Request for Generic Clearance for Cognitive Interviews and Focus Groups for the PATH Study (NIDA)
A
Attachment 1
NIDA's Data Collection
Authority



1980—Subsec. (a). Pub. L. 96-180, § 16(a), substituted: in first sentence "biomedical, behavioral, and social is- sues related to alcoholism and alcohol abuse" for "al-cohol problems"; in par. (1)(B) "facilities (including laboratory, reference, and data analysis facilities) to carry out the research plan contained in the applica- tion" for "laboratory facilities and reference services (including reference services that will afford access to scientific alcohol literature)"; and in par. (1) (E) "medi- cal and osteopathic, nursing, social work, and other specialized graduate students; and" for "medical and osteopathic students and physicians;", and added par. (1) (F).

Subsec. (b). Pub. L. 96-180, § 16(b), increased annual grant limitation to \$1,500,000 from \$1,000,000.

Subsec. (c). Pub. L. 96-180, § 16(c), authorized appro- priation of \$8,000,000 and \$9,000,000 for fiscal years end- ing Sept. 30, 1980, and 1981.

1978—Subsec. (a). Pub. L. 95-622 inserted provision following par. (2) relating to approval of applications under this subsection by the Secretary in a manner which results in equitable geographic distribution of Centers.

### EFFECTIVE DATE OF 1992 AMENDMENTS

Amendment by Pub. L. 102-352 effective immediately upon effectuation of amendment made by Pub. L. 102-321, see section 3(1) of Pub. L. 102-352, set out as a note under section 285n of this title.

Amendment by Pub. L. 102-321 effective Oct. 1, 1992, with provision for programs providing financial assist- ance, see section 801(c), (d) of Pub. L. 102-321, set out as a note under section 236 of this title.

SUBPART 15—NATIONAL INSTITUTE ON DRUG ABUSE

### § 2850. Purpose of Institute

### (a) In general

The general purpose of the National Institute on Drug Abuse (hereafter in this subpart referred to as the "Institute") is the conduct and support of biomedical and behavioral research, health services research, research training, and health information dissemination with respect to the prevention of drug abuse and the treat- ment of drug abusers.

### (b) Research program

The research program established under this subpart shall encompass the social, behavioral, and biomedical etiology, mental and physical health consequences, and social and economic consequences of drug abuse. In carrying out the program, the Director of the Institute shall give special consideration to projects relating to drug abuse among women (particularly with re-spect to pregnant women).

### (c) Collaboration

The Director of the Institute shall collaborate with the Substance Abuse and Mental Health Services Administration in focusing the services research activities of the Institute and in dis- seminating the results of such research to health professionals and the general public.

(July 1, 1944, ch. 373, title IV, § 464L, as added Pub. L. 102-321, title I, § 123(a), July 10, 1992, 106
Stat. 360; amended Pub. L. 102-352, § 2(a)(3), Aug. 26, 1992, 106 Stat. 938; Pub. L. 109-482, title I, § 103(b)(33), Jan. 15, 2007, 120 Stat. 3688.)

#### **A**MENDMENTS

2007—Subsec. (d). Pub. L. 109-482 struck out subsec.

1992—Subsec. (d)(1). Pub. L. 102-352 inserted "other than section 2850-4 of this title," after "this subpart,".

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102-352 effective immediately upon effectuation of amendment made by Pub. L. 102-321, see section 3(1) of Pub. L. 102-352, set out as a note under section 285n of this title.

### **EFFECTIVE DATE**

Section effective Oct. 1, 1992, with provision for pro- grams providing financial assistance, see

section 801(c), (d) of Pub. L. 102-321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

### § 2850-1. Associate Director for Prevention (a) In general

There shall be in the Institute an Associate Director for Prevention who shall for the responsible full-time coordination and promotion of the programs in the Institute concerning the prevention of drug abuse. The Associate Direc- tor shall be appointed by the Director of the In- stitute from individuals because of their professional training or expertise are experts in drug abuse and the prevention of such abuse.

