

Virtual Focus Groups with Primary Care Physicians and OBGYNs:  
Attitudes about Proposed Hepatitis C Screening Guidelines  
DVH 2019

Generic Information Collection under Formative Research and Tool  
Development OMB #0920-0840

**Attachment #1**

**Authorizing Legislation**

**Privacy Act Statement:**

This information is collected under the authority of the Public Health Service Act, Section 301, "Research and Investigation," (42 U.S.C. 241); and Sections 304, 306 and 308(d) which discuss authority to maintain data and provide assurances of confidentiality for health research and related activities (42 U.S.C. 242 b, k, and m(d)). This information is also being collected in conjunction with the provisions of the Government Paperwork Elimination Act and the Paperwork Reduction Act (PRA). This information will only be used by the Centers for Disease Control and Prevention (CDC) staff to inform activities of the Division of Viral Hepatitis (DVH).

Public reporting burden of this collection of information is estimated to average 90 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; Attn: OMB-PRA (0920-0840)

**2 USC 241: Research and investigations generally**Text contains those laws in effect on July 29, 2019

**From Title 42-THE PUBLIC HEALTH AND WELFARE**CHAPTER 6A-PUBLIC HEALTH SERVICES  
SUBCHAPTER II-GENERAL POWERS AND DUTIESPart A-Research and Investigations

[https://uscode.house.gov/view.xhtml?req=\(title:42%20section:241%20edition:prelim\)](https://uscode.house.gov/view.xhtml?req=(title:42%20section:241%20edition:prelim))

### **1.1.1 §241. Research and investigations generally**

#### *(a) Authority of Secretary*

The Secretary shall conduct in the Service, and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man, including water purification, sewage treatment, and pollution of lakes and streams. In carrying out the foregoing the Secretary is authorized to-

- (1) collect and make available through publications and other appropriate means, information as to, and the practical application of, such research and other activities;
- (2) make available research facilities of the Service to appropriate public authorities, and to health officials and scientists engaged in special study;
- (3) make grants-in-aid to universities, hospitals, laboratories, and other public or private institutions, and to individuals for such research projects as are recommended by the advisory council to the entity of the Department supporting such projects and make, upon recommendation of the advisory council to the appropriate entity of the Department, grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research;
- (4) secure from time to time and for such periods as he deems advisable, the assistance and advice of experts, scholars, and consultants from the United States or abroad;
- (5) for purposes of study, admit and treat at institutions, hospitals, and stations of the Service, persons not otherwise eligible for such treatment;
- (6) make available, to health officials, scientists, and appropriate public and other nonprofit institutions and organizations, technical advice and assistance on the application of statistical methods to experiments, studies, and surveys in health and medical fields;
- (7) enter into contracts, including contracts for research in accordance with and subject to the provisions of law applicable to contracts entered into by the military departments under [sections 2353 and 2354 of title 10](#), except that determination, approval, and certification required thereby shall be by the Secretary of Health and Human Services; and
- (8) adopt, upon recommendations of the advisory councils to the appropriate entities of the Department or, with respect to mental health, the National Advisory Mental Health Council, such additional means as the Secretary considers necessary or appropriate to carry out the purposes of this section.

#### *(b) Testing for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects; consultation*

(1) The Secretary shall conduct and may support through grants and contracts studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects. In carrying out this paragraph, the Secretary shall consult with entities of the Federal Government, outside of the Department of Health and Human Services, engaged in

comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct for such entity studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects.

(2)(A) The Secretary shall establish a comprehensive program of research into the biological effects of low-level ionizing radiation under which program the Secretary shall conduct such research and may support such research by others through grants and contracts.

(B) The Secretary shall conduct a comprehensive review of Federal programs of research on the biological effects of ionizing radiation.

(3) The Secretary shall conduct and may support through grants and contracts research and studies on human nutrition, with particular emphasis on the role of nutrition in the prevention and treatment of disease and on the maintenance and promotion of health, and programs for the dissemination of information respecting human nutrition to health professionals and the public. In carrying out activities under this paragraph, the Secretary shall provide for the coordination of such of these activities as are performed by the different divisions within the Department of Health and Human Services and shall consult with entities of the Federal Government, outside of the Department of Health and Human Services, engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct and support such activities for such entity.

