

118TH CONGRESS  
1ST SESSION

# S. 2191

To amend the Public Health Service Act to ensure the consensual donation and respectful disposition of human bodies and human body parts donated or transferred for education, research, or the advancement of medical, dental, or mortuary science and not for use in human transplantation, and for other purposes.

---

IN THE SENATE OF THE UNITED STATES

JUNE 22, 2023

Mr. MURPHY (for himself and Mr. TILLIS) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

---

## A BILL

To amend the Public Health Service Act to ensure the consensual donation and respectful disposition of human bodies and human body parts donated or transferred for education, research, or the advancement of medical, dental, or mortuary science and not for use in human transplantation, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Consensual Donation  
5 and Research Integrity Act of 2023”.

1 **SEC. 2. HUMAN BODIES AND HUMAN BODY PARTS DO-**  
 2 **NATED OR TRANSFERRED FOR EDUCATION,**  
 3 **RESEARCH, OR THE ADVANCEMENT OF MED-**  
 4 **ICAL, DENTAL, OR MORTUARY SCIENCE AND**  
 5 **NOT FOR USE IN HUMAN TRANSPLANTATION.**

6 (a) IN GENERAL.—Title III of the Public Health  
 7 Service Act (42 U.S.C. 241 et seq.) is amended by insert-  
 8 ing after section 373 the following new section:

9 **“SEC. 373A. HUMAN BODIES AND HUMAN BODY PARTS DO-**  
 10 **NATED OR TRANSFERRED FOR EDUCATION,**  
 11 **RESEARCH, OR THE ADVANCEMENT OF MED-**  
 12 **ICAL, DENTAL, OR MORTUARY SCIENCE AND**  
 13 **NOT FOR USE IN HUMAN TRANSPLANTATION.**

14 “(a) REGISTRATION.—

15 “(1) IN GENERAL.—A person who acquires  
 16 human bodies and sells for profit a whole human  
 17 body or human body part in or affecting interstate  
 18 commerce shall register with the Secretary at such  
 19 time and in such manner as the Secretary may re-  
 20 quire.

21 “(2) EXCEPTION.—Paragraph (1) does not  
 22 apply to the Organ Procurement and Transplan-  
 23 tation Network under section 372 and any entity  
 24 that is a member of the Network pursuant to section  
 25 121.3 of title 42, Code of Federal Regulations (or  
 26 any successor regulations), funeral service profes-

1       sionals in regard to the preparation, transportation,  
2       and final disposition of the human body or body  
3       parts, and schools of medicine, dentistry, and mor-  
4       tuary science and research, training organizations,  
5       and other entities that do not sell for profit a whole  
6       body or body part.

7               “(3) CONTENTS OF APPLICATION.—An appli-  
8       cant for registration or renewal of registration under  
9       this section shall submit an application to the Sec-  
10      retary containing such information as the Secretary  
11      may by regulation require on the activities to be car-  
12      ried out pursuant to the registration. Unless the  
13      Secretary specifies otherwise by regulation, an appli-  
14      cation shall include—

15               “(A) the name of the applicant, including  
16              all trade names under which the applicant con-  
17              ducts business;

18               “(B) the date on which the applicant first  
19              began or will begin commencing activities de-  
20              scribed in paragraph (1);

21               “(C) a list of all addresses at which the  
22              applicant conducts business;

23               “(D) a description of the premises and  
24              equipment used by the applicant;

1           “(E) a description of the types of service  
2 provided by the applicant;

3           “(F) an identification of a representative  
4 of the applicant who has attained the age of 18  
5 and has the authority to ensure that the appli-  
6 cant complies with this section;

7           “(G) an assurance that the Secretary will  
8 be permitted to inspect the premises and  
9 records of the applicant at the times and in the  
10 manners prescribed under subsection (b);

11           “(H) an assurance that the applicant will  
12 keep records in accordance with subsection (c);

13           “(I) an assurance that the applicant will  
14 label and package all human bodies or human  
15 body parts in accordance with subsection (d);  
16 and

17           “(J) an assurance that the applicant will  
18 limit the use and disclosure of information in  
19 accordance with the regulations promulgated  
20 pursuant to subsection (e).

21           “(4) FEES.—

22           “(A) AUTHORITY.—The Secretary shall es-  
23 tablish a fee for registration under paragraph  
24 (1) and renewal under paragraph (5) in an  
25 amount in accordance with subparagraph (B).

