

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 521  
(A-22)

Introduced by: Medical Student Section

Subject: Encouraging Brain and Other Tissue Donation for Research and Educational Purposes

Referred to: Reference Committee E

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1 Whereas, Postmortem tissue contains invaluable information that can be used for medical  
2 research and educational purposes to improve our understanding of human physiology and  
3 pathophysiology and thus enhance patient care<sup>1</sup>; and  
4

5 Whereas, Recent research using postmortem brain tissue has been critical to our understanding  
6 of the pathogenesis of neurological and psychiatric illnesses such as Parkinson's disease,  
7 dementia, PTSD, autism, and major depression, and builds upon advances from neuroimaging,  
8 genetic, biomarker, and animal studies<sup>2-8</sup>; and  
9

10 Whereas, States have taken efforts to raise awareness of and increase donation for organ  
11 transplant, such as by asking individuals if they would like to join transplant donor registries  
12 when they apply for or renew their driver's licenses<sup>9,10</sup>; and  
13

14 Whereas, In Texas alone, nearly 7 million people have joined the Texas Donor Registry since a  
15 question regarding organ donation for transplantation was added to driver's license  
16 applications<sup>11</sup>; and  
17

18 Whereas, Ninety-eight percent of organ donation registration occurs at the Bureau of Motor  
19 Vehicles, and promotional materials and clerk educational training has been shown to increase  
20 organ donation registration by up to 7.8%<sup>10,12</sup>; and  
21

22 Whereas, Although some states offer an option for organ donation and/or tissue donation for  
23 research purposes via donor cards, brain tissue donation requires a separate consenting  
24 process that often occurs after death through the next of kin<sup>13,14</sup>; and  
25

26 Whereas, Willed body program recruitment is not standardized across institutions and can  
27 create a large financial and logistic burden on institutions<sup>1</sup>; and  
28

29 Whereas, Widespread efforts to inform individuals of the importance of tissue donation for  
30 research and health professions education and allow interested individuals the opportunity to  
31 easily provide informed consent to donate their bodies for research or education purposes could  
32 increase donation rates, decrease costs, and eliminate the need for families to make decisions  
33 for their loved ones postmortem<sup>15</sup>; and  
34

35 Whereas, These efforts could include strategies used to increase organ donation for  
36 transplantation, such as asking individuals if they would like to donate other tissue for research  
37 purposes when applying for or renewing a driver's license<sup>10</sup>; and  
38

1 Whereas, A study of public perceptions surrounding whole-body donation found that 58.8% of  
2 participants reported insufficient understanding of the body and tissue donation process for  
3 research and educational purposes, 77.4% reported that they did not know how to register to  
4 become a whole-body donor, and 23.9% reported that they did not know they could be  
5 registered as both a transplant organ donor and whole-body donor or tissue donor<sup>16</sup>; and  
6

7 Whereas, Several studies have found that after receiving information about the tissue donation  
8 process, the majority of participants would be likely or somewhat likely to donate their brain  
9 tissue (>60%) for research<sup>17-19</sup>; and  
10

11 Whereas, While current AMA policies H-370.984, H-370.995, H-370.996, and H-370.998  
12 address increasing public education and donation rates for transplantation, they do not address  
13 postmortem tissue donation for primarily scientific or educational purposes; therefore be it  
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15 RESOLVED, That our AMA support the production and distribution of educational materials  
16 regarding the importance of postmortem tissue donation for the purposes of medical research  
17 and education; (Directive to Take Action) and be it further  
18

19 RESOLVED, That our AMA encourage the inclusion of additional information and consent  
20 options for brain and other tissue donation for research purposes on appropriate donor  
21 documents; (Directive to Take Action) and be it further  
22

23 RESOLVED, That our AMA encourage all persons to consider consenting to tissue donation  
24 including brain tissue for research purposes; (Directive to Take Action) and be it further  
25

26 RESOLVED, That our AMA encourage efforts to facilitate recovery of postmortem tissue  
27 including brain tissue for research and education purposes. (Directive to Take Action)