(4) The Secretary shall publish a biennial report which contains-

(A) a list of all substances (i) which either are known to be carcinogens or may reasonably be anticipated to be carcinogens and (ii) to which a significant number of persons residing in the United States are exposed;

(B) information concerning the nature of such exposure and the estimated number of persons exposed to such substances;

(C) a statement identifying (i) each substance contained in the list under subparagraph (A) for which no effluent, ambient, or exposure standard has been established by a Federal agency, and (ii) for each effluent, ambient, or exposure standard established by a Federal agency with respect to a substance contained in the list under subparagraph (A), the extent to which, on the basis of available medical, scientific, or other data, such standard, and the implementation of such standard by the agency, decreases the risk to public health from exposure to the substance; and

(D) a description of (i) each request received during the year involved-

(I) from a Federal agency outside the Department of Health and Human Services for the Secretary, or

(II) from an entity within the Department of Health and Human Services to any other entity within the Department,

to conduct research into, or testing for, the carcinogenicity of substances or to provide information described in clause (ii) of subparagraph (C), and (ii) how the Secretary and each such other entity, respectively, have responded to each such request.

(5) The authority of the Secretary to enter into any contract for the conduct of any study, testing, program, research, or review, or assessment under this subsection shall be effective for any fiscal year only to such extent or in such amounts as are provided in advance in appropriation Acts.

*(c) Diseases not significantly occurring in United States*

The Secretary may conduct biomedical research, directly or through grants or contracts, for the identification, control, treatment, and prevention of diseases (including tropical diseases) which do not occur to a significant extent in the United States.

*(d) Protection of privacy of individuals who are research subjects*

(1)(A) If a person is engaged in biomedical, behavioral, clinical, or other research, in which identifiable, sensitive information is collected (including research on mental health and research on the use and effect of alcohol and other psychoactive drugs), the Secretary, in coordination with other agencies, as applicable-

(i) shall issue to such person a certificate of confidentiality to protect the privacy of individuals who are the subjects of such research if the research is funded wholly or in part by the Federal Government; and

(ii) may, upon application by a person engaged in research, issue to such person a certificate of confidentiality to protect the privacy of such individuals if the research is not so funded.

(B) Except as provided in subparagraph (C), any person to whom a certificate is issued under subparagraph (A) to protect the privacy of individuals described in such subparagraph shall not disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

(C) The disclosure prohibition in subparagraph (B) shall not apply to disclosure or use that is-

(i) required by Federal, State, or local laws, excluding instances described in subparagraph (D);

(ii) necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;

(iii) made with the consent of the individual to whom the information, document, or biospecimen pertains; or

(iv) made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

(D) Any person to whom a certificate is issued under subparagraph (A) to protect the privacy of an individual described in such subparagraph shall not, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, disclose or provide the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, except in the circumstance described in subparagraph (C)(iii).

(E) Identifiable, sensitive information protected under subparagraph (A), and all copies thereof, shall be immune from the legal process, and shall not, without the consent of the individual to whom the information pertains, be admissible as evidence or used for any purpose in any action, suit, or other judicial, legislative, or administrative proceeding.

(F) Identifiable, sensitive information collected by a person to whom a certificate has been issued under subparagraph (A), and all copies thereof, shall be subject to the protections afforded by this section for perpetuity.

(G) The Secretary shall take steps to minimize the burden to researchers, streamline the process, and reduce the time it takes to comply with the requirements of this subsection.

(2) The Secretary shall coordinate with the heads of other applicable Federal agencies to ensure that such departments have policies in place with respect to the issuance of a certificate of confidentiality pursuant to paragraph (1) and other requirements of this subsection.

(3) Nothing in this subsection shall be construed to limit the access of an individual who is a subject of research to information about himself or herself collected during such individual's participation in the research.

(4) For purposes of this subsection, the term "identifiable, sensitive information" means information that is about an individual and that is gathered or used during the course of research described in paragraph (1)(A) and-

(A) through which an individual is identified; or

(B) for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual.

*(e) Preterm labor and delivery and infant mortality*

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall expand, intensify, and coordinate the activities of the Centers for Disease Control and Prevention with respect to preterm labor and delivery and infant mortality.

*(f) Exemption of certain biomedical information from disclosure*

(1) The Secretary may exempt from disclosure under [section 552\(b\)\(3\) of title 5](#) biomedical information that is about an individual and that is gathered or used during the course of biomedical research if-

(A) an individual is identified; or

(B) there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, the request, and other available data sources could be used to deduce the identity of an individual.

(2)(A) Each determination of the Secretary under paragraph (1) to exempt information from disclosure shall be made in writing and accompanied by a statement of the basis for the determination.

(B) Each such determination and statement of basis shall be available to the public, upon request, through the Office of the Chief FOIA Officer of the Department of Health and Human Services.

(3) Nothing in this subsection shall be construed to limit a research participant's access to information about such participant collected during the participant's participation in the research.

*(g) Inapplicability of Federal information policy*

Subchapter I of [chapter 35 of title 44](#) shall not apply to the voluntary collection of information during the conduct of research by the National Institutes of Health.