1           “(B) AMOUNT.—The Secretary shall deter-  
2           mine the amount of the fees authorized by sub-  
3           paragraph (A) on an annual basis based on the  
4           projected cost of implementing and enforcing  
5           this section, including the cost of inspections  
6           under subsection (b).

7           “(C) COLLECTIONS AND APPROPRIATIONS  
8           ACTS.—The fees authorized by subparagraph  
9           (A) shall be available for obligation only to the  
10          extent and in the amounts provided in advance  
11          in appropriations Acts.

12          “(5) REGISTRATION RENEWAL.—The Secretary  
13          shall require that the registration of a registrant be  
14          renewed by such registrant at such intervals as the  
15          Secretary determines appropriate.

16          “(6) CHANGE OF INFORMATION.—Not later  
17          than 30 days after any change of any information  
18          listed in paragraph (3), an applicant or registrant  
19          shall notify the Secretary of such change in writing  
20          as prescribed by regulation by the Secretary.

21          “(b) INSPECTIONS.—The Secretary shall inspect at  
22          regular intervals (to be prescribed by the Secretary) the  
23          premises described in subsection (a)(3)(D).

24          “(c) RECORD KEEPING.—

1           “(1) IN GENERAL.—A registrant shall maintain  
2 a record for each case in which the registrant ac-  
3 quires a human body or human body part.

4           “(2) RECORD REQUIREMENTS.—A record under  
5 paragraph (1) shall contain such information as the  
6 Secretary may by regulation require. Unless the Sec-  
7 retary specifies otherwise by regulation, a record  
8 under paragraph (1) shall include the following:

9           “(A) Documentation that the donor has  
10 knowingly consented to the transfer of the  
11 human body or human body part (not for use  
12 in transplantation) involved for education, re-  
13 search, or the advancement of medical, dental,  
14 or mortuary science in accordance with all ap-  
15 plicable laws pertaining to the disposition of  
16 human remains.

17           “(B) Documentation that the donor has  
18 been informed of the obligation of the reg-  
19 istrant under subsection (e) to dispose of the  
20 human body or human body part.

21           “(C) The date and time of the donation or  
22 transfer from the donor.

23           “(D) The name of the person, including  
24 any trade or business name, who transferred

1 the human body or human body part to the reg-  
2 istrant, if applicable.

3 “(E) The full name and most recent ad-  
4 dress of the donor.

5 “(F) A description of the human body or  
6 human body part being acquired or transferred.

7 “(G) The medical history of the donor, in-  
8 cluding the autopsy report if an autopsy was  
9 conducted.

10 “(H) The identity and address of each per-  
11 son that has been in possession of the human  
12 body or human body part prior to the reg-  
13 istrant, including any funeral home, coroner,  
14 hospital, organ procurement organization, or  
15 tissue bank.

16 “(I) Documentation of the use and dispo-  
17 sition of each human body or human body part  
18 by the registrant.

19 “(J) Documentation of the name and ad-  
20 dress of each person to whom the registrant  
21 transfers such human body or human body  
22 part.

23 “(d) LABELING AND PACKAGING.—

24 “(1) IN GENERAL.—A registrant shall ensure  
25 that all human bodies and human body parts in the

1 possession of, or transferred by, a registrant are la-  
2 beled and packaged in accordance with paragraphs  
3 (2) and (3) and that a proper chain of custody is  
4 maintained.

5 “(2) LABELING REQUIREMENTS.—

6 “(A) PLACEMENT.—The labeling required  
7 by paragraph (1) shall be affixed beneath the  
8 outer packaging.

9 “(B) CONTENTS.—The labeling required  
10 by paragraph (1) shall contain such information  
11 as the Secretary may by regulation require con-  
12 sistent with any applicable Federal privacy pro-  
13 visions. Unless the Secretary specifies otherwise  
14 by regulation, a label under paragraph (1) shall  
15 include the following:

16 “(i) The proper name of the donor.

17 “(ii) A description of the contents of  
18 the packaging, indicating whether it is a  
19 human body or human body parts, includ-  
20 ing a list of all such parts.

21 “(iii) The name, address, and any ap-  
22 plicable license or registration number of  
23 the person transferring the human body or  
24 human body part.



1                   “(iv) The tissue types of the human  
2                   body or human body part.

