

**REGISTRATION
RECORDS**

Wednesday,
April 4, 1979

Part VII

**Department of
Health, Education,
and Welfare**

Public Health Service

Protection of Identity—Research Subjects

**DEPARTMENT OF HEALTH,
EDUCATION, AND WELFARE**

Public Health Service

42 CFR Part 2a

**Protection of Identity—Research
Subjects**

AGENCY: Public Health Service, HEW.

ACTION: Final regulations.

SUMMARY: These final regulations set forth procedures under which persons engaged in research on mental health, including research on the use and effect of alcohol and other psychoactive drugs, may apply for an authorization under section 303(a) of the Public Health Service Act, as amended by Public Law 93-282 (42 U.S.C. 242a(a)). Such an authorization affords the person to whom it is given a privilege to protect the privacy of research subjects by withholding the names or other identifying characteristics of such research subjects from all persons not connected with the conduct of the research. Persons so authorized may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.

EFFECTIVE DATE: April 4, 1979.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: On December 4, 1975, the Department published in the **Federal Register** (40 FR 56692) a notice of proposed rulemaking setting forth a new Part 2a of Title 42 of the Code of Federal Regulations, entitled "Protection of Identity—Research Subjects." Interested persons were invited to submit written comments, suggestions, or objections regarding the proposed regulations within 45 days of the date of publication of that notice. All comments so submitted were carefully reviewed and considered.

Discussion of Major Comments

Federal Role Too Elaborate and Restrictive

Several of the 15 respondents considered the proposed Federal Role in issuing Confidentiality Certificates to be unnecessarily elaborate and cumbersome. Some commenters asserted that the information required of

an applicant is supportive of a qualitative review going to the merits of the research, inappropriately casting the Federal Government in the role of censor. Others noted that information requirements duplicated material already submitted by recipients of Federal grant and contract support in the course of applying for that grant or contract support.

Accordingly, the final rules have been amended to simplify the Secretary's criteria for issuing a Confidentiality Certificate. The Secretary will not be required to specifically consider, as required by the proposed rules, the soundness of the purposes and methods of the research project nor the suitability for use in the research project of the proposed subject population and the protections to be afforded to the subjects (§ 2a.6(a)). Nor must the Secretary make a determination that a decision is warranted to allow subjects at risk to accept that risk (§ 2a.4(g)(2)). (Proposed rules required such a determination in the case of a person requesting a Confidentiality Certificate for a research project for which DHEW grant or contract support has not been sought or received.) Rather, final regulations require, among other items which remain as proposed, that the Secretary determine whether the project constitutes bona fide research which is within the scope of these regulations (§ 2a.6(a)).

The process of making application, too, has been made easier (1) by eliminating the requirement for material not germane to the simplified criteria for issuance, e.g., requested information on methodology is less detailed (§ 2a.4(d)), (2) by consolidating into a single provision procedures regarding coordination among the Institutes and with other Federal agencies (§ 2a.3(b)), and (3) by providing for use of previously or concurrently submitted material if the applicant is the recipient of DHEW grant or contract support (§ 2a.3(c)).

Mandatory Use vs. Disclosure to Subjects

Some respondents stated that the recipient of a Confidentiality Certificate should be required to provide an assurance that the authorization will be used to protect the identity of research subjects or, in the alternative, that the recipient of a Confidentiality Certificate provide assurance that research subjects will be informed of the extent to which a Confidentiality Certificate will protect their identity. Both of these approaches have been adopted in the final rules.

Any person making application for an authorization of confidentiality must assure the Secretary that he or she will use the authority to refuse to disclose identifying characteristics of research subjects in any proceedings to compel disclosure (§ 2a.4(i)).

Applicants must also assure that detailed information concerning the existence, effect, and limits of a Confidentiality Certificate will be furnished to research subjects who participate during the period a Certificate is in effect (§ 2a.4(j)). Subjects who enter a project after termination of a Certificate must be informed that the authorization has ended and the effect of termination (§ 2a.4(k)).

In addition, the effect of a Confidentiality Certificate has been clarified through a new paragraph (c) of § 2a.1 which distinguishes between the restrictions on voluntary disclosure imposed by 42 CFR Part 2 and these regulations which protect against compulsory disclosure.

Definitions

Two respondents discussed the accuracy of the definition of "identifying characteristics". That definition has been revised, in part, to reflect that any item or combination of data is protected by an authorization of confidentiality only if it could lead directly or indirectly to identification of a research subject (§ 2a.2(g)).

