

Attachment A. Authorizing Legislation

A1. Comprehensive Environmental Response, Compensation and Liability Act of 1980 (CERCLA) and Superfund Amendments and Reauthorization Act of 1986 (SARA)

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 103--COMPREHENSIVE ENVIRONMENTAL RESPONSE, COMPENSATION, AND LIABILITY

[42 U.S.C. 9604(i)]

Section 9604. (i) Agency for Toxic Substances and Disease Registry; establishment, functions, etc.

(1) There is hereby established within the Public Health Service an agency, to be known as the Agency for Toxic Substances and Disease Registry, which shall report directly to the Surgeon General of the United States. The Administrator of said Agency shall, with the cooperation of the Administrator of the Environmental Protection Agency, the Commissioner of the Food and Drug Administration, the Directors of the National Institute of Medicine, National Institute of Environmental Health Sciences, National Institute of Occupational Safety and Health, Centers for Disease Control and Prevention, the Administrator of the Occupational Safety and Health Administration, the Administrator of the Social Security Administration, the Secretary of Transportation, and appropriate State and local health officials, effectuate and implement the health related authorities of this chapter. In addition, said Administrator shall—

(A) in cooperation with the States, establish and maintain a national registry of serious diseases and illnesses and a national registry of persons exposed to toxic substances;

(B) establish and maintain inventory of literature, research, and studies on the health effects of toxic substances;

(C) in cooperation with the States, and other agencies of the Federal Government, establish and maintain a complete listing of areas closed to the public or otherwise restricted in use because of toxic substance contamination;

(D) in cases of public health emergencies caused or believed to be caused by exposure to toxic substances, provide medical care and testing to exposed individuals, including but not limited to tissue sampling, chromosomal testing where appropriate, epidemiological studies, or any other assistance appropriate under the circumstances; and

(E) either independently or as part of other health status survey, conduct periodic survey and screening programs to determine relationships between exposure to toxic substances and illness. In cases of public health emergencies, exposed persons shall be eligible for admission to hospitals and other facilities and services operated or provided by the Public Health Service.

(2)

(A) Within 6 months after October 17, 1986, the Administrator of the Agency for Toxic Substances and Disease Registry (ATSDR) and the Administrator of the Environmental Protection Agency (“EPA”)

shall prepare a list, in order of priority, of at least 100 hazardous substances which are most commonly found at facilities on the National Priorities List and which, in their sole discretion, they determine are posing the most significant potential threat to human health due to their known or suspected toxicity to humans and the potential for human exposure to such substances at facilities on the National Priorities List or at facilities to which a response to a release or a threatened release under this section is under consideration.

(B) Within 24 months after October 17, 1986, the Administrator of ATSDR and the Administrator of EPA shall revise the list prepared under subparagraph (A). Such revision shall include, in order of priority, the addition of 100 or more such hazardous substances. In each of the 3 consecutive 12-month periods that follow, the Administrator of ATSDR and the Administrator of EPA shall revise, in the same manner as provided in the 2 preceding sentences, such list to include not fewer than 25 additional hazardous substances per revision. The Administrator of ATSDR and the Administrator of EPA shall not less often than once every year thereafter revise such list to include additional hazardous substances in accordance with the criteria in subparagraph (A).

(3) Based on all available information, including information maintained under paragraph (1)(B) and data developed and collected on the health effects of hazardous substances under this paragraph, the Administrator of ATSDR shall prepare toxicological profiles of each of the substances listed pursuant to paragraph (2). The toxicological profiles shall be prepared in accordance with guidelines developed by the Administrator of ATSDR and the Administrator of EPA. Such profiles shall include, but not be limited to each of the following:

(A) An examination, summary, and interpretation of available toxicological information and epidemiologic evaluations on a hazardous substance in order to ascertain the levels of significant human exposure for the substance and the associated acute, subacute, and chronic health effects.

(B) A determination of whether adequate information on the health effects of each substance is available or in the process of development to determine levels of exposure which present a significant risk to human health of acute, subacute, and chronic health effects.

(C) Where appropriate, an identification of toxicological testing needed to identify the types or levels of exposure that may present significant risk of adverse health effects in humans.