Fiscal Note: Not yet determined

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**RELEVANT AMA POLICY**

**Importance of Clinical Research H-460.930**

- (1) Given the profound importance of clinical research as the transition between basic science discoveries and standard medical practice of the future, the AMA will a) be an advocate for clinical research; and b) promote the importance of this science and of well-trained researchers to conduct it.
- (2) Our AMA continues to advocate vigorously for a stable, continuing base of funding and support for all aspects of clinical research within the research programs of all relevant federal agencies, including the National Institutes of Health, the Agency for Healthcare Research and Quality, the Centers for Medicare & Medicaid Services, the Department of Veterans Affairs and the Department of Defense.
- (3) The AMA believes it is an inherent obligation of capitation programs and managed care organizations to invest in broad-based clinical research (as well as in health care delivery and outcomes research) to assure continued transition of new developments from the research bench to medical practice. The AMA strongly encourages these groups to make significant financial contributions to support such research.
- (4) Our AMA continues to encourage medical schools a) to support clinical research; b) to train and develop clinical researchers; c) to recognize the contribution of clinical researchers to academic medicine; d) to assure the highest quality of clinical research; and e) to explore innovative ways in which clinical researchers in academic health centers can actively involve practicing physicians in clinical research.
- (5) Our AMA encourages and supports the development of community and practice-based clinical research networks. CSA Rep. 2, I-96; Reaffirmed: CSA Rep. 13, I-99; Reaffirmation: A-00; Reaffirmed: CME Rep. 4, I-08; Modified: CSAPH Rep. 1, A-18

**Physician Involvement in Research: Opinion E-7.1.1**

Biomedical and health research is intended to contribute to the advancement of knowledge and the welfare of society and future patients, rather than to the specific benefit of the individuals who participate as research subjects.

However, research involving human participants should be conducted in a manner that minimizes risks and avoids unnecessary suffering. Because research depends on the willingness of participants to accept risk, they must be able to make informed decisions about whether to participate or continue in a given protocol.

Physician researchers share their responsibility for the ethical conduct of research with the institution that carries out research. Institutions have an obligation to oversee the design, conduct, and dissemination of research to ensure that scientific, ethical, and legal standards are upheld. Institutional review boards (IRBs) and individual investigators should ensure that each participant has been appropriately informed and has given voluntary consent.

Physicians who are involved in research with human participants have an ethical obligation to ensure that participants' interests are protected and to safeguard participants' welfare, safety, and comfort.

To fulfill these obligations, individually, physicians who are involved in research should:

- (a) Participate only in those studies for which they have relevant expertise.
- (b) Ensure that voluntary consent has been obtained from each participant or from the participant's legally authorized representative if the participant lacks the capacity to consent, in keeping with ethics guidance. This requires that:
  - (i) prospective participants receive the information they need to make well-considered decisions, including informing them about the nature of the research and potential harms involved;
  - (ii) physicians make all reasonable efforts to ensure that participants understand the research is not intended to benefit them individually;
  - (iii) physicians also make clear that the individual may refuse to participate or may withdraw from the protocol at any time.
- (c) Assure themselves that the research protocol is scientifically sound and meets ethical guidelines for research with human participants. Informed consent can never be invoked to justify an unethical study design.
- (d) Demonstrate the same care and concern for the well-being of research participants that they would for patients to whom they provide clinical care in a therapeutic relationship. Physician researchers should advocate for access to experimental interventions that have proven effectiveness for patients.
- (e) Be mindful of conflicts of interest and assure themselves that appropriate safeguards are in place to protect the integrity of the research and the welfare of human participants.
- (f) Adhere to rigorous scientific and ethical standards in conducting, supervising, and disseminating the results of the research.

AMA Principles of Medical Ethics: I, II, III, V Issued: 2016

#### **Organ Donation D-370.985**

Our AMA will study potential models for increasing the United States organ donor pool.