The definition of "research" has also been revised (§ 2a.2(c)) to correspond with the definition of that term in proposed regulations entitled, "Scientific Peer Review of Grant Applications and Contract Projects" which appeared in the **Federal Register** on March 29, 1976 (41 FR 12986).

Medical Welfare Limitation

Three respondents addressed the issue of who should determine, for the purpose of limiting the effective scope of a Confidentiality Certificate, whether a research subject's medical welfare is threatened (§ 2a.7(b)(2) of the proposed regulations).

The medical welfare limitation on the effect of a Confidentiality Certificate has been eliminated. Initially, a decision was made to leave the determination of when a research subject's medical welfare is threatened to the person holding the Certificate (in lieu of more elaborate alternatives aimed at objectivity). Inasmuch as these regulations do not govern voluntary disclosure of identifying characteristics in any case, including a situation which the person holding the Certificate

determines to be threatening to the medical welfare of research subjects, the medical welfare limitation was deemed to have such limited application as to be unwarranted.

Federal Food, Drug, and Cosmetic Act Limitation

Two respondents stated that the citation in § 2a.7(b) to the entire Federal Food, Drug, and Cosmetic Act and implementing regulations is an unnecessarily broad limitation on the scope of a Confidentiality Certificate and it undermines the confidence research subjects may place in the effect of an authorization of confidentiality.

The primary reason for this limitation is to facilitate verification by the Food and Drug Administration of research data on new drugs. (See section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355)). Other sections of the Act also authorize activity which could require access to identifying information. The suggestion that citation to the several pertinent sections of the Act would be more reassuring or informative to research subjects than citation to the whole Act was not supported by persuasive evidence and has not been accepted. Therefore, the recommendation that the Federal Food, Drug, and Cosmetic Act limitation be omitted or made specific to certain sections of the Act has not been adopted.

Discussion of other Changes

Added Limitation

A provision has been added stating that the Certificate may not be relied upon to refuse to reveal identifying information to authorized personnel of DHEW for the purpose of conducting audits or program evaluation for research assisted by a DHEW grant or contract or for investigating DHEW grantees or contractors and their employees or agents (§ 2a.7(b)(2)). DHEW regulations, 45 CFR 5.71, require that any identifying information so obtained be held strictly confidential.

Evidence of Approval

The final regulations (§ 2a.4(a)) retain the requirement in the proposed regulations (§ 2a.4(a)(1)) for identification of the institution (if any) with which the individual primarily responsible for the research is affiliated. In addition, the final regulations (§ 2a.4(a)) require the furnishing of evidence of institutional approval in the event of such an institutional affiliation.

Evidence of institutional approval in a person's application insures that institutional personnel are aware of and

supportive of research as described in the application for an authorization of confidentiality. Review and approval of research at the institutional level also provides the Secretary with evidence to be weighed when determining whether a project is, in fact, bona fide research.

Similarly, in order to insure the support and approval of the person primarily responsible for the conduct of the research, final regulations require that the specific request for an authorization of confidentiality be signed by the individual primarily responsible for the conduct of the research (§ 2a.4(f)).

Statutory Language

That portion of section 303(a) of the Public Health Service Act which authorizes issuance of a Confidentiality Certificate is quoted in its entirety in the first section of the final regulations (§ 2a.1(a)). The proposed regulations quoted only the first sentence, leaving unstated the statutory language describing the privilege to withhold identifying information in proceedings to compel such information which is afforded a person to whom an authorization of confidentiality is granted.

Federal Assistance Not Required

Two respondents were uncertain as to whether Federal grant or contract assistance is necessary to apply for an authorization of confidentiality. In a phrase added to § 2a.1(a) it is made clear that Federal assistance is not necessary in order to apply for a Confidentiality Certificate.

Exceptions

The word "exceptions" has been omitted from the title of § 2a.7 and paragraph (b) of that section. The section title "Effect of Confidentiality Certificate" accurately describes the content of both paragraphs (a) and (b). Paragraph (b) limits the effect of a Confidentiality Certificate in certain circumstances.