Any toxicological profile or revision thereof shall reflect the Administrator of ATSDR's assessment of all relevant toxicological testing which has been peer reviewed. The profiles required to be prepared under this paragraph for those hazardous substances listed under subparagraph (A) of paragraph (2) shall be completed, at a rate of no fewer than 25 per year, within 4 years after October 17, 1986. A profile required on a substance listed pursuant to subparagraph (B) of paragraph (2) shall be completed within 3 years after addition to the list. The profiles prepared under this paragraph shall be of those substances highest on the list of priorities under paragraph (2) for which profiles have not previously been prepared. Profiles required under this paragraph shall be revised and republished as necessary, but no less often than once every 3 years. Such profiles shall be provided to the States and made available to other interested parties.

(4) The Administrator of the ATSDR shall provide consultations upon request on health issues relating to exposure to hazardous or toxic substances, on the basis of available information, to the Administrator of EPA, State officials, and local officials. Such consultations to individuals may be provided by States under cooperative agreements established under this chapter.

(5)

(A) For each hazardous substance listed pursuant to paragraph (2), the Administrator of ATSDR (in consultation with the Administrator of EPA and other agencies and programs of the Public Health Service) shall assess whether adequate information on the health effects of such substance is available. For any such substance for which adequate information is not available (or under development), the Administrator of ATSDR, in cooperation with the Director of the National Toxicology Program, shall assure the initiation of a program of research designed to determine the health effects (and techniques for development of methods to determine such health effects) of such substance. Where feasible, such program shall seek to develop methods to determine the health effects of such substance in combination with other substances with which it is commonly found. Before assuring the initiation of such program, the Administrator of ATSDR shall consider recommendations of the Interagency Testing Committee established under section 4(e) of the Toxic Substances Control Act [15 U.S.C. 2603(e)] on the types of research that should be done. Such program shall include, to the extent necessary to supplement existing information, but shall not be limited to—

- (i) laboratory and other studies to determine short, intermediate, and long-term health effects;
- (ii) laboratory and other studies to determine organ-specific, site-specific, and system-specific acute and chronic toxicity;
- (iii) laboratory and other studies to determine the manner in which such substances are metabolized or to otherwise develop an understanding of the biokinetics of such substances; and
- (iv) where there is a possibility of obtaining human data, the collection of such information.

(B) In assessing the need to perform laboratory and other studies, as required by subparagraph (A), the Administrator of ATSDR shall consider—

- (i) the availability and quality of existing test data concerning the substance on the suspected health effect in question;
- (ii) the extent to which testing already in progress will, in a timely fashion, provide data that will be adequate to support the preparation of toxicological profiles as required by paragraph (3); and
- (iii) such other scientific and technical factors as the Administrator of ATSDR may determine are necessary for the effective implementation of this subsection.

(C) In the development and implementation of any research program under this paragraph, the Administrator of ATSDR and the Administrator of EPA shall coordinate such research program implemented under this paragraph with the National Toxicology Program and with programs of toxicological testing established under the Toxic Substances Control Act [15 U.S.C. 2601 et seq.] and the Federal Insecticide, Fungicide and Rodenticide Act [7 U.S.C. 136 et seq.]. The purpose of such coordination shall be to avoid duplication of effort and to assure that the hazardous substances listed pursuant to this subsection are tested thoroughly at the earliest practicable date. Where appropriate, consistent with such purpose, a research program under this paragraph may be carried out using such programs of toxicological testing.

(D) It is the sense of the Congress that the costs of research programs under this paragraph be borne by the manufacturers and processors of the hazardous substance in question, as required in programs of toxicological testing under the Toxic Substances Control Act [15 U.S.C. 2601 et seq.]. Within 1 year

after October 17, 1986, the Administrator of EPA shall promulgate regulations which provide, where appropriate, for payment of such costs by manufacturers and processors under the Toxic Substances Control Act, and registrants under the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.], and recovery of such costs from responsible parties under this chapter.

