



***Submitter Guidance
for
Human Subjects Use
or Animal Testing
in
Research***

**NOTICE TO ALL RESPONDERS
REGARDING PROPOSALS THAT INCLUDE
HUMAN SUBJECTS USE or ANIMAL TESTING
IN RESEARCH.**

*AS A COMPONENT OF THE DEPARTMENT OF DEFENSE THE
CTTSO IS RESPONSIBLE, BY LAW, TO ENSURE THE
PROTECTION OF HUMAN SUBJECTS AND THE HUMANE
TREATMENT OF ANIMALS USED IN RESEARCH PROJECTS.*

OFFERORS PROPOSING SOLUTIONS THAT INCLUDE THE USE
OF ANIMALS OR HUMAN SUBJECTS WILL BE REQUIRED, AS A
CONDITION OF AWARD, TO DEMONSTRATE COMPLIANCE WITH
THE FEDERAL PROTECTION STANDARDS REQUIRED BY THE
DoD.

BAA Section 2

2.9. ANIMAL OR HUMAN TESTING COMPLIANCE	9
2.9.1. Animal Testing	9
2.9.2. Human Subjects Testing	0

In the event of an award, submitter compliance with all federal regulations and directives is required. Read the BAA section on Animal or Human Testing Compliance carefully, consult with all team members, including legal to ensure compliance is achievable.

2.9. Animal or Human Testing Compliance.

The contractor shall comply with all laws and regulations governing the use of animals or human subjects in research projects.

2.9.1. Animal Testing.

Any contract resulting from this BAA that potentially involves the testing of animals shall include the following language:

Any contractor performing research on warm blooded vertebrate animals shall comply with the Laboratory Animal Welfare Act of 1966, as amended, 7 U.S.C. §§ 2131 - 2156, and the regulations promulgated thereunder by the Secretary of Agriculture in 9 C.F.R. Parts 1 through 4, pertaining to the care, handling, and treatment of vertebrate animals held or used for research, teaching, or other activities supported by Federal contract awards. In addition, the contractor shall comply with the provisions of Department of Defense Directive 3216.1, as implemented by SECNAVINST 3900.38B, and DFARS 252.235-7002, "Animal Welfare," which is incorporated into this contract.

2.9.2. Human Subjects Testing.

Any contract resulting from this BAA that potentially involves the use of Human Subjects in the research or study shall include with the following language:

The contractor shall comply with all regulations promulgated by the Office of the Secretary of Defense in 32 C.F.R. Part 219, pertaining to the protection of human subjects. In addition, the contractor shall comply with the provisions of Department of Defense Directive 3216.2. If human subjects are to be used at any time during the project, the contractor shall have a Federal assurance that is acceptable to the CTTSO before involving human subjects. Additionally, the protocol shall be approved by a Federally-assured Institutional Review Board (IRB) office named in the institution's assurance. The contractor shall prepare these documents and shall ensure that they are on file with CTTSO prior to the start of research involving human subjects. Collaborators with the contractor, to include IRBs, shall also comply with regulations to protect human subjects for both classified and unclassified research. The contractor shall report all changes in the protocol or consent form to the CTTSO Contracting Officer's Representative (COR) as they occur. Release of initial and follow-up funding will be contingent upon initial and continuing reviews, and to other IRB and component requirements.

Required contract statements in the event an award arises from a submission to a BAA.

BAA - Section Three

Full Proposals

Submitters must include a statement regarding human subject use, or animal testing involvement in research.

3.7.5.13. Human Subjects and Animal Testing.

The proposal shall provide a statement regarding the anticipated use of human subjects or animals in testing; or if none, so state. If yes, procedures for complying with all laws and regulations governing the use of animals or human subjects in research projects shall be included in the technical proposal. See section 2 General Information, "Animal or Human Testing Compliance" in this document for details.

Submission Upload

Cancel

New **Quad Chart** for QED
BAA: 08-Q-TESTSC Requirement: 5454 Requirement 5454

*Note: Please review the BAA to be aware of any recent revisions.

Fields marked with an asterisk (*) are required.