Start Date

Paragraph (e) of § 2a.4 has been amended to require that the person making application furnish, in addition to the estimated date for completion, the date on which research will begin or has begun. Paragraph (b)(7) of § 2a.6, relating to the content of Confidentiality Certificates, has been amended so that the Confidentiality Certificate will include the date or event upon which the Certificate becomes effective (which shall not be before the later of the commencement of the research project

or the date of issuance of the Certificate), as well as the date or event upon which the Certificate will expire. These changes have been made to clarify that although a Confidentiality Certificate may be applied for and issued either before or after the research begins, the Certificate cannot become effective until the date of its issuance, if the research project is in progress at the date of issuance or until the commencement of the research project if the Certificate is issued prior to that commencement.

Unfilled Positions

Paragraph (c) of § 2a.4 has been expanded to require that a person making application not only describe the training and experience of all personnel having major responsibilities in the research project but also that the training and experience requirements for major unfilled positions be furnished.

Certificate Is Not Endorsement

The proposed regulations require that a person making application furnish 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 (§ 2a.4(a)(7) of the proposed regulations; § 2a.4(h) of the final regulations). This provision has been strengthened by the addition of a similar statement in the Certificate itself (§ 2a.6(b)(5)) and in the information which must be provided to research subjects who participate while a Confidentiality Certificate is in effect (§ 2a.4(j)(5)).

Consistency

Wherever the term "researcher", "applicant", or "individual" is used in the proposed regulations to denote the person to whom a certificate is issued, that term has been changed to "person" for consistency. "Person" is deemed to be the most meaningful of the terms previously used because it is defined at § 2a.2(b).

Reordering

The sentence in § 2a.1 pertaining to coordination among the National Institute on Drug Abuse, the National Institute of Mental Health and the National Institute on Alcohol Abuse and Alcoholism to insure processing of an application by the most appropriate Institute has been moved to § 2a.3 and is reworded in paragraph (b). Similarly, the paragraph in § 2a.1 which provides for coordination of requests with other authorities which issue authorizations of confidentiality for other types of research has been moved to § 2a.3(b).

Technical and Editorial

There are other changes in the final regulations of a technical nature necessitated, for example, by redesignation of a section in the Code of Federal Regulations and a change of address. Changes of an editorial nature have also been made in the interest of simplicity and clarity.

CONCLUSION

Although the final regulations modify the proposed regulations published on December 4, 1975, the changes generally respond to public comment against intrusive review on the merits of research for the purpose of issuing an authorization of confidentiality. Other changes simplify the process of making application. New statements clarify issues raised by respondents. Additional assurances by researchers provide (1) that the protection available to research subjects through an authorization of confidentiality is asserted for the protection of the research subjects in proceedings to compel disclosure of identifying information and (2) that research subjects are informed specifically of the effects and limits of a Confidentiality Certificate.

Accordingly, 42 CFR is revised by adding a new Part 2a to read as set forth below.

Note.—The Department of Health, Education, and Welfare has determined that this document does not contain a major proposal requiring preparation of an Inflation Impact Statement under Executive Order 11821 and OMB Circular A-107.

Dated: April 5, 1978.

Julius B. Richmond,

Assistant Secretary for Health.

Approved: March 27, 1979.

Joseph A. Califano, Jr.

Secretary.

Subchapter A of Chapter I, Title 42 CFR, is amended by adding a new Part 2a to read as follows:

PART 2a—PROTECTION OF IDENTITY—RESEARCH SUBJECTS

Sec.

2a.1 Applicability.

2a.2 Definitions.

2a.3 Application; coordination.

2a.4 Contents of application; in general.

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

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

2a.7 Effect of Confidentiality Certificate.

2a.8 Termination.

Authority: Sec. 3(a), Pub. L 91-513 as amended by sec. 122(b), Pub. L 93-282; 84 Stat. 1241 (42 U.S.C. 242a(a)), as amended by 88 Stat. 132.

§ 2a.1 Applicability.

(a) Section 303(a) of the Public Health Service Act (42 U.S.C. 242a(a)) provides that “[t]he Secretary [of Health, Education, and Welfare] may authorize persons engaged in research on mental health, including research on the use and effect of alcohol and other psychoactive drugs, to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.” The regulations in this part establish procedures under which any person engaged in research on mental health including research on the use and effect of alcohol and other psychoactive drugs (whether or not the research is federally funded) may, subject to the exceptions set forth in paragraph (b) of this section, apply for such an authorization of confidentiality.

