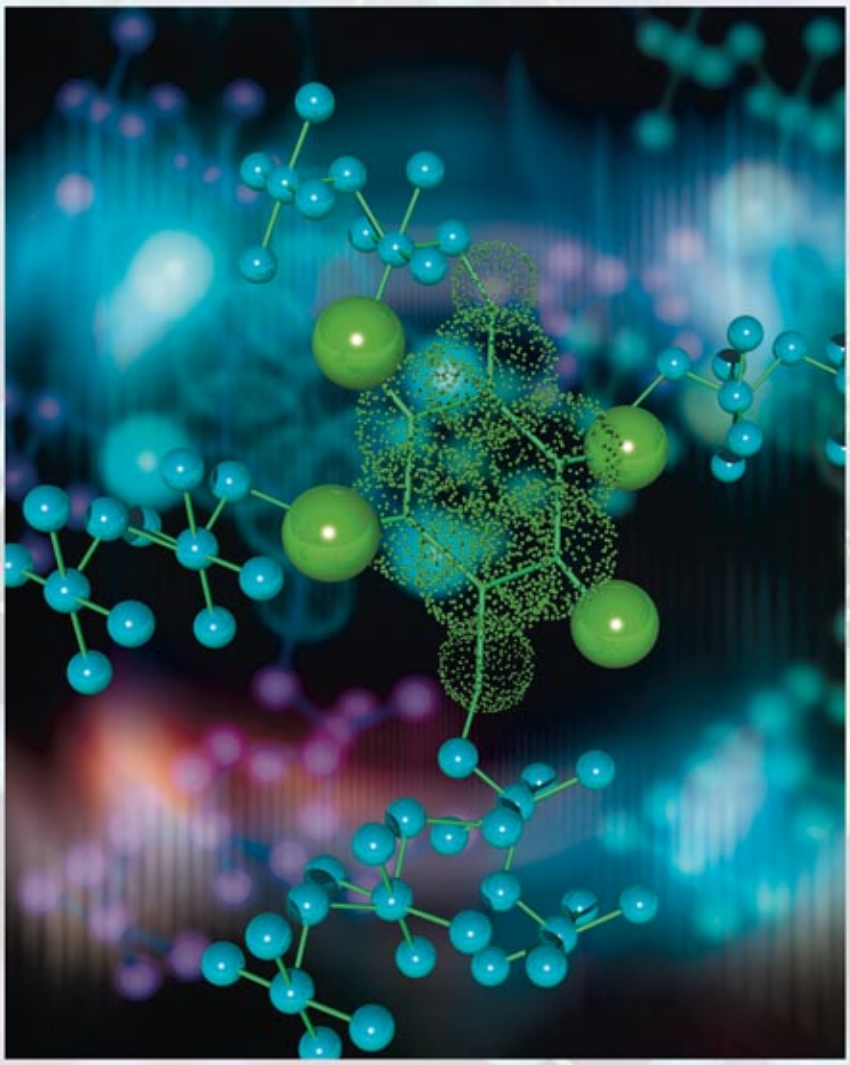
ADVANCED TECHNOLOGY PROGRAM



Guidelines and Documentation Requirements for Research Involving Human and Animal Subjects

February 2004

National Institute of Standards and Technology
Technology Administration U.S. Department of Commerce

CONTENTS

I. Research Involving Human Subjects

A. Introduction

The Advanced Technology Program (ATP) will fund research involving human subjects. Research involving human subjects must comply with all applicable federal statutes, Executive Orders, federal regulations, and policies. Applicable authorities are listed in Appendix 1.

For certain types of research involving human subjects, the National Institute of Standards and Technology (NIST) has procedures that require NIST as an institution to approve documentation in addition to ATP review and approval.

The Federal Policy for the Protection of Human Subjects (the Common Rule), adopted by the Department of Commerce (DOC) at 15 C.F.R. Part 27, sets forth the appropriate policies and procedures for the protection of human subjects in research. The Common Rule is available at http://www.access.gpo.gov/nara/cfr/cfr-table-search.html.[1]

The Common Rule defines *human subject* as a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual or (2) 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 provides a systematic means, based on established, internationally recognized ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities. An awardee institution bears the responsibility for safeguarding the rights and welfare of human subjects in DOC-supported research.

To help you determine whether your research includes the use of human subjects, you are encouraged to review the Human Subjects Determination Checklist in Appendix 2 before submitting your proposal to ATP.

B. Assurance of Compliance

Applicant organizations proposing to involve human subjects in nonexempt research must have on file a written assurance approved for federalwide use from the Office for Human Research Protections (OHRP) within the Department of Health and Human Services (DHHS).

[1] Websites listed in this publication are accurate as of the publishing date. Check www.atp.nist.gov/atp/helpful.htm for updates to websites.

The Common Rule at section 27.103(a) requires that each institution engaged in federally supported human subject research file an assurance of compliance. An assurance formalizes the institution's commitment to protect human subjects.

Under the Common Rule at section 27.102(f), awardees and their collaborating institutions become engaged in human subject research whenever their employees or agents (1) obtain data through intervention or interaction with living individuals for research purposes or (2) obtain identifiable private information for research purposes.

Awardee institutions are considered to be engaged in human subject research whenever they receive a direct DOC award to support such research, even when all activities involving human subjects are carried out by a joint venture partner, subcontractor, or formal collaborator. In such cases, the awardee institution bears ultimate responsibility for protecting human subjects under the award.

Awardees are also responsible for ensuring that each joint venture partner, subcontractor, and formal collaborating institution that is engaged in human subject research hold an assurance approved for federalwide use from OHRP.

ATP will accept either a current Federalwide Assurance (FWA) or a current Multiple Project Assurance (MPA) from OHRP. ATP does not grant or accept a Single Project Assurance (SPA). Information regarding the FWA process can be found at http://ohrp.osophs.dhhs.gov/humansubjects/assurance/fwas.htm.

C. Protected Classes

Research involving pregnant women, human fetuses, neonates, prisoners, or children must comply with 45 C.F.R. Part 46 Subparts B, C, and D, respectively, which describe additional protections required for these human subjects.

NIST considers all custom collection of gestational tissues (e.g., yolk sac) or cells to be covered by subpart B.

The regulations for research involving the protected classes identified in subparts B, C, and D can be found at http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm.

The use of cadaveric materials is governed by applicable state and local laws and is not directly regulated by the Common Rule.

D. Clinical Trials

On a case-by-case basis, ATP may support research as part of a Phase I clinical trial. ATP expects requests to support Phase I clinical trials to be rare. If the research proposed includes all or any portion of a Phase I clinical trial, the research must be deemed consistent with all ATP requirements for scientific and technological merit selection criteria. Although the criteria may be met, ATP reserves the right not to fund the Phase I clinical trial, and ATP may ask the proposer to describe the impact on the project if that activity is removed from the project.

Under no circumstances will ATP support research included in a Phase II, Phase III, or Phase IV clinical trial.

E. Human Subjects in Foreign Countries

Generally, ATP does not fund research involving human subjects in foreign countries. ATP will consider, however, the use of tissue, cells, or data from a foreign source on a limited basis if all of the following criteria are satisfied:

1. the scientific source is considered unique,
2. an equivalent source is unavailable within the United States,
3. an alternative approach is not scientifically of equivalent merit, and
4. the specific use qualifies for an exemption from the Common Rule.

F. Transplantation of Fetal Tissue

Research involving the transplantation of human fetal tissue must meet all of the requirements set forth at section 498A(b) and (c) of the Public Health Service Act, 42 U.S.C. §§ 289g(b) and (c), and section 111 of the NIH Revitalization Act of 1993, 42 U.S.C. § 289(g)1. Guidance can be found at http://ohrp.osophs.dhhs.gov/humansubjects/guidance/publiclaw103-43.htm.

G. Research Involving Embryos and Embryonic Stem Cells

ATP adheres to all federal statutes, Executive Orders, federal regulations, and policies regarding the use of human embryos and human embryonic stem cells.