*(h) Availability of substances and living organisms for biomedical and behavioral research*

(1) The Secretary may make available to individuals and entities, for biomedical and behavioral research, substances and living organisms. Such substances and organisms shall be made available under such terms and conditions (including payment for them) as the Secretary determines appropriate.

(2) Where research substances and living organisms are made available under paragraph (1) through contractors, the Secretary may direct such contractors to collect payments on behalf of the Secretary for the costs incurred to make available such substances and organisms and to forward amounts so collected to the Secretary, in the time and manner specified by the Secretary.

(3) Amounts collected under paragraph (2) shall be credited to the appropriations accounts that incurred the costs to make available the research substances and living organisms involved, and shall remain available until expended for carrying out activities under such accounts.

[\(July 1, 1944, ch. 373, title III, §301, 58 Stat. 691 ; July 3, 1946, ch. 538, §7\(a\), \(b\), 60 Stat. 423 ; June 16, 1948, ch. 481, §4\(e\), \(f\), 62 Stat. 467 ; June 24, 1948, ch. 621, §4\(e\), \(f\), 62 Stat. 601 ; June 25, 1948, ch. 654, §1, 62 Stat. 1017 ; July 3, 1956, ch. 510, §4, 70 Stat. 490 ; Pub. L. 86-798, Sept. 15, 1960, 74 Stat. 1053 ; Pub. L. 87-838, §2, Oct. 17, 1962, 76 Stat. 1073 ; Pub. L. 89-115, §3, Aug. 9, 1965, 79 Stat.](#)

448 ; Pub. L. 90-174, §9, Dec. 5, 1967, 81 Stat. 540 ; Pub. L. 91-513, title I, §3(a), Oct. 27, 1970, 84 Stat. 1241 ; Pub. L. 91-515, title II, §292, Oct. 30, 1970, 84 Stat. 1308 ; Pub. L. 92-218, §6(a)(2), Dec. 23, 1971, 85 Stat. 785 ; Pub. L. 92-423, §7(b), Sept. 19, 1972, 86 Stat. 687 ; Pub. L. 93-282, title I, §122(b), May 14, 1974, 88 Stat. 132 ; Pub. L. 93-348, title I, §104(a)(1), July 12, 1974, 88 Stat. 346 ; Pub. L. 93-352, title I, §111, July 23, 1974, 88 Stat. 360 ; Pub. L. 94-278, title I, §111, Apr. 22, 1976, 90 Stat. 405 ; Pub. L. 95-622, title II, §§261, 262, Nov. 9, 1978, 92 Stat. 3434 ; Pub. L. 96-88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695 ; Pub. L. 99-158, §3(a)(5), Nov. 20, 1985, 99 Stat. 879 ; Pub. L. 99-570, title IV, §4021(b)(2), Oct. 27, 1986, 100 Stat. 3207-124 ; Pub. L. 99-660, title I, §104, Nov. 14, 1986, 100 Stat. 3751 ; Pub. L. 100-607, title I, §163(1), (2), Nov. 4, 1988, 102 Stat. 3062 ; Pub. L. 103-43, title XX, §2009, June 10, 1993, 107 Stat. 213 ; Pub. L. 109-450, §3(a), Dec. 22, 2006, 120 Stat. 3341 ; Pub. L. 114-255, div. A, title II, §§2012(a), 2013, 2035, 2043, Dec. 13, 2016, 130 Stat. 1049 , 1050, 1062, 1074.)

#### AMENDMENTS

**2016-**Subsec. (a). Pub. L. 114-255, §2043(1), redesignated concluding provisions of subsec. (a) as par. (1) of subsec. (h).

Subsec. (d). Pub. L. 114-255, §2012(a), amended subsec. (d) generally. Prior to amendment, text read as follows: "The Secretary may authorize persons engaged in biomedical, behavioral, clinical, or other research (including research on mental health, including research on the use and effect of alcohol and other psychoactive drugs) to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals."

Subsec. (f). Pub. L. 114-255, §2013, added subsec. (f).

Subsec. (g). Pub. L. 114-255, §2035, added subsec. (g).

Subsec. (h). Pub. L. 114-255, §2043, redesignated concluding provisions of subsec. (a) as par. (1) of subsec. (h) and added pars. (2) and (3).

**2006-**Subsec. (e). Pub. L. 109-450 added subsec. (e).

**1993-**Subsec. (b)(4). Pub. L. 103-43 substituted "a biennial report" for "an annual report" in introductory provisions.