User Name: QED
Submission Date: 31-JAN-2007
* Proposal Title:
* Submitter Internal Tracking #: TAW-5454-QED-
The SIT# is a company internal tracking number. Place the cursor in the textbox and enter a tracking number for the submittal. See FAQ section [Submission Preparation](#) for clarification on completing this naming process.
* Total Cost Estimate: US\$
*Unlimited rights in intellectual property, technical data, and/or software are proposed: Yes No
***Animal or human subjects will be used in the proposed research or testing:** Yes No
For more information on submission preparation, refer to the [Downloads](#) section on the [Home](#) page or the [Materials](#) section on the [Home](#) page.

Comments:

Call SpellCheck

* Attachment:
 Browse...

There are no attachments on this document. Please upload an attachment of 0.5 MB or less.

Submit for Processing

During the BIDS upload process submitters must identify human subject or animal testing projects in the submission record. Make the selection that is appropriate to the submission.

Mandatory Contract Clauses

For animal testing in research projects

2.9.1. Animal Testing.

Any contract resulting from this BAA that potentially involves the testing of animals shall include the following language:

Any contractor performing research on warm blooded vertebrate animals shall comply with the Laboratory Animal Welfare Act of 1966, as amended, 7 U.S.C. §§ 2131 - 2156, and the regulations promulgated thereunder by the Secretary of Agriculture in 9 C.F.R. Parts 1 through 4, pertaining to the care, handling, and treatment of vertebrate animals held or used for research, teaching, or other activities supported by Federal contract awards. In addition, the contractor shall comply with the provisions of Department of Defense Directive 3216.1, as implemented by SECNAVINST 3900.38B, and DFARS 252.235-7002, "Animal Welfare," which is incorporated into this contract.

In the event of contract award the Government requires compliance with:

- **The Laboratory Animal Welfare Act of 1966, as amended, 7 U.S.C. §§ 2131 - 2156, and the regulations promulgated thereunder by the Secretary of Agriculture in 9 C.F.R. Parts 1 through 4, pertaining to the care, handling, and treatment of vertebrate animals held or used for research, teaching, or other activities supported by Federal contract awards.**
- **Department of Defense Directive 3216.1, as implemented by SECNAVINST 3900.38B, and DFARS 252.235-7002, "Animal Welfare,"**

Proposers intending to submit solutions that include animals

- Review all Government regulations as stipulated in the BAA package with all team members, including legal, for applicability to proposed project.
- Assemble documentation and obtain certifications required for full compliance.
- In the event of an award, submitters must be prepared to offer proof of compliance upon request.

Mandatory Contract Clauses

For human subjects in research projects

2.9.2. Human Subjects Testing.

Any contract resulting from this BAA that potentially involves the use of Human Subjects in the research or study shall include with the following language:

The contractor shall comply with all regulations promulgated by the Office of the Secretary of Defense in 32 C.F.R. Part 219, pertaining to the protection of human subjects. In addition, the contractor shall comply with the provisions of Department of Defense Directive 3216.2. If human subjects are to be used at any time during the project, the contractor shall have a Federal assurance that is acceptable to the CTTSO before involving human subjects. Additionally, the protocol shall be approved by a Federally-assured Institutional Review Board (IRB) office named in the institution's assurance. The contractor shall prepare these documents and shall ensure that they are on file with CTTSO prior to the start of research involving human subjects. Collaborators with the contractor, to include IRBs, shall also comply with regulations to protect human subjects for both classified and unclassified research. The contractor shall report all changes in the protocol or consent form to the CTTSO Contracting Officer's Representative (COR) as they occur. Release of initial and follow-up funding will be contingent upon initial and continuing reviews, and to other IRB and component requirements.

BAA excerpt, section 2

The Government requires compliance with provisions in 32 C.F.R. Part 219 and DoDDirective 3216.2 in the event of an award.

The submitter's Federal assurance must be acceptable to the CTTSO before involving human subjects.

Research protocol shall be approved by the IRB named in the assurance.

Submitters must have the documents on file with CTTSO prior to the start of research involving human subjects.

All persons or entities involved with project are required to comply with Government regulations for classified and unclassified research.

