Foundation of North Carolina, and by the existence of the North Carolina Board of Anatomy, a unit in the Department of Human Resources.

I am here to speak for the Board of Anatomy. This Board is composed of representatives of the medical schools in the state, one member from each of the four schools. As stated in the old and so-called North Carolina Anatomical Law, the Board is charged with receipt and distribution among the medical schools of bodies to be used in instruction in Anatomy.

The group assembled here hardly needs to be reminded that the study of Anatomy is classically the beginning in a medical education and that in many specialties the study of Anatomy is a continuing activity. We sometimes tell our students that in his repairing and caring for the lame, the halt, and the blind the physician is to a considerable degree a mechanic tending a fearful and wonderful machine, and that he must know where the carburetor and the distributor are located and how they are assembled.

For many years the need for bodies for anatomic study was met by unclaimed bodies -- defined by statute as bodies that must be buried at public expense. In those less complex days the number of unclaimed bodies available was far higher than today, and the number of students receiving anatomic instruction was far less. It has been a curious coincidence that the increase in numbers of students and the decrease in numbers of unclaimed bodies were simultaneous, and the disparity grows.

It was not until about 1955 that bequeathing the body was authorized by statute; the practice was not forbidden before that time, but it was not authorized. Since that time the number of willed bodies used in anatomic study has steadily increased to the point that they now amount to perhaps 75 per cent of the bodies studied in the four schools of medicine. If the practice of bequeathing the body continues to grow, willed bodies should in time meet the need. We know of hundreds of concerned and public spirited persons who have bequeathed their bodies.

The unhappy problem of the medical schools is the provision of satisfactory instruction in the interval during which receipt of willed bodies is below need.

I am convinced that much of our present problem is that the medical schools do not receive all or nearly all of the unclaimed bodies. For a variety of commendable reasons the number of such bodies has declined, but it seems most unlikely that the decline in the number of such bodies should be as precipitous as the decline in the number of such bodies received by the medical schools.

It is my impression -- almost my conviction -- that the explanation is lack of familiarity with the Anatomical Law. This Law states that the agency or person having control of an unclaimed body is required to offer it to the Board of Anatomy. My evidence that there is unfamiliarity with this law is our receiving telephone calls from hospitals and county departments of social services in which we are told "We have the body of a patient or client who

has recently died and we do not know what to do. After much search we have learned that perhaps you can tell us what to do". Another evidence, unless there has been a recent exception, is that no unclaimed body has gone to any medical school from Mecklenburg County in nearly fifty years, and this is the most populous county. The number of unclaimed bodies from the western half of the state has dropped to but two or three a year.

Our situation is nearly desperate. At the end of May the four medical schools had on hand approximately one-half of the bodies we shall need when instruction begins in August. We need help. We need cooperation. And all we ask is that responsible persons abide by the law.

When a patient receives a kidney transplant his life is likely to be saved and his health restored. When a body goes to a medical school for anatomic study at least four fledgling or trained physicians participate in the study. Every patient that every one of these students ever has should benefit from study of that body, and that amounts to literally thousands of persons.

It is our plea that in your efforts to make provision for transplants you leave the way open for bequest and donations of bodies for anatomic study. We also need your advice on the matter of getting unclaimed bodies to the medical schools in keeping with requirements of the law.

For further information contact:

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3026 Hanson Dr.
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The North Carolina Medical Society
P. O. Box 27167
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Rev. Howard E. Seymour
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The North Carolina Anatomical Board
Dr. Charles W. Hooker
University of North Carolina
Chapel Hill, North Carolina 27514

The North Carolina Hospital Association
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P. O. Box 10937
Raleigh, N. C. 27605

The Association for the North Carolina Regional
Medical Program
P. O. Box 8248
Durham, North Carolina 27704

DONATION OF HUMAN TISSUE

FOR TRANSPLANTATION

JOINT STATEMENT

OF POLICY

NORTH CAROLINA MEDICAL SOCIETY

AND

NORTH CAROLINA HOSPITAL ASSOCIATION

APPENDIX X

Transfusions of blood, the most common transplant, have been universally accepted for years. Well established today, but for many years beyond the realm of surgical research, are the transplantations of corneas (the clear portion of the front of the eye) to those persons whose corneas have been clouded by injury or disease.

NEEDED HUMAN TISSUES

Not all blindness can be cured, but it is estimated that one in every twenty-five blind persons could have their vision restored through the transplantation of a donated cornea. Eye donations are received from those people who have generously pledged their eyes to be used following their death. At the current rate of receiving these donations, decades will pass before the supply meets the demand.

The North Carolina Medical Society and the North Carolina Hospital Association recognize that, as science perfects methods of improved matching of donor and recipient tissues, the need for whole organs for transplantation, and whole bodies for medical education may increase substantially.

The first whole organ transplant from one person to another was accomplished in 1954. Since that time, numerous tissues and parts, from persons both living and dead, have been used to give life and to treat victims of disease and injuries. It is not unusual for a deceased donor to contribute a kidney to each of two recipients, his corneas to two blind persons and possibly other organs to still other persons.

The human tissues now needed are: Blood, Blood Vessels, Bone, Bone Marrow, Cartilage, Eyes, Fascia, Heart, Intestine, Kidney, Liver, Lung, Pituitary Glands, Skin, Spleen, Teeth, Thymus Glands.

KIDNEY DONATIONS

The kidney is the organ most frequently transplanted. Nationally, there have been more than ten thousand kidney transplants performed. Renal grafting, after a decade of intensive research, is now an accepted therapy for selected patients dying of end stage kidney disease.

The North Carolina Medical Society and the North Carolina Hospital Association recognize that there are many North Carolina citizens undergoing expensive, but essential, dialysis treatment in order to remain alive. They further recognize that if there were sufficient donor kidneys available from recently deceased persons, many of these victims could be significantly helped and the need for dialysis reduced.

PITUITARY GLAND DONATIONS

The human Pituitary gland is the only source of a substance known as Human Growth Hormone. In 1958 medical scientists made a dramatic breakthrough in the fight against one form of dwarfism. They discovered that this hormone, when injected into hypopituitary dwarf children during their vital growth years, may double or triple the growth rate. A single human pituitary gland will yield up to 5 mg of growth hormone. The major problem with this course of treatment is obtaining enough donated pituitaries. In some cases of potential dwarfism it may take hormones from fifty pituitary glands, in others as many as two hundred may be needed.

UNIFORM ANATOMICAL GIFT ACT

The transplantation of tissues and organs has become so well accepted that a Uniform Anatomical Gift Act is now the law in most states. North Carolina passed this law in 1969, making it possible for an individual's wishes to be respected regarding the disposition of part or all of his body immediately following his death.

Essentially, the model law for donation states: (1) any person eighteen or more years of age may donate all or part of his body for research, transplantation or placement in a tissue bank; (2) a donor's valid statement of gift is paramount to the rights of others except where a state autopsy law may prevail; (3) if a donor has not acted in his lifetime, his survivors may do so, in a specified order of priority; (4) physicians who accept organs or tissues in good faith are protected from law suits. The physician attending at the time of death, if acquainted with the donor's wishes, may dispose of the body under the Uniform Anatomical Gift Act; (5) the time of death must be determined by a doctor who is not involved in the transplantation, and the attending physician must not be a member of the transplant team; (6) the donor may revoke the will and the donation may be rejected. The most important clause permits the donation to be made by will (without waiting for probate) or other written or witnessed documents.

The provisions of the Uniform Anatomical Gift Act are so designed that the offer is exercised after death. Therefore, the donor should reveal his intentions to as many of his relatives and friends as possible, including his physician.

Other Needs for Human Bodies

Research is in need of whole bodies for medical education. All physicians must have a thorough knowledge of the structure of the human body. This is taught early in their medical training by a course in anatomy. The need for

these can be met by those persons who were interested enough, during their lifetime, to make such a pledge to science for the betterment of all mankind.