**1988-**Subsec. (d). Pub. L. 100-607 redesignated concluding provisions of subsec. (a) of [section 242a of this title](#) as subsec. (d) of this section, substituted "biomedical, behavioral, clinical, or other research (including research on mental health, including" for "research on mental health, including", and substituted "drugs)" for "drugs,".

**1986-**Subsec. (a)(3). Pub. L. 99-570 struck out "or, in the case of mental health projects, by the National Advisory Mental Health Council;" after "Department supporting such projects" and struck out "or the National Advisory Mental Health Council" after "appropriate entity of the Department".

Subsec. (c). Pub. L. 99-660 added subsec. (c).

**1985-**Subsec. (a)(3). Pub. L. 99-158, §3(a)(5)(A), substituted "as are recommended by the advisory council to the entity of the Department supporting such projects or, in the case of mental health projects, by the National Advisory Mental Health Council; and make, upon recommendation of the advisory council to the appropriate entity of the Department or the National Advisory Mental Health Council, grants-in-aid to public or nonprofit universities,

hospitals, laboratories, and other institutions for the general support of their research" for "as are recommended by the National Advisory Health Council, or, with respect to cancer, recommended by the National Cancer Advisory Board, or, with respect to mental health, recommended by the National Advisory Mental Health Council, or with respect to heart, blood vessel, lung, and blood diseases and blood resources, recommended by the National Heart, Lung, and Blood Advisory Council, or, with respect to dental diseases and conditions, recommended by the National Advisory Dental Research Council; and include in the grants for any such project grants of penicillin and other antibiotic compounds for use in such project; and make, upon recommendation of the National Advisory Health Council, grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research: *Provided*, That such uniform percentage, not to exceed 15 per centum, as the Secretary may determine, of the amounts provided for grants for research projects for any fiscal year through the appropriations for the National Institutes of Health may be transferred from such appropriations to a separate account to be available for such research grants-in-aid for such fiscal year".

Subsec. (a)(8). Pub. L. 99–158, §3(a)(5)(B), substituted "recommendations of the advisory councils to the appropriate entities of the Department or, with respect to mental health, the National Advisory Mental Health Council, such additional means as the Secretary considers" for "recommendation of the National Advisory Health Council, or, with respect to cancer, upon recommendation of the National Cancer Advisory Board, or, with respect to mental health, upon recommendation of the National Advisory Mental Health Council, or, with respect to heart, blood vessel, lung, and blood diseases and blood resources, upon recommendation of the National Heart, Lung and Blood Advisory Council, or, with respect to dental diseases and conditions, upon recommendations of the National Advisory Dental Research Council, such additional means as he deems".

**1978**-Pub. L. 95–622 designated existing provisions as subsec. (a), redesignated former pars. (a) to (h) as (1) to (8), respectively, substituted "Secretary" for "Surgeon General" wherever appearing, and inserted following par. (8) provisions relating to authority of Secretary to make available to individuals and entities substances and living organisms, and added subsec. (b).

**1976**-Subsecs. (c), (h). Pub. L. 94–278 substituted "heart, blood vessel, lung, and blood diseases and blood resources" for "heart diseases" and "National Heart, Lung and Blood Advisory Council" for "National Heart and Lung Advisory Council".

**1974**-Subsec. (c). Pub. L. 93–348, §104(a)(1), redesignated subsec. (d) as (c) and substituted "research projects" for "research or research training projects" in two places, "general support of their research" for "general support of their research and research training programs" and "research grants-in-aid" for "research and research training program grants-in-aid". Former subsec. (c), authorizing Surgeon General to establish and maintain research fellowships in the Public Health Service with such stipends and allowances, including traveling and subsistence expenses, as he may deem necessary to procure the assistance of the most brilliant and promising research fellows from the United States and abroad, was struck out.

Subsec. (d). Pub. L. 93–348, §104(a)(1)(C), redesignated subsec. (e) as (d).

Pub. L. 93–282 substituted "mental health, including research on the use and effect of alcohol and other psychoactive drugs" for "the use and effect of drugs" in former concluding provisions of [section 242a\(a\) of this title](#). See 1988 Amendment note above.

Subsecs. (e), (f). Pub. L. 93–348, §104(a)(1)(C), redesignated subsecs. (f) and (g) as (e) and (f), respectively. Former subsec. (e) redesignated (d).

Subsec. (g). Pub. L. 93–352 struck out "during the fiscal year ending June 30, 1966, and each of the eight succeeding fiscal years" after "Enter into contracts". Notwithstanding directory language that amendment be made to subsec. (h), the amendment was executed to subsec. (g) to reflect the probable intent of Congress and the intervening redesignation of subsec. (h) as (g) by Pub. L. 93–348.