3                   “(v) The cause of death of the donor,  
4                   if applicable and known.

5                   “(vi) Serological test results, if any  
6                   such results exist.

7                   “(vii) Record of the presence of radio-  
8                   active materials or implants.

9                   “(viii) Any known infectious disease  
10                  agents of such human body or human body  
11                  part.

12                  “(ix) A statement about the use of  
13                  personal protective equipment and uni-  
14                  versal precautions when handling a human  
15                  body or human body part as required by  
16                  law.

17                  “(x) The statement ‘not for transplan-  
18                  tation’.

19                  “(3)     PACKAGING     REQUIREMENTS.—Each  
20                  human body or human body part described in para-  
21                  graph (1) shall be wrapped and packaged in such  
22                  manner as the Secretary may by regulation require.  
23                  Unless the Secretary specifies otherwise by regula-  
24                  tion, each such human body or human body part  
25                  shall be wrapped and packaged in a manner that—

1           “(A) mitigates potential contamination and  
2           cross contamination;

3           “(B) mitigates potential safety hazards;

4           “(C) is sealed to prevent leakage; and

5           “(D) ensures the integrity of the human  
6           body or human body part.

7           “(e) LIMITATIONS ON USE AND DISCLOSURE OF IN-  
8           FORMATION.—Individually identifiable information relat-  
9           ing to the donor of a human body or human body part  
10          acquired or transferred pursuant to a registration under  
11          this section shall be used and disclosed only for such pur-  
12          poses (including the return of remains for burial) as the  
13          Secretary may explicitly authorize by regulation.

14          “(f) DISPOSITION.—The registrant shall ensure the  
15          proper disposition of a human body or human body part,  
16          in accordance with applicable Federal and State law, by—

17                 “(1) returning the human body or human body  
18                 part to a relative or personal representative of the  
19                 donor or carrying out the disposition of such human  
20                 body or human body part in accordance with the  
21                 written instructions of the person or persons with  
22                 the right to control the disposition of the human  
23                 body or body parts; or

24                 “(2) if the registrant is transferring the human  
25                 body or human body part to another person, con-

1       tracting with such person to assume the obligation  
2       described in paragraph (1).

3       “(g) VIOLATIONS.—

4             “(1) IN GENERAL.—Any person who violates a  
5       requirement of this section shall be fined in accord-  
6       ance with title 18, United States Code.

7             “(2) REVOCATION OF REGISTRATION.—The  
8       Secretary may suspend or revoke the registration of  
9       any registrant found to be in violation of this sec-  
10      tion.

11            “(3) ALTERATION OR FALSIFICATION OF  
12      LABEL.—It shall be a violation of this section for  
13      any person to alter or falsify any information in a  
14      label required by subsection (d).

15      “(h) DEFINITIONS.—In this section:

16            “(1) DONOR.—The term ‘donor’ means a per-  
17      son who has knowingly consented in accordance with  
18      applicable law to the transfer of such person’s de-  
19      ceased body or deceased or living body part (not for  
20      use in transplantation) for education, research, or  
21      the advancement of medical, dental, or mortuary  
22      science.

23            “(2) EDUCATION.—The term ‘education’ means  
24      the use of a human body or body parts for teaching  
25      or training individuals, including medical, dental, or

1       mortuary science students or professionals, with re-  
2       gard to the anatomy and characteristics of the  
3       human body, disease detection, and such other uses  
4       as may be specified by the Secretary by regulation.

5           “(3) HUMAN BODY.—The term ‘human body’  
6       means a deceased human body.

7           “(4) HUMAN BODY PART.—The terms ‘human  
8       body part’ or ‘body part’ mean an organ, tissue, eye,  
9       bone, blood vessel or any other portion of a deceased  
10      or living human body that is subject to an anatom-  
11      ical gift or other transfer made pursuant to State  
12      law, but do not include—

13           “(A) blood drawn for medical purposes; or

14           “(B) a growing cell line.

15           “(5) RESEARCH.—The term ‘research’ does not  
16      include an autopsy or examination, conducted as  
17      part of a criminal investigation.”.

18      (b) RULE OF APPLICABILITY.—The amendments  
19      made by this section shall apply with respect to any acqui-  
20      sition or transfer of a human body or human body parts  
21      after the date that is 2 years after the date of the enact-  
22      ment of this Act.

○