Department of Commerce

address: [Insert Contracting Officer name and Address]
(c) Agency protests filed with the agency Protest Decision Authority shall be sent to the following address: [Insert appropriate Protest Decision Authority name and Address]
(d) A complete copy of all agency protests, including all attachments, shall be served upon the Contract Law Division of the Office of the General Counsel within one day of filing a protest with either the Contracting Officer or the Protest Decision Authority.
(e) Service upon the Contract Law Division shall be made as follows: U.S. Department of Commerce, Office of the General Counsel, Chief, Contract Law Division, Room 5893, Herbert C. Hoover Building, 14th Street and Constitution Avenue, NW., Washington, DC 20230. FAX: (202) 482-5858.

(End of clause)

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

1352.233–71 GAO and Court of Federal Claims protests.

As prescribed in 48 CFR 1333.104–70(a), insert the following provision:

GAO AND COURT OF FEDERAL CLAIMS PROTESTS (APR 2010)
(a) A protest may be filed with either the Government Accountability Office (GAO) or the Court of Federal Claims unless an agency protest has been filed.
(b) A complete copy of all GAO or Court of Federal Claims protests, including all attachments, shall be served upon (i) the Contracting Officer, and (ii) the Contract Law Division of the Office of the General Counsel, within one day of filing a protest with either GAO or the Court of Federal Claims.
(c) Service upon the Contract Law Division shall be made as follows: U.S. Department of Commerce, Office of the General Counsel, Chief, Contract Law Division, Room 5893, Herbert C. Hoover Building, 14th Street and Constitution Avenue, NW., Washington, DC 20230. FAX: (202) 482-5858.

(End of clause)

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

1352.235–70 Protection of human subjects.

As prescribed in 48 CFR 1335.006(a), insert the following provision:

PROTECTION OF HUMAN SUBJECTS (APR 2010)
(a) Research involving human subjects is not permitted under this award unless expressly authorized in writing by the Contracting Officer. Such authorization will specify the details of the approved research involving human subjects and will be incorporated by reference into this contract.
(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 contractors to maintain appropriate policies and procedures for the protection of human subjects in research. 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, designed to develop or contribute to generalizable knowledge. The Common Rule also sets forth categories of research that may be considered exempt from 15 CFR part 27. These categories may be found at 15 CFR 27.101(b).
(c) In the event the human subjects research involves pregnant women, prisoners, or children, the contractor is also required to follow the guidelines set forth at 45 CFR part 46 subpart B, C and D, as appropriate, for the protection of members of a protected class.
(d) Should research involving human subjects be included in the proposal, prior to issuance of an award, the contractor shall submit the following documentation to the Contracting Officer:
(1) Documentation to verify that contractor has established a relationship with an appropriate Institutional Review Board (“cognizant IRB”). An appropriate IRB is one that is located within the United States and within the community in which the human subjects research will be conducted;
(2) Documentation to verify that the cognizant IRB possesses a valid registration with the United States Department of Health and Human Services’ Office for Human Research Protections (“OHRP”);
(3) Documentation to verify that the contractor has a valid Federal-wide Assurance (FWA) issued by OHRP.
(e) Prior to starting any research involving human subjects, the contractor shall submit appropriate documentation to the Contracting Officer for institutional review and approval. This documentation may include:
(1) Copies of the human subjects research protocol, all questionnaires, surveys, advertisements, and informed consent forms approved by the cognizant IRB;
(2) Documentation of approval for the human subjects research protocol, questionnaires, surveys, advertisements, and informed consent forms by the cognizant IRB;
(3) Documentation of continuing IRB approval by the cognizant IRB at appropriate
tracting Officer for any change to the exist-

obtain prior written approval from the Con-

proceed until notified in writing of the Con-

exemption approval. Contractor shall not

change and make a determination as to

change. The Government will review the

tractor shall immediately notify the Con-

this contract.

of research involving human subjects under

contained in the attachments in its conduct

tractor must use the informed consent form

sent form for the exempt research, con-

hereby incorporated by reference into this

the Government and the attachments are

Rule for the Protection of Human Subjects.

empt from the requirements of the Common

research involving human subjects is exempt

determination that the research is exempt

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].

(f) In addition, if the contractor modifies a

human subjects research protocol, question-
aire, survey, advertisement, or informed

consent form approved by the cognizant IRB,

the contractor shall submit a copy of all

modified material along with documentation

of approval for said modification by the cog-
nizant IRB to the Contracting Officer for in-
stitutional review and approval. The con-

tractor shall not implement any IRB ap-

proved-modification without written ap-

proval by the Contracting Officer.

(g) 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.

(End of provision)

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

1352.235–71 Protection of human sub-
jects—exemption.

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

PROTECTION OF HUMAN SUBJECTS (APR 2010)

(a) Contractor has satisfied the require-
ments set forth in solicitation # , re-
lated to the Protection of Human Subjects in
research. The Government has determined
that the research involving human subjects
to be conducted under this contract is ex-
empt from the requirements of the Common
Rule for the Protection of Human Subjects.
The exemption memorandum executed by
the Government and the attachments are
hereby incorporated by reference into this
contract. If contractor uses an informed con-
sent form for the exempt research, con-
tractor must use the informed consent form
contained in the attachments in its conduct
of research involving human subjects under
this contract.

(b) If the conditions upon which the exemp-
tion is based should change in any way, con-
tractor shall immediately notify the Con-
tracting Officer in writing of the specified
change. The Government will review the
change and make a determination as to
whether the change requires a change to the
exemption approval. Contractor shall not
proceed until notified in writing of the Con-
tracting Officer’s approval. Contractor shall
obtain prior written approval from the Con-
tracting Officer for any change to the exist-
ing human subjects protocol or informed
consent form before proceeding.

(c) No other research involving human sub-
jects is permitted under this award unless
expressly authorized in writing by the Con-
tracting Officer. Such writing will specify
the details of the approved research involv-
ing human subjects and will be incorporated
by reference into this contract.

(d) The Federal Policy for the Protection
of Human Subjects (the “Common Rule”),
adopted by the Department of Commerce at
15 CFR Part 27, requires contractors to
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.

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

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

(g) Should additional research involving
human subjects be required under the con-
tract, prior to beginning such research, con-
tractor shall submit the following docu-
mentation to the Contracting Officer:

(1) Documentation to verify that con-
tractor has established a relationship with
an appropriate Institutional Review Board
(“cognizant IRB”). An appropriate IRB is
one that is located within the United States
and within the community in which the
human subjects research will be conducted;

(2) Documentation to verify that the cog-
nizant IRB is registered with the United
States Department of Health and Human
Services’ Office for Human Research Protec-
tions (“OHRP”) and is designated as contrac-
tor’s cognizant IRB;

(3) Documentation to verify that con-
tractor has a valid Federal-wide Assurance
(PWA) issued by OHRP; or

(4) Documentation necessary to support a
determination that the research is exempt
from the requirements of the Common Rule
for the Protection of Human Subjects.

(h) Prior to starting any additional re-
search involving human subjects, the con-
tractor shall submit appropriate documenta-
tion to the Contracting Officer for institu-
tional review and approval or exemption de-
termination. This documentation may in-
clude: