insert the following clause:

1352.235–73 Research involving human

(c) The Common Rule also sets forth cat-

(d) In the event that human subjects re-

(e) Contractor must report all adverse
events to the cognizant IRB and to the Con-
tracting Officer. In the event that adverse
events are reported to the cognizant IRB and
the Contracting Officer, the Government
may suspend this contract pending a full re-
view of the adverse event by the cognizant
IRB.

(f) If the conditions upon which IRB ap-
proval is based should change in any way,
contractor shall immediately notify the Con-
tracting Officer, in writing, of the specified
change.

(g) Failure to comply with this contract
clause will be considered material non-
compliance with the contract, and the Con-
tracting Officer may take appropriate en-
forcement action, including disallowing
costs, suspension or termination of the con-
tract.

(End of clause)

[75 FR 10570, Mar. 8, 2010; 75 FR 14496, Mar. 26,
2010]

1352.235–73 Research involving human
subjects—after initial contract
award.

As prescribed in 48 CFR 1335.006(d), insert the following clause:

RESEARCH INVOLVING HUMAN SUBJECTS—
AFTER INITIAL CONTRACT AWARD (APR 2010)

(a) No research involving human subjects
is currently included in this contract/task
order, and no research involving human sub-
jects is permitted under this contract/task
order unless expressly authorized, in writing,
by the Contracting Officer.

(b) The Federal Policy for the Protection
of Human Subjects (the “Common Rule”),
adopted by the Department of Commerce at
15 CFR part 27, requires that contractors
maintain appropriate policies and procedures
for the protection of human subjects in re-
search. The Common Rule defines a “human
subject” as a living individual about whom
an investigator conducting research obtains
data through intervention or interaction
with the individual, or identifiable private
information. The term “research” means a
systematic investigation, including research,
development, testing and evaluation, de-
signed to develop or contribute to generaliz-
able knowledge.

(c) The Common Rule also sets forth cat-
egories of research that may be considered
exempt from this policy. These categories
are specified at 15 CFR 27.101(b).

(d) In the event that human subjects re-
search involves pregnant women, prisoners,
or children, the contractor is also required
to follow the guidelines set forth at 45 CFR
part 46 subparts B, C and D, as appropriate,
for the protection of members of a protected
class.

(e) Should research involving human sub-
jects become necessary for carrying out this
contract/task order, prior to undertaking or
conducting such human subjects research,
contractor shall submit the following docu-
mentation to the Contracting Officer:

1. Documentation to verify that con-
tractor has a valid Federal-wide Assurance
(FWA) issued by the OHRP.

2. Prior to starting any research involving
human subjects, contractor shall submit ap-
propriate documentation to the Contracting
Officer for Government institutional review
and approval. This documentation may in-
clude:

(1) Copies of the human subjects research
protocol, advertisements, recruitment mate-
rial, and informed consent forms approved by
the cognizant IRB;

(2) Documentation of approval for the
human subjects research protocol, advertise-
ments, recruitment material, and informed
consent forms by the cognizant IRB;

(3) Documentation of continuing IRB ap-
proval for the cognizant IRB at appropriate
intervals as designated by the IRB, but not
less than annually; and/or

(4) Documentation to support an exemp-
tion for the project from the Common Rule
(Note: this option is not available for activi-
ties that fall under 45 CFR part 46 subpart
C).

(g) In addition, if contractor modifies a
human subjects research protocol, advertise-
ment, recruitment material, or informed
consent form approved by the cognizant IRB,
contractor shall submit a copy of all modi-
ified material, along with documentation of
approval for said modification by the cog-
низант IRB, to the Contracting Officer for
Agency institutional review and approval.
Contractor may not implement any IRB-ap-
proved modification without written ap-
proval by the Contracting Officer.

(h) No work involving human subjects
may be undertaken, conducted, or costs incurred
and/or charged to the project, until the Con-
tracting Officer approves the required ap-
propriate documentation in writing.
1352.237–70 Security processing requirements—high or moderate risk contracts.

As prescribed in 48 CFR 1337.110–70 (b), insert the following clause:

SECURITY PROCESSING REQUIREMENTS—HIGH OR MODERATE RISK CONTRACTS (APR 2010)

(a) Investigative Requirements for High and Moderate Risk Contracts. All contractor (and subcontractor) personnel proposed to be employed under a High or Moderate Risk contract shall undergo security processing by the Department’s Office of Security before being eligible to work on the premises of any Department of Commerce owned, leased, or controlled facility in the United States or overseas, or to obtain access to a Department of Commerce IT system. All Department of Commerce security processing pertinent to this contract will be conducted at no cost to the contractor. The level of contract risk will determine the type and scope of such processing, as noted below.

(i) Investigative requirements for Non-IT Service Contracts are:

(1) High Risk—Background Investigation (BI).

(2) Moderate Risk—Moderate Background Investigation (MBI).

(ii) Investigative requirements for IT Service Contracts are:

(1) High Risk IT—Background Investigation (BI).

(2) Moderate Risk IT—Background Investigation (BI).

(b) In addition to the investigations noted above, non-U.S. citizens must have a pre-appointment check that includes an Immigration and Customs Enforcement agency check.

(c) Additional Requirements for Foreign Nationals (Non-U.S. Citizens). To be employed under this contract within the United States, non-U.S. citizens must have:

(i) Official legal status in the United States;

(ii) Continuously resided in the United States for the last two years; and

(iii) Obtained advance approval from the servicing Security Officer of the contracting operating unit in consultation with the DOC Office of Security (OSY) headquarters. (OSY routinely consults with appropriate agencies regarding the use of non-U.S. citizens on contracts and can provide up-to-date information concerning this matter.)

(d) Security Processing Requirement. Processing requirements for High and Moderate Risk Contracts are as follows:

(1) The contractor must complete and submit the following forms to the Contracting Officer’s Representative (COR):

(i) Standard Form 85P (SF-85P), Questionnaire for Public Trust Positions;

(ii) FD–258, Fingerprint Chart with OPM’s designation in the ORI Block; and

(iii) Credit Release Authorization.

(e) Notification of Disqualifying Information. If the Office of Security receives disqualifying information on a contract employee, the COR will be notified. The Sponsor, in coordination with the Contracting Officer, will immediately remove the contract employee from duties requiring access to Departmental facilities or IT systems. Contract employees may be barred from working on the premises of a facility for any of the following:

(i) Conviction of a felony crime of violence or of a misdemeanor involving moral turpitude;

(ii) Falsification of information entered on security screening forms or on other documents submitted to the Department;

(iii) Improper conduct once performing on the contract, including criminal, infamous, dishonest, immoral, or notoriously disgraceful conduct or other conduct prejudicial to the Government, regardless of whether the conduct was directly related to the contract;

(iv) Any behavior judged to pose a potential threat to Departmental information systems, personnel, property, or other assets.

(f) Failure to comply with security processing requirements may result in termination of the contract or removal of contract employees from Department of Commerce facilities or denial of access to IT systems.

(g) Access to National Security Information. Compliance with these requirements...