When anatomical donations have been made through the North Carolina Eye and Human Tissue Bank, Inc., using the Uniform Donor Pledge, several different opportunities are presented for one to give the gifts of sight and life. One may pledge: his eyes, any needed organs or parts, only the specific organs or parts designated by the donor, or his entire body for anatomical study. There is no fee charged for the services of the North Carolina Eye and Human Tissue Bank and all necessary arrangements are made through their office.

The North Carolina Medical Society and the North Carolina Hospital Association, fully aware of the importance of the physician and the community hospital, to a successful, coordinated anatomical gift program for North Carolina:

- 1) Encourage the study of transplantation and research, the diffusion of knowledge and an expanded program of public education as to the need, and the legal and medical methodology of making anatomical gifts to medical science.
- 2) Support legislative efforts to achieve maximal organ procurement and transportation service potential.
- 3) Encourage all its members to keep a supply of the necessary donation forms and informative literature in their offices and hospitals so that the public will be aware of the need for organs and aware of their physician's and hospital's approval of such donations.
- 4) Urge its members to assist the North Carolina Eye and Human Tissue Bank, Inc., the North Carolina Kidney Foundation, the North Carolina Human Growth Foundation, the North Carolina Anatomical Board and other interested agencies in attaining their objectives to secure more donors, retrieve more needed human tissues, organs and bodies to be used by the transplanting surgeons, hospitals and medical schools of the State.
- 5) Encourage its members to actively participate in the retrieval of donated organs and tissues and to provide leadership in the development of community resources through hospitals, civic and professional organizations, committees and etc. to accomplish this..

Research Commission on Human Tissue Donations
% Mr. Terry Sullivan, Counsel
State of North Carolina Legislative Research Commission

Presentation Before Commission on Human Tissue Affairs
June 28, 1974

The enclosures in this letter are in addition to the suggested areas below in which we could be aided by the legislature:

- 1) Adoption of some type of legislation comparable to the Wisconsin Tissue Acquisition and Transplant bill.
- 2) Amending the criteria of death to recognize that other manifestations of death may be used in certain situations to pronounce a patient dead. These should include brain death*, but brain death itself as such should not be specifically defined at this time (e.g. stating that an EEG of some other specific parameter be present prior to diagnosing brain death should not be included at this time).
- 3) A mandate or suggestion to the state and local police to cooperate as a matter of vital importance on the intrastate transportation of kidneys. It would help if this suggestion specified the need for speed and precision in the delivery of these organs.
- 4) Insure that the North Carolina government continues to provide the necessary funds to:
 - a. initiate and carry out educational programs (so that kidney donation is a "people problem" and acquisition of organs is not primarily a "physician problem")
 - b. Continue to support the organ harvest efforts of the four medical centers until these become self-supporting programs
 - c. Encourage the four medical centers to meet four times a year in order to develop a cooperative effort between the centers. Funding of this type of meeting for interchange of the groups would be most important in maintaining a high level of efficiency in organ procurement and transplantation in North Carolina.
- 5) Appoint someone to study how best to expedite federal re-imbusement, so programs will not lack funds to perpetuate their activities due to long delays of 6-12 months in repayment for funds available through HR-1 (e.g. There are funds available to surgeon harvesting kidneys, but often are not paid for 6-12 months.)
- 6) Move for approval of the driver's license sticker as a method for identifying organ donor participants.
- 7) Go on record as absolutely not wanting any combination of any type between the tissue harvesting program (which is a gift of life) and the anatomical acquisition of cadavers for medical school research which is a totally different problem.

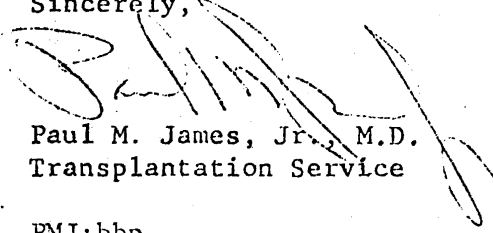
- 8) Go on record as favoring the further development of the four current state centers for transplantation as the best means of serving the needs of the widely distributed population in North Carolina.
- 9) Recognize in your deliberations the two-fold obligation of the transplant team:
 1. To insure that the best possible efforts have been made to salvage the donor and,
 2. that the kidney (once the donor is pronounced dead) be treated by means that will provide the recipient with the best possible kidney tissue and, therefore, the best chance for survival and successful outcome.

* The reason brain death is important is that often other vital functions (respiration, circulation, heart beat) may be artificially supported for some time even though the brain is irreversibly injured and will never function again (as evidenced by no spontaneous respiration, absent reflexes, absent movements of the extremities, no eye activity or response to pain stimuli). This is the type of patient that is ideal for donating kidneys which have the best chance of surviving.

I hope these suggestions are of some help to you. I would be happy to discuss any area or particular point in depth with the group if this would be helpful.

Again, thank you for the privilege of appearing before your commission.

Sincerely,



Paul M. James, Jr., M.D.
Transplantation Service

PMJ:bbp

PROPOSAL FOR ESTABLISHMENT OF A
HUMAN TISSUE UTILIZATION PROGRAM IN NORTH CAROLINA

John L. Weinerth, M. D.
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and

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Duke Medical Center
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Introduction

The need for useable human tissues and organs for the treatment of citizens of North Carolina is beyond the present availability of these tissues. Part of the difficulties in providing human tissues and organs for treatment of the citizens of North Carolina arises from the lack of an organized program for identifying donors, harvesting tissues, preserving tissues and bringing the tissues and recipients together. A second difficulty arises in the lack of specific knowledge concerning the tissues needed and the medical-biological limitations surrounding their procurement and preservation as well as utilization.

This brief report will attempt to outline the needed tissues and organs with specific requirements and to provide an outline for a possible state-wide program for the implementation of human tissue utilization.

Specific Tissues

Corneas

Corneas are needed in a large number of North Carolinians for the treatment of specific ophthalmologic conditions. Often these conditions are chronic but occasionally the need is acute, especially when infective processes threaten the survival of the entire eyeball. These tissues are available from a large number of people dying in the state of North Carolina with the only limitation being that the donor be of adult size and less than 60 years old as well as being free of ophthalmologic disease. These tissues (corneas) can be ~~used~~ kept up to 12 to 16 hours after death with no specific care of the remains except for the installation of ophthalmologic ointment immediately after death. It has been the general experience that it is preferable to remove the entire eyeball so that the cornea will not be damaged during the procurement. This does not prove to be a detriment to open casket funerals since morticians generally pack the eyeballs to provide normal contours. Shortly after death the eyeballs shrinks due to the loss of tissue and the mortician has to perform cosmetic services in order to retain normal contours. The removal of the eyeball does not preclude this cosmetic maneuver. These tissues and eyeballs should be preserved in a balanced salt solution, preferably a sterile tissue culture solution, inside a sterile container. Storage time is up to 24 hours under these conditions with good graft acceptance. Harvesting can be done in any location where there is knowledgeable technical assistance. Primarily this can be done wherever there is an ophthalmologist available. The tissue can be utilized in any hospital where the ophthalmologist perform corneal transplants.

Priority for this need is high.

Kidneys

There are several hundred North Carolinians who need kidney transplants for the treatment of their chronic renal failure. These tissues are not available in a large number of routine deaths. The situations where they are available are in patients who have had massive brain injury and their bodies are being maintained by artificial means, although the patient is truly dead. These conditions must be assessed very carefully in order to provide maximum care of the donor. There are other special requirements for these tissues including maintenance of good blood flow and avoidance of nephrotoxic drugs prior to the removal of the kidneys. Maximum time after death that the kidney can be removed is approximately 15 minutes. At the end of the 15 minutes the kidney temperature must be below 10° centigrade to provide good preservation. Storage time on kidney perfusion machines will be in the range of 48 to 50 hours. Most preservation is two types. (1) simple hypothermic storage: the kidney is flushed out with a special salt solution chilled to the temperature of 5° centigrade and then stored in a sterile container in ice slush. These kidneys are useable 18 to 24 hours after procurement. (2) the kidneys are placed on special kidney perfusion pumps and storage time on these pumps is up to 50 hours. The areas of harvesting will be limited to locations where the appropriate technical and medical support is available for assessment of the donor, procurement of the kidneys, and preservation. With the proper instructions the procurement and assessment of the donor can be done in many of the larger hospitals in the state of North Carolina. With appropriate technical support of the transplant centers (University of North Carolina, Chapel Hill, Duke University, Bowman-Gray University and Charlotte Memorial Hospital) preservation techniques can be made available to the harvesting hospitals. Areas where the tissues can be used are limited to four major transplant centers in the state of North Carolina. Because North Carolina is involved in a sharing program some of the kidneys procured in the state will be used outside the state realizing that this contribution will mean outside kidneys will be sent to North Carolina for use in North Carolina citizens.

