Submitter Guidance for Human Subjects Use or Animal Testing in Research

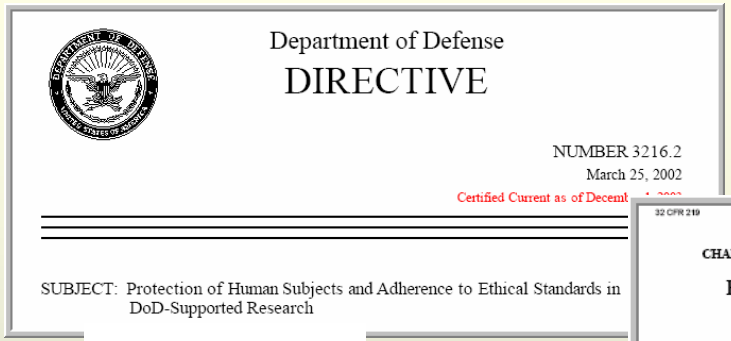
Published 4/2/2007

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.

The Government has published guidance that requires all DoD component agencies or activities, when funding projects that involve human subjects or animal testing, to adhere to the mandatory protections provided in federal regulations and DoD Directives.

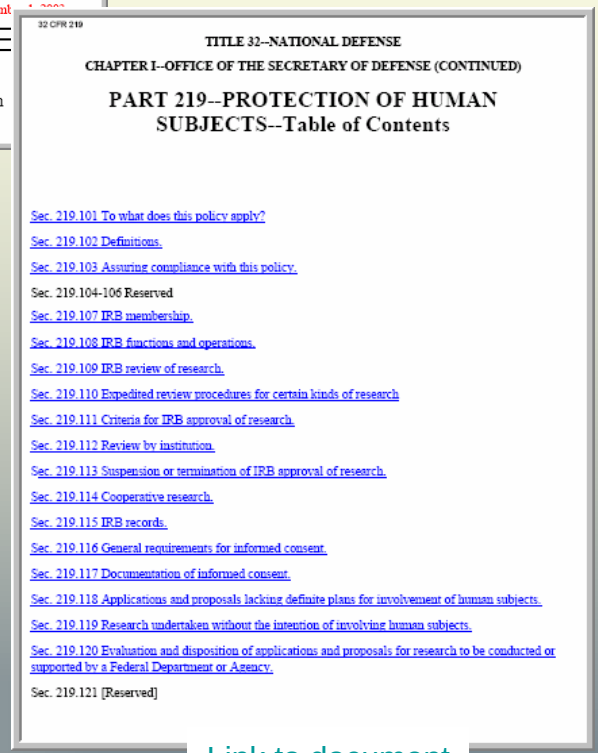


Department of Defense
DIRECTIVE

NUMBER 3216.2
March 25, 2002
Certified Current as of Decem

SUBJECT: Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research

Link to document



32 CFR 219

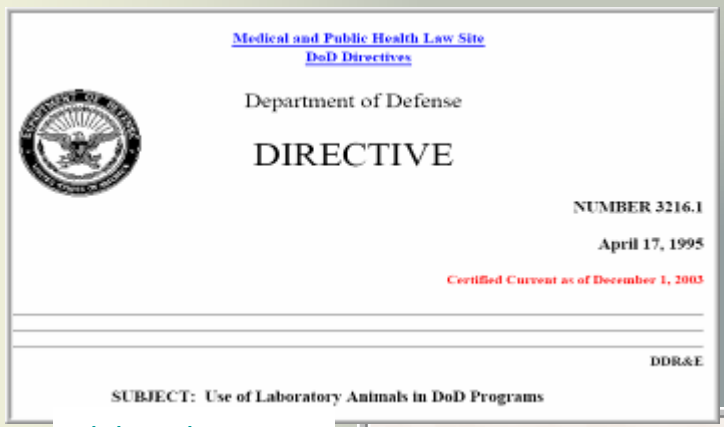
TITLE 32--NATIONAL DEFENSE

CHAPTER I--OFFICE OF THE SECRETARY OF DEFENSE (CONTINUED)

PART 219--PROTECTION OF HUMAN SUBJECTS--Table of Contents

Sec. 219.101 To what does this policy apply?
Sec. 219.102 Definitions.
Sec. 219.103 Assuring compliance with this policy.
Sec. 219.104-106 Reserved
Sec. 219.107 IRB membership.
Sec. 219.108 IRB functions and operations.
Sec. 219.109 IRB review of research.
Sec. 219.110 Expedited review procedures for certain kinds of research
Sec. 219.111 Criteria for IRB approval of research.
Sec. 219.112 Review by institution.
Sec. 219.113 Suspension or termination of IRB approval of research.
Sec. 219.114 Cooperative research.
Sec. 219.115 IRB records.
Sec. 219.116 General requirements for informed consent.
Sec. 219.117 Documentation of informed consent.
Sec. 219.118 Applications and proposals lacking definite plans for involvement of human subjects.
Sec. 219.119 Research undertaken without the intention of involving human subjects.
Sec. 219.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.
Sec. 219.121 [Reserved]

Link to document



Medical and Public Health Law Site
DoD Directives

Department of Defense

DIRECTIVE

NUMBER 3216.1

April 17, 1995

Certified Current as of December 1, 2003

DDR&E

SUBJECT: Use of Laboratory Animals in DoD Programs

Link to document

TITLE 9: CODE OF FEDERAL REGULATIONS, CHAPTER 1

Animal and Plant Health Inspection Service, USDA

SubChapter A: Animal Welfare

Link to document

BAA Section 2

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.