Although other federal agencies may permit the use of human embryonic stem cells in federally funded research, ATP will not consider any proposal that intends to create, destroy, derive, characterize, or use human embryonic stem cells.

H. Research Exempt From the Regulations

Certain research activities may qualify for an exemption from the requirements of the Common Rule. The categories of research that qualify for an exemption can be found at 15 C.F.R. § 27.101(b). The exemptions most commonly cited in ATP awards are the following:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. [15 C.F.R. § 27.101(b)(1)]
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public

behavior, unless (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects, and (ii) any disclosure of the human subjects' responses outside the research could reasonably place subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. [15 C.F.R. § 27.101(b)(2)]

3. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. [15 C.F.R. § 27.101(b)(4)]

Exemptions are not available for research involving the protected classes identified at 45 C.F.R. Part 46 Subpart C (prisoners). Also, the exemption at 15 C.F.R. § 27.101(b)(2) for research involving survey or interview procedures or observation of public behavior does not apply to research with children, except for research involving observations of public behavior when the investigator or investigators do not participate in the activities being observed.

To determine whether your research qualifies for an exemption from the Common Rule or 45 C.F.R. Part 46 Subparts B or D, please see the Human Subjects Determination Checklist in Appendix 2.

I. Required Documentation

You are required to indicate on Form NIST-1262 or Form NIST-1263, at item 13.D in the *ATP Proposal Preparation Kit,* whether your research involves human subjects.

The Human Subjects Determination Checklist in Appendix 2 will assist you in determining whether your research involves human subjects. You are strongly encouraged to review the authorities found in Appendix 2 before submitting your Gate 1 proposal.

NIST and ATP reserve the right to make an independent determination of whether your research involves human subjects. If NIST or ATP determines that your research project includes human subjects, you will be required to provide additional information for review and approval.

The documentation requirements for the use of human subjects are listed below. In addition, a timeline for the submission of required documents is presented in Appendix 5.

1. Research Exempt From the Common Rule

If your use of human subjects qualifies for an exemption from the Common Rule, you are required to submit a completed exemption request form (see Appendix 3 or 4, as applicable) with your Gate 1 proposal.

2. Research Not Exempt From the Common Rule

If your use of human subjects does not qualify for an exemption, and the research is scheduled to begin during the first year, you are required to submit the following at Gate 3:

a. a signed copy of the final Institutional Review Board (IRB) approved human subjects research protocol for each of the specific research tasks;

b. a copy of all IRB approved consent forms and advertisements;

c. a signed and dated approval letter from the IRB that indicates the start and end dates for the approved research; and

d. if applicable, any IRB required interim reporting requirements.

3. Research Beginning After Year 1 of the Proposal

If there are no research tasks involving human subjects in the first year of the proposal, but there are tasks anticipated beyond the first year, a detailed request for deferred IRB approval or exemption as appropriate under 15 C.F.R. § 27.118 must be submitted to ATP at Gate 1. A deferral request must include the following information:

a. an outline of the tasks that will be performed using human subjects;

b. the projected start date for the use of human subjects (e.g., second quarter of year 3);

c. an outline of when the ATP and NIST required documentation will be submitted to ATP for review and approval; and

d. if the research requires IRB review and approval, the name of the institution housing the IRB and the assurance number on file with OHRP.

J. Contact Information

If you have any questions regarding the use of human subjects in research, please call the ATP Human and Animal Subjects Advisor at 301–975–8779.

The information contained in this booklet is also available on the ATP website at http://www.atp.nist.gov/atp/helpful.htm.

K. Definitions

Terms used in this booklet are defined in the Common Rule at 15 C.F.R. Part 27.

The regulations under 15 C.F.R. Part 27 can be found at http://www.doc.gov/oebam/gforms.htm.

Clinical Trial: A prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices).

Custom Collection: The collection or gathering of organs, tissues, cells, or data for the purpose of research that would have otherwise not been collected or gathered.

Human Subject: A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information. [15 C.F.R. § 27.102(f)]

The regulations governing human subjects extend to the use of human organs, tissues, cells, and bodily fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects.