Priority for this tissue is high.

Hearts

The need for cardiac transplantation is growing, but there is no place in North Carolina that heart transplants are being carried out. The procurement of hearts is very similar to that of kidneys but there need to be very special technical considerations. Hearts can only be taken in major centers where cardiac surgeons knowledgeable in heart transplantation are available.

Priority for North Carolina is low.

Heart Valves

Heart valves are being used in the treatment of specific heart valve disease although the need for human heart valves has decreased greatly over the past few years with the development of mechanical heart valves. Heart valves can be taken from cadavers within 24 hours of death and

their preservation includes freeze-drying after a period of nutrient media storage.

Priority for North Carolina is low.

Bone

The need for bone is continually growing. Major reconstructive procedures often need bone for reinforcement of fusions or other orthopaedic procedures. Availability of this tissue is good since appropriate bone can be removed from a large number of the cadavers in North Carolina. The only specific requirements are that the donor be free of cancer or communicable disease. Maximum time after death that bone fragments can be removed from a donor is approximately 12 to 24 hours. Preservation of bone can be by simple hyperthermia (freezing) or by freeze-drying. There are places in the United States who will provide the service of freeze-drying of the tissue if long-term storage is needed. Simple freezing will provide a storage time up to 6 months. There are no specific harvesting needs with the exception of a sterile operating room. Harvesting of bone can be done anywhere where there is a sterile operating room and appropriate surgical skills. The bone can be used in any hospital doing orthopaedic surgery.

Priority for this tissue is moderate.

Tissue-Pituitary

The pituitary gland, located in the base of the skull, is the source of all of the major hormone stimulating substances in the human body. These tissues are needed for both research and patient treatment. This tissue can be obtained from a large number of persons dying in North Carolina who fall in the age group of 20 through 45. Only special requirements are the patients are free of pituitary disease, cancer, and communicable disease. Maximum time after death that these tissues should be obtained is 6 to 12 hours. Storage time is for several months by freezing. There are no special harvesting needs with the exception of sterile nutrient solutions. These tissues can be harvested in any hospital where sterile conditions are available and a competent neurosurgical or pathological assistance is available. Tissues are generally used in specific centers where endocrine therapy is being carried out.

Priority for this tissue is moderate.

Skin

Skin is not a successfully transplantable tissue. However, it has been extremely useable as a biologic dressing in patients who have sustained large burns. Tissues that have been either irradiated or freeze-dried have been extremely useful in maintaining body fluids and providing a coverage until underlying tissues are ready to accept skin grafts from other parts of the patient's body. Availability is good since skin can be obtained from most patients who die, with no age limits imposed. The

only special requirements are that the patient does not have communicable disease or obvious dermatologic abnormalities.

Fascia Lata

The tissue is the thick covering over the muscles of the thighs and is used as a supportive element in reconstructive surgery especially orthopaedic and fistula procedures. The tissue is available in a large number of patients who die in North Carolina with the standard exceptions of communicable disease and cancer. There are no special requirements other than a sterile operating room and nutrient media for the procurement. The maximum time after death that the tissues can be procured in 24 hours. Storage time by freeze-drying is in excess of a year; by freezing and irradiation approximately 6 months. The harvesting of these tissues can be done in any hospital where sterile facilities and surgical support is available. The tissues can be used in any areas where the above mentioned procedures are done.

Priority for this tissue is moderate.

Dura mater

Dura mater is the thick covering inside the skull over the brain and is an excellent tissue for neurosurgical closures of central nervous fluid leakage. In addition, this tissue can be used as an adjunct to fistula operations. The availability is in a large number of patients. Special requirements are none with the exception of communicable disease and cancer. Maximum time after death that this tissue can be harvested in approximately 24 hours. Its storage time is approximately 6 months with freezing-irradiation and several years when preserved by freeze-drying. There are no special harvesting requirements with the exception of neurosurgical or pathologic personnel and sterile operating facility. Areas can be harvested in any hospital where these facilities are available and can be used in any hospital where the above mentioned procedures are carried out.

Priority for this tissue is moderate.

Miscellaneous Tissues

There are several other tissues which are being used on a limited therapeutic basis and extensive experimental basis. These include nerves, arteries, veins, and tendons. These tissues are used in a number of reconstructive procedures experimentally and have been used in several clinical series. The availability of these tissues is good since it is possible to secure them from a large number of patients who die in the state of North Carolina. Special requirements for the procurement of this tissue is the absence of specific tissue disease as well as the absence of cancer or communicable disease in the donor. Preservation methods are primarily freezing and freeze-drying. The maximum time after death that they can be obtained is 24 hours. The special harvesting needs are minimal since sterile nutrient media is the only thing needed at the harvesting facility. Harvesting can be done in any facility where a sterile operating room is available and technical ability is available. These tissues

are used only in institutions where these frontier procedures are being carried out or where the research is being undertaken.

Implementation of a Program of Human Tissue Utilization.

It is possible that the state of North Carolina may wish to undertake the establishment of a program which will support, coordinate and guide state-wide utilization of human tissues. This will include areas such as public education, communication, transportation, rosters of expert persons, training programs, etc. Many of the tissues previously described can be obtained throughout the state of North Carolina, but it is necessary to educate both medical personnel and laymen regarding their needs, techniques of harvesting and preservation and finally avenues of communication and transportation.

A possible method of implementation of such a program is to set up a special group under the state government for the support of such activities. See Figure 1.

Under the state government the most appropriate place for this activity may be the Department of Human Resources. Within its Division of Health Services, the Chronic Disease Branch would coordinate and implement a human tissue utilization program.

There should be an advisory council to the human tissue program to make sure that all of the necessary needs of North Carolina are met. This certainly would include medical personnel, informed citizen and legislators.

Under the Human Tissue Utilization Program there could be several specific activities. The first would be the education program which would support, coordinate, and guide many of the already energetic and efficient private organizations in the state of North Carolina such as the North Carolina Kidney Foundation, the North Carolina Medical Society, the North Carolina Eye and Human Tissue Bank, Incorporated, etc. in the dissemination of appropriate information to the public as well as the maintenance of registries and information sources. This educational activity of the Human Tissue Utilization Program would make certain funds and contacts available to these private programs and assist in a state-wide awareness of the needs of tissues and the means whereby individuals can donate tissues.

The second general activity would be a communications/transportation activity whereby communications from various parts of North Carolina can be centrally handled. It is not outside the realm of possibility that the already available Emergency Medical Services might be incorporated into this particular activity providing communications between hospitals with donors and hospitals with possible recipients as well as the transportation of vitally needed tissues. This area can also act as a central information center whereby state-wide inquiries regarding tissue donation or tissue harvesting can be handled immediately or referred to the appropriate institutions or persons.

A third area of activity would be in the development of a roster of expertise and the development of training programs under the direction of expert civilian physicians or institutions. It would be extremely important that there be an

accumulation of information regarding talent already available in the state for distribution to all persons involved in human tissue utilization. This would include medical personnel and institutions who have specific knowledge in the requirements for human donation, the maintenance of registries, the specific requirements of donation situations, harvesting procedures, and preservation methods. In addition this area would make available to all interested persons specific guidelines prepared by experts in the field. This area would support and guide seminars given on a one or two day basis throughout the state dealing with the specifics of human tissue utilization. These seminars would certainly utilize civilian experts in a formal program as well as a general question and answer session.

It is felt that a state-wide effort with the centralization of information and communication would greatly assist in not only the procurement of more donors but their more effective utilization throughout the state of North Carolina. There are many areas of specific endeavors which have been quite successful within this state but it is felt that at the present time we need a greater communication among all of these areas in order to more fully utilize our expanding human resources. This brief outline is presented as a suggestion which must be amended according to the needs of North Carolina and the abilities of North Carolina to meet these challenges.