Any changes in the protocol or consent form are to be reported as they occur.

All funding for the project is contingent upon full compliance throughout the life of the project.

The Principle Investigator Role

Principle Investigators are company or agency representatives that are responsible to:

- Protect the rights and welfare of research participants in accordance with the CFR and DoD Directive.
- Comply with institutional assurance.
- Understand Federal policies and procedures.
- Conduct research according to the IRB-approved protocol.
- Comply with IRB determinations.
- Ensure all potential participants fully understand the content of research.
- Obtain and document the informed consent of each participant.
- Report any changes and/or developments to the CTTSO PM upon occurrence.
- Report any serious and unexpected adverse events of the research to the CTTSO PM.
- Transmit updated assurances, IRB approval and continuing IRB reviews, IRB approved protocols, unsigned consent forms, this includes all updates to any documentation to the CTTSO PM.
- Ensure the institution engaged in CTTSO-sponsored research has a Federal assurance that is acceptable to CTTSO before involving human subjects. Additionally, ensure the protocol is approved by the IRB named in the institution's assurance.
- Ensure collaborators with the institution, to include IRBs, comply with regulations to protect human subjects for both classified and unclassified research.
- Ensure that all changes in the protocol or consent form are reported to the CTTSO Program Manager immediately upon occurrence. NOTE: Release of initial and follow-on funding is tied to reviews and other IRB and component requirements.

Documentation Requirements

Federal Assurances must include:

- *A statement of principles governing the institution's responsibilities.*
- *The Institutional Review Board(s) must be named.*
- *A list of IRB members.*
- *A written procedure describing the review process and,*
- *A written procedure for reporting problems or suspensions.*

[Click here to see a Federal Wide Assurance \(FWA\)](#)

Other supporting documents include:

- *A human subject's certificate stating that the protocol has been reviewed and approved by the IRB designated in the assurance.*

[Click here to review a certificate.](#)

- *A copy of the unsigned consent form.*

For more information regarding consent forms see "Common Rule" guidance Sec. 219.116, General Requirements for informed consent; and Sec. 219.117, Documentation of informed consent.

Risk to Subjects

**Determine when documentation must be on file with the CTTSO.
Risk is accessed during the evaluation process.**

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. (Source: 32 CFR 219 – Definitions)

Research involving GREATER than minimal risk involves:

- Use of investigational new drugs or devices.
- Most invasive procedures.
- Intentional deception of subjects, such as misleading or untruthful information.
- Surveys or interviews likely to be stressful to the subject. (i.e., research on very complex or problematic behaviors, such as sexuality, criminality, relationship dysfunction, or substance abuse)
- Non-exempt research that involves vulnerable populations, such as children, prisoners, mentally retarded, mentally disabled, or pregnant women.

What if I don't have an assurance?

Small businesses and non-DoD entities that do not have an assurance should visit the Department of Health and Human Services, Office for Human Research Protections (OHRP) website for guidance.



The screenshot shows the OHRP website interface. At the top left is the HHS logo and the text "United States Department of Health & Human Services". To the right is a search bar with a "Search" button and a link for "Questions & Answers". Below the header is a navigation bar with links: "OHRP Home", "About OHRP", "Search OHRP", "Contact OHRP", and "OHRP News". The main content area is titled "Office for Human Research Protections (OHRP) Assurances" with a version date of 10/25/2006. It contains introductory text about the two-step process for obtaining an assurance, a link to "FAQs on Assurances", and a section titled "LIST OF APPROVED ASSURANCES AND REGISTERED IRBs/IECs" with a sub-section for "Basic Assurance Requirement". A sidebar on the left lists various topics like "IRB Registration", "Assurances", "Regulations", etc.

Read the information carefully. To access areas below the viewing screen use the scroll bar.

To apply for a Federal Wide Assurance follow the guidance under *Assurance Submission*.

To find a IRB in your area use the Search feature under *List of Approved Assurance and Registered IRBs/IECs*

To register an IRB follow the guidance in the *IRB/IEC Registration* section.

http://www.hhs.gov/ohrp/assurances/assurances_index.html