Pub. L. 93–348, §104(a)(1)(C), redesignated subsec. (h) as (g). Former subsec. (g) redesignated (f).

Subsecs. (h), (i). Pub. L. 93–348, §104(a)(1)(C), redesignated subsecs. (h) and (i) as (g) and (h), respectively.

**1972**-Subsecs. (d), (i). Pub. L. 92–423 substituted "National Heart and Lung Advisory Council" for "National Advisory Heart Council".

**1971**-Subsecs. (d), (i). Pub. L. 92–218 substituted "National Cancer Advisory Board" for "National Advisory Cancer Council".

**1970**-Subsec. (d). Pub. L. 91–513 added subsec. (d). See 1988 Amendment note above.

Subsec. (h). Pub. L. 91–515 substituted "eight" for "five" succeeding fiscal years.

**1967**-Subsec. (h). Pub. L. 90–174 substituted "five" for "two" succeeding fiscal years.

**1965**-Subsecs. (h), (i). Pub. L. 89–115 added subsec. (h) and redesignated former subsec. (h) as (i).

**1962**-Subsec. (d). Pub. L. 87–838 inserted "or research training" in two places.

**1960**-Subsec. (d). Pub. L. 86–798 authorized the Surgeon General, upon recommendation of the National Advisory Health Council, to make grants to public or non-profit universities, hospitals, laboratories, and other institutions to support research and research training programs, and to make available for such research and research training programs, up to 15 per centum of amounts provided for research grants through the appropriations for the National Institutes of Health.

**1956**-Subsecs. (g), (h). Act July 3, 1956, added subsec. (g) and redesignated former subsec. (g) as (h).

**1948**-Subsec. (d). Acts June 16, 1948, §4(e), and June 24, 1948, §4(e), made provisions applicable to the National Advisory Heart Council and the National Advisory Dental Research Council, respectively.

Subsec. (d). Act June 25, 1948, continued in basic legislation the authority to purchase penicillin and other antibiotic compounds for use in research projects.

Subsec. (g). Acts June 16, 1948, §4(f), and June 24, 1948, §4(f), made provisions applicable to the National Advisory Heart Council and the National Advisory Dental Research Council, respectively.

**1946**-Subsec. (d). Act July 3, 1946, made the National Advisory Mental Health Council the body to make recommendations to the Surgeon General on awarding of grants-in-aid for research projects with respect to mental health.

Subsec. (g). Act July 3, 1946, gave National Advisory Health Council the right to make recommendations to carry out purposes of this section.



#### *CHANGE OF NAME*

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in subsec. (a)(7), and "Department of Health and Human Services" substituted for "Department of Health, Education, and Welfare" in subsec. (b)(1), (3), and (4)(D)(I), (II), pursuant to section 509(b) of Pub. L. 96–88 which is classified to [section 3508\(b\) of Title 20, Education](#).

#### *EFFECTIVE DATE OF 1978 AMENDMENT*

Sections 261 and 262 of Pub. L. 95–622 provided that the amendments made by those sections are effective Oct. 1, 1978.

#### *EFFECTIVE DATE OF 1974 AMENDMENT*

Section 104(b) of Pub. L. 93–348 provided that: "The amendments made by subsection (a) [amending this section and sections 242a, 282, 286a, 286b, 287a, 287b, 287d, 288a, 289c, 289c–1, 289g, 289k, and heading preceding [section 289l of this title](#)] shall not apply with respect to commitments made before the date of the enactment of this Act [July 12, 1974] by the Secretary of Health, Education, and Welfare for research training under the provisions of the Public Health Service Act amended or repealed by subsection (a)."

#### *EFFECTIVE DATE OF 1972 AMENDMENT*

Amendment by Pub. L. 92–423 effective 60 days after Sept. 19, 1972, or on such prior date after Sept. 19, 1972, as the President shall prescribe and publish in the Federal Register, see section 9 of Pub. L. 92–423, set out as a note under [section 218 of this title](#).

#### *EFFECTIVE DATE OF 1971 AMENDMENT*

Amendment by Pub. L. 92–218 effective 60 days after Dec. 23, 1971, or on such prior date after Dec. 23, 1971, as the President shall prescribe and publish in the Federal Register, see section 7 of Pub. L. 92–218, set out as a note under [section 218 of this title](#).

#### *APPLICABILITY OF 2016 AMENDMENT*

[Pub. L. 114–255, div. A, title II, §2012\(b\), Dec. 13, 2016, 130 Stat. 1050](#), provided that: "Beginning 180 days after the date of enactment of this Act [Dec. 13, 2016], all persons engaged in research and authorized by the Secretary of Health and Human Services to protect information under section 301(d) of the Public Health Service Act (42 U.S.C. 241(d)) prior to the date of enactment of this Act shall be subject to the requirements of such section (as amended by this Act)."