Respectfully submitted:

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Durham, North Carolina 27710

and

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State of North Carolina

Department of Human Resources

Division Health Services

Chronic Disease Branch

Human Tissue Utilization Program

Emergency Medical Services

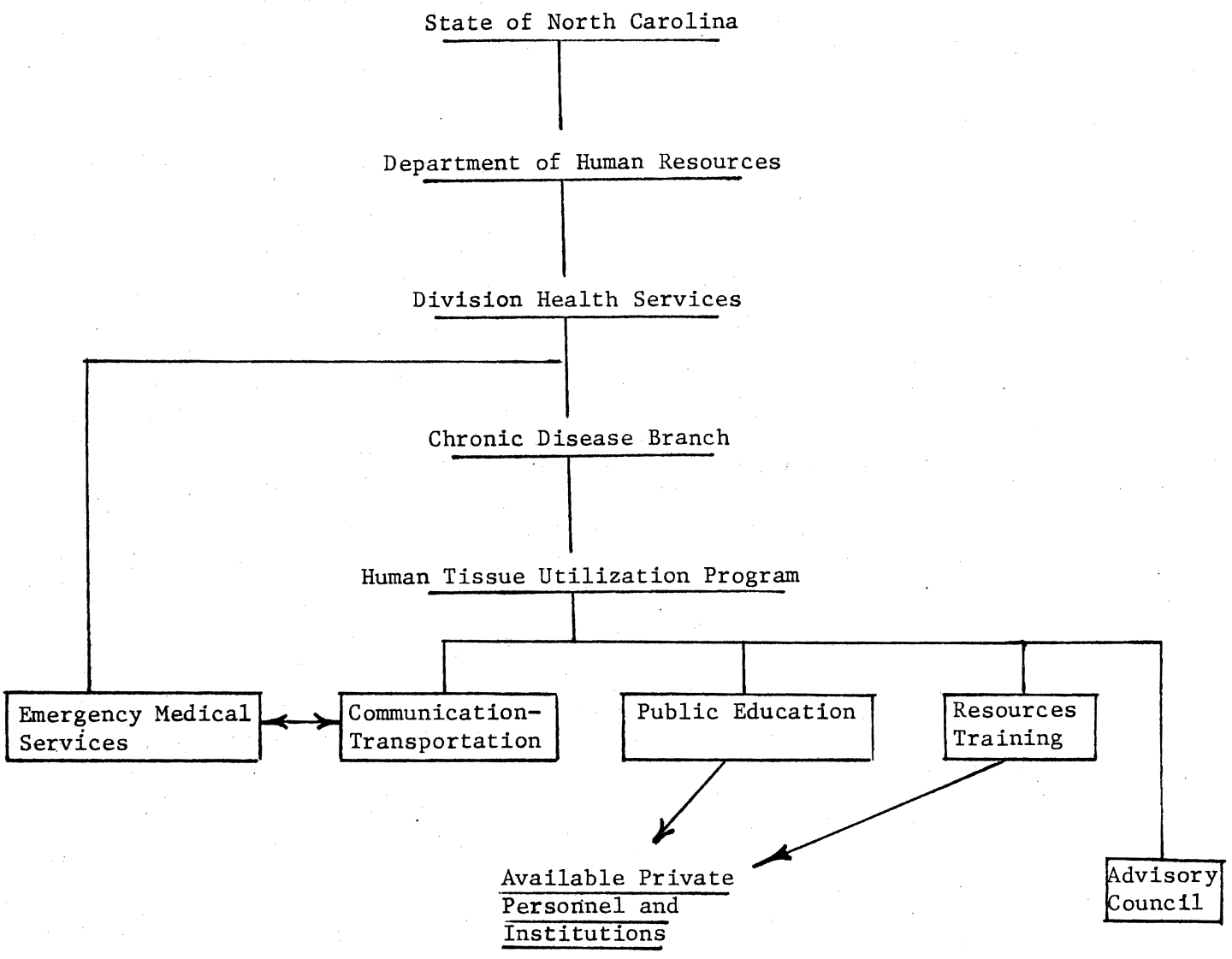
Communication-Transportation

Public Education

Resources Training

Available Private Personnel and Institutions

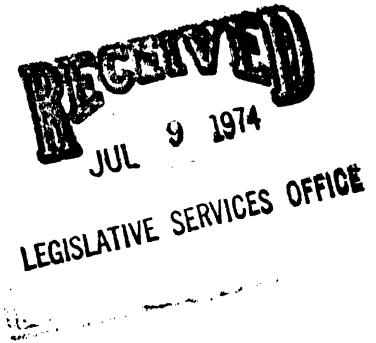
Advisory Council



THE UNIVERSITY OF NORTH CAROLINA
 AT CHAPEL HILL
 CHAPEL HILL, NORTH CAROLINA 27514

THE SCHOOL OF MEDICINE
 DEPARTMENT OF ANATOMY

July 5, 1974



Mr. Terrence D. Sullivan, Committee Counsel
 Committee on Human Tissue Donations
 Legislative Research Commission
 State Legislative Building
 Raleigh, North Carolina 27611

Dear Mr. Sullivan:

You have my warm thanks for permitting me to attend the meeting of the Committee on June 28 and for the privilege of making the remarks I offered. I was much struck by the evident interest of the Committee in their important problem and by their remarkable courtesy and patience.

In keeping with your request, a copy of my remarks is enclosed. I recognize that the problem I represent is not an obvious element of the problem that is the Committee's concern. I am persuaded, however, that in their preoccupation with organs for transplantation any group could unwittingly adopt policies or take actions that might unintentionally interfere with bequeathal of bodies for anatomic study, a pursuit no less important than provision of organs for transplantation. I am happy that the Committee seemed to concur that bodies for anatomic study are a sine qua non in medical education and training.

You invited persons attending your meeting to relay to you further information or suggestions. In response to that invitation, I offer the following comments of one or another significance.

The funeral homes in the state and the North Carolina Funeral Directors Association through its Executive Director, Mr. Dan L. Shackelford, have been highly cooperative in the matter of getting to the medical schools both willed and unclaimed bodies. Their function in this circumstance involves picking up the body at the place of death, embalming the body, and transporting it to the appropriate medical school. In some instances all this is more or less routine; in other instances the funeral director becomes involved as an intermediary between a medical school and the family of the deceased. Under present circumstances they are an indispensable part of a "team", and they deserve credit for their contribution. Of course, the medical school receiving the body pays the funeral home fees for embalming and transportation and attempts reimbursement for out-of-pocket costs incurred by the funeral home.

You will observe that paragraph 90-212 is more or less addressed to morticians. This may have been in order at one time, but it is my view -- and I have urged it upon funeral directors -- that the funeral director should have little or no responsibility for the decision whether a body is unclaimed or whether it has been bequeathed. Although paragraph 90-212 specifically includes undertakers among those required to offer an unclaimed body to the Board of Anatomy, I question the propriety of a funeral director's making the decision that body is unclaimed or claimed. He lacks the information and facilities of a department of social services, a hospital, or a sheriff's department for ascertaining whether there is a legal claimant. His making this decision leaves him open to the unfounded charge that he is selling a body to a medical school, a problem that some of the black funeral homes have had to face. My own view is that in

July 5, 1974

delivering a body, unclaimed or willed, to a medical school a funeral home is performing its usual professional services in response, as usual, to the request of a responsible person authorized to make decisions and give directives. I should be grateful for your criticism of my position.

