

subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. 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.

(Approved by the Office of Management and Budget under Control Number 0990-0260)

[56 FR 28012, 28021, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§ 219.118 Applications and proposals lacking definite plans for involvement of human subjects.

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 include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for research exempted or waived under § 219.101 (b) or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the department or agency.

§ 219.119 Research undertaken without the intention of involving human subjects.

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 re-

viewed 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.

§ 219.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.

(a) The department or agency head will evaluate all applications and proposals involving human subjects submitted to the department or agency through such officers and employees of the department or agency and such experts and consultants as the department or agency head determines to be appropriate. 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.

(b) On the basis of this evaluation, the department or agency head may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

§ 219.121 [Reserved]

§ 219.122 Use of Federal funds.

Federal funds administered by a department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

§ 219.123 Early termination of research support: Evaluation of applications and proposals.

(a) The department or agency head may require that department or agency support for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the department or agency head finds an institution has materially failed to comply with the terms of this policy.

(b) In making decisions about supporting or approving applications or proposals covered by this policy the department or agency head may take into account, in addition to all other eligibility requirements and program

criteria, factors such as whether the applicant has been subject to a termination or suspension under paragraph (a) of this section and whether the applicant or the person or persons who would direct or has have directed the scientific and technical aspects of an activity has have, in the judgment of the department or agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to federal regulation).

§219.124 Conditions.

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.

PART 220—COLLECTION FROM THIRD PARTY PAYERS OF REASONABLE CHARGES FOR HEALTHCARE SERVICES

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- 220.12 [Reserved]
- 220.13 Special rules for workers' compensation programs.
- 220.14 Definitions.

AUTHORITY: 5 U.S.C. 301; 10 U.S.C. 1095.

SOURCE: 55 FR 21748, May 29, 1990, unless otherwise noted.

§220.1 Purpose and applicability.

(a) This part implements the provisions of 10 U.S.C. 1095, 1097b(b), and 1079b. In general, 10 U.S.C. 1095 estab-

lishes the statutory obligation of third party payers to reimburse the United States the reasonable charges of healthcare services provided by facilities of the Uniformed Services to covered beneficiaries who are also covered by a third party payer's plan. Section 1097b(b) elaborates on the methods for computation of reasonable charges. Section 1079b addresses charges for civilian patients who are not normally beneficiaries of the Military Health System. This part establishes the Department of Defense interpretations and requirements applicable to all healthcare services subject to 10 U.S.C. 1095, 1097b(b), and 1079b.

(b) This part applies to all facilities of the Uniformed Services; the Department of Transportation administers this part with respect to facilities to the Coast Guard, not the Department of Defense.

(c) This part applies to pathology services provided by the Armed Forces Institute of Pathology. However, in lieu of the rules and procedures otherwise applicable under this part, the Assistant Secretary of Defense (Health Affairs) may establish special rules and procedures under the authority of 10 U.S.C. 176 and 177 in relation to cooperative enterprises between the Armed Forces Institute of Pathology and the American Registry of Pathology.

[67 FR 57740, Sept. 12, 2002]

§220.2 Statutory obligation of third party payer to pay.

(a) *Basic rule.* Pursuant to 10 U.S.C. 1095(a)(1), a third party payer has an obligation to pay the United States the reasonable charges for healthcare services provided in or through any facility of the Uniformed Services to a covered beneficiary who is also a beneficiary under the third party payer's plan. The obligation to pay is to the extent that the beneficiary would be eligible to receive reimbursement or indemnification from the third party payer if the beneficiary were to incur the costs on the beneficiary's own behalf.

(b) *Application of cost shares.* If the third party payer's plan includes a requirement for a deductible or copayment by the beneficiary of the plan, then the amount the United States may collect from the third party payer