pose is to evaluate the safety or effectiveness of a drug, medical device, or treatment and for which such entity is receiving assistance from the Secretary.

(c) Identifying and reporting to Secretary

The Secretary shall by regulation require that each entity described in subsection (a) that applies for assistance under this chapter for any project described in subsection (b) submit in or with its application for such assistance—

(1) assurances satisfactory to the Secretary that such entity has established and has in effect an administrative process under subsection (a) to identify financial interests (as defined under subsection (a)) that exist regarding the project; and

(2) an agreement that the entity will report to the Secretary such interests identified by the entity and how any such interests identified by the entity will be managed or eliminated in order that the project in question will be protected from bias that may stem from such interests; and

(3) an agreement that the entity will comply with regulations issued under this section.

(d) Monitoring of process

The Secretary shall monitor the establishment and conduct of the administrative process established by an entity pursuant to subsection (a).

(e) Response

In any case in which the Secretary determines that an entity has failed to comply with subsection (c) regarding a project of research described in subsection (b), the Secretary—

(1) shall require that, as a condition of receiving assistance, the entity disclose the existence of a financial interest (as defined under subsection (a)) in each public presentation of the results of such project; and

(2) may take such other actions as the Secretary determines to be appropriate.

(f) Definitions

For purposes of this section:

(1) The term ''financial interest'' includes the receipt of consulting fees or honoraria and the ownership of stock or equity.

(2) The term ''assistance'', with respect to conducting a project of research, means a grant, contract, or cooperative agreement.

(July 1, 1944, ch. 373, title IV, § 493A, as added Pub. L. 103–43, title I, § 164, June 10, 1993, 107 Stat. 142.)

REGULATIONS

Final rule for regulations required in this section to be issued not later than 180 days after June 10, 1993, see section 165 of Pub. L. 103–43, set out as a note under section 289b of this title.

§ 289c. Research on public health emergencies

If the Secretary determines, after consultation with the Director of NIH, the Commissioner of the Food and Drug Administration, or the Director of the Centers for Disease Control and Prevention, that a disease or disorder constitutes a public health emergency, the Secretary, acting through the Director of NIH—

(1) shall expedite the review by advisory councils under section 284a of this title and by peer review groups under section 289a of this title of applications for grants for research on such disease or disorder or proposals for contracts for such research;

(2) shall exercise the authority in section 6101 of title 41 respecting public exigencies to waive the advertising requirements of such section in the case of proposals for contracts for such research;

(3) may provide administrative supplemental increases in existing grants and contracts to support new research relevant to such disease or disorder; and

(4) shall disseminate, to health professionals and the public, information on the cause, prevention, and treatment of such disease or disorder that has been developed in research assisted under this section.

The amount of an increase in a grant or contract provided under paragraph (3) may not exceed one-half the original amount of the grant or contract.

(July 1, 1944, ch. 373, title IV, § 494, as added Pub. L. 99–158, § 2, Nov. 20, 1985, 99 Stat. 875; amended Pub. L. 102–531, title III, § 312(d)(9), Oct. 27, 1992, 106 Stat. 3504; Pub. L. 109–482, title I, § 104(b)(1)(P), Jan. 15, 2007, 120 Stat. 3693.)

CODIFICATION

In par. (2), ''section 6101 of title 41'' substituted for ''section 3709 of the Revised Statutes (41 U.S.C. 5)'' on authority of Pub. L. 111–350, § 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

AMENDMENTS

2007—Pub. L. 109–482 struck out subsec. (a) designation before ''If the Secretary'' and subsec. (b) which read as follows: ''Not later than 90 days after the end of a fiscal year, the Secretary shall report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate on actions taken under subsection (a) of this section in such fiscal year.''

1992—Subsec. (a). Pub. L. 102–531 substituted ''Centers for Disease Control and Prevention'' for ''Centers for Disease Control''.

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.

§ 289c–1. Collaborative use of certain health services research funds

The Secretary shall ensure that amounts made available under subparts 14, 15 and 16 of part C for health services research relating to alcohol abuse and alcoholism, drug abuse and mental health be used collaboratively, as appropriate, and in consultation with the Agency for Healthcare Research and Quality.

(July 1, 1944, ch. 373, title IV, § 494A, as added Pub. L. 102–321, title I, § 125, July 10, 1992, 106 Stat. 366; amended Pub. L. 103–43, title XX, § 2016(c), June 10, 1993, 107 Stat. 218; Pub. L. 104–66, title I, § 1062(b), Dec. 21, 1995, 109 Stat. 720; Pub. L. 105–362, title VI, § 601(a)(1)(F), Nov. 10, 1998, 112 Stat. 3285; Pub. L. 106–129, § 2(b)(2), Dec. 6, 1999, 113 Stat. 1670.)