

§ 1316.23

investigative or law enforcement personnel of the Drug Enforcement Administration.

[54 FR 31670, Aug. 1, 1989]

§ 1316.23 Confidentiality of identity of research subjects.

(a) Any person conducting a bona fide research project directly related to the enforcement of the laws under the jurisdiction of the Attorney General concerning drugs or other substances which are or may be subject to control under the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801) who intends to maintain the confidentiality of the identity of those persons who are the subjects of such research may petition the Administrator of the Drug Enforcement Administration for a grant of confidentiality: *Providing, That:*

(1) The Attorney General is authorized to carry out such research under the provisions of Section 502(a) (2-6) of the Controlled Substances Act of 1970 (21 U.S.C. 872(a) (2-6)); and the research is being conducted with funds provided in whole or part by the Department of Justice; or

(2) The research is of a nature that the Attorney General would be authorized to carry out under the provisions of Section 502(a) (2-6) of the Controlled Substances Act (21 U.S.C. 872(a) (2-6), and is being conducted with funds provided from sources outside the Department of Justice.

(b) All petitions for Grants of Confidentiality shall be addressed to the Administrator, Drug Enforcement Administration (see the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address):

(1) A statement as to whether the research protocol requires the manufacture, production, import, export, distribution, dispensing, administration, or possession of controlled substances, and if so the researcher's registration number or a statement that an application for such registration has been submitted to DEA;

(2) The location of the research project;

(3) The qualifications of the principal investigator;

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(4) A general description of the research or a copy of the research protocol;

(5) The source of funding for the research project;

(6) A statement as to the risks posed to the research subjects by the research procedures and what protection will be afforded to the research subjects;

(7) A statement as to the risks posed to society in general by the research procedures and what measures will be taken to protect the interests of society;

(8) A specific request to withhold the names and/or any other identifying characteristics of the research subjects; and

(9) Statements establishing that a grant of confidentiality is necessary to the successful completion of the research project.

(c) The grant of confidentiality of identity of research subjects shall consist of a letter issued by the Administrator, which shall include:

(1) The researcher's name and address.

(2) The researcher's registration number, if applicable.

(3) The title and purpose of the research.

(4) The location of the research project.

(5) An authorization for all persons engaged in the research to withhold the names and identifying characteristics of persons who are the subjects of such research, stating that persons who obtain this authorization may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding to identify the subjects of such research for which this authorization was obtained.

(6) The limits of this authorization, if any.

(7) A statement to the effect that the grant of confidentiality of identity of research subjects shall be perpetual but shall pertain only to the subjects of the research described in the research protocol, the description of the research submitted to DEA, or as otherwise established by DEA.

(d) Within 30 days of the date of completion of the research project, the researcher shall so notify the Administrator. The Administrator shall issue another letter including the information required in paragraph (c) of this section and stating the starting and finishing dates of the research for which the confidentiality of identity of research subjects was granted; upon receipt of this letter, the research shall return the original letter of exemption.

[42 FR 54946, Oct. 12, 1977. Redesignated at 54 FR 31670, Aug. 1, 1989, as amended at 62 FR 13970, Mar. 24, 1997; 75 FR 10685, Mar. 9, 2010]

§ 1316.24 Exemption from prosecution for researchers.

(a) Upon registration of an individual to engage in research in controlled substances under the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801), the Administrator of the Drug Enforcement Administration, on his own motion or upon request in writing from the Secretary or from the researcher or researching practitioner, may exempt the registrant when acting within the scope of his registration, from prosecution under Federal, State, or local laws for offenses relating to possession, distribution or dispensing of those controlled substances within the scope of his exemption. However, this exemption does not diminish any requirement of compliance with the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301).

(b) All petitions for Grants of Exemption from Prosecution for the Researcher shall be addressed to the Administrator, Drug Enforcement Administration, (see the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address) and shall contain the following:

- (1) The researcher's registration number if any, for the project;
- (2) The location of the research project;
- (3) The qualifications of the principal investigator;
- (4) A general description of the research or a copy of the research protocol;
- (5) The source of funding for the research project;
- (6) A statement as to the risks posed to the research subjects by the re-

search procedures and what protection will be afforded to the research subjects;

(7) A statement as to the risks posed to society in general by the research procedures and what measures will be taken to protect the interests of society;

(8) A specific request for exemption from prosecution by Federal, State, or local authorities for offenses related to the possession, distribution, and dispensing of controlled substances in accord with the procedures described in the research protocol;

(9) A statement establishing that a grant of exemption from prosecution is necessary to the successful completion of the research project.

(c) Any researcher or practitioner proposing to engage in research requesting both exemption from prosecution and confidentiality of identity of research subjects may submit a single petition incorporating the information required in §§ 1316.23(b) and 1316.24(b).

(d) The exemption shall consist of a letter issued by the Administrator, which shall include:

- (1) The researcher's name and address;
- (2) The researcher's registration number for the research project;
- (3) The location of the research project;
- (4) A concise statement of the scope of the researcher's registration;
- (5) Any limits of the exemption; and
- (6) A statement that the exemption shall apply to all acts done in the scope of the exemption while the exemption is in effect. The exemption shall remain in effect until completion of the research project or until the registration of the researcher is either revoked or suspended or his renewal of registration is denied. However, the protection afforded by the grant of exemption from prosecution during the research period shall be perpetual.

(e) Within 30 days of the date of completion of the research project, the researcher shall so notify the Administrator. The Administrator shall issue another letter including the information required in paragraph (d) of this section and stating the date of which the period of exemption concluded;