Intervention: Includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. [15 C.F.R. § 27.102(f)]

Phase I Clinical Trial: A clinical trial done to test a new biomedical or behavioral intervention in a small group of people (e.g., 20–80) for the first time to evaluate safety, efficacy, and effectiveness (e.g., determine a safe dosage range and identify side effects).

Private Information: Includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects. [15 C.F.R. § 27.102(f)]

Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. [15 C.F.R. § 27.102(d)]

II. Research Involving Vertebrate Animals

A. Introduction

ATP will fund research involving live vertebrate animals. Research involving live vertebrate animals must be in compliance with all applicable federal statutes, federal regulations, and policies.

For research involving live vertebrate animal subjects, NIST has procedures that require NIST as an institution to approve documentation in addition to ATP review and approval.

NIST and ATP follow the regulations in the Animal Welfare Act at 7 U.S.C. §§ 2131–2159. In addition, the Institutional Animal Care and Use Committee (IACUC) should follow the recommendations in the National Research Council's *Guide for the Care and Use of Laboratory Animals* (the *Guide*) as a basis for developing and implementing an institutional animal care and use program.

These policies do not affect applicable state or local laws or regulations that may impose more stringent standards for the care and use of laboratory animals.

The requirements described below do not apply to proposed research using preexisting images of animals (e.g., a wildlife documentary or pictures of animals in newscasts) or to research plans that *do not* include animals that are being cared for, euthanized, or used by the project participants to accomplish research goals, teaching, or testing.

These requirements also do not apply to obtaining animal materials from commercial processors of animal products or to animal cell lines or tissues from tissue banks.

B. IACUC Review and Compliance

NIST and ATP require that the IACUC that reviews and approves the care and use of live vertebrate animals maintain and comply with appropriate institutional assurances, certifications, or accreditations.

Depending on the research and type of live vertebrate animal involved in the research, NIST and ATP require that the IACUC maintain at least one of the following:

1. documentation of an Animal Welfare Assurance from the Office of Laboratory Animal Welfare (OLAW) of the Public Health Service/National Institutes of Health (PHS/NIH); or
2. documentation of a United States Department of Agriculture (USDA) Animal Welfare Act certification; or

3. if only using rodents, birds, or fish, and the above USDA or OLAW documents have not been attained, evidence of full accreditation from the Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC).

C. Animal Study Protocols

NIST and ATP require that each use of live vertebrate animals be reviewed and approved through the use of an Animal Study Protocol (ASP). The ASP must be completed by the Principal Investigator or designee and reviewed and approved by the IACUC where the animals will be housed, cared for, and manipulated before any research has started.

NIST and ATP recommend that an approved ASP should include the elements suggested by OLAW. These elements can be found online at http://grants.nih.gov/grants/olaw/olaw.htm.

Please note: An example of an ASP or an ASP that is similar to what may eventually be submitted to an IACUC for review is not acceptable.

Also, if the ASP includes tasks not applicable to the ATP project, or if the ASP is supported by multiple funding sources, you must include a brief description of what portions of the ASP are specifically included in the ATP project. In addition, a nonduplication-of-funding letter indicating that no other federal funds will be used to support the tasks ATP will pay for must be submitted before issuance of an award.

D. Required Documentation

You are required to indicate on Form NIST-1262 or Form NIST-1263, at item 13.E (see the *ATP Proposal Preparation Kit*), whether your research will involve the use of live vertebrate animals. The documentation requirements for the use of live vertebrate animals are listed below. In addition, a timeline for the submission of required documents is presented in Appendix 6.

1. Live Vertebrate Animal Research Beginning in Year 1

If your research proposal includes plans to use live vertebrate animals in the first year, the following is required at Gate 3:

a. a signed copy of the IACUC approved ASP;

b. documentation of the IACUC approval indicating the approval and expiration dates of the ASP; and

c. if applicable, a nonduplication-of-funding letter.

2. Live Vertebrate Animal Research Beginning After Year 1

If your research proposal includes the use of live vertebrate animals beginning after year 1, the following documentation is required at Gate 3:

a. the name of the organization(s) that may be performing the animal studies;

b. an indication of whether the organizational IACUC has an appropriate OLAW Assurance, USDA certification, or AAALAC accreditation; and

c. a timeline for the use of live vertebrate animals, including an approximate date of IACUC approval.