The question of the desirability and practicality of one central registry for records concerning bequests of organs and bodies was raised at the meeting. The proposal has obvious merit. There would be some one office that would know whether an organ or the body has been bequeathed by a specific person. This office would presumably have a telephone manned 24 hours of every day by someone able to provide accurate information and suggestions as to procedure in the confusion immediately following the death of a possible donor. Such manning of a telephone should relieve the medical schools, the Eye Bank, the Kidney Foundation, and possibly other agencies of a difficult assignment not uniformly met at present. There are obvious problems to be met, however. Every group receiving notification of a bequest would have to furnish details to the Central Registry promptly upon learning of that bequest. Some simple and fool-proof means of notification would need to be devised and adopted; otherwise, the Registry would be perpetually out of date. It will be imperative that all groups cooperate fully and to some extent sacrifice a bit of their individuality; this may not come easily. It will be essential that the Registry be impersonal in preferring no one donee to any other donee. It will be imperative that red-tape not take precedence over the specific, if sometimes odd, wishes of individual donors. It must be recognized that some donors wish their bodies or organs to go to a specific donee or to none; this group includes exceedingly loyal alumni of the universities and exceedingly grateful patients of specific hospitals. In short, the proposal is a good proposal, as I see it, but implementing it will require information and careful thought.

It seems fairly clear that the problems that concern the Committee include the differences in modus operandi of the different hospitals and medical schools. These differences may not be great, but it is likely that they exist and that they constitute problems. As a small example, I do not know that, say, Bowman Gray would consider a Central Registry more or less effective than their present methods.

A recurring suggestion at your meeting had to do with use of the media, especially television, in encouraging people to bequeath organs and the body. I have the feeling that is only a feeling that although such appeals for bequests of organs could be made in good taste, appeals for bequeathal of the body could be offensive even if skillfully made. You will recall that Dr. James from Bowman Gray expressed the same view, but many of my colleagues do not agree with me. It is possible that suggesting bequeathal of the body as a small portion of an appeal for donation of organs would not be offensive. Many persons have a revulsion toward dissection that is comparable to their revulsion toward snakes, and they look upon anatomic study as being utterly different from the live-saving donation of a kidney that is no longer needed. I cannot escape the fear that appeals in the media for donation of the body are as likely to repel persons seriously considering bequeathing the body as they are to persuade other persons to bequeath the body.

In contrast to my feeling about appeals made on television, it is my guess that Dr. Mandel's suggestion that an appeal presented with the driver's license may have real merit. My reason is that the written word seems somewhat more dignified and restrained than a statement on television, and it can be read repeatedly. At the moment I should prefer having a statement and donor card enclosed in the notice that the driver's license is soon to expire to having a

July 5, 1974

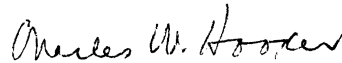
donor card issued with the license. If but 100,000 of 3,000,000 drivers even consider the statement and the card, the number would be large. The statement would need to be prepared carefully.

An organization that might interest you if you are not already familiar with it is Triangle Cremation Services, Inc. (Box 2070, Chapel Hill and telephone number 732-8605 in Hillsborough). As the name suggests, this is primarily a crematory, but the president, Mr. Arthur Hurow, has become much interested in bequeathal of the body and of organs. It seems that he receives many inquiries about donations along with inquiries concerning cremation. The informed cooperation of this organization might prove to be an asset in the program that is our concern.

Let me repeat that the Board of Anatomy is renewing efforts to acquaint Social Services, county commissioners, and hospitals with the Anatomical Law and with the Uniform Anatomical Gift Act and to encourage them to cooperate. This is a large assignment in which we have not done well in the past. The Department of Correction is fully informed and fully cooperative.

Again, thank you for your interest and your courtesies.

Respectfully yours,



Charles W. Hooker

NEW MAILING ADDRESS:

University of North Carolina at Chapel Hill
Division of Health Affairs
Department of Anatomy
306 MacNider
Chapel Hill, North Carolina 27514

THE UNIVERSITY OF NORTH CAROLINA
AT CHAPEL HILL

RECEIVED
SEP 18 1974

School of Medicine
Department of Anatomy

September 16, 1974

Telephone: 966-1237
Area Code: 919

MAILING SERVICES OFFICE
The University of North Carolina
at Chapel Hill
DIVISION OF HEALTH AFFAIRS
Department of Anatomy
306 MacNider
Chapel Hill, N.C. 27514

Mr. Terrence D. Sullivan, Committee Counsel
Committee on Human Tissue Donations
Legislative Research Commission
State Legislative Building
Raleigh, North Carolina 27611

Dear Mr. Sullivan:

I have finally succeeded in drafting a letter to Mr. William White of the Department of Human Resources, and a copy is enclosed herewith. In it I have tried to call attention to the more obvious problems and to inquire into the practices that may have been devised to meet these problems. It was my sincere intention to be polite in these inquiries, but a real possibility exists that the problems created are larger than the problems solved. Moreover, there is evidence that the Department of Human Resources has been given responsibilities that they do not understand. Failure to report the change in the statutes to the medical schools and to the old Board of Anatomy was undoubtedly a simple oversight, but that failure has created much uncertainty in a situation that tolerates a minimum of uncertainty.

Do you happen to know the thinking that prompted the General Assembly to change these statutes and the objectives they had in mind? Do you know what group promoted the change? We may assume that the motives were good and that the thinking was sound, and it would be reassuring to know that steps have been taken or are contemplated that will attain the objectives. So far as I can learn, the only information available is the fact that the statutes were changed (and my only information came from you at the meeting of the Committee on August 9).

In another vein, I have given thought to your question whether some one person in each county should be given responsibility for the decision that a body is unclaimed. At first glance this appears to be a simple plan and one that might bring order to a situation that can be involved - in short, a good administrative arrangement. I am not sure that it is a practical solution, however. You suggested a Medical Examiner as possibly the appropriate person, and certainly he is a candidate for consideration. Such an arrangement would, I presume, place the ultimate responsibility with the Chief Medical Examiner. Against such a choice are such considerations as (1) the Medical Examiner as such is ordinarily involved only in unattended deaths or deaths under suspicious conditions; (2) the local Medical Examiner is usually a practitioner, already overworked; (3) as Medical Examiner, a local Medical Examiner might have no enthusiasm for expansion of his duties into largely clerical work; (4) the Chief Medical Examiner has been quite cooperative, but he has usually referred the problem to me in the past.

Mr. Terrence D. Sullivan

-2-

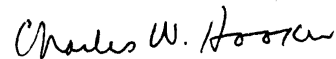
September 16, 1974

Under present circumstances, the agency or person having custody at the time of death has the responsibility for the decision that the body is properly claimed or unclaimed. That person or agency usually seeks assistance of every group that can help. My perhaps uninformed guess is that the best solution is the present solution - the agency having custody must inescapably dispose of the body in one way or another. As I have seen it, the problem is not the decision; the problem is keeping these people informed that there is a way of disposing of an unclaimed body and that they are required to utilize it.

I find that I do not remember the other questions on your long list. Another of the guests at the Committee's meeting was to send me a copy, but it has not arrived as yet.

Thank you for your interest and courtesy.

Sincerely yours,



Charles W. Hooker

CWH/mwp

Enclosure

THE UNIVERSITY OF NORTH CAROLINA
AT CHAPEL HILL

LEGISLATIVE SERVICES OFFICE

School of Medicine
Department of Anatomy

September 13, 1974

Telephone:
Area Code: 919

Mailing Address:
The University of North Carolina
at Chapel Hill
DIVISION OF HEALTH AFFAIRS
Department of Anatomy
306 MacNider
Chapel Hill, N.C. 27514

Mr. William White
Special Assistant to the Secretary
Department of Human Resources
325 North Salisbury Street
Raleigh, North Carolina 27611

Dear Mr. White:

It has been suggested that you are the person in the Department of Human Resources to whom I should address questions.

I have learned to my surprise and, indeed, consternation that the General Assembly in a recent session has significantly changed the portion of the General Statutes (paragraphs 90-211 through 90-216) that has been known as The Anatomical Law of North Carolina.

It is my understanding that the changes include, among others, abolition of the North Carolina Board of Anatomy and the requirement that unclaimed bodies are to be offered to the Department of Human Resources rather than the Board of Anatomy.

