

**Pt. 74, App. E**

5. *Rights to Inventions Made Under a Contract or Agreement*— Contracts or agreements for the performance of experimental, developmental, or research work shall provide for the rights of the Federal Government and the recipient in any resulting invention in accordance with 37 CFR part 401, "Rights to Inventions Made by Nonprofit Organizations and Small Business Firms Under Government Grants, Contracts and Cooperative Agreements," and any further implementing regulations issued by HHS.

6. *Clean Air Act (42 U.S.C. 7401 et seq.) and the Federal Water Pollution Control Act as amended (33 U.S.C. 1251 et seq.)*— Contracts and subgrants of amounts in excess of \$100,000 shall contain a provision that requires the recipient to agree to comply with all applicable standards, orders or regulations issued pursuant to the Clean Air Act, 42 U.S.C. 7401 et seq., and the Federal Water Pollution Control Act, as amended 33 U.S.C. 1251 et seq. Violations shall be reported to the HHS and the appropriate Regional Office of the Environmental Protection Agency.

7. *Byrd Anti-Lobbying Amendment (31 U.S.C. 1352)*— Contractors who apply or bid for an award of more than \$100,000 shall file the required certification. Each tier certifies to the tier above that it will not and has not used Federal appropriated funds to pay any person or organization for influencing or attempting to influence an officer or employee of any Federal agency, a member of Congress, officer or employee of Congress, or an employee of a member of Congress in connection with obtaining any Federal contract, grant or any other award covered by 31 U.S.C. 1352. Each tier shall also disclose any lobbying with non-Federal funds that takes place in connection with obtaining any Federal award. Such disclosures are forwarded from tier to tier up to the recipient. (See also 45 CFR part 93).

8. *Debarment and Suspension (E.O.s 12549 and 12689)*— Certain contracts shall not be made to parties listed on the nonprocurement portion of the General Services Administration's "Lists of Parties Excluded from Federal Procurement or Nonprocurement Programs" in accordance with E.O.s 12549 and 12689, "Debarment and Suspension." (See 45 CFR part 76.) This list contains the names of parties debarred, suspended, or otherwise excluded by agencies, and contractors declared ineligible under statutory authority other than E.O. 12549. Contractors with awards that exceed the simplified acquisition threshold shall provide the required certification regarding their exclusion status and that of their principals prior to award.

[59 FR 43760, Aug. 25, 1994, as amended at 61 FR 11747, Mar. 22, 1996; 62 FR 41878, Aug. 4, 1997]

**45 CFR Subtitle A (10-1-07 Edition)**

**APPENDIXES B-D TO PART 74  
[RESERVED]**

**APPENDIX E TO PART 74—PRINCIPLES  
FOR DETERMINING COSTS APPLICABLE  
TO RESEARCH AND DEVELOPMENT  
UNDER GRANTS AND CONTRACTS  
WITH HOSPITALS**

**I. PURPOSE AND SCOPE**

A. *Objectives.* This appendix provides principles for determining the costs applicable to research and development work performed by hospitals under grants and contracts with the Department of Health and Human Services. These principles are confined to the subject of cost determination and make no attempt to identify the circumstances or dictate the extent of hospital participation in the financing of a particular research or development project. The principles are designed to provide recognition of the full allocated costs of such research work under generally accepted accounting principles. These principles will be applicable to both proprietary and non-profit hospitals. No provision for profit or other increment above cost is provided for in these principles. However, this is not to be interpreted as precluding a negotiated fee between contracting parties when a fee is appropriate.

B. *Policy guides.* The successful application of these principles requires development of mutual understanding between representatives of hospitals and of the Department of Health and Human Services as to their scope, applicability and interpretation. It is recognized that:

1. The arrangements for hospital participation in the financing of a research and development project are properly subject to negotiation between the agency and the hospital concerned in accordance with such Government-wide criteria as may be applicable.

2. Each hospital, possessing its own unique combination of staff, facilities and experience, should be encouraged to conduct research in a manner consonant with its own institutional philosophies and objectives.

3. Each hospital in the fulfillment of its contractual obligations should be expected to employ sound management practices.

4. The application of the principles established herein shall be in conformance with the generally accepted accounting practices of hospitals.

5. Hospitals receive reimbursements from the Federal Government for differing types of services under various programs such as support of Research and Development (including discrete clinical centers) Health Services Projects, Medicare, etc. It is essential that consistent procedures for determining reimbursable costs for similar services be employed without regard to program differences. Therefore, both the direct and