(6)

(A)The Administrator of ATSDR shall perform a health assessment for each facility on the National Priorities List established under section 9605 of this title. Such health assessment shall be completed not later than December 10, 1988, for each facility proposed for inclusion on such list prior to October 17, 1986, or not later than one year after the date of proposal for inclusion on such list for each facility proposed for inclusion on such list after October 17, 1986.

(B)The Administrator of ATSDR may perform health assessments for releases or facilities where individual persons or licensed physicians provide information that individuals have been exposed to a hazardous substance, for which the probable source of such exposure is a release. In addition to other methods (formal or informal) of providing such information, such individual persons or licensed physicians may submit a petition to the Administrator of ATSDR providing such information and requesting a health assessment. If such a petition is submitted and the Administrator of ATSDR does not initiate a health assessment, the Administrator of ATSDR shall provide a written explanation of why a health assessment is not appropriate.

(C)In determining the priority in which to conduct health assessments under this subsection, the Administrator of ATSDR, in consultation with the Administrator of EPA, shall give priority to those facilities at which there is documented evidence of the release of hazardous substances, at which the potential risk to human health appears highest, and for which in the judgment of the Administrator of ATSDR existing health assessment data are inadequate to assess the potential risk to human health as provided in subparagraph (F). In determining the priorities for conducting health assessments under this subsection, the Administrator of ATSDR shall consider the National Priorities List schedules and the needs of the Environmental Protection Agency and other Federal agencies pursuant to schedules for remedial investigation and feasibility studies.

(D)Where a health assessment is done at a site on the National Priorities List, the Administrator of ATSDR shall complete such assessment promptly and, to the maximum extent practicable, before the completion of the remedial investigation and feasibility study at the facility concerned.

(E)Any State or political subdivision carrying out a health assessment for a facility shall report the results of the assessment to the Administrator of ATSDR and the Administrator of EPA and shall include recommendations with respect to further activities which need to be carried out under this section. The Administrator of ATSDR shall state such recommendation in any report on the results of any assessment carried out directly by the Administrator of ATSDR for such facility and shall issue periodic reports which include the results of all the assessments carried out under this subsection.

(F)For the purposes of this subsection and section 9611(c)(4) of this title, the term "health assessments" shall include preliminary assessments of the potential risk to human health posed by individual sites and facilities, based on such factors as the nature and extent of contamination, the existence of potential pathways of human exposure (including ground or surface water contamination, air emissions, and food chain contamination), the size and potential susceptibility of the community within the likely pathways of exposure, the comparison of expected human exposure levels to the short-term and long-term health

effects associated with identified hazardous substances and any available recommended exposure or tolerance limits for such hazardous substances, and the comparison of existing morbidity and mortality data on diseases that may be associated with the observed levels of exposure. The Administrator of ATSDR shall use appropriate data, risk assessments, risk evaluations and studies available from the Administrator of EPA.

(G)The purpose of health assessments under this subsection shall be to assist in determining whether actions under paragraph (11) of this subsection should be taken to reduce human exposure to hazardous substances from a facility and whether additional information on human exposure and associated health risks is needed and should be acquired by conducting epidemiological studies under paragraph (7), establishing a registry under paragraph (8), establishing a health surveillance program under paragraph (9), or through other means. In using the results of health assessments for determining additional actions to be taken under this section, the Administrator of ATSDR may consider additional information on the risks to the potentially affected population from all sources of such hazardous substances including known point or nonpoint sources other than those from the facility in question.

(H)At the completion of each health assessment, the Administrator of ATSDR shall provide the Administrator of EPA and each affected State with the results of such assessment, together with any recommendations for further actions under this subsection or otherwise under this chapter. In addition, if the health assessment indicates that the release or threatened release concerned may pose a serious threat to human health or the environment, the Administrator of ATSDR shall so notify the Administrator of EPA who shall promptly evaluate such release or threatened release in accordance with the hazard ranking system referred to in section 9605(a)(8)(A) of this title to determine whether the site shall be placed on the National Priorities List or, if the site is already on the list, the Administrator of ATSDR may recommend to the Administrator of EPA that the site be accorded a higher priority.