As background, may I mention that the Board of Anatomy, as authorized by earlier statutes, existed and functioned for many years without having much obvious official status or recognition. When state government was reorganized during the term of Governor Scott the Board of Anatomy was asked which of the state's departments seemed its appropriate location, Higher Education or Human Resources. The Board expressed preference for being in the same department as the former State Department of Health, the Chief Medical Examiner, the former Department of Mental Health, and the former Department of Social Services. The request was granted. As prescribed by paragraph 90-211 of the General Statutes, the Board consisted of one representative from each of the three medical schools, Bowman Gray, Duke, and the University, each designated by the Dean of his School of Medicine. I was named Chairman of the Board. When the School of Medicine at East Carolina was organized that school, I was told unofficially, named a representative to the Board as approved at some level in Raleigh. The Board of Anatomy was invited to request funds for a budget. We declined the invitation on the grounds that no need for a budget was apparent.

So far as I can learn, no member of the Board of Anatomy has received notification that the Board has been abolished and that the Anatomical Law has been changed. For that reason it is possible that the old Board of Anatomy

has been guilty of continuing to perform its old functions.

For reason of lack of definitive information as to the changes made in the statute, I can offer no comment and I must assume that the changes are wise. I should be grateful, however, for information and suggestions regarding the meeting of day-to-day problems under the modifications. The chief problem is who is authorized to make the decisions that must be made and to take the actions that must be taken.

One of the changes in the statutes, as I recall and understand the changes, is the requirement that unclaimed bodies be offered to the Department of Human Resources - unit not specified. Has some person or office been named to assume this responsibility? More specifically, when a hospital or a sheriff's department or a county department of social services or a funeral home has an unclaimed body will a call to the Department of Human Resources, as I understand the changed requirement, readily elicit information as to whether the body will be accepted, where it should be delivered, whether it should be embalmed, whether the mortician's fees will be paid and by whom? If a particular office in the Department is to be called, do these several agencies and organizations know which office or its telephone number? Is there a plan for distribution of such bodies among the four medical schools? If there is such a plan, does it take into account the different needs of the four medical schools?

These are small problems with respect to the work of your department, but the continuation of medical education in this state to a large extent hinges upon them. Moreover, it is our observation and experience that dawdling, indecision, and inaction are real deterrents to delivery of unclaimed bodies to the medical schools.

Another problem upon which we need advice is the matter of bequeathed bodies. As you may know, the practice of bequeathing the body is growing. Indeed, over one half of the bodies used for study in North Carolina are now bequeathed bodies. The increase in such bequests has been a response to efforts by the Board of Anatomy and other groups of concerned persons. In some instances the body is bequeathed to a specific medical school; in other instances the body is bequeathed to the Board of Anatomy. We have in a low-key way urged that the bequest be made to the Board because this provision permits the body to be used by the school with the greatest need and because it may be used more nearly in accordance with the dictates of good taste.

Am I correct in presuming that we should discontinue advising people to will their bodies to the Board of Anatomy? A more urgent problem is the people who have already bequeathed their bodies to the Board of Anatomy. Should we advise each of them to change his or her will because the Board of Anatomy no longer exists?

The Department of Human Resources has presumably had little time to identify problems that have been created by the changes in the statutes, and the Department has presumably had still less time to formulate solutions to these problems. It would be comforting to know that these problems are receiving the attention they require. I cannot overemphasize that to a large

September 13, 1974

extent the future of medical education in this state is at stake.

During its existence the Board of Anatomy did not enjoy glowing success, but it is fair to say that its job got done. Moreover, progress was being made in eliciting the cooperation of a wide variety of agencies and organizations. I presume that these efforts on our part are to be terminated.

In my ignorance of the details of the changes in the statutes I am reluctant to make suggestions, and making suggestions might be improper in any case. Nevertheless, I am emboldened to ask if it would be helpful and efficient if the old Board of Anatomy were to have delegated to it its old duties and responsibilities under the supervision of the Department, this without its being officially a unit in the Department and without any official or recognized status.

I should, of course, be glad in any case to come to Raleigh to discuss the problems and duties of the old Board of Anatomy with you or some other appropriate person.

Sincerely yours,

Charles W. Hooker

CWH/mwp

Cc: Dr. A. S. Bennett

APPENDIX XIV

Legislative Proposals

Legislative Proposal A

A BILL TO BE ENTITLED

AN ACT TO ESTABLISH A COORDINATED HUMAN TISSUE DONATION PROGRAM.

The General Assembly of North Carolina enacts:

Section 1. A new article is added to Chapter 130 of the General Statutes to read as follows:

"Article 26A

Coordinated Human Tissue Donation Program

§130-235.1 Legislative findings and purpose.--The General Assembly of North Carolina finds that there is an increasing need for human tissues for transplantation purposes; that there is a continuing need for human tissues, including entire human cadavers, for the purposes of medical education and research; and that these needs are not being sufficiently filled at the present because of, among other reasons, a shortage of human tissue donors. The General Assembly establishes this program to facilitate the acquisition and distribution of human tissues, including human cadavers, so as to lead to bettering the public health of the people of this State.

§130-235.2 Coordinated Human Tissue Donation Program established.--(a) The Department of Human Resources shall establish a coordinated program among departments and agencies of the State and all groups, both public and private, involved in the acquisition and distribution of human tissue to:

- (1) encourage the publicizing of the need for human tissue donations and of the methods by which these donations are made;

- (2) make itself aware of the existing programs of human tissue transplantation and of medical research and education which employ human tissue, including whole cadavers, and funnel information of useful developments to groups and individuals within this State which such information might benefit;
- (3) study the problems surrounding the acquisition and distribution of human tissue and cadavers in this State and make suggestions as to their solution;
- (4) disseminate information to health and other professionals concerning the techniques of human tissue retrieval and transplantation, the legalities involved in making anatomical gifts, and the legal responsibilities of individuals under Article 14 of Chapter 90 of the General Statutes which deals with cadavers for medical schools; and
- (5) arrange for the quick and precise transportation of donated human tissue in emergency transplant situations.

(b) All departments and agencies of the State and county and municipal law enforcement agencies shall cooperate, insofar as possible and not inconsistent with existing law, in the coordinated program instituted by the Department under the authority of this Article.

§130-235.3 Creation of the Human Tissue Advisory Council.---

- (a) There is created a Human Tissue Advisory Council. There shall be thirteen members of this Council, consisting of the following:
- a representative from each of the following institutions--

the Bowman-Gray School of Medicine,
the Duke University School of Medicine,
the North Carolina Association of the Blind,
the North Carolina Eye and Human Tissue Bank,
the North Carolina Funeral Directors' Association,
the North Carolina Hospital Association,
the North Carolina Kidney Foundation,
the North Carolina Medical Society,
the University of North Carolina at Chapel Hill School of
Medicine,
the University of North Carolina at Greenville School of
Medicine;

one member appointed by the Speaker of the House of Representa-
tives;

one member appointed by the President of the Senate; and
the Secretary of Human Resources or his representative.

The Council shall elect its chairman from among its membership.

(b) The Council shall have the duty to advise, confer with,
and make recommendations to the Secretary of Human Resources
relating to the establishment and conduct of the Coordinated
Program for Human Tissue Donations. The Council shall meet upon
the call of its chairman or upon agreement of a majority of its
membership but shall meet not fewer than three times a year.

(c) The Secretary shall furnish to the Council such secretarial,
clerical and other services as he deems necessary. Members of
the Council shall serve without compensation but shall be reimbursed
for travel and subsistence expenses in accordance with the
provisions of G.S. 138-5(b)."

Sec. 2. There is appropriated from the General Fund of the State to the Department of Human Resources the sum of seventy-two thousand eight hundred and forty dollars (\$72,840) for the establishment and conduct of the program which is authorized by this Act for the fiscal year beginning July 1, 1975 and ending June 30, 1976. ⁷*

Sec. 3. This act shall become effective upon ratification.

⁷* If the General Assembly desires to fund this program on a biennial basis, the revised figures will be found in Recommendation 1 on pages 17 and 18 of this Report. ⁷

Legislative Proposal B

A BILL TO BE ENTITLED

AN ACT TO AMEND THE UNIFORM ANATOMICAL GIFT ACT TO INCREASE THE NUMBER OF THOSE PERSONS QUALIFIED TO ENUCLEATE EYES.