Before live vertebrate animal studies may begin, the required documents mentioned in Section D.1 of this chapter must be reviewed and approved by ATP and NIST.

3. Continuing Review of Animal Study Protocols

ATP requires documentation of annual continuing approval of all ASPs. The awardee is required to submit, as it occurs, documentation from the cognizant IACUC that continuing approval has been granted. In addition, ATP requires that all forms and/or amendments submitted to the IACUC for continuing approval also be submitted to ATP.

E. Contact Information

If you have any questions regarding the use of animal subjects in research, please call the ATP Human and Animal Subjects Advisor at 301–975–8779.

The information contained in this booklet is also available on the ATP website at http://www.atp.nist.gov/atp/helpful.htm.

F. Definitions

The following definitions can be found in the Animal Welfare Act at 7 U.S.C. §§ 2131–2159 or in the National Research Council's *Guide for the Care and Use of Laboratory Animals*.

Animal Study Protocol: A document that is submitted to an IACUC that outlines the care and use of animal subjects in a research setting. The *Guide* at page 10.

IACUC: The Institutional Animal Care and Use Committee. The IACUC is appointed by the responsible administrative official at each institution and is charged with overseeing and evaluating the institution's animal program, procedures, and facilities to ensure they are consistent with all applicable statutes, regulations, and policies. The *Guide* at page 9.

Vertebrate Animal: Any live dog, cat, nonhuman primate, guinea pig, hamster, rabbit, or any other warm-blooded animal that is being used or is intended for use in research, teaching, testing, experimentation, or exhibition purposes.

In addition, ATP considers live vertebrate animals to include rats of the genus *Rattus,* mice of the genus *Mus,* birds, and any farm animal or other warm-blooded animal.

Applicable Authorities

Federal statutes, Executive Orders, federal regulations, policies, and guidelines have been issued concerning many types of research activities involving human subjects. Although NIST may not be directly named in these authorities, to ensure that research involving human subjects funded by NIST is consistent with national policy, NIST hereby declares that it will fully adhere to these authorities. Shown below is a partial list of the statutes, regulations, policies, and guidelines applicable to research involving human subjects and research involving vertebrate animal subjects. The proposer is advised to read and comply with all applicable authorities when submitting a proposal.

Animal Welfare Act. 1966. Pub. L. No. 89-544, as amended, codified at 7 U.S.C. §§ 2131–2159. Available at http://www.aphis.usda.gov/ac/publications.html#awa.

National Research Council. 1996. *Guide for the Care and Use of Laboratory Animals.* Washington, DC: National Academies Press. Available at http://www.nap.edu/readingroom/books/labrats.

Research on Transplantation of Human Fetal Tissue: http://ohrp.osophs.dhhs.gov/humansubjects/guidance/publiclaw103-43.htm.

Office of Laboratory Animal Welfare of the Public Health Service: http://grants.nih.gov/grants/olaw/olaw.htm.

U.S. Department of Commerce. Protection of Human Subjects. 15 C.F.R. Part 27. Available at http://www.access.gpo.gov/nara/cfr/waisidx_99/15cfr27_99.html.

U.S. Department of Health and Human Services. Protection of Human Subjects. 45 C.F.R. Part 46. Available at http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm.

APPENDIX 2

Human Subjects Determination Checklist

This checklist should be used to determine whether human subjects are involved in the research project and whether the research is exempt under the Department of Commerce regulations for the protection of human subjects found at 15 C.F.R. Part 27. A proposal may contain more than one research activity involving human subjects that requires different levels of review. This checklist should be used for each potential use of human subjects.

1. Is there an intervention or an interaction with a living person that would not be occurring or would be occurring in some other fashion but for this research? Examples: videotaping people, observing children using software, surveying manufacturing personnel during a pilot test of new equipment, gathering tissue or cells from human donors.

   ☐ Yes—Human subjects are involved. Go to question 3.

   ☐ No—Go to question 2.