(7)

(A)Whenever in the judgment of the Administrator of ATSDR it is appropriate on the basis of the results of a health assessment, the Administrator of ATSDR shall conduct a pilot study of health effects for selected groups of exposed individuals in order to determine the desirability of conducting full scale epidemiological or other health studies of the entire exposed population.

(B)Whenever in the judgment of the Administrator of ATSDR it is appropriate on the basis of the results of such pilot study or other study or health assessment, the Administrator of ATSDR shall conduct such full scale epidemiological or other health studies as may be necessary to determine the health effects on the population exposed to hazardous substances from a release or threatened release. If a significant excess of disease in a population is identified, the letter of transmittal of such study shall include an assessment of other risk factors, other than a release, that may, in the judgment of the peer review group, be associated with such disease, if such risk factors were not taken into account in the design or conduct of the study.

(8)In any case in which the results of a health assessment indicate a potential significant risk to human health, the Administrator of ATSDR shall consider whether the establishment of a registry of exposed persons would contribute to accomplishing the purposes of this subsection, taking into account circumstances bearing on the usefulness of such a registry, including the seriousness or unique character of identified diseases or the likelihood of population migration from the affected area.

(9)Where the Administrator of ATSDR has determined that there is a significant increased risk of adverse health effects in humans from exposure to hazardous substances based on the results of a health assessment conducted under paragraph (6), an epidemiologic study conducted under paragraph (7), or an exposure registry that has been established under paragraph (8), and the Administrator of ATSDR has determined that such exposure is the result of a release from a facility, the Administrator of ATSDR shall initiate a health surveillance program for such population. This program shall include but not be limited to—

(A)periodic medical testing where appropriate of population subgroups to screen for diseases for which the population or subgroup is at significant increased risk; and

(B)a mechanism to refer for treatment those individuals within such population who are screened positive for such diseases.

(10)Two years after October 17, 1986, and every 2 years thereafter, the Administrator of ATSDR shall prepare and submit to the Administrator of EPA and to the Congress a report on the results of the activities of ATSDR regarding—

(A)health assessments and pilot health effects studies conducted;

(B)epidemiologic studies conducted;

(C)hazardous substances which have been listed under paragraph (2), toxicological profiles which have been developed, and toxicologic testing which has been conducted or which is being conducted under this subsection;

(D)registries established under paragraph (8); and

(E)an overall assessment, based on the results of activities conducted by the Administrator of ATSDR, of the linkage between human exposure to individual or combinations of hazardous substances due to releases from facilities covered by this chapter or the Solid Waste Disposal Act [42 U.S.C. 6901 et seq.] and any increased incidence or prevalence of adverse health effects in humans.

(11)If a health assessment or other study carried out under this subsection contains a finding that the exposure concerned presents a significant risk to human health, the President shall take such steps as may be necessary to reduce such exposure and eliminate or substantially mitigate the significant risk to human health. Such steps may include the use of any authority under this chapter, including, but not limited to—

(A)provision of alternative water supplies, and

(B)permanent or temporary relocation of individuals.

In any case in which information is insufficient, in the judgment of the Administrator of ATSDR or the President to determine a significant human exposure level with respect to a hazardous substance, the President may take such steps as may be necessary to reduce the exposure of any person to such hazardous substance to such level as the President deems necessary to protect human health.

(12)In any case which is the subject of a petition, a health assessment or study, or a research program under this subsection, nothing in this subsection shall be construed to delay or otherwise affect or impair the authority of the President, the Administrator of ATSDR, or the Administrator of EPA to exercise any authority vested in the President, the Administrator of ATSDR or the Administrator of EPA under any

other provision of law (including, but not limited to, the imminent hazard authority of section 7003 of the Solid Waste Disposal Act [42 U.S.C. 6973]) or the response and abatement authorities of this chapter.

(13) All studies and results of research conducted under this subsection (other than health assessments) shall be reported or adopted only after appropriate peer review. Such peer review shall be completed, to the maximum extent practicable, within a period of 60 days. In the case of research conducted under the National Toxicology Program, such peer review may be conducted by the Board of Scientific Counselors. In the case of other research, such peer review shall be conducted by panels consisting of no less than three nor more than seven members, who shall be disinterested scientific experts selected for such purpose by the Administrator of ATSDR or the Administrator of EPA, as appropriate, on the basis of their reputation for scientific objectivity and the lack of institutional ties with any person involved in the conduct of the study or research under review. Support services for such panels shall be provided by the Agency for Toxic Substances and Disease Registry, or by the Environmental Protection Agency, as appropriate.