### (b) Report

The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section 284b 1 of this title a description of the prevention activities of the Institute, in-cluding a description of the staff and resources

(d) which related to authorization of appropriations

and allocation for health

services research.

allocated to those activities. (July 1, 1944, ch. 373, title IV, § 464M, as added Pub. L. 102-321, title I, § 123(b), July 10, 1992, 106 Stat. 361.)

### REFERENCES IN TEXT

Section 284b of this title, referred to in subsec. (b), was repealed by Pub. L. 109-482, title I, § 104(b)(1)(C), Jan. 15, 2007, 120 Stat. 3693.

### EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for pro-grams providing provision financial assistance, see section 801(c), (d) of Pub. L. 102-321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

## § 2850-2. Drug Abuse Research Centers (a) Authority

The Director of the Institute may designate National Drug Abuse Research Centers for the purpose interdisciplinary of research relating to drug abuse and other biomedical, behavioral, and social issues related to drug abuse. No en- tity may be designated as a Center unless an ap- plication therefore has been submitted to, and approved by, the Secretary. Such an application shall be submitted in such manner and contain such information as the Secretary may reason- ably require. The Secretary may not approve such an application unless

(1) the application contains or is supported by reasonable assurances that-

<sup>1</sup> See References in Text note below.

the (A) the applicant has (A) the applicant has the experience, or ca- pability, to conduct, through biomedical, besocial, and related disciplines, long-term research on drug abuse and to pro- vide coordination of such research among such disciplines;

(B) the applicant has available to it suffi-

facilities cient (includina laboratory, ref- erence, and data analysis facilities) to carry out the research plan contained in the appli- cation;

(C) the applicant has facilities and person-

nel to provide training in the prevention and treatment of drug abuse;

(D) the the applicant capacity to train has predoctoral and postdoctoral students for careers in research on drug abuse;

applicant (E) the has the capacity to con-

duct courses on drug abuse problems and re- search on drug abuse for undergraduate and graduate students, and medical and osteo-pathic, nursing, social work, and other spe-cialized graduate students; and

the applicant capacity to con-(F) the has

duct programs of continuing education in such medical, legal, and social service fields as the Secretary may require.1

(2) the application contains a detailed five- year plan for research relating to drug abuse.

### (b) Grants

The Director of the Institute shall, under such conditions as the Secretary may reasonably require, make annual grants to Centers which have been designated under this section. No funds provided under a grant under this sub- section may be used for the purchase of any land or the purchase, construction, preservation, or repair of any building. For the purposes of the preceding sentence, the term "construction" has the meaning given that term by section 292a(1) 2 of this title.

## (c) Drug abuse and addiction research

### (1) Grants or cooperative agreements

The Director of the Institute may make grants or enter cooperative agreements expand the current and ongoing interdiscipli- nary research and clinical trials with treat- ment centers of the National Drug Abuse Treatment Clinical Trials Network relating to drug abuse and addiction, including related biomedical, behavioral, and social issues.

### (2) Use of funds

Amounts made available under a grant or cooperative agreement under paragraph (1) for drug abuse and addiction may be used

for re- search and clinical trials relating to-(A) the effects of drug abuse on the human

body, including the brain;

- the addictive nature of drugs and how such effects differ with respect to different individuals;
  - (C) the connection between drug abuse and

mental health;

(D) the identification and evaluation of the most effective methods of prevention of drug abuse and addiction;

<sup>1</sup> So in original. The period probably should be "; and".

<sup>2</sup> See References in Text note below.

(E) the identification and development of the most effective methods of treatment of drug addiction, including pharmacological treatments;

(F) risk factors for drug abuse;

(G) effects of drug abuse and addiction on pregnant women and their fetuses; and

(H) cultural, social, behavioral, neuro-

logical, and psychological reasons that indi- viduals abuse drugs, or refrain from abusing drugs.

### (3) Research results

The Director shall promptly disseminate re- search results under this subsection to Federal, State, and local entities involved in com- bating drug abuse and addiction.