2. a. Will data/information/specimens collected originally from people or about people be used in this research? Examples: broadcast video, Web-use logs, medical information, cells or tissues, survey questions.

      ☐ Yes—Identifiable human subjects may be involved. Go to question 2.b.

      ☐ No—Go to question 6. It appears that human subjects may not be involved in the project. However, an exemption determination may be required. Please review question 3 for additional information about research that may require an exemption determination.

   b. Does that information contain private information in a form in which the identity of the subject is or may readily be ascertained from the information? Examples: medical records, donor name or address, sales transaction records.

      ☐ Yes—Identifiable human subjects are involved. Go to question 3 to see if an exemption may apply. If you know that an exemption does not apply, proceed to question 5.

      ☐ No—Go to question 3. The research may not be within the scope of 15 C.F.R. Part 27; however, it may require an exemption determination to be made due to the use of data, recordings, or specimens that could be linked to humans without appropriate safeguards.

3. Do you think the research may either not be within the scope of 15 C.F.R. Part 27 or qualify for an exemption under 15 C.F.R. § 27.101(b)? The following questions will help you evaluate whether to request an exemption determination by ATP or provide documentation that the research may not be within the scope of 15 C.F.R. Part 27:

   a. Will the task involving human subjects use only existing data, recordings (audio or visual), or specimens? Examples: patient records, a company's customer data, Web-use logs, cells, or tissue.

      ☐ Yes—Go to question 3.d.

      ☐ No—Go to question 3.b.

   b. Will the research plan involve normal educational practices such as instructional strategies or comparison of instructional techniques, curricula, or classroom management methods? Examples: observation of student-teacher interactions, video of instruction.

      ☐ Yes—Go to question 3.d.

      ☐ No—Go to question 3.c.

   c. Will the research plan involve educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior? Examples: broadcast video, software usage testing.

      ☐ Yes—Go to question 3.d.

      ☐ No—Go to question 5. This research is probably not exempt and will require Institutional Review Board (IRB) review and approval.

   d. Do any of the data, recordings, specimens, or practices/procedures involve or come from a protected class? Protected classes include prisoners, children, pregnant women, human in vitro fertilization, fetuses, and nonviable fetuses or fetal sources of data, cells, or tissue. Examples: testing educational software with children, surveys of obstetric patients.

      ☐ Yes—Go to question 5. This research is probably not exempt and will require IRB review and approval.

      ☐ No—Go to question 3.e.

   e. Are the data, recordings (audio or visual), or specimens publicly available? NOTE: Publicly available may include items for sale, items that are freely available to the public, or items that reside in the public domain. Examples: customer data sets, catalog orders of cells or tissues, donations of pathological specimens, shareware.

☐ Yes—Go to question 4. This research may be exempt under 15 C.F.R. § 27.101(b).

☐ No—Go to question 3.f.

f. Will the data, recordings (audio or visual), or specimens be stripped of all identifiable information that could be linked to a human subject prior to being received by the investigator?

☐ Yes—Go to question 4. This research may not be within the scope of 15 C.F.R. Part 27, or this research may be exempt under 15 C.F.R. § 27.101(b).

☐ No—Go to question 3.g.

g. Will information be recorded by the investigator in such a way that it can be linked to the human subject? Examples: Web-use logs tied to e-mail address, patient records, or specimens that include patient identifiers.

☐ Yes—Go to question 5. This research is probably not exempt and will need an IRB review.

☐ No—Go to question 4. This research may be exempt under 15 C.F.R. § 27.101(b).

4. An exemption under 15 C.F.R. § 27.101(b) may apply to the task, or the task may not be within the scope of 15 C.F.R. Part 27. In order to complete the necessary requirements for research considered exempt under 15 C.F.R § 27.101(b), please review this booklet. Complete Appendix 3 and/or Appendix 4 in this booklet as required and submit with Gate 1 proposal.

5. An exemption probably does not apply to the proposed research and further documentation is required. Please review this ATP booklet. See Appendix 5 for required documentation list.