#### *COORDINATION OF DATA SURVEYS AND REPORTS*

[Pub. L. 106–113, div. B, §1000\(a\)\(6\) \[title VII, §703\(e\)\], Nov. 29, 1999, 113 Stat. 1536, 1501A–402](#), provided that: "The Secretary of Health and Human Services, through the Assistant Secretary for Planning and Evaluation, shall establish a clearinghouse for the consolidation and coordination of all Federal databases and reports regarding children's health."

#### *FEMALE GENITAL MUTILATION*

[Pub. L. 104–134, title I, §101\(d\) \[title V, §520\], Apr. 26, 1996, 110 Stat. 1321–211, 1321–250](#); renumbered title I, [Pub. L. 104–140, §1\(a\), May 2, 1996, 110 Stat. 1327](#), provided that:

"(a) Congress finds that-

"(1) the practice of female genital mutilation is carried out by members of certain cultural and religious groups within the United States; and

"(2) the practice of female genital mutilation often results in the occurrence of physical and psychological health effects that harm the women involved.

"(b) The Secretary of Health and Human Services shall do the following:

"(1) Compile data on the number of females living in the United States who have been subjected to female genital mutilation (whether in the United States or in their countries of origin), including a specification of the number of girls under the age of 18 who have been subjected to such mutilation.

"(2) Identify communities in the United States that practice female genital mutilation, and design and carry out outreach activities to educate individuals in the communities on the physical and psychological health effects of such practice. Such outreach activities shall be designed and implemented in collaboration with representatives of the ethnic groups practicing such mutilation and with representatives of organizations with expertise in preventing such practice.

"(3) Develop recommendations for the education of students of schools of medicine and osteopathic medicine regarding female genital mutilation and complications arising from such mutilation. Such recommendations shall be disseminated to such schools.

"(c) For purposes of this section the term 'female genital mutilation' means the removal or infibulation (or both) of the whole or part of the clitoris, the labia minor, or the labia major.

"(d) The Secretary of Health and Human Services shall commence carrying out this section not later than 90 days after the date of enactment of this Act [Apr. 26, 1996]."

#### *SENTINEL DISEASE CONCEPT STUDY*

[Pub. L. 103–43, title XIX, §1910, June 10, 1993, 107 Stat. 205](#), directed Secretary of Health and Human Services, in cooperation with Agency for Toxic Substances and Disease Registry and Centers for Disease Control and Prevention, to design and implement a pilot sentinel disease surveillance system for identifying relationship between occupation of household members and incidence of subsequent conditions or diseases in other members of household, and required Director of the National Institutes of Health to prepare and submit to Congress, not later than 4 years after June 10, 1993, a report concerning this project.

#### *STUDY OF THYROID MORBIDITY FOR HANFORD, WASHINGTON*

[Pub. L. 100–607, title I, §161, Nov. 4, 1988, 102 Stat. 3059](#), as amended by [Pub. L. 102–531, title III, §312\(e\)\(1\), Oct. 27, 1992, 106 Stat. 3506](#), directed Secretary of Health and Human Services, acting through Director of Centers for Disease Control and Prevention, to conduct a study of thyroid morbidity of the population, including Indian tribes and tribal organizations, in vicinity of Hanford, in State of Washington, authorized Director to contract out portions of study, and required Director, not later than 42 months after Nov. 4, 1988, to transmit a report, including such study, to Congress, chief executive officers of States of Oregon and Washington, and governing officials of Indian tribes in vicinity of Hanford, Washington.

#### *NATIONAL COMMISSION ON SLEEP DISORDERS RESEARCH*

[Pub. L. 100–607, title I, §162, Nov. 4, 1988, 102 Stat. 3060](#), directed Secretary of Health and Human Services, after consultation with Director of National Institutes of Health, to establish a National Commission on Sleep Disorders Research to conduct a comprehensive study of present state of knowledge of incidence, prevalence, morbidity, and mortality resulting from sleep disorders, and of social and economic impact of such disorders, evaluate public and private facilities and resources (including trained personnel and research activities) available for diagnosis, prevention, and treatment of, and research into, such disorders, and identify programs (including biological, physiological, behavioral, environmental, and social programs) by which improvement in management and research into sleep disorders could be accomplished and, not later than 18 months after initial meeting of Commission, to submit to

appropriate Committees of Congress a final report, and provided for termination of the Commission 30 days after submission of final report.

