

§ 2a.4

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request DHHS grant or contract assistance in order to apply for a Confidentiality Certificate. If a person has previously submitted any information required in this part in connection with a DHHS grant or contract, he or she may substitute a copy of information thus submitted, if the information is current and accurate. If a person requests a Confidentiality Certificate at the same time he or she submits an application for DHHS grant or contract assistance, the application for a Confidentiality Certificate may refer to the pertinent section(s) of the DHHS grant or contract application which provide(s) the information required to be submitted under this part. (See §§ 2a.4 and 2a.5.)

(d) A separate application is required for each research project for which an authorization of confidentiality is requested.

§ 2a.4 Contents of application; in general.

In addition to any other pertinent information which the Secretary may require, each application for an authorization of confidentiality for a research project shall contain:

(a) The name and address of the individual primarily responsible for the conduct of the research and the sponsor or institution with which he or she is affiliated, if any. Any application from a person affiliated with an institution will be considered only if it contains or is accompanied by documentation of institutional approval. This documentation may consist of a written statement signed by a responsible official of the institution or of a copy of or reference to a valid certification submitted in accordance with 45 CFR part 46.

(b) The location of the research project and a description of the facilities available for conducting the research, including the name and address of any hospital, institution, or clinical laboratory facility to be utilized in connection with the research.

(c) The names, addresses, and summaries of the scientific or other appropriate training and experience of all personnel having major responsibilities in the research project and the training

and experience requirements for major positions not yet filled.

(d) An outline of the research protocol for the project including a clear and concise statement of the purpose and rationale of the research project and the general research methods to be used.

(e) The date on which research will begin or has begun and the estimated date for completion of the project.

(f) A specific request, signed by the individual primarily responsible for the conduct of the research, for authority to withhold the names and other identifying characteristics of the research subjects and the reasons supporting such request.

(g) An assurance (1) From persons making application for a Confidentiality Certificate for a research project for which DHHS grant or contract support is received or sought that they will comply with all the requirements of 45 CFR part 46, “Protection of Human Subjects,” or

(2) From all other persons making application that they will comply with the informed consent requirements of 45 CFR 46.103(c) and document legally effective informed consent in a manner consistent with the principles stated in 45 CFR 46.110, if it is determined by the Secretary, on the basis of information submitted by the person making application, that subjects will be placed at risk. If a modification of paragraphs (a) or (b) of 45 CFR 46.110 is to be used, as permitted under paragraph (c) of that section, the applicant will describe the proposed modification and submit it for approval by the Secretary.

(h) An assurance that if an authorization of confidentiality is given it will not be represented as an endorsement of the research project by the Secretary or used to coerce individuals to participate in the research project.

(i) An assurance that any person who is authorized by the Secretary to protect the privacy of research subjects will use that authority to refuse to disclose identifying characteristics of research subjects in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to compel disclosure of the identifying characteristics of research subjects.

(j) An assurance that all research subjects who participate in the project during the period the Confidentiality Certificate is in effect will be informed that:

(1) A Confidentiality Certificate has been issued;

(2) The persons authorized by the Confidentiality Certificate to protect the identity of research subjects may not be compelled to identify research subjects in any civil, criminal, administrative, legislative, or other proceedings whether Federal, State, or local;

(3) If any of the following conditions exist the Confidentiality Certificate does not authorize any person to which it applies to refuse to reveal identifying information concerning research subjects:

(i) The subject consents in writing to disclosure of identifying information,

(ii) Release is required by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301) or regulations promulgated thereunder (title 21, Code of Federal Regulations), or

(iii) Authorized personnel of DHHS request identifying information for audit or program evaluation of a research project funded by DHHS or for investigation of DHHS grantees or contractors and their employees or agents carrying out such a project. (See § 2a.7(b));

(4) The Confidentiality Certificate does not govern the voluntary disclosure of identifying characteristics of research subjects;

(5) The Confidentiality Certificate does not represent an endorsement of the research project by the Secretary.

(k) An assurance that all research subjects who enter the project after the termination of the Confidentiality Certificate will be informed that the authorization of confidentiality has ended and that the persons authorized to protect the identity of research subjects by the Confidentiality Certificate may not rely on the Certificate to refuse to disclose identifying characteristics of research subjects who were not participants in the project during the period the Certificate was in effect. (See § 2a.8(c)).

§ 2a.5 Contents of application; research projects in which drugs will be administered.

(a) In addition to the information required by § 2a.4 and any other pertinent information which the Secretary may require, each application for an authorization of confidentiality for a research project which involves the administering of a drug shall contain:

(1) Identification of the drugs to be administered in the research project and a description of the methods for such administration, which shall include a statement of the dosages to be administered to the research subjects;

(2) Evidence that individuals who administer drugs are authorized to do so under applicable Federal and State law; and

(3) In the case of a controlled drug, a copy of the Drug Enforcement Administration Certificate of Registration (BND Form 223) under which the research project will be conducted.

(b) An application for an authorization of confidentiality with respect to a research project which involves the administering of a controlled drug may include a request for exemption of persons engaged in the research from State or Federal prosecution for possession, distribution, and dispensing of controlled drugs as authorized under section 502(d) of the Controlled Substances Act (21 U.S.C. 872(d)) and 21 CFR 1316.22. If the request is in such form, and is supported by such information, as is required by 21 CFR 1316.22, the Secretary will forward it, together with his or her recommendation that such request be approved or disapproved, for the consideration of the Administrator of the Drug Enforcement Administration.

§ 2a.6 Issuance of Confidentiality Certificates; single project limitation.

(a) In reviewing the information provided in the application for a Confidentiality Certificate, the Secretary will take into account:

(1) The scientific or other appropriate training and experience of all personnel having major responsibilities in the research project;

(2) Whether the project constitutes bona fide "research" which is within