(July 1, 1944, ch. 373, title IV, § 464N, as added Pub. L. 102-321, title I, § 123(b), July 10, 1992, 106 Stat. 361; amended Pub. L. 102-352, § 2(a)(4), Aug. 26, 1992, 106 Stat. 938; Pub. L. 106-310, div. B, title XXXVI, § 3631, Oct. 17, 2000, 114 Stat. 1235; Pub. L. 107-273, div. B, title II, § 2203, Nov.

L. 107-273, div. B, title II, § 2203, Nov. 2, 2002, 116 Stat. 1794; Pub. L. 109-482, title I, § 103(b)(34), Jan. 15, 2007, 120 Stat. 3688.)

### REFERENCES IN TEXT

Section 292a of this title, referred to in subsec. (b), was in the original a reference to section 701 of act July 1, 1944. Section 701 of that Act was omitted in the gen- eral revision of subchapter V of this chapter by Pub. L. 102-408, title I, § 102, Oct. 13, 1992, 106 Stat. 1994. Pub. L. 102-408 enacted a new section 701 of act July 1, 1944, re- lating to statement of purpose, and a new section 702, relating to scope and duration of loan insurance pro- gram, which are classified to sections 292 and 292a, respectively, of this title. For provisions relating to defi- nitions, see sections 2920 and 295p of this title.

### AMENDMENTS

2007—Subsec. (c)(4). Pub. L. 109-482 struck out par. (4) which authorized appropriations and provided they were supplemental to other funding of research on drug abuse.

2002—Subsec. (c). Pub. L. 107-273 amended heading and text of subsec. (c) generally, substituting provisions relating to grants or cooperative agreements for research and clinical trials relating to drug abuse and addiction for similar provisions relating to grants or cooperative agreements for research and clinical trials relating to methamphetamine abuse and addiction.

2000—Subsec. (c). Pub. L. 106-310 added subsec. (c). 1992—Subsec. (b). Pub. L. 102-352 substituted "292a(1)" for "292a(2)".

### EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

# EFFECTIVE DATE OF 1992 AMENDMENT

immediately upon effectuation of amendment made by Pub. L. 102-321, see section 3(1) of Pub. L. 102-352, set out as a note under section 285n of this title.

### EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for pro- grams providing financial assistance, see section 801(c), (d) of Pub. L. 102-321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

### § 285o-3. Office on AIDS

The Director of the Institute shall establish within the Institute an Office on AIDS. The Of-

fice shall be responsible for the coordination of research and determining the direction of the Institute with respect to AIDS research related to—

(1) primary prevention of the spread of HIV, including transmission via drug abuse;

(2) drug abuse services research; and

(3) other matters determined appropriate by the Director.

(July 1, 1944, ch. 373, title IV, § 4640, as added Pub. L. 102-321, title I, § 123(b), July 10, 1992, 106 Stat. 362.)

### EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for pro- grams providing financial assistance, see section 801(c), (d) of Pub. L. 102-321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

## STUDY BY NATIONAL ACADEMY OF SCIENCES

Section 706 of Pub. L. 102-321 directed Secretary of Health and Human Services to contract for a study or studies relating to programs that provide both sterile hypodermic needles and bleach to individuals in order to reduce the risk of contracting acquired immune defi- ciency syndrome or related conditions, in order to de- termine extent to which such programs promote the abuse of drugs or otherwise altered any behaviors constituting a substantial risk of contracting AIDS or hepatitus, or of transmitting such conditions, and fur- ther directed Secretary to ensure that a report is submitted to Congress on the results of this study not later than 18 months after July 10, 1992.