6. It appears that human subjects are not involved in this project. This checklist is only a tool for general guidance and does not constitute a final legal opinion from NIST on whether human subjects are involved, or whether an exemption determination under the regulations is needed. If, upon NIST/ATP review of your proposal, it is determined that additional documentation is needed to reach a final determination, and your proposal is selected as a semifinalist (Gate 3), you will be asked to provide the additional documentation prior to an oral review.

APPENDIX 3

Request for an Exemption From 15 C.F.R. Part 27 for Research Involving Human Subjects in Information Technology, Manufacturing, or Imaging Studies

If the research may be exempt under 15 C.F.R. § 27.101(b), as indicated by your responses to the questions in The Human Subjects Determination Checklist (Appendix 2), then responses to the following questions must be supplied along with the initial proposal submission (Gate 1) to allow NIST and ATP to perform an independent determination of whether the use of human subjects qualifies for an exemption from 15 C.F.R. Part 27. Proposers are reminded that the term *data* includes collection of data from voice, video, digital, or image recordings made for research purposes. For proposals involving biological studies, please complete Appendix 4. If a question is not applicable, please indicate "NA."

1. What is the time frame (start and end dates) for human subject/data/image involvement?

2. State the technical justification for human subject/data/image involvement (i.e., Is there no other way to achieve an equivalent technical outcome? Why?).

3. Are the data/images stripped of any identifiable information (e.g., personal identifiers such as names or codes that can be traced back to the human donor or source)? Explain.

4. Are the data/images publicly available from a named source? Explain and name the source(s) being considered or planned, if appropriate.

   NOTE: An answer of "no" to either question 3 or question 4 may disqualify the project from an exemption. In those cases, an appropriate IRB approval may be required and should accompany the proposal if the work is within the first year of the project.

5. Are the data/images/recording preexisting, being collected for the express purpose of the research, or being obtained by some combination of the two?

6. What is the source of the data/images/recording (e.g., video archives, proprietary database, security systems/records, medical records, video conference records)?

7. What is the extent of data/images/recording handling by the Principal Investigator: collecting, receiving, and/or sending data/images?

8. What is the extent of contact by the Principal Investigator with human subjects: personal observation, image recording, survey questions?

9. What is the extent of control by the Principal Investigator of the environment in which the human subjects will be monitored?

10. Do the data/images/recording come from individuals (e.g., minor children or prisoners) who may need special safeguards? NOTE: An answer of "yes" to question 10 disqualifies the project from exemption under 15 C.F.R. Part 27. In these cases, the proposal protocol/task descriptions MUST be reviewed and approved by an IRB that possesses a current assurance appropriate for the research in question. The assurance must be on file with the OHRP, and approved by OHRP for federalwide use. This IRB approval MUST be submitted by the time of oral review (Gate 3).

11. Is the image/recording in fact "public behavior"? Some indicators of public behavior are the following:

    a. The image of behavior does not give rise to any cause of action under any legal theory protecting personal privacy.

    b. No trade secrets or other confidential information pertaining to any person are in the image or recording.

    c. No copyright restrictions exist, or the copyright holder has granted written permission to the proposer.

    d. The image of behavior contains other matter the proposer deems germane to this issue.

12. If the answer to question 11 is "yes":

    a. Can the human subjects be identified directly or through identifiers?

    b. If the human subjects can be identified, would any disclosure reasonably place the subjects at risk of criminal or civil liability, or would it jeopardize standing, employability, or reputation?

13. Has the research been reviewed by an IRB? If yes, attach a copy of the review.

The following signed statement must accompany the answers to the above questions:

This is an accurate description of the proposed research involving human subjects. Any changes in protocol or task descriptions will be submitted in advance to the IRB as appropriate and to ATP before notification of ATP award decisions.

_____ _____

Name of Principal Investigator Date

APPENDIX 4

Request for an Exemption From 15 C.F.R. Part 27 for Research Involving Human Subjects in Biological Studies

If the research may be exempt under 15 C.F.R. § 27.101(b), as indicated by your responses to the questions in The Human Subjects Determination Checklist (Appendix 2), then responses to the following questions must be supplied along with the initial proposal submission (Gate 1) to allow NIST and ATP to perform an independent determination of whether the use of human subjects qualifies for an exemption from 15 C.F.R. Part 27. For proposals involving the collection of data from voice, video, or digital sources or involving other uses of informatics, please complete Appendix 3.

