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 252.235–7005 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 5219.02, and 10 U.S.C. 980, including research that meets exemption criteria under 32 CFR 219.101(b). This clause does not apply to subcontracts that involve only the use of cadaver materials.

(End of clause)

[74 FR 37648, July 29, 2009]

252.235–7005—252.235–7009 [Reserved]

252.235–7010 Acknowledgment of support and disclaimer.

As prescribed in 253.072(c), use the following clause:

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) 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)).

(End of clause)

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

252.235–7011 Final scientific or technical report.

As prescribed in 253.072(d), use the following clause:

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

(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.