

117TH CONGRESS  
1ST SESSION

# H. R. 4062

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.

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## IN THE HOUSE OF REPRESENTATIVES

JUNE 22, 2021

Mr. RUSH (for himself and Mr. BILIRAKIS) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## 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 2021”.

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 or  
16 transfers in or affecting interstate commerce a  
17 human body or human body part for education, re-  
18 search, or the advancement of medical, dental, or  
19 mortuary science (and not for use in human trans-  
20 plantation) shall register with the Secretary at such  
21 time and in such manner as the Secretary may re-  
22 quire.

23 “(2) EXCEPTION.—Paragraph (1) does not  
24 apply to the Organ Procurement and Transplan-  
25 tation Network under section 372 and any entity  
26 that is a member of the Network pursuant to section

1       121.3 of title 42, Code of Federal Regulations (or  
2       any successor regulations).

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

11           “(A) the name of the applicant, including  
12           all trade names under which the applicant con-  
13           ducts business;

14           “(B) the date on which the applicant first  
15           began or will begin commencing activities de-  
16           scribed in paragraph (1);

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

19           “(D) a description of the premises and  
20           equipment used by the applicant;

21           “(E) a description of the types of service  
22           provided by the applicant;

23           “(F) an identification of a representative  
24           of the applicant who has attained the age of 18

1 and has the authority to ensure that the appli-  
2 cant complies with this section;

3 “(G) an assurance that the Secretary will  
4 be permitted to inspect the premises and  
5 records of the applicant at the times and in the  
6 manners prescribed under subsection (b);

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

9 “(I) an assurance that the applicant will  
10 label and package all human bodies or human  
11 body parts in accordance with subsection (d);  
12 and

13 “(J) an assurance that the applicant will  
14 limit the use and disclosure of information in  
15 accordance with the regulations promulgated  
16 pursuant to subsection (e).

17 “(4) FEES.—

18 “(A) AUTHORITY.—The Secretary shall es-  
19 tablish a fee for registration under paragraph  
20 (1) and renewal under paragraph (5) in an  
21 amount in accordance with subparagraph (B).

22 “(B) AMOUNT.—The Secretary shall deter-  
23 mine the amount of the fees authorized by sub-  
24 paragraph (A) on an annual basis based on the  
25 projected cost of implementing and enforcing

1           this section, including the cost of inspections  
2           under subsection (b).

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

8           “(5) REGISTRATION RENEWAL.—The Secretary  
9           shall require that the registration of a registrant be  
10          renewed by such registrant at such intervals as the  
11          Secretary determines appropriate.

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

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

20          “(c) RECORD KEEPING.—

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

24                 “(2) RECORD REQUIREMENTS.—A record under  
25                 paragraph (1) shall contain such information as the

1 Secretary may by regulation require. Unless the Sec-  
2 retary specifies otherwise by regulation, a record  
3 under paragraph (1) shall include the following:

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

12 “(B) Documentation that the donor has  
13 been informed of the obligation of the reg-  
14 istrant under subsection (e) to dispose of the  
15 human body or human body part.

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

18 “(D) The name of the person, including  
19 any trade or business name, who transferred  
20 the human body or human body part to the reg-  
21 istrant, if applicable.

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

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

1           “(G) The medical history of the donor, in-  
2           cluding the autopsy report if an autopsy was  
3           conducted.

4           “(H) The identity and address of each per-  
5           son that has been in possession of the human  
6           body or human body part prior to the reg-  
7           istrant, including any funeral home, coroner,  
8           hospital, organ procurement organization, or  
9           tissue bank.

10          “(I) Documentation of the use and disposi-  
11          tion of each human body or human body part  
12          by the registrant.

13          “(J) Documentation of the name and ad-  
14          dress of each person to whom the registrant  
15          transfers such human body or human body  
16          part.

17          “(d) LABELING AND PACKAGING.—

18               “(1) IN GENERAL.—A registrant shall ensure  
19               that all human bodies and human body parts in the  
20               possession of, or transferred by, a registrant are la-  
21               beled and packaged in accordance with paragraphs  
22               (2) and (3).

23               “(2) LABELING REQUIREMENTS.—

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

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

11               “(i) The proper name of the donor.

12               “(ii) A description of the contents of  
13               the packaging, indicating whether it is a  
14               human body or human body parts, includ-  
15               ing a list of all such parts.

16               “(iii) The name, address, and any ap-  
17               plicable license or registration number of  
18               the person transferring the human body or  
19               human body part.

20               “(iv) The tissue types of the human  
21               body or human body part.

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

24               “(vi) Serological test results, if any  
25               such results exist.



1 “(vii) Any known infectious disease  
2 agents of such human body or human body  
3 part.

4 “(viii) A statement about the use of  
5 personal protective equipment and uni-  
6 versal precautions when handling a human  
7 body or human body part as required by  
8 law.

9 “(ix) The statement ‘not for trans-  
10 plantation.’.

11 “(3) PACKAGING REQUIREMENTS.—Each  
12 human body or human body part described in para-  
13 graph (1) shall be wrapped and packaged in such  
14 manner as the Secretary may by regulation require.  
15 Unless the Secretary specifies otherwise by regula-  
16 tion, each such human body or human body part  
17 shall be wrapped and packaged in a manner that—

18 “(A) mitigates potential contamination and  
19 cross contamination;

20 “(B) mitigates potential safety hazards;

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

22 “(D) ensures the integrity of the human  
23 body or human body part.

24 “(e) LIMITATIONS ON USE AND DISCLOSURE OF IN-  
25 FORMATION.—Individually identifiable information relat-

1 ing to the donor of a human body or human body part  
2 acquired or transferred pursuant to a registration under  
3 this section shall be used and disclosed only for such pur-  
4 poses (including the return of remains for burial) as the  
5 Secretary may explicitly authorize by regulation.

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

9 “(1) returning the human body or human body  
10 part to a relative or personal representative of the  
11 donor or carrying out the disposition of such human  
12 body or human body part; or

13 “(2) if the registrant is transferring the human  
14 body or human body part to another person, con-  
15 tracting with such person to assume the obligation  
16 described in paragraph (1).

17 “(g) VIOLATIONS.—

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

21 “(2) REVOCATION OF REGISTRATION.—The  
22 Secretary may suspend or revoke the registration of  
23 any registrant found to be in violation of this sec-  
24 tion.

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

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

6           “(1) DONOR.—The term ‘donor’ means a per-  
7 son who has knowingly consented in accordance with  
8 applicable law to the transfer of such person’s de-  
9 ceased body or deceased or living body part (not for  
10 use in transplantation) for education, research, or  
11 the advancement of medical, dental, or mortuary  
12 science.

13           “(2) EDUCATION.—The term ‘education’ means  
14 the use of a human body or body parts for teaching  
15 or training individuals, including medical, dental, or  
16 mortuary science students or professionals, with re-  
17 gard to the anatomy and characteristics of the  
18 human body, disease detection, and such other uses  
19 as may be specified by the Secretary by regulation.

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

22           “(4) HUMAN BODY PART.—The terms ‘human  
23 body part’ or ‘body part’ mean an organ, tissue, eye,  
24 bone, blood vessel or any other portion of a deceased  
25 or living human body that is subject to an anatom-

1        ical gift or other transfer made pursuant to State  
2        law, but do not include—

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

4                “(B) a growing cell line.

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

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

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