The General Assembly of North Carolina enacts:

Section 1. Subsection 9 of G.S. 90-220.1 is repealed.

Sec. 2. Subsection 8 of G.S. 90-220.1 is renumbered as Subsection 9 and a new Subsection 8 is added to read as follows:

"(8) 'Qualified individual' means:

- (a) an embalmer holding a valid license to practice in this State,
- (b) a physician's assistant approved by and registered with the Board of Medical Examiners pursuant to G.S. 90-18(13),
- (c) a registered or a licensed practical nurse certified by the Board of Nursing pursuant to Article 9 of Chapter 90 of the General Statutes, or
- (d) a student who is enrolled in an accredited school of medicine operating within this State and who has completed two or more years of a course of study leading to the awarding of a degree of doctor of medicine from such school,

and who has completed a course in eye enucleation and has been certified as competent to enucleate eyes by an accredited school of medicine operating within North Carolina."

Sec. 3. The last two sentences of subsection (d) of G.S. 90-220.4 are deleted, and in their place the following paragraph is added:

"In respect to a gift of an eye, a qualified individual, as defined by G.S. 90-220.1(8), may enucleate eyes for such gift after the proper certification of death by a physician and upon the express direction of any physician other than the one who certified the death of the donor."

Sec. 4. This act shall become effective upon ratification.

Secretary of Human Resources

State Health Director - Division Level

Assistant Director of State Services

Assistant Director of Local Services
etc.

Section Level

Epidemiology
etc.

Medical Examiner
etc.

Dental Health
etc.

Personal Health

Laboratory
etc.

Sanitary Engineering
etc.

Branch Level

Family Planning
etc.

Nutrition and Dietary Services
etc.

Chronic Disease

Maternal and Child Care
etc.

Developmental Disabilities
etc.

Unit Level

Health Care Services
etc.

Medical Care

Chronic Disease Detection
etc.

Neurological and Sensory Program

Cancer Program - G.S. 130-180
through 186

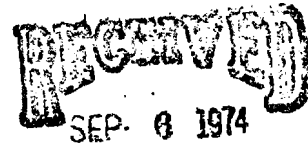
Chronic Renal Disease Control Program -
G.S. 130-236 through 239

Proposed

Coordinated Human Tissue Donation
Program

POSITION PAPER

HUMAN TISSUE DONATION PROGRAM



LEGISLATIVE SERVICES OFFICE

The legislation regarding human tissue donation drafted by the Committee on Human Tissue Donations is relevant and timely. At present, kidney transplant services are being sponsored through the Renal Disease Program of the Division of Health Services. There are also extensive corneal procurement and transplant efforts being carried on in the state. As other organ transplant processes become effective, there will be an even greater need for human donors. It seems quite appropriate to inaugurate a planning and coordination process to cope with developments in the field. It is recommended that the Division of Health Services and the Department of Human Resources endorse the draft legislation.

The functions of the program stated in Section 2 of the draft bill are appropriate. Additional operational activities during the first year of the program could be as follows:

1. Prepare a status report on current donor and transplant activities and resources for the Advisory Committee, the Secretary, Department of Human Resources, and the Committee on Human Tissue Donations.
2. Develop and initiate a professional education program for health providers, particularly medical specialists and hospital administrators.
3. Develop and initiate a public education program, stimulating public awareness of the life-saving potential of transplants and motivating individuals to become donors.
4. Prepare studies and recommendations for the appropriate authorities to establish policies and guidelines on the subject of tissue donations and transplants. (E.g., in other complex, expensive, and highly technical medical procedures, it has been found that a large number of institutions performing few procedures is less effective and less economical than a smaller number doing more procedures. The State should establish and adhere to a position in this matter.)

The membership of the Human Tissue Advisory Council is apt. The following additions are suggested:

1. Legal representation

Because of the complicated and controversial legal implications of tissue donation, a member of the legal profession would be helpful; such a person might come from the Attorney General's Office or the Institute of Government.

2. Representative of Medical Schools' Departments of Anatomy

The draft bill speaks of "acquisition and distribution . . . of cadavers" [Section 2, (3)]. This and other language seem to fall within the scope of G.S. 90, article 14, "Cadavers for Medical Schools." If the legislation does relate to this field, a representative of this area of special interest might reasonably be included on the Council.

3. Two members from non-academic institutions

A great deal of tissue procurement and transplantation occurs in medical centers other than academic institutions. Delegates from such centers, appointed by the Secretary, could serve these interests on the Council.

The designation of the Department of Human Resources as the operable agent for the new program is fitting. It is respectfully recommended that the Secretary, Department of Human Resources, consider locating the program in the Division of Health Services. Establishing the program in the Chronic Disease Branch, Personal Health Section, would site this effort in an organizational area already involved in organ procurement and transplant through the extant Kidney Program.

With regard to budget, it would not seem suitable to suggest large appropriations in an endeavor where the first order of business is status assessment and program development. A staff and budget adequate to inaugurate the effort is listed in the appendix.

STAFF AND BUDGET

HUMAN TISSUE DONATION PROGRAM

	<u>1975-76</u>	<u>1976-77</u>
Personnel		
Program Manager I: Under the direction of the Unit Supervisor and Branch Head, carries out the functions listed in the bill and the position paper.	\$12,240	
Health Educator II: (administratively located in the Health Education Branch, Administrative Services Section) Plans and implements the public education program, assists in the professional education program.	10,644	
Stenographer II	6,456	
Fringe Benefits	<u>3,000</u>	
Total Personnel	\$32,340	\$34,765
Travel	2,500	2,500
Travel of Council	1,200	1,200
Equipment	2,000	2,000
Supplies	1,500	1,500
Communications	1,200	1,200
Educational and Promotional Expenses	30,000	25,000
Data Processing	1,500	1,500
Other	<u>600</u>	<u>600</u>
TOTAL	\$72,840	\$70,265

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DEPARTMENT OF PUBLIC INSTRUCTION
LEGISLATIVE SERVICES OFFICE



STATE OF NORTH CAROLINA

RALEIGH

September 12, 1974

Committee on Human Tissue Donations
Legislative Research Commission
2129 State Legislative Building
Raleigh, North Carolina 27601

Dear Committee Members:

I was pleased to meet with your committee and learn of the work in which you are involved.

The members of the committee and other guests certainly were interested and informed. It is always a pleasure to work with those that show such dedication to a task.

The Department of Public Instruction certainly wants you to know of our interest and concern.

We feel that education in this area can be brought about through our existing courses in health, science, and other related fields. The attention to this area of study and concern, we feel, is prevalent. We do not feel a need for additional courses as mandates.

To make young people knowledgeable in this area reflects our philosophy of a comprehensive health education program.

Thank you again for the privilege of working with the committee.

Sincerely,

A handwritten signature in cursive script that reads "George G. Shackelford".

George G. Shackelford
Consultant
Health Education

GGS/scn

State of North Carolina



Department of Motor Vehicles
 Driver License Division
 Raleigh 27611

September 12, 1974

EDWARD H. WADE
 DIRECTOR

J. T. BAKER, JR.
 ASST. DIRECTOR

BOYD C. WALKER, JR.
 COMMISSIONER

H. Y. KINARD
 J. M. PENNY
 ASST. COMMISSIONERS

Mr. Terrence D. Sullivan, Committee Counsel
 North Carolina General Assembly
 Legislative Services Office
 2129 State Legislative Building
 Raleigh, North Carolina 27601

Dear Mr. Sullivan:

Thank you for your letter of September 9, 1974 concerning this Division participating in the Human Tissue Donor Program.

Please be advised that we are happy to cooperate with you in this very worthwhile program. As I view this, there are some mechanics of the program that need to be worked out, and I would suggest a further meeting with you and the Chief Examiner in order that this may be done. One thing I might mention is that our capabilities are limited insofar as stuffing the donor identification cards with our renewal applications.

If you will advise me as to a convenient time for you, I will attempt to arrange the meeting. The Chief Examiner will be out of his office for the next two weeks.