(b) These regulations do not apply to:

(1) Authorizations of confidentiality for research requiring an Investigational New Drug exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) or to approved new drugs, such as methadone, requiring continuation of long-term studies, records, and reports. Attention is called to 21 CFR 291.505(g) relating to authorizations of confidentiality for patient records maintained by methadone treatment programs.

(2) Authorizations of confidentiality for research which are related to law enforcement activities or otherwise within the purview of the Attorney General’s authority to issue authorizations of confidentiality pursuant to section 502(c) of the Controlled Substances Act (21 U.S.C. 872(c)) and 21 CFR 1316.21.

(c) The Secretary’s regulations on confidentiality of alcohol and drug abuse patient records (42 CFR Part 2) and the regulations of this part may, in some instances, concurrently cover the same transaction. As explained in 42 CFR 2.24 and 2.24-1 42 CFR Part 2 restricts voluntary disclosures of information from applicable patient records while a Confidentiality Certificate issued pursuant to the regulations of this part protects a person engaged in applicable research from being compelled to disclose identifying

characteristics of individuals who are the subject of such research.

§ 2a.2 Definitions

(a) “Secretary” means the Secretary of Health, Education, and Welfare and any other officer or employee of the Department of Health, Education, and Welfare to whom the authority involved has been delegated.

(b) “Person” means any individual, corporation, government, or governmental subdivision or agency, business trust, partnership, association, or other legal entity.

(c) “Research” means systematic study directed toward new or fuller knowledge and understanding of the subject studied. The term includes, but is not limited to, behavioral science studies, surveys, evaluations, and clinical investigations.

(d) “Drug” has the meaning given that term by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)).

(e) “Controlled drug” means a drug which is included in schedule I, II, III, IV, or V of Part B of the Controlled Substances Act (21 U.S.C. 811-812).

(f) “Administer” refers to the direct application of a drug to the body of a human research subject, whether such application be by injection, inhalation, ingestion, or any other means, by (1) a qualified person engaged in research (or, in his or her presence, by his or her authorized agent), or (2) a research subject in accordance with instructions of a qualified person engaged in research, whether or not in the presence of a qualified person engaged in research.

(g) “Identifying characteristics” refers to the name, address, any identifying number, fingerprints, voiceprints, photographs or any other item or combination of data about a research subject which could reasonably lead directly or indirectly by reference to other information to identification of that research subject.

(h) “Psychoactive drug” means, in addition to alcohol, any drug which has as its principal action an effect on thought, mood, or behavior.

§ 28.3 Application; coordination.

(a) Any person engaged in (or who intends to engage in) the research to which this part applies, who desires authorization to withhold the names and other identifying characteristics of individuals who are the subject of such research from any person or authority not connected with the conduct of such research may apply to the Office of the Director, National Institute on Drug

Abuse, the Office of the Director, National Institute of Mental Health, or the Office of the Director, National Institute on Alcohol Abuse and Alcoholism, 5600 Fishers Lane, Rockville, Maryland 20857 for an authorization of confidentiality.

(b) If there is uncertainty with regard to which Institute is appropriate or if the research project falls within the purview of more than one Institute, an application need be submitted only to one Institute. Persons who are uncertain with regard to the applicability of these regulations to a particular type of research may apply for an authorization of confidentiality under the regulations of this part to one of the Institutes. Requests which are within the scope of the authorities described in § 2a.1(b) will be forwarded to the appropriate agency for consideration and the person will be advised accordingly.

(c) An application may accompany, precede, or follow the submission of a request for DHEW grant or contract assistance, though it is not necessary to request DHEW 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 DHEW 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 DHEW grant or contract assistance, the application for a Confidentiality Certificate may refer to the pertinent section(s) of the DHEW 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 DHEW 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 DHEW request identifying information for audit or program evaluation of a research project funded by DHEW or for investigation of DHEW 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 the scope of the regulations of this part; and

(3) Such other factors as he or she may consider necessary and appropriate. All applications for Confidentiality Certificates shall be evaluated by the Secretary through such officers and employees of the Department and such experts or consultants engaged for this purpose as he or she determines to be appropriate.

