

252.235-7004 Protection of Human Subjects.

As prescribed in 235.072(e), use the following clause:

PROTECTION OF HUMAN SUBJECTS (JUL 2009)

(a) *Definitions.* As used in this clause—

(1) *Assurance of compliance* means a written assurance that an institution will comply with requirements of 32 CFR Part 219, as well as the terms of the assurance, which the Human Research Protection Official determines to be appropriate for the research supported by the Department of Defense (DoD) component (32 CFR 219.103).

(2) *Human Research Protection Official (HRPO)* means the individual designated by the head of the applicable DoD component and identified in the component's Human Research Protection Management Plan as the official who is responsible for the oversight and execution of the requirements of this clause, although some DoD components may use a different title for this position.

(3) *Human subject* means 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 (32 CFR 219.102(f)). For example, this could include the use of human organs, tissue, and body fluids from individually identifiable living human subjects as well as graphic, written, or recorded information derived from individually identifiable living human subjects.

(4) *Institution* means any public or private entity or agency (32 CFR 219.102(b)).

(5) *Institutional Review Board (IRB)* means a board established for the purposes expressed in 32 CFR Part 219 (32 CFR 219.102(g)).

(6) *IRB approval* means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and Federal requirements (32 CFR 219.102(h)).

(7) *Research* means a systematic investigation, including research, development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of 32 CFR Part 219, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities (32 CFR 219.102(d)).

(b) The Contractor shall oversee the execution of the research to ensure compliance with this clause. The Contractor shall comply fully with 32 CFR Part 219 and DoD Directive 3216.02, applicable DoD component policies, 10 U.S.C. 980, and, when applicable,

Food and Drug Administration policies and regulations.

(c) The Contractor shall not commence performance of research involving human subjects that is covered under 32 CFR Part 219 or that meets exemption criteria under 32 CFR 219.101(b), or expend funding on such effort, until and unless the conditions of either the following paragraph (c)(1) or (c)(2) have been met:

(1) The Contractor furnishes to the HRPO, with a copy to the Contracting Officer, an assurance of compliance and IRB approval and receives notification from the Contracting Officer that the HRPO has approved the assurance as appropriate for the research under the Statement of Work and also that the HRPO has reviewed the protocol and accepted the IRB approval for compliance with the DoD component policies. The Contractor may furnish evidence of an existing assurance of compliance for acceptance by the HRPO, if an appropriate assurance has been approved in connection with previous research. The Contractor shall notify the Contracting Officer immediately of any suspensions or terminations of the assurance.

(2) The Contractor furnishes to the HRPO, with a copy to the Contracting Officer, a determination that the human research proposed meets exemption criteria in 32 CFR 219.101(b) and receives written notification from the Contracting Officer that the exemption is determined acceptable. The determination shall include citation of the exemption category under 32 CFR 219.101(b) and a rationale statement. In the event of a disagreement regarding the Contractor's furnished exemption determination, the HRPO retains final judgment on what research activities or classes of research are covered or are exempt under the contract.

(d) DoD staff, consultants, and advisory groups may independently review and inspect the Contractor's research and research procedures involving human subjects and, based on such findings, DoD may prohibit research that presents unacceptable hazards or otherwise fails to comply with DoD procedures.

(e) Failure of the Contractor to comply with the requirements of this clause will result in the issuance of a stop-work order under Federal Acquisition Regulation clause 52.242-15 to immediately suspend, in whole or in part, work and further payment under this contract, or will result in other issuance of suspension of work and further payment for as long as determined necessary at the discretion of the Contracting Officer.

(f) The Contractor shall include the substance of this clause, including this paragraph (f), in all subcontracts that may include research involving human subjects in accordance with 32 CFR Part 219, DoD Directive 3216.02, and 10 U.S.C. 980, including research that meets exemption criteria under

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32 CFR 219.101(b). This clause does not apply to subcontracts that involve only the use of cadaver materials.

(End of clause)

(End of clause)

[69 FR 65092, Nov. 10, 2004, 1991, as amended at 73 FR 42279, July 21, 2008]

[74 FR 37648, July 29, 2009]

252.236-7000 Modification proposals—price breakdown.

252.235-7005—252.235-7009 [Reserved]

As prescribed in 236.570(a), use the following clause:

252.235-7010 Acknowledgment of support and disclaimer.

MODIFICATION PROPOSALS—PRICE BREAKDOWN (DEC 1991)

As prescribed in 235.072(c), use the following clause:

(a) The Contractor shall furnish a price breakdown, itemized as required and within the time specified by the Contracting Officer, with any proposal for a contract modification.

ACKNOWLEDGMENT OF SUPPORT AND DISCLAIMER (MAY 1995)

(a) The Contractor shall include an acknowledgment of the Government's support in the publication of any material based on or developed under this contract, stated in the following terms: This material is based upon work supported by the (name of contracting agency(ies)) under Contract No. (Contracting agency(ies) contract number(s)).

(b) The price breakdown—
(1) Must include sufficient detail to permit an analysis of profit, and of all costs for—

(b) All material, except scientific articles or papers published in scientific journals, must, in addition to any notices or disclaimers by the Contractor, also contain the following disclaimer: Any opinions, findings and conclusions or recommendations expressed in this material are those of the author(s) and do not necessarily reflect the views of the (name of contracting agency(ies)).

- (i) Material;
- (ii) Labor;
- (iii) Equipment;
- (iv) Subcontracts; and
- (v) Overhead; and

(2) Must cover all work involved in the modification, whether the work was deleted, added, or changed.

(c) The Contractor shall provide similar price breakdowns to support any amounts claimed for subcontracts.

(d) The Contractor's proposal shall include a justification for any time extension proposed.

(End of clause)

(End of clause)

252.236-7001 Contract drawings and specifications.

[60 FR 29503, June 5, 1995, as amended at 73 FR 42279, July 21, 2008]

As prescribed in 236.570(a), use the following clause:

252.235-7011 Final scientific or technical report.

CONTRACT DRAWINGS AND SPECIFICATIONS (AUG 2000)

As prescribed in 235.072(d), use the following clause:

(a) The Government will provide to the Contractor, without charge, one set of contract drawings and specifications, except publications incorporated into the technical provisions by reference, in electronic or paper media as chosen by the Contracting Officer.

FINAL SCIENTIFIC OR TECHNICAL REPORT (NOV 2004)

The Contractor shall—

(a) Submit two copies of the approved scientific or technical report delivered under this contract to the Defense Technical Information Center, Attn: DTIC-O, 8725 John J. Kingman Road, Fort Belvoir, VA 22060-6218;

(b) The Contractor shall—
(1) Check all drawings furnished immediately upon receipt;

(b) Include a completed Standard Form 298, Report Documentation Page, with each copy of the report; and

(2) Compare all drawings and verify the figures before laying out the work;

(c) For submission of reports in other than paper copy, contact the Defense Technical Information Center or follow the instructions at <http://www.dtic.mil>.

(3) Promptly notify the Contracting Officer of any discrepancies;

(4) Be responsible for any errors that might have been avoided by complying with this paragraph (b); and

(5) Reproduce and print contract drawings and specifications as needed.

(c) In general—