Res. 1, A-14; Reaffirmed in lieu of: Res. 5, I-14; Reaffirmed in lieu of: Res. 002, I-16

#### **Organ Donation and Honoring Organ Donor Wishes H-370.998**

Our AMA: (1) continues to urge the citizenry to sign donor cards and supports continued efforts to educate the public on the desirability of, and the need for organ donations, as well as the importance of discussing personal wishes regarding organ donation with appropriate family members; and (2) when a good faith effort has been made to contact the family, actively encourage Organ Procurement Organizations and physicians to adhere to provisions of the Uniform Anatomical Gift Act which allows for the procurement of organs when the family is absent and there is a signed organ donor card or advanced directive stating the decedent's desire to donate the organs.

CSA Rep. D, I-80; CLRPD Rep. B, I-90; Amended: Res. 504, I-99, Reaffirmed: CSA Rep. 6, A-00; Reaffirmed: CSA Rep. 4, I-02; Reaffirmed: CSAPH Rep.1, A-12

#### **Ethical Considerations in the Allocation of Organs and Other Scarce Medical Resources Among Patients H-370.982**

Our AMA has adopted the following guidelines as policy: (1) Decisions regarding the allocation of scarce medical resources among patients should consider only ethically appropriate criteria relating to medical need. (a) These criteria include likelihood of benefit, urgency of need, change in quality of life, duration of benefit, and, in some cases, the amount of resources required for successful treatment. In general, only very substantial differences among patients are ethically relevant; the greater the disparities, the more justified the use of these criteria becomes. In making quality of life judgments, patients should first be prioritized so that death or extremely poor outcomes are avoided; then, patients should be prioritized according to change in quality of life, but only when there are very substantial differences among patients. (b) Research should be pursued to increase knowledge of outcomes and thereby improve the accuracy of these criteria. (c) Non-medical criteria, such as ability to pay, social worth, perceived obstacles to treatment, patient contribution to illness, or past use of resources should not be considered.

(2) Allocation decisions should respect the individuality of patients and the particulars of individual cases as much as possible. (a) All candidates for treatment must be fully considered according to ethically appropriate criteria relating to medical need, as defined in Guideline 1. (b) When very substantial differences do not exist among potential recipients of treatment on the basis of these criteria, a "first-come-first-served" approach or some other equal opportunity mechanism should be employed to make final allocation decisions. (c) Though there are several ethically acceptable strategies for implementing these criteria, no single strategy is ethically mandated. Acceptable approaches include a three-tiered system, a minimal threshold approach, and a weighted formula.

(3) Decision making mechanisms should be objective, flexible, and consistent to ensure that all patients are treated equally. The nature of the physician-patient relationship entails that physicians of patients competing for a scarce resource must remain advocates for their patients, and therefore should not make the actual allocation decisions.

(4) Patients must be informed by their physicians of allocation criteria and procedures, as well as their chances of receiving access to scarce resources. This information should be in addition to all the customary information regarding the risks, benefits, and alternatives to any medical procedure. Patients denied access to resources have the right to be informed of the reasoning behind the decision.

(5) The allocation procedures of institutions controlling scarce resources should be disclosed to the public as well as subject to regular peer review from the medical profession.

(6) Physicians should continue to look for innovative ways to increase the availability of and access to scarce medical resources so that, as much as possible, beneficial treatments can be provided to all who need them.

(7) Physicians should accept their responsibility to promote awareness of the importance of an increase in the organ donor pool using all available means.