(b) After consideration and evaluation of an application for an authorization of confidentiality, the Secretary will either issue a Confidentiality Certificate or a letter denying a Confidentiality

Certificate, which will set forth the reasons for such denial, or will request additional information from the person making application. The Confidentiality Certificate will include:

(1) The name and address of the person making application:

(2) The name and address of the individual primarily responsible for conducting the research, if such individual is not the person making application:

(3) The location of the research project:

(4) A brief description of the research project;

(5) A statement that the Certificate does not represent an endorsement of the research project by the Secretary:

(6) The Drug Enforcement Administration registration number for the project, if any; and

(7) The date or event upon which the Confidentiality Certificate becomes effective, which shall not be before the later of either the commencement of the research project or the date of issuance of the Certificate, and the date or event upon which the Certificate will expire.

(c) A Confidentiality Certificate is not transferable and is effective only with respect to the names and other identifying characteristics of those individuals who are the subjects of the single research project specified in the Confidentiality Certificate. The recipient of a Confidentiality Certificate shall, within 15 days of any completion or discontinuance of the research project which occurs prior to the expiration date set forth in the Certificate, provide written notification to the Director of the Institute to which application was made. If the recipient determines that the research project will not be completed by the expiration date set forth in the Confidentiality Certificate he or she may submit a written request for an extension of the expiration date which shall include a justification for such extension and a revised estimate of the date for completion of the project. Upon approval of such a request, the Secretary will issue an amended Confidentiality Certificate.

(d) The protection afforded by a Confidentiality Certificate does not extend to significant changes in the research project as it is described in the application for such Certificate (e.g., changes in the personnel having major responsibilities in the research project, major changes in the scope or direction of the research protocol, or changes in the drugs to be administered and the persons who will administer them). The recipient of a Confidentiality Certificate shall notify the Director of the Institute

to which application was made of any proposal for such a significant change by submitting an amended application for a Confidentiality Certificate in the same form and manner as an original application. On the basis of such application and other pertinent information the Secretary will either:

(1) Approve the amended application and issue an amended Confidentiality Certificate together with a Notice of Cancellation terminating the original Confidentiality Certificate in accordance with § 2a.8; or

(2) Disapprove the amended application and notify the applicant in writing that adoption of the proposed significant changes will result in the issuance of a Notice of Cancellation terminating the original Confidentiality Certificate in accordance with § 2a.8.

§ 2a.7 Effect of Confidentiality Certificate.

(a) A Confidentiality Certificate authorizes the withholding of the names and other identifying characteristics of individuals who participate as subjects in the research project specified in the Certificate while the Certificate is in effect. The authorization applies to all persons who, in the performance of their duties in connection with the research project, have access to information which would identify the subjects of the research. Persons so authorized may not, at any time, be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify the research subjects encompassed by the Certificate, except in those circumstances specified in paragraph (b) of this section.

(b) A Confidentiality Certificate granted under this part does not authorize any person to refuse to reveal the name or other identifying characteristics of any research subject in the following circumstances: (1) The subject (or, if he or she is legally incompetent, his or her guardian) consents, in writing, to the disclosure of such information, (2) Authorized personnel of DHEW request such information for audit or program evaluation of a research project funded by DHEW or for investigation of DHEW grantees or contractors and their employees or agents carrying out such a project. (See 45 CFR 5.71 for confidentiality standards imposed on such DHEW personnel), or (3) Release of such information is required by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301) or the regulations promulgated thereunder (Title 21, Code of Federal Regulations).

(c) Neither a Confidentiality Certificate nor the regulations of this part govern the voluntary disclosure of identifying characteristics of research subjects.

§ 2a.8 Termination.

(a) A Confidentiality Certificate is in effect from the date of its issuance until the effective date of its termination. The effective date of termination shall be the earlier of:

(1) The expiration date set forth in the Confidentiality Certificate; or

(2) Ten days from the date of mailing a Notice of Cancellation to the applicant, pursuant to a determination by the Secretary that the research project has been completed or discontinued or that retention of the Confidentiality Certificate is otherwise no longer necessary or desirable.

(b) A Notice of Cancellation shall include: an identification of the Confidentiality Certificate to which it applies; the effective date of its termination; and the grounds for cancellation. Upon receipt of a Notice of Cancellation the applicant shall return the Confidentiality Certificate to the Secretary.

(c) Any termination of a Confidentiality Certificate pursuant to this section is operative only with respect to the names and other identifying characteristics of individuals who begin their participation as research subjects after the effective date of such termination. (See § 2a.4(k) requiring researchers to notify subjects who enter the project after the termination of the Confidentiality Certificate of termination of the Certificate). The protection afforded by a Confidentiality Certificate is permanent with respect to subjects who participated in research during any time the authorization was in effect.

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