(14) In the implementation of this subsection and other health-related authorities of this chapter, the Administrator of ATSDR shall assemble, develop as necessary, and distribute to the States, and upon request to medical colleges, physicians, and other health professionals, appropriate educational materials (including short courses) on the medical surveillance, screening, and methods of diagnosis and treatment of injury or disease related to exposure to hazardous substances (giving priority to those listed in paragraph (2)), through such means as the Administrator of ATSDR deems appropriate.

(15) The activities of the Administrator of ATSDR described in this subsection and section 9611(c)(4) of this title shall be carried out by the Administrator of ATSDR, either directly or through cooperative agreements with States (or political subdivisions thereof) which the Administrator of ATSDR determines are capable of carrying out such activities. Such activities shall include provision of consultations on health information, the conduct of health assessments, including those required under section 3019(b) of the Solid Waste Disposal Act [42 U.S.C. 6939a(b)], health studies, registries, and health surveillance.

(16) The President shall provide adequate personnel for ATSDR, which shall not be fewer than 100 employees. For purposes of determining the number of employees under this subsection, an employee employed by ATSDR on a part-time career employment basis shall be counted as a fraction which is determined by dividing 40 hours into the average number of hours of such employee's regularly scheduled workweek.

(17) In accordance with section 9620 of this title (relating to Federal facilities), the Administrator of ATSDR shall have the same authorities under this section with respect to facilities owned or operated by a department, agency, or instrumentality of the United States as the Administrator of ATSDR has with respect to any nongovernmental entity.

(18) If the Administrator of ATSDR determines that it is appropriate for purposes of this section to treat a pollutant or contaminant as a hazardous substance, such pollutant or contaminant shall be treated as a hazardous substance for such purpose.

A2. Public Health Service Act

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 6A—PUBLIC HEALTH SERVICE

[42 U.S.C. 241] and [42 U.S.C. 243]

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.

243 – General grant of authority for cooperation

(a) Enforcement of quarantine regulations; prevention of communicable diseases

The Secretary is authorized to accept from State and local authorities any assistance in the enforcement of quarantine regulations made pursuant to this chapter which such authorities may be able and willing to provide. The Secretary shall also assist States and their political subdivisions in the prevention and suppression of communicable diseases and with respect to other public health matters, shall cooperate with and aid State and local authorities in the enforcement of their quarantine and other health regulations, and shall advise the several States on matters relating to the preservation and improvement of the public health.

(b) Comprehensive and continuing planning; training of personnel for State and local health work; fees

The Secretary shall encourage cooperative activities between the States with respect to comprehensive and continuing planning as to their current and future health needs, the establishment and maintenance of adequate public health services, and otherwise carrying out public health activities. The Secretary is also authorized to train personnel for State and local health work. The Secretary may charge only private entities reasonable fees for the training of their personnel under the preceding sentence.

(c)Development of plan to control epidemics and meet emergencies or problems resulting from disasters; cooperative planning; temporary assistance; reimbursement of United States

(1)The Secretary is authorized to develop (and may take such action as may be necessary to implement) a plan under which personnel, equipment, medical supplies, and other resources of the Service and other agencies under the jurisdiction of the Secretary may be effectively used to control epidemics of any disease or condition and to meet other health emergencies or problems. The Secretary may enter into agreements providing for the cooperative planning between the Service and public and private community health programs and agencies to cope with health problems (including epidemics and health emergencies).

(2)The Secretary may, at the request of the appropriate State or local authority, extend temporary (not in excess of six months) assistance to States or localities in meeting health emergencies of such a nature as to warrant Federal assistance. The Secretary may require such reimbursement of the United States for assistance provided under this paragraph as he may determine to be reasonable under the circumstances. Any reimbursement so paid shall be credited to the applicable appropriation for the Service for the year in which such reimbursement is received.