CEJA Rep. K, A-93, Reaffirmed: CSA Rep. 12, I-99, Reaffirmed: CSA Rep. 6, A-00, Appended: Res. 512, A-02, Reaffirmed: CEJA Rep. 3, A-12

#### **Tissue and Organ Donation H-370.983**

Our AMA will assist the United Network for Organ Sharing in the implementation of their recommendations through broad-based physician and patient education. (Res. 533, A-92 Reaffirmed: CSA Rep. 12, I-99; Reaffirmed: CSA Rep. 6, A00; Reaffirmed: CSA Rep. 4, I-02; Reaffirmed: CSAPH Rep. 1, A-12

#### **Organ Donor Recruitment H-370.995**

Our AMA supports development of "state of the art" educational materials for the medical community and the public at large, demonstrating at least the following: (1) the need for organ donors;(2) the success rate for organ transplantation;(3) the medico-legal aspects of organ transplantation; (4) the integration of organ recruitment, preservation and transplantation; (5) cost/reimbursement mechanisms for organ transplantation; and(6) the ethical considerations of organ donor recruitment. Res. 32, A-82; Reaffirmed: CLRPD Rep. A, I-92; Reaffirmed: CSA Rep. 6, A-00; Reaffirmed: CSA Rep. 4, I-02; Reaffirmed: CSAPH Rep. 1, A-12)

#### **Organ Donor Recruitment H-370.996**

Our AMA (1) continues to urge Americans to sign donor cards; (2) supports continued efforts to teach physicians through continuing medical education courses, and the lay public through health education programs, about transplantation issues in general and the importance of organ donation in particular; (3) encourages state governments to attempt pilot studies on promotional efforts that stimulate each adult to respond "yes" or "no" to the option of signing a donor card; and (4) in collaboration with all other interested parties, support the exploration of methods to greatly increase organ donation, such as the "presumed consent" modality of organ donation. CSA Rep. D, A-81; Reaffirmed: CLRPD Rep. F, I-91; Appended: Res. 509, I-98; Reaffirmed: CSA Rep. 6, A-00; Reaffirmed: CSA Rep. 4, I-02; Reaffirmed: CSAPH Rep. 1, A-12; Reaffirmed: Res. 006, A-18

#### **Importance of Autopsies H-85.954**

1. Our AMA supports seeking the cooperation of the National Advisory Council on Aging of the National Institutes of Health in recommending to physicians, hospitals, institutes of scientific learning, universities, and most importantly the American people the necessity of autopsy for pathological correlation of the results of the immeasurable scientific advancements which have occurred in recent years. Our AMA believes that the information garnered from such stringent scientific advancements and correlation, as well as coalitions, should be used in the most advantageous fashion; and that the conclusions obtained from such investigations should be widely shared with the medical and research community and should be interpreted by these groups with the utmost scrutiny and objectivity.
2. Our AMA: (a) supports the efforts of the Institute of Medicine and other national organizations in formulating national policies to modernize and promote the use of autopsy to meet present and future needs of society; (b) promotes the use of updated autopsy protocols for medical research, particularly in the areas of cancer, cardiovascular, occupational, and infectious diseases; (c) promotes the revision of standards of accreditation for medical undergraduate and graduate education programs to more fully integrate autopsy into the curriculum and require postmortems as part of medical educational programs; (d) encourages the use of a national computerized autopsy data bank to validate technological methods of diagnosis for medical research and to validate death certificates for public health and the benefit of the nation; (e) requests The Joint Commission to consider amending the Accreditation Manual for Hospitals to require that the complete autopsy report be made part of the medical record within 30 days after the postmortem; (f) supports the formalization of methods of reimbursement for autopsy in order to identify postmortem examinations as medical prerogatives and necessary medical procedures; (g) promotes programs of education for physicians to inform them of the value of autopsy for medical legal purposes and claims processing, to learn the likelihood of effects of disease on other family members, to establish the cause of death when death is unexplained or poorly understood, to establish the protective action of necropsy in litigation, and to inform the bereaved families of the benefits of autopsy; and (h) promotes the incorporation of updated postmortem examinations into risk management and quality assurance programs in hospitals.
3. Our AMA reaffirms the fundamental importance of the autopsy in any effective hospital quality assurance program and urges physicians and hospitals to increase the utilization of the autopsy so as to further advance the cause of medical education, research and quality assurance.
4. Our AMA representatives to the Liaison Committee on Medical Education ask that autopsy rates and student participation in autopsies continue to be monitored periodically and that the reasons that schools do or do not require attendance be collected. Our AMA will continue to work with other interested groups to increase the rate of autopsy attendance.
5. Our AMA requests that the National Committee on Quality Assurance (NCQA) and other accrediting bodies encourage the performance of autopsies to yield benchmark information for all managed care entities seeking accreditation.
6. Our AMA calls upon all third-party payers, including CMS, to provide adequate payment directly for autopsies, and encourages adequate reimbursement by all third-party payers for autopsies.
7. It is the policy of our AMA: (a) that the performance of autopsies constitutes the practice of medicine; and (b) in conjunction with the pathology associations represented in the AMA House, to continue to implement all the

