

Health and Human Services

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PUBLICATIONS AND PUBLICITY (JUL 1991)

(a) Unless otherwise specified in this contract, the Contractor is encouraged to publish the results of its work under this contract. A copy of each article submitted by the Contractor for publication shall be promptly sent to the Project Officer. The Contractor shall also inform the Project Officer when the article or other publication is published, and furnish a copy of it as finally published.

(b) The Contractor shall include in any publication resulting from work performed under this contract a disclaimer reading as follows:

The content of this publication does not necessarily reflect the views or policies of the Department of Health and Human Services, nor does mention of trade names, commercial products, or organizations imply endorsement by the U.S. Government."

(End of clause)

352.270-7 Paperwork Reduction Act.

Insert the following clause in all solicitations and contracts.

PAPERWORK REDUCTION ACT (JAN 2001)

(a) In the event that it subsequently becomes a contractual requirement to collect or record information calling either for answers to identical questions from 10 or more persons other than Federal employees, or information from Federal employees which is outside the scope of their employment, for use by the Federal government or disclosure to third parties, the Paperwork Reduction Act of 1995 (Pub. L. 104-13) shall apply to this contract. No plan, questionnaire, interview guide or other similar device for collecting information (whether repetitive or single-time) may be used without first obtaining clearance from the Office of Management and Budget (OMB). Contractors and Project Officers should be guided by the provisions of 5 CFR Part 1320, Controlling Paperwork Burdens on the Public, and seek the advice of the HHS operating division or Office of the Secretary Reports Clearance Officer to determine the procedures for acquiring OMB clearance.

(b) The Contractor shall obtain the required OMB clearance through the Project Officer before expending any funds or making public contracts for the collection of data. The authority to expend funds and proceed with the collection of information shall be in writing by the Contracting Officer. The Contractor must plan at least 120 days for OMB clearance. Excessive delays caused by the Government which arises out of causes beyond the control and without the fault or negligence of the Contractor will be consid-

ered in accordance with the Excusable Delays or Default clause of this contract.

(End of clause)

352.270-8 Protection of human subjects.

(a) The following provision shall be included in solicitations expected to involve human subjects:

NOTICE TO OFFERORS OF REQUIREMENTS OF 45 CFR PART 46, PROTECTION OF HUMAN SUBJECTS (JAN 2001)

(a) Copies of the Department of Health and Human Services (Department) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office for Human Research Protections (OHRP), Bethesda, Maryland 20892. The regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the Department.

(b) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information. The regulations extend to the use of human organs, tissue, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR Part 46.

(c) Activities in which the only involvement of human subjects will be in one or more of the categories set forth in 45 CFR 46.101(b)(1-6) are exempt from coverage.

(d) Inappropriate designations of the non-involvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal. The OpDiv will make a final determination of whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the proposal. In doubtful cases, prior consultation with OPRR, (telephone: 301-496-7014), is recommended.

(e) In accordance with 45 CFR Part 46, prospective Contractors being considered for award shall be required to file with OPRR an acceptable Assurance of Compliance with the regulations, specifying review procedures and assigning responsibilities for the protection of human subjects. The initial and continuing review of a research project by an institutional review board shall assure that the rights and welfare of the human subjects involved are adequately protected, that the

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risks to the subjects are reasonable in relation to the potential benefits, if any, to the subjects and the importance of the knowledge to be gained, and that informed consent will be obtained by methods that are adequate and appropriate. The contracting officer will direct the offeror/contractor to the OHRP IRB Registration and Assurance Filing website, found at <http://www.hhs.gov/ohrp/> or to the physical address if the offeror/contractor cannot access the Internet. HHS regulations for the protection of human subjects may be found at: http://www.access.gpo.gov/nara/cfr/waisidx_01/45cfr46_01.html

(f) It is recommended that OPRR be consulted for advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects.

(End of provision)

(b) The following clause shall be included in solicitations and resultant contracts involving human subjects:

PROTECTION OF HUMAN SUBJECTS (JAN 2001)

(a) The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR Part 46 and with the Contractor's current Assurance of Compliance on file with the Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH). The Contractor further agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with 45 CFR Part 46 and the Assurance of Compliance.

(b) The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. Nothing in this contract shall be deemed to constitute the Contractor or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgement or otherwise, as an independent contractor without imputing liability on the part of the Government for the acts of the Contractor or its employees.

(c) If at any time during the performance of this contract, the Contracting officer determines, in consultation with the OPRR,

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NIH, that the Contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (a) and (b) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OPRR, NIH, terminate this contract in a whole or in part, and the Contractor's name may be removed from the list of those contractors with approved Health and Human Services Human Subject Assurances.

(End of clause)

[66 FR 4255, Jan. 17, 2001, as amended at 70 FR 41, Jan. 3, 2005]

352.270-9 Care of laboratory animals.

(a) The following provision shall be included in solicitations expected to involve vertebrate animals:

NOTICE TO OFFERORS OF REQUIREMENT FOR COMPLIANCE WITH THE PUBLIC HEALTH SERVICE POLICY ON HUMANE CARE AND USE OF LABORATORY ANIMALS (REVISED 1986, REPRINTED 2000)

The PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions establishes a number of requirements for research activities involving animals. Before award may be made to an applicant organization, the organization shall file, with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), a written Animal Welfare Assurance which commits the organization to comply with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources. In accordance with the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, applicant organizations must establish a committee, qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities and procedures. No award involving the use of animals shall be made unless the Animal Welfare Assurance has been approved by OPRR. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects that involve live vertebrate animals that an Animal Welfare