Sincerely,

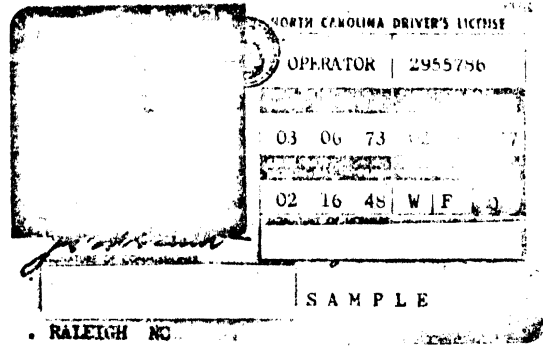
J. T. BAKER, JR.
 DIRECTOR

JTB:aj

cc: Mr. Edward H. Wade

Enclosures

DRIVER LICENSE STICKER PROPOSAL



RESTRICTION CODE

1. Corrective lenses.
2. 45 MPH speed limit.
3. Daylight driving.
4. Corrective lenses and 45 MPH speed limit.
5. Corrective lenses, 45 MPH speed limit, and daylight driving only.
6. Corrective lenses and daylight driving only.
7. 45 MPH speed limit and daylight driving only.
8. No interstate driving.
- *9. As shown on face of license.

IMPORTANT

I am a Human Tissues Donor. Check personal effects for Donor Identification.

A DONATED ORGAN or TISSUE is a GIFT of SIGHT or LIFE.

What is the need for organ and tissue donations?

The need for human organs and tissue for transplantation is urgent. Thousands of people die or remain sightless each year because there are not enough organ donors.

What is the need for body donations?

The physician's knowledge of the structure of the human being he is treating was acquired by careful study of the human body. Donation of the body will benefit the hundreds of thousands of persons who will be under the care of the physicians who have studied that body.

Who can be a donor?

Any individual who is of sound mind and 18 years of age or older.

What must I do to make this gift possible?

All that is necessary is to sign the Uniform Donor Card above and carry it on your person at all times. This card should be witnessed by two people.

Mention it in your will if you so desire.

Identical information should be placed on the Eye and Human Tissue Bank card at the bottom and mailed for purposes of registration.

How are organs and tissues for transplantation obtained?

They are donated by concerned individuals such as yourself—with the donation becoming effective at the time of death.

APPENDIX XVIII

The following should be signed by the donor and two witnesses in the presence of each other:

Signature of Donor _____
 City & State _____ Date Signed _____
 Witness _____ Soc. Sec. No. of Donor _____
 Witness _____ Phone Number of Donor _____
 THIS IS A LEGAL DOCUMENT UNDER THE UNIFORM ANATOMICAL GIFT ACT.
 Hospital or other emergency personnel, call (803) 800-0000 for instructions.

Will my estate be paid, or have to pay, for organ donation?
 No.

Will organ or tissue donation affect funeral and burial arrangements?
 No.

Will donation of my body preclude a funeral service?
 No.

Can I change my mind later?
 Certainly. All you have to do is destroy the card you signed and are carrying. Then give written notification to the North Carolina Eye and Human Tissue Bank, 3195 Maplewood Ave., Winston-Salem, N. C. 27103.

What else can I do to advance the organ and tissue preservation program?
 Acquaint others with the donor card and transplantation program.

THIS INFORMATION IS A NECESSARY RECORD OF YOUR DONATION WHICH WILL BE FILED WITH THE N. C. EYE AND HUMAN TISSUE BANK, INC. PLEASE COMPLETE INFORMATION EXACTLY AS YOUR DONOR CARD READS AND MAIL TO 3195 MAPLEWOOD AVE., WINSTON-SALEM, N. C. 27103

In the hope that I may help others, I hereby make this anatomical gift, if medically acceptable, to take effect upon my death. The words and marks below indicate my desires:

- give: (1) _____ any needed organs or parts
 (2) _____ my eyes
 (3) _____ only the following organs or parts _____
 specify organ(s) or part(s)
 (4) _____ my entire body for anatomical study, transplant, therapy, research or medical education

NAME (Please print or type)

SOCIAL SECURITY NO.

ADDRESS

CITY

STATE

ZIP

PLACE
STAMP
HERE

THE NORTH CAROLINA EYE AND
HUMAN TISSUE BANK, INC.

3195 Maplewood Ave.
Winston-Salem, N. C. 27103

This guide is provided as a public service to aid individuals who are considering donations of organs and tissues for transplantation and scientific study.

PLEASE

- Advise your family
- Advise your minister
- Advise your doctor
- Advise your legal counsellor

THANK YOU

For further information, contact any of the below organizations:

THE NORTH CAROLINA EYE AND HUMAN TISSUE BANK, INC.

3195 Maplewood Ave.
Winston-Salem, N. C. 27103
Phone (919) 765-0932

**UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL
DIVISION OF HEALTH AFFAIRS
DEPARTMENT OF ANATOMY**

306 MacNider
Chapel Hill, North Carolina 27514
Phone: (919) 966-1237

THE KIDNEY FOUNDATION OF NORTH CAROLINA, INC.

P. O. Box 2383, Chapel Hill, N. C. 27514
Phone (919) 477-0461

IT IS IMPORTANT THAT YOU CARRY
YOUR DONOR CARD WITH YOU AT
ALL TIMES

UNIFORM DONOR CARD

(Please print or type)

DONOR

In the hope that I may help others, I hereby make this anatomical gift, if medically acceptable, to take effect upon my death. The words and marks below indicate my desires.

- I give: 1. _____ my kidneys
2. _____ my eyes
3. _____ any needed organs or parts
4. _____ only the following organs or parts

Specify organ(s) or part(s)

5. _____ for the purpose of transplantation, medical research or education, I give my entire body.

Limitations or special wishes, if any _____

Leave
Someone A
Tomorrow





RECEIVED
SEP 13 1974

State Highway Patrol

1100 New Bern Avenue
Raleigh 27611

LEGISLATIVE SERVICES OFFICE

SECRETARY TROY A. DOBY
DEPARTMENT OF TRANSPORTATION
AND HIGHWAY SAFETY

COLONEL EDWARD W. JONES
COMMANDING
STATE HIGHWAY PATROL

11 September 1974

Mr. Terrence D. Sullivan
North Carolina General Assembly
Legislative Services Office
Committee Counsel
2129 State Legislative Building
Raleigh, North Carolina 27601

Dear Mr. Sullivan:

Reference is made to your letter of 9 September 1974.

The Highway Patrol is happy to continue its program in providing assistance in the emergency transportation of blood and human tissues. I feel that consideration should be given to limiting the transportation by members of the Highway Patrol of the vital life saving components to properly defined emergencies.

We have taken the position when we receive a request, that we will cooperate and ask questions later. If proper guidelines are drawn up and followed, there will be no need for us to ask questions about the deployment of our personnel. I have no knowledge that we have encountered any problems in transportation of body tissues; on the other hand, I am sure that we have transported blood at times when it could have been transported by other persons employed for that purpose.

You may be assured that we will cooperate fully in this vital program.

Cordially yours,

A handwritten signature in cursive script that reads "E. W. Jones".

E. W. Jones
Colonel
Commanding

EWJ/jgj

Statement of the Executive Council
of the North Carolina Medical Society

STATIONERY. _____

Memorandum

Dr. Ernest Larkin
Chairman
Eye Care and Eye Bank Committee
211 N. Market Street
Washington, N. C. 27889

Dear Tad:

I would like to report to you that the following items from your Comm. were presented to the Executive Council meeting Sunday and favorably received:

1. Information

- a. it was announced that a committee is to be appointed by you to study and prepare recommendations to correct fee disparities with optometrists (Mr. John Anderson might be of some help in this regards).
- b. Dr. Wayne Woodard - commended and reappointed

2. Action :

- a. ~~Duo~~ staffing of blind clinics was denounced
- b. Use of registered nurses, LPN's and registered PA's in eye enucleation supported (after giving adequate documented training)...use of ophthalmologists assistants and 4th yr. medical residents not approved as no licensing or registration system for these health workers exists in N.C. at the present time)

It always a pleasure to serve your committee.

With kindest personal regards, I am,

SY
JMCC/je

[Handwritten signature]