*RESEARCH WITH RESPECT TO HEALTH RESOURCES AND SERVICES ADMINISTRATION*

Pub. L. 100–607, title VI, §632, Nov. 4, 1988, 102 Stat. 3147, provided that with respect to any program of research pursuant to this chapter, any such program carried out in fiscal year 1987 by an agency other than Health Resources and Services Administration (or appropriate to be carried out by such an agency) could not, for each of fiscal years 1989 through 1991, be carried out by such Administration.

*CONTINUING CARE FOR PSYCHIATRIC PATIENTS IN FORMER CLINICAL RESEARCH CENTER AT NATIONAL INSTITUTE ON DRUG ABUSE*

Pub. L. 99–117, §10, Oct. 7, 1985, 99 Stat. 494, provided that: "In any fiscal year beginning after September 30, 1981, from funds appropriated for carrying out section 301 of the Public Health Service Act [42 U.S.C. 241] with respect to mental health, the Secretary of Health and Human Services may provide, by contract or otherwise, for the continuing care of psychiatric patients who were under active and continuous treatment at the National Institute on Drug Abuse Clinical Research Center on the date such Clinical Research Center ceased operations."

*ANALYSIS OF THYROID CANCER; CREATION AND PUBLICATION OF RADIOEPIDEMIOLOGICAL TABLES*

Pub. L. 97–414, §7, Jan. 4, 1983, 96 Stat. 2059, as amended by Pub. L. 109–482, title I, §104(b)(3)(A), Jan. 15, 2007, 120 Stat. 3694, provided that:

"(a) In carrying out section 301 of the Public Health Service Act [42 U.S.C. 241], the Secretary of Health and Human Services shall-

"(1) conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the risks of thyroid cancer that are associated with thyroid doses of Iodine 131;

"(2) conduct scientific research and prepare analyses necessary to develop valid and credible methods to estimate the thyroid doses of Iodine 131 that are received by individuals from nuclear bomb fallout; and

"(3) conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the exposure to Iodine 131 that the American people received from the Nevada atmospheric nuclear bomb tests.

"(b)(1) Within one year after the date of enactment of this Act [Jan. 4, 1983], the Secretary of Health and Human Services shall devise and publish radioepidemiological tables that estimate the likelihood that persons who have or have had any of the radiation related cancers and who have received specific doses prior to the onset of such disease developed cancer as a result of these doses. These tables shall show a probability of causation of developing each radiation related cancer associated with receipt of doses ranging from 1 millirad to 1,000 rads in terms of sex, age at time of exposure, time from exposure to the onset of the cancer in question, and such other categories as the Secretary, after consulting with appropriate scientific experts, determines to be relevant. Each probability of causation shall be calculated and displayed as a single percentage figure.

"(2) At the time the Secretary of Health and Human Services publishes the tables pursuant to paragraph (1), such Secretary shall also publish-

"(A) for the tables of each radiation related cancer, an evaluation which will assess the credibility, validity, and degree of certainty associated with such tables; and

"(B) a compilation of the formulas that yielded the probabilities of causation listed in such tables. Such formulas shall be published in such a manner and together with information necessary to determine the probability of causation of any individual who has or has had a radiation related cancer and has received any given dose.

"(3) The tables specified in paragraph (1) and the formulas specified in paragraph (2) shall be devised from the best available data that are most applicable to the United States, and shall be devised in accordance with the best available scientific procedures and expertise."

#### *TERMINATION OF ADVISORY COMMITTEES*

Pub. L. 93-641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

#### *EXECUTIVE ORDER NO. 13435*

Ex. Ord. No. 13435, June 20, 2007, 72 F.R. 34591, which directed research with stem cells not derived from the creation or destruction of a human embryo or fetus, was revoked by Ex. Ord. No. 13505, §5(b), Mar. 9, 2009, 74 F.R. 10668, set out below.

#### *EX. ORD. NO. 13505. REMOVING BARRIERS TO RESPONSIBLE SCIENTIFIC RESEARCH INVOLVING HUMAN STEM CELLS*

Ex. Ord. No. 13505, Mar. 9, 2009, 74 F.R. 10667, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. *Policy.* Research involving human embryonic stem cells and human non-embryonic stem cells has the potential to lead to better understanding and treatment of many disabling diseases and conditions. Advances over the past decade in this promising scientific field have been encouraging, leading to broad agreement in the scientific community that the research should be supported by Federal funds.

For the past 8 years, the authority of the Department of Health and Human Services, including the National Institutes of Health (NIH), to fund and conduct human embryonic stem cell research has been limited by Presidential actions. The purpose of this order is to remove these limitations on scientific inquiry, to expand NIH support for the exploration of human stem cell research, and in so doing to enhance the contribution of America's scientists to important new discoveries and new therapies for the benefit of humankind.