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.

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

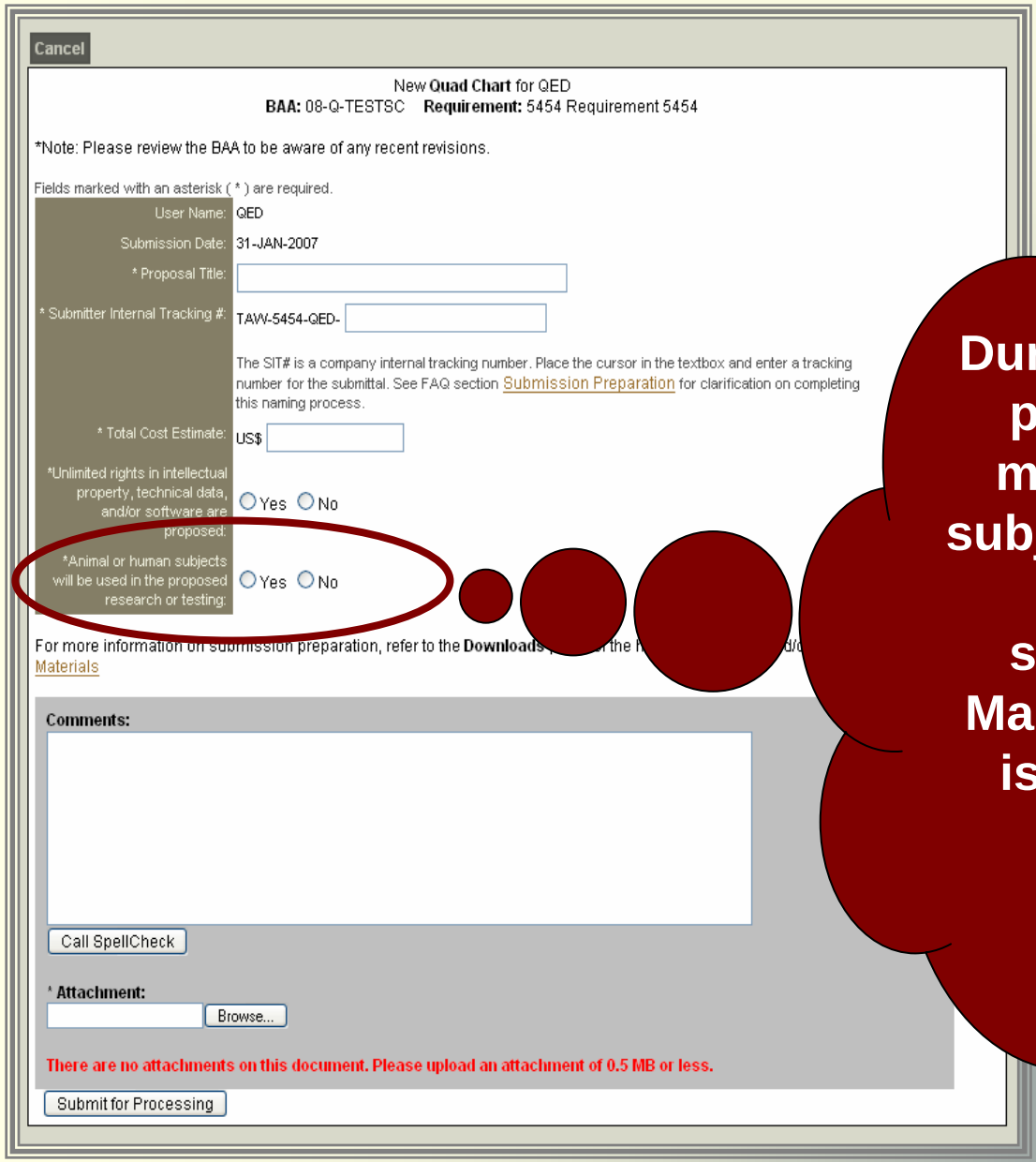
BAA - Section Three
Full Proposals

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.

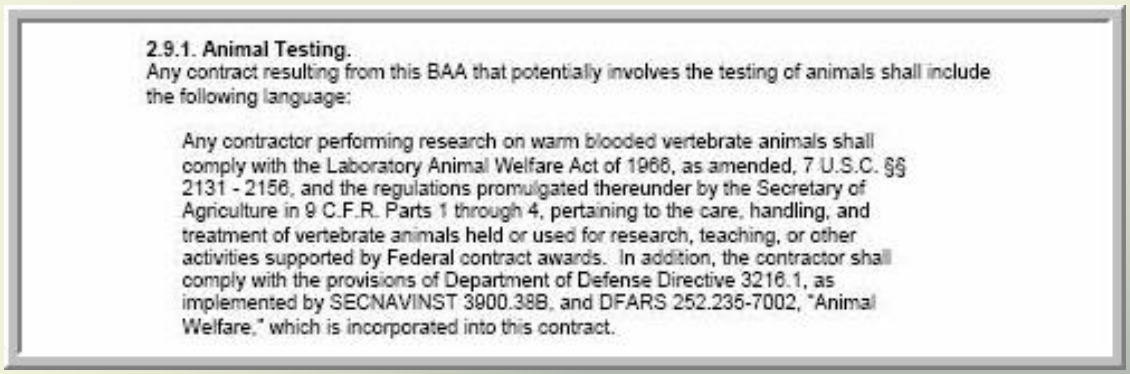
Submission Upload



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.

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

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.