recommendations regarding the effects of decreased utilization of autopsy on medical education and research, quality assurance programs, insurance claims processing, and cost containment.

8. Our AMA affirms the importance of autopsies and opposes the use of any financial incentives for physicians who acquire autopsy clearance.

CCB/CLRPD Rep. 3, A-14

#### **Endorsement of the Uniform Anatomical Gift Act (2006) H-370.968**

Our AMA endorses the Uniform Anatomical Gift Act of 2006 and urges all constituent state medical societies to work with donation stakeholders, including organ procurement organizations, eye banks, tissue banks, and other donation-related organizations, toward persuading their state legislatures to adopt UAGA (2006) in place of earlier versions of the UAGA. BOT Action in response to referred for decision, Res. 901, I-06; Reaffirmed: BOT Rep. 06, A-16

#### **Organ Donation Education H-370.984**

"Our AMA encourages all states and local organ procurement organizations to provide educational materials to driver education and safety classes."

Res. 504, I-91; Reaffirmed: Sunset Report, I-01; Reaffirmed: CSA Rep. 4, I-02; Reaffirmed: CSAPH Rep.1, A-12; Modified: Res. 3, A-13

#### **Improving Body Donation Regulation H-460.890**

Our AMA recognizes the need for ethical, transparent, and consistent body and body part donation regulations. Res. 012, A-19

#### **Organ Donation After Cardiac Death Code of Medical E-6.1.2**

Increasing the supply of organs available for transplant serves the interests of patients and the public and is in keeping with physicians' ethical obligation to contribute to the health of the public and to support access to medical care. Physicians should support innovative approaches to increasing the supply of organs for transplantation while balancing this obligation with their duty to protect the interests of their individual patients.

Organ donation after cardiac death is one approach being undertaken to make greater numbers of transplantable organs available. In what is known as "controlled" donation after cardiac death, a patient who has decided to forgo life-sustaining treatment (or the patient's authorized surrogate when the patient lacks decision-making capacity) may be offered the opportunity to discontinue life support under conditions that would permit the patient to become an organ donor by allowing organs to be removed promptly after death is pronounced. Organ retrieval under this protocol thus differs from usual procedures for cadaveric donation when the patient has died as a result of catastrophic illness or injury.

Donation after cardiac death raises a number of special ethical concerns, including how and when death is declared, potential conflicts of interest for physicians in managing the withdrawal of life support for a patient whose organs are to be retrieved for transplantation, and the use of a surrogate decision maker.

In light of these concerns, physicians who participate in retrieving organs under a protocol of donation after cardiac death should observe the following safeguards:

- (a) Promote the development of and adhere to clinical criteria for identifying prospective donors whose organs are reasonably likely to be suitable for transplantation.
- (b) Promote the development of and adhere to clear and specific institutional policies governing donation after cardiac death.
- (c) Avoid actual or perceived conflicts of interest by:
  - (i) ensuring that the health care professionals who provide care at the end of life are distinct from those who will participate in retrieving organs for transplant;
  - (ii) ensuring that no member of the transplant team has any role in the decision to withdraw treatment or the pronouncement of death
- (d) Ensure that the decision to withdraw life-sustaining treatment is made prior to and independent of any offer of opportunity to donate organs (unless organ donation is spontaneously broached by the patient or surrogate).
- (e) Obtain informed consent for organ donation from the patient (or surrogate), including consent specifically to the use of interventions intended not to benefit the patient but to preserve organs in order to improve the opportunity for successful transplantation.
- (f) Ensure that relevant standards for good clinical practice and palliative care are followed when implementing the decision to withdraw a life-sustaining intervention.