Sec. 2. *Research.* The Secretary of Health and Human Services (Secretary), through the Director of NIH, may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law.

Sec. 3. *Guidance.* Within 120 days from the date of this order, the Secretary, through the Director of NIH, shall review existing NIH guidance and other widely recognized guidelines on human stem cell research, including provisions establishing appropriate safeguards, and issue new NIH guidance on such research that is consistent with this order. The Secretary, through NIH, shall review and update such guidance periodically, as appropriate.

Sec. 4. *General Provisions.* (a) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(b) Nothing in this order shall be construed to impair or otherwise affect:

(i) authority granted by law to an executive department, agency, or the head thereof; or

(ii) functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity, by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

Sec. 5. *Revocations.* (a) The Presidential statement of August 9, 2001, limiting Federal funding for research involving human embryonic stem cells, shall have no further effect as a statement of governmental policy.

(b) Executive Order 13435 of June 20, 2007, which supplements the August 9, 2001, statement on human embryonic stem cell research, is revoked.

BARACK OBAMA.

*GUIDELINES FOR HUMAN STEM CELL RESEARCH*

Memorandum of President of the United States, July 30, 2009, 74 F.R. 38885, provided:

Memorandum for the Heads of Executive Departments and Agencies

As outlined in Executive Order 13505 of March 9, 2009, my Administration is committed to supporting and conducting ethically responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law. Pursuant to that order, the National Institutes of Health (NIH) published final "National Institutes of Health Guidelines for Human Stem Cell Research" (Guidelines), effective July 7, 2009. These Guidelines apply to the expenditure of NIH funds for research using human embryonic stem cells and certain uses of human induced pluripotent stem cells. The Guidelines are based on the principles that responsible research with human embryonic stem cells has the potential to improve our understanding of human biology and aid in the discovery of new ways to prevent and treat illness, and that individuals donating embryos for research purposes should do so freely, with voluntary and informed consent. These Guidelines will ensure that NIH-funded research adheres to the highest ethical standards.

In order to ensure that all federally funded human stem cell research is conducted according to these same principles and to promote a uniform Federal policy across the executive branch, I hereby direct the heads of executive departments and agencies that support and conduct stem cell research to adopt these Guidelines, to the fullest extent practicable in light of legal authorities and obligations. I also direct those departments and agencies to submit to the Director of the Office of Management and Budget (OMB), within 90 days, proposed additions or revisions to any other guidance, policies, or procedures related to human stem cell research, consistent with Executive Order 13505 and this memorandum. The Director of the OMB shall, in coordination with the Director of NIH, review these proposals to ensure consistent implementation of Executive Order 13505 and this memorandum.

This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person. Executive departments and agencies shall carry out the provisions of this memorandum to the extent permitted by law and consistent with their statutory and regulatory authorities and their enforcement mechanisms.

The Director of the OMB is hereby authorized and directed to publish this memorandum in the Federal Register.

BARACK OBAMA.

*ENGAGING IN PUBLIC HEALTH RESEARCH ON THE CAUSES AND PREVENTION OF GUN VIOLENCE*

Memorandum of President of the United States, Jan. 16, 2013, 78 F.R. 4295, provided that:

Memorandum for the Secretary of Health and Human Services

In addition to being a law enforcement challenge, gun violence is also a serious public health issue that affects thousands of individuals, families, and communities across the Nation. Each year in the United States there are approximately 30,000 firearm-related deaths, and approximately 11,000 of those deaths result from homicides. Addressing this critical issue requires a comprehensive, multifaceted approach.

Recent research suggests that, in developing such an approach, a broader public health perspective is imperative. Significant strides can be made by assessing the causes of gun violence and the successful efforts in place for preventing the misuse of firearms. Taking these steps will improve our understanding of the gun violence epidemic and will aid in the continued development of gun violence prevention strategies.

Therefore, by the authority vested in me as President by the Constitution and the laws of the United States of America, I hereby direct the following:

*Section 1. Research.* The Secretary of Health and Human Services (Secretary), through the Director of the Centers for Disease Control and Prevention and other scientific agencies within the Department of Health and Human Services, shall conduct or sponsor research into the causes of gun violence and the ways to prevent it. The Secretary shall begin by identifying the most pressing research questions with the greatest potential public health impact, and by assessing existing public health interventions being implemented across the Nation to prevent gun violence.

*Sec. 2. General Provisions.* (a) Nothing in this memorandum shall be construed to impair or otherwise affect:

- (i) the authority granted by law to an executive department or agency, or the head thereof; or
- (ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This memorandum shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

*Sec. 3. Publication.* You are hereby authorized and directed to publish this memorandum in the Federal Register.