

(1) A new precedent or a new point of law is involved; or

(2) A question of policy is or may be involved; or

(3) The United States is or may be entitled to indemnity or contribution from a third party and the Department is unable to adjust the third party claim; or

(4) The compromise of a particular claim, as a practical matter, will or may control the disposition of a related claim in which the amount to be paid may exceed \$25,000.

(c) An administrative claim may be adjusted, determined, compromised or settled only after consultation with the Department of Justice when it is learned that the United States or an employee, agent or cost plus contractor of the United States is involved in litigation based on a claim arising out of the same incident or transaction.

PART 36—INDEMNIFICATION OF HHS EMPLOYEES

§36.1 Policy.

(a) The Department of Health and Human Services may indemnify, in whole or in part, its employees (which for the purpose of this regulation includes former employees) for any verdict, judgment or other monetary award which is rendered against any such employee, provided that the conduct giving rise to the verdict, judgment or award was taken within the scope of his or her employment with the Department and that such indemnification is in the interest of the United States, as determined by the Secretary, or his or her designee, in his or her discretion.

(b) The Department of Health and Human Services may settle or compromise a personal damage claim against its employee by the payment of available funds, at any time, provided the alleged conduct giving rise to the personal damage claim was taken within the scope of employment and that such settlement or compromise is in the interest of the United States, as determined by the Secretary, or his or her designee, in his or her discretion.

(c) Absent exceptional circumstances, as determined by the Sec-

retary or his or her designee, the Department will not entertain a request either to agree to indemnify or to settle a personal damage claim before entry of an adverse verdict, judgment or monetary award.

(d) When an employee of the Department of Health and Human Services becomes aware that an action has been filed against the employee in his or her individual capacity as a result of conduct taken within the scope of his or her employment, the employee should immediately notify the Department that such an action is pending.

(e) The employee may, thereafter, request either (1) indemnification to satisfy a verdict, judgment or award entered against the employee or (2) payment to satisfy the requirements of a settlement proposal. The employee shall submit a written request, with documentation including copies of the verdict, judgment, award or settlement proposal, as appropriate, to the head of his employing component, who shall thereupon submit to the General Counsel, in a timely manner, a recommended disposition of the request. The General Counsel shall also seek the views of the Department of Justice. The General Counsel shall forward the request, the employing component's recommendation and the General Counsel's recommendation to the Secretary for decision.

(f) Any payment under this section either to indemnify a Department of Health and Human Services employee or to settle a personal damage claim shall be contingent upon the availability of appropriated funds of the employing component of the Department of Health and Human Services.

(Authority: 5 U.S.C. 301)

[53 FR 11280, Apr. 6, 1988]

PART 46—PROTECTION OF HUMAN SUBJECTS

Subpart A—Basic HHS Policy for Protection of Human Research Subjects

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46.101 To what does this policy apply?

46.102 Definitions.

46.103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.

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- 46.104–46.106 [Reserved]
- 46.107 IRB membership.
- 46.108 IRB functions and operations.
- 46.109 IRB review of research.
- 46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
- 46.111 Criteria for IRB approval of research.
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- 46.114 Cooperative research.
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- 46.116 General requirements for informed consent.
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- 46.118 Applications and proposals lacking definite plans for involvement of human subjects.
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Subpart B—Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research

- 46.201 To what do these regulations apply?
- 46.202 Definitions.
- 46.203 Duties of IRBs in connection with research involving pregnant women, fetuses, and neonates.
- 46.204 Research involving pregnant women or fetuses.
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- 46.206 Research involving, after delivery, the placenta, the dead fetus or fetal material.
- 46.207 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.

Subpart C—Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

- 46.301 Applicability.
- 46.302 Purpose.
- 46.303 Definitions.
- 46.304 Composition of Institutional Review Boards where prisoners are involved.
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- 46.306 Permitted research involving prisoners.

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- 46.401 To what do these regulations apply?
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- 46.404 Research not involving greater than minimal risk.
- 46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.
- 46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject’s disorder or condition.
- 46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.
- 46.408 Requirements for permission by parents or guardians and for assent by children.
- 46.409 Wards.

Subpart E—Registration of Institutional Review Boards

- 46.501 What IRBs must be registered?
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AUTHORITY: 5 U.S.C. 301; 42 U.S.C. 289(a).

EFFECTIVE DATE NOTE: At 82 FR 7273, Jan. 19, 2017, the authority citation for part 46 was revised, effective Jan. 19, 2018. For the convenience of the user, the revised text is set forth as follows:

AUTHORITY: 5 U.S.C. 301; 42 U.S.C. 289(a); 42 U.S.C. 300v–1(b).

EDITORIAL NOTE: The Department of Health and Human Services issued a notice of waiver regarding the requirements set forth in part 46, relating to protection of human subjects, as they pertain to demonstration projects, approved under section 1115 of the Social Security Act, which test the use of cost-sharing, such as deductibles, copayment and coinsurance, in the Medicaid program. For further information see 47 FR 9208, Mar. 4, 1982.