# § 2850-4. Medication Development Program (a) Establishment

There is established in the Institute a Medica- tion Development Program through which the Director of such Institute shall—

(1) conduct periodic meetings with the Com- missioner of Food and Drugs to discuss meas- ures that may facilitate the approval process of drug abuse treatments;

(2) encourage and promote (through grants, contracts, international collaboration, or otherwise) expanded research programs, inves- tigations, experiments, community trials, and studies, into the development and use of medi- cations to treat drug addiction;

(3) establish or provide for the establishment of research

(4) report on the activities of other relevant agencies relating to the development and use of pharmacotherapeutic treatments for drug addiction;

(5) collect, analyze, and disseminate data useful in the development and use of pharmacotherapeutic treatments for drug ad- diction and collect, catalog, analyze, and dis-

seminate through international channels, the results of such research;

(6) directly or through grants, contracts, or cooperative agreements, support training in the fundamental sciences and clinical dis- ciplines related to the pharmacotherapeutic treatment of drug abuse, including the use of training stipends, fellowships, and awards where appropriate; and

(7) coordinate the activities conducted under this section with related activities conducted

of Mental Health, and other appropriate insti- tutes and shall consult with the Directors of such Institutes.

### (b) Duties

In carrying out the activities described in sub-section (a) of this section, the Director of the Institute—

(1) shall collect and disseminate through publications and other appropriate means, information pertaining to the research and other activities under this section;

(2) shall make grants to or enter into con-

tracts and cooperative agreements with indi-viduals and public and private entities to fur-ther the goals of the program;

(3) may, in accordance with section 289e of

this title, and in consultation with the Na- tional Advisory Council on Drug Abuse, acquire, construct, improve, repair, operate, and maintain pharmacotherapeutic research cen- ters, laboratories, and other necessary facili- ties and equipment, and such other real or per- sonal property as the Director determines nec- essary, and may, in consultation with such Advisory Council, make grants for the con-struction or renovation of facilities to carry out the purposes of this section;

(4) may accept voluntary and uncompensated services;

(5) may accept gifts, or donations of serv- ices, money, or property, real, personal, or

within the National Institute on Abuse and Alcoholism, the National Institute mixed, tangible or intangible; and (6) shall take necessary action to ensure

that all channels for the dissemination and ex- change of scientific knowledge and information are maintained between the Institute and the other scientific, medical, and biomedical disciplines and organizations nationally and internationally.

### (c) Report

### (1) In general

Not later than December 31, 1992, and each December 31 thereafter, the Director of the Institute shall submit to the Office of National Drug Control Policy established under section 1501 <sup>1</sup> of title 21 a report, in accordance with paragraph (3), that describes the objectives and activities of the program assisted under this section.

### (2) National Drug Control Strategy

The Director of National Drug Control Pol- icy shall incorporate, by reference or other- wise, each report submitted under this subsection in the National Drug Control Strategy submitted the following February 1 under section 1504  $^{\rm 1}$  of title 21.

### (d) "Pharmacotherapeutics" defined

For purposes of this section, the term "pharmacotherapeutics" means medications used to treat the symptoms and disease of drug abuse, including medications to—

(1) block the effects of abused drugs;

(2) reduce the craving for abused drugs;

(3) moderate or eliminate

withdrawal symp- toms;
(4) block or reverse the toxic effect of abused

drugs; or Alcohol

See References in Text note below.

(5) prevent relapse in persons who have been detoxified from drugs of abuse.

(July 1, 1944, ch. 373, title IV, § 464P, as added Pub. L. 102-321, title I, § 123(b), July 10, 1992, 106
Stat. 362; amended Pub. L. 103-43,

title XX, § 2008(b)(10), June 10, 1993, 107 Stat. 211; Pub. L.

109-482, title I, § 103(b)(35), Jan. 15, 2007, 120 Stat.

3688.)

### REFERENCES IN TEXT

Sections 1501 and 1504 of title 21, referred to in subsec. (c), were repealed by Pub. L. 100-690, title I, § 1009, Nov. 18, 1988, 102 Stat. 4188, as amended.