1. What is the time frame (start and end dates) for human tissue/subject involvement?
2. State the technical justification for human tissue/subject involvement (i.e., Is there no other way to achieve an equivalent technical outcome? Why?).
3. Are the samples stripped of any identifiable information (e.g., personal identifiers such as names or codes that can be traced back to the human donor or source)? Explain.
4. Is the tissue publicly available from a named source? Explain and name the source(s) being considered or planned, if appropriate.

   NOTE: An answer of "no" to either question 3 or question 4 may disqualify the project from an exemption. In those cases, an appropriate IRB approval may be required and should accompany the proposal if the work is within the first year of the project.
5. What is the anatomical source of the cell or tissue (e.g., liver, skin)?
6. What is the extent of tissue handling by the Principal Investigator: collecting, receiving, and/or sending specimens?
7. Are the samples preexisting, being collected for the express purpose of the research, or being obtained by some combination of the two?
8. Are the samples "custom collected" from individuals who may need special safeguards (i.e., minor children, pregnant women, human in vitro fertilization, fetuses, or prisoners)?

   NOTE: An answer of "yes" to question 8 disqualifies the project from exemption under 15 C.F.R. Part 27. In these cases, the proposal protocol/task descriptions MUST be reviewed and approved by an IRB that possesses a current assurance appropriate for the research in question. The assurance must be on file with the OHRP, and approved by

OHRP for federalwide use. This IRB approval MUST be submitted by the time of oral review (Gate 3).

9. Has the research been reviewed by an IRB? If yes, attach a copy of the review.

The following signed statement must accompany the answers to the above questions:

This is an accurate description of the proposed research involving human subjects/tissues. Any changes in protocol or task descriptions will be submitted in advance to the IRB as appropriate and to ATP before notification of ATP award decisions.

_____ _____

Name of Principal Investigator Date

Submission Timeline for Required Documentation—Human Subjects

Determination of Type and Date of Human Subjects Use As Indicated From Appendix 2	Gate 1 (Initial Proposal)	Gate 3 (Oral Review)
Year 1 Exempt (Item 4 from Appendix 2)	Completed answers to Appendix 3 and/or Appendix 4 as required	All other NIST required materials or clarifications as requested in pre-oral-review questions
Year 1 IRB review required (Item 5 from Appendix 2)	• Name of the IRB that will be reviewing the protocol • FWA or MPA number of the "engaged" institution and the expected date of IRB review	• Signed copy of the IRB approved protocol • Signed and dated approval letter from the IRB indicating approval and expiration dates • Copy of all IRB approved consent forms and advertisements
After year 1 Deferred exemption or deferred IRB review required	No documents are required to be submitted with the initial proposal	A projected date of human subjects use and a schedule of when NIST required materials will be submitted in accordance with the categories listed above

FWA = Federalwide Assurance
IRB = Institutional Review Board
MPA = Multiple Project Assurance
NIST = National Institute of Standards and Technology

Submission Timeline for Required Documentation—Vertebrate Animals

Date of Animal Use	Gate 1 (Initial ATP Proposal)	Gate 3 (Oral Review)
Year 1	• Location of use and housing of all vertebrate animals • Name of the IACUC that will be reviewing and approving each ASP	• Signed and dated copy of the IACUC-approved ASP • Documentation of the IACUC approval indicating the approval and expiration dates of the ASP
After year 1 Deferred	No documents are required to be submitted with the initial proposal	• Name of the IACUC that may be reviewing and approving each ASP • Timeline for submission of the approved ASP to NIST for review

ASP = Animal Study Protocol
IACUC = Institutional Animal Care and Use Committee
NIST = National Institute of Standards and Technology

U.S. Department of Commerce
Donald L. Evans, Secretary

Technology Administration
Phillip J. Bond, Under Secretary of Commerce for Technology

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February 2004

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