[AMA Principles of Medical Ethics: I,III,V](#) Issued: 2016

#### **Studying Financial Incentives for Cadaveric Organ Donation E-6.1.3**

Physicians' ethical obligations to contribute to the health of the public and to support access to medical care extend to participating in efforts to increase the supply of organs for transplantation. However, offering financial incentives for donation raises ethical concerns about potential coercion, the voluntariness of decisions to donate, and possible adverse consequences, including reducing the rate of altruistic organ donation and unduly encouraging perception of the human body as a source of profit.

These concerns merit further study to determine whether, overall, the benefits of financial incentives for organ donation outweigh their potential harms. It would be appropriate to carry out pilot studies among limited populations to investigate the effects of such financial incentives for the purpose of examining and possibly revising current policies in the light of scientific evidence.

Physicians who develop or participate in pilot studies of financial incentives to increase donation of cadaveric organs should ensure that the study:

- (a) Is strictly limited to circumstances of voluntary cadaveric donation with an explicit prohibition of the selling of organs.

- (b) Is scientifically well designed and clearly defines measurable outcomes and time frames in a written protocol.
- (c) Has been developed in consultation with the population among whom it is to be carried out.
- (d) Has been reviewed and approved by an appropriate oversight body, such as an institutional review board, and is carried out in keeping with guidelines for ethical research.
- (e) Offers incentives of only modest value and at the lowest level that can reasonably be expected to increase organ donation.

AMA Principles of Medical Ethics: I, III, V, VII, VIII, IX, Issued: 2016

#### **Presumed Consent & Mandated Choice for Organs from Deceased Donors E-6.1.4**

Organ transplantation offers hope for patients suffering end-stage organ failure. However, the supply of organs for transplantation is inadequate to meet the clinical need. Proposals to increase donation have included studying possible financial incentives for donation and changing the approach to consent for cadaveric donation through “presumed consent” and “mandated choice.”

Both presumed consent and mandated choice models contrast with the prevailing traditional model of voluntary consent to donation, in which prospective donors indicate their preferences, but the models raise distinct ethical concerns. Under presumed consent, deceased individuals are presumed to be organ donors unless they have indicated their refusal to donate. Donations under presumed consent would be ethically appropriate only if it could be determined that individuals were aware of the presumption that they were willing to donate organs and if effective and easily accessible mechanisms for documenting and honoring refusals to donate had been established. Physicians could proceed with organ procurement based on presumed consent only after verifying that there was no documented prior refusal and that the family was not aware of any objection to donation by the deceased.

Under mandated choice, individuals are required to express their preferences regarding donation at the time they execute a state-regulated task. Donations under mandated choice would be ethically appropriate only if an individual’s choice was made on the basis of a meaningful exchange of information about organ donation in keeping with the principles of informed consent. Physicians could proceed with organ procurement based on mandated choice only after verifying that the individual’s consent to donate was documented.

These models merit further study to determine whether either or both can be implemented in a way that meets fundamental ethical criteria for informed consent and provides clear evidence that their benefits outweigh the ethical concerns.

Physicians who propose to develop or participate in pilot studies of presumed consent or mandated choice should ensure that the study adheres to the following guidelines:

- (a) Is scientifically well designed and defines clear, measurable outcomes in a written protocol.
- (b) Has been developed in consultation with the population among whom it is to be carried out.
- (c) Has been reviewed and approved by an appropriate oversight body and is carried out in keeping with guidelines for ethical research.

Unless there are data that suggest a positive effect on donation, neither presumed consent nor mandated choice for cadaveric organ donation should be widely implemented.

[AMA Principles of Medical Ethics: I,III,V](#), Issued: 2016