#### AMENDMENTS

2007—Subsec. (e). Pub. L. 109-482 struck out heading and text of subsec. (e). Text read as follows: "For the purpose of carrying out this section, there are author-ized to be appropriated \$85,000,000 for fiscal year 1993, and \$95,000,000 for fiscal year 1994." 1993—Subsec. (b)(6). Pub. L. 103-43 substituted "Institute" for "Administration".

### EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of this title.

### EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for pro- grams providing financial assistance, see section 801(c), (d) of Pub. L. 102-321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

### REPORT BY INSTITUTE ON MEDICINE

Section 701 of Pub. L. 102-321 directed Secretary of Health and Human Services to enter into a contract with a public or nonprofit private entity to conduct a study concerning (1) role of the private sector in devel- opment of anti-addiction medications, including legis- lative proposals designed to encourage private sector development of such medications, (2) process by which anti-addiction medications receive marketing approval from Food and Drug Administration, including an as- sessment of feasibility of expediting marketing ap- proval process in a manner consistent with maintaining safety and effectiveness of such medications, (3) with respect to pharmacotherapeutic treatments for drug addition. addiction (A) recommendations respect to a national strategy developing such treatments with and improvements in such strategy, (B) state of the sci- entific knowledge concerning such treatments, and (C) assessment of progress toward development of safe, effective pharmacological treatments for fective pharmacological treatments for drug addiction, and (4) other related information determined appro- priate by the authors of the study, and to submit to Congress a report of the results of such study not later than 18 months after July 10. 1992.

# SUBPART 16—NATIONAL INSTITUTE OF MENTAL HEALTH

# § 285p. Purpose of Institute (a) In general

The general purpose of the National Institute of Mental Health (hereafter in this subpart re- ferred

to as the "Institute") is the conduct and support of biomedical and behavioral research, health services research, research training, and health information dissemination with respect to the cause, diagnosis, treatment, control and prevention of mental illness.

### (b) Research program

The research program established under this subpart shall include support for biomedical and

behavioral neuroscience and shall be designed to further the treatment and prevention of mental illness, the promotion of mental health, and the study of the psychological, social and legal fac- tors that influence behavior.

### (c) Collaboration

The Director of the Institute shall collaborate with the Administrator of the Substance Abuse and Mental Health Services Administration in focusing the services research activities of the Institute and in disseminating the results of such research to health professionals and the general public.

## (d) Information with respect to suicide

### (1)In general

The Director of the Institute shall

(A) develop and publish information with respect to the causes of suicide and the means of preventing suicide; and

(B) make such information generally available to the public and to health profes- sionals.

### (2) Youth suicide

Information described in paragraph (1) shall especially relate to suicide among individuals under 24 years of age.

# (e) Associate Director for Special Populations (1) In general

The Director of the Institute shall designate an Associate Director for Special Populations.

### (2) Duties

The Associate Director for Special Popu- lations shall—

(A) develop and coordinate research poli-

cies and programs to assure increased em- phasis on the mental health needs of women and minority populations:

and minority populations;
(B) support programs of basic and applied

social and behavioral research on the mental health problems of women and minority populations;

(C) study the effects of discrimination on

institutions and individuals, including ma- jority institutions and individuals;

(D) support and develor research designed

to eliminate institutional discrimination; and

(E) provide increased emphasis on the con-

cerns of women and minority populations in training programs, service delivery programs, and research endeavors of the Insti- tute.

(July 1, 1944, ch. 373, title IV, § 464R, as added Pub. L. 102-321, title I, § 124(a), July 10, 1992, 106 Stat. 364; amended Pub. L. 102-352, § 2(a)(5), Aug. 26, 1992, 106 Stat. 938; Pub. L. 109-482, title I, § 103(b)(36), Jan. 15, 2007, 120 Stat. 3688.)

### **A**MENDMENTS

2007—Subsec. (f). Pub. L. 109-482 struck out subsec. (f) which authorized appropriations and provided that at least 15% of the appropriated amounts were to carry out health services research relating to mental health. 1992—Subsec. (f)(1). Pub. L. 102-352 struck out "other than section 2850-4 of this title" after "this subpart".

## EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or