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Chapter 1 : [46 CFR 45] Title 46 Part 45 : Code of Federal Regulations

45 CFR Pre Requirements. Requirements. Content created by Office for Human Research Protections (OHRP) Content last reviewed on February 16,

This includes research conducted by federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the federal government outside the United States. Except when otherwise required by statute, Executive Order, or the department or agency head, notices of these actions as they occur will be published in the Federal Register or will be otherwise published as provided in department or agency procedures. Except when otherwise required by statute or Executive Order, the department or agency head shall forward advance notices of these actions to the Office for Human Research Protections, Department of Health and Human Services HHS , or any successor office, and shall also publish them in the Federal Register or in such other manner as provided in department or agency procedures. Some of the other Departments and Agencies have incorporated all provisions of title 45 CFR part 46 into their policies and procedures as well. However, the exemptions at 45 CFR The exemption at 45 CFR Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public for example, a medical record. Private information must be individually identifiable i. In lieu of requiring submission of an assurance, individual department or agency heads shall accept the existence of a current assurance, appropriate for the research in question, on file with the Office for Human Research Protections, HHS, or any successor office, and approved for federalwide use by that office. When the existence of an HHS-approved assurance is accepted in lieu of requiring submission of an assurance, reports except certification required by this policy to be made to department and agency heads shall also be made to the Office for Human Research Protections, HHS, or any successor office. Assurances applicable to federally supported or conducted research shall at a minimum include: This may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institution itself. The department or agency head may limit the period during which any particular approved assurance or class of approved assurances shall remain effective or otherwise condition or restrict approval. Such certification must be submitted with the application or proposal or by such later date as may be prescribed by the department or agency to which the application or proposal is submitted. Institutions without an approved assurance covering the research shall certify within 30 days after receipt of a request for such a certification from the department or agency, that the application or proposal has been approved by the IRB. If the certification is not submitted within these time limits, the application or proposal may be returned to the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects. No IRB may consist entirely of

members of one profession. These individuals may not vote with the IRB. In order to fulfill the requirements of this policy each IRB shall: In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing. The list will be amended, as appropriate after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in the Federal Register. Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research. The IRB should not consider possible long-range effects of applying knowledge gained in the research for example, the possible effects of the research on public policy as among those research risks that fall within the purview of its responsibility. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB. Cooperative research projects are those projects covered by this policy which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. With the approval of the department or agency head, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. Except as provided in paragraph c or d of this section, in seeking informed consent the following information shall be provided to each subject: When appropriate, one or more of the following elements of information shall also be provided to each subject: A copy shall be given to the person signing the form. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research. Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These applications need not be reviewed by an IRB before an award may be made. In the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in this policy, a certification submitted, by the institution, to the department or agency, and final approval given to the proposed change by the department or agency. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained. Evaluation of applications and proposals. With respect to any research

project or any class of research projects the department or agency head may impose additional conditions prior to or at the time of approval when in the judgment of the department or agency head additional conditions are necessary for the protection of human subjects. With respect to any research project or any class of research projects the department or agency head of either the conducting or the supporting Federal department or agency may impose additional conditions prior to or at the time of approval when in the judgment of the department or agency head additional conditions are necessary for the protection of human subjects.

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Chapter 2 : 45 CFR Part 46 - PROTECTION OF HUMAN SUBJECTS | US Law | LII / Legal Information Ins

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The IRB shall be sufficiently qualified through the experience and expertise of its members professional competence , and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments including policies and resources and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects. These individuals may not vote with the IRB. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing. A Data analysis, including analysis of identifiable private information or identifiable biospecimens, or B Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care. The Secretary will evaluate the list at least every 8 years and amend it, as appropriate, after consultation with other federal departments and agencies and after publication in the Federal Register for public comment. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research. The IRB should not consider possible long-range effects of applying knowledge gained in the research e. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons. Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research. The institution or IRB may maintain the records in printed form, or electronically. All records shall be accessible for inspection and copying by authorized representatives of the Federal department or agency at reasonable times and in a reasonable manner. General requirements for informed consent, whether written or oral, are set forth in this paragraph and apply to consent obtained in accordance with the requirements set forth in paragraphs b through d of this section. Broad consent may be obtained in lieu of informed consent obtained in accordance with paragraphs b and c of this section only with respect to the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens. Waiver or alteration of consent in research involving public benefit and service programs conducted by or subject to the approval of state or local officials is described in paragraph e of this section. General waiver or alteration of informed consent is described in paragraph f of this section. Except as provided elsewhere in this policy: This part of the informed consent must be organized and presented in a way that facilitates comprehension. Except as provided in paragraph d , e , or f of this section, in seeking informed consent the following information shall be provided to each subject or the legally authorized representative:

Except as provided in paragraph d , e , or f of this section, one or more of the following elements of information, when appropriate, shall also be provided to each subject or the legally authorized representative: Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens collected for either research studies other than the proposed research or nonresearch purposes is permitted as an alternative to the informed consent requirements in paragraphs b and c of this section. An IRB may waive the requirement to obtain informed consent for research under paragraphs a through c of this section, provided the IRB satisfies the requirements of paragraph e 3 of this section. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements at paragraph d of this section, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens. An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in paragraphs b and c of this section provided the IRB satisfies the requirements of paragraph e 3 of this section. An IRB may not omit or alter any of the requirements described in paragraph a of this section. If a broad consent procedure is used, an IRB may not omit or alter any of the elements required under paragraph d of this section. A Public benefit or service programs; B Procedures for obtaining benefits or services under those programs; C Possible changes in or alternatives to those programs or procedures; or D Possible changes in methods or levels of payment for benefits or services under those programs; and ii The research could not practicably be carried out without the waiver or alteration. An IRB may waive the requirement to obtain informed consent for research under paragraphs a through c of this section, provided the IRB satisfies the requirements of paragraph f 3 of this section. An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in paragraphs b and c of this section provided the IRB satisfies the requirements of paragraph f 3 of this section. The informed consent requirements in this policy are not intended to preempt any applicable Federal, state, or local laws including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe that require additional information to be disclosed in order for informed consent to be legally effective. Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, state, or local law including tribal law passed by the official governing body of an American Indian or Alaska Native tribe. A written copy shall be given to the person signing the informed consent form. The IRB shall approve a written summary of what is to be said to the subject or the legally authorized representative. When this method is used, there shall be a witness to the oral presentation. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. Certain types of applications for grants, cooperative agreements, or contracts are submitted to Federal departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.

Chapter 3 : Common Rule - Wikipedia

This is a list of United States Code sections, Statutes at Large, Public Laws, and Presidential Documents, which provide rulemaking authority for this CFR Part.. This list is taken from the Parallel Table of Authorities and Rules provided by GPO [Government Printing Office].

Chapter 4 : 45 CFR - General requirements for informed consent.

45 CFR 46 - PROTECTION OF HUMAN The Department of Health and Human Services issued a notice of waiver regarding the requirements set forth in part 46, relating to.

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Chapter 5 : [45 CFR 46] Title 45 Subtitle A Subchapter A Part 46 : Code of Federal Regulations

In the United States, the Code of Federal Regulations Title Public Welfare, part 46 (45 CFR 46) provides protection for human subjects in research carried out or supported by most federal departments and agencies. 45 CFR 46 created a common federal policy for the protection of such human subjects that was accepted by the Office of Science.