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ADVANCED TECHNOLOGY PROGRAM
GUIDELINES AND DOCUMENTATION
REQUIREMENTS FOR RESEARCH INVOLVING
HUMAN AND ANIMAL SUBJECTS

NOVEMBER 2000

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Research Involving Human Subjects

This booklet outlines the regulations and policies NIST applies to research proposals that include the use of human and animal subjects. This booklet should be used in conjunction with the ATP Proposal Preparation Kit. Research involving human subjects sponsored by ATP must be in compliance with applicable federal regulations and NIST policy. Before research that may involve human subjects may begin, NIST will independently determine if your research proposal involves the use of human subjects. The term “research” is often misunderstood. Research means “a systematic investigation, including research, development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” Activities that fall within this definition constitute research whether or not they are conducted or supported under a program that is considered research for other purposes. For example, using medical databases/records, conducting employee surveys, human testing of computer software or video quality, and collecting data from voice video, digital or image recordings that include human subjects generally fall within the scope of this rule if the knowledge derived from the research is generalizable. The purpose of the regulations and policies is to protect human subjects from risk or harm resulting from the research activities themselves or publication of research results. Personal harm may include placing a person at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability or reputation, in addition to the traditional concerns about personal health and safety risks. To assist you in determining whether your research involves human subjects, as defined by the regulations, a human subjects checklist is provided for you in **Appendix 1** of this booklet. **Under no circumstance may human subjects be used in your research until NIST has made an independent determination and reviewed and approved the use of human subjects in your research project.**

If you have any questions regarding this information, please call the ATP Human and Animal Subjects Advisor, Mr. Tryn Stimart at 301-975-8779 for additional guidance.

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

Authorities

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

1. Department of Commerce (DOC) regulations entitled “Protection of Human Subjects,” found at 15 CFR Part 27 (<http://www.doc.gov/oebam/gforms.htm>).
2. Department of Health and Human Services (DHHS) regulations found at 45 CFR Part 46 Subparts B , C and D for the protected classes (<http://ohrp.osops.dhhs.gov/humansubjects/guidance/45cfr46.htm>).

3. Children's Online Privacy Protection Act of 1998, 16 CFR Part 312 15 U.S.C. Section 6501 et seq., and implementing regulations found at 16 CFR Part 312 (<http://www.ftc.gov/opa/1999/9910/childfinal.htm>).
4. Section 111 of the NIH Revitalization Act of 1993, 42 U.S.C. Section 289g-1, on transplantation of fetal tissue into human subjects (<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/publiclaw103-43.htm>).
5. Section 498(b) of the Public Health Service Act, 42 U.S.C. Section 289g on the use of fetal tissue.
6. Section 513 of the Departments of Labor, DHHS, and Education, and Related Agencies Appropriations Act of 1998, Public Law 105-78, 111 Stat. 1467 regarding research involving embryos (<http://grants.nih.gov/grants/guide/notice-files/not98-013.html>).
7. The Food and Drug Administration (FDA) guidelines published at 61 FR 49919 (September 23, 1996) regarding research involving xenotransplantation into human subjects (<http://fda.gov/cber/gdlns/xeno.txt>).
8. Presidential Directive, 33 Weekly Comp. Pres. Doc. 281 (March 10, 1997), prohibiting federal conduct and funding of research involving human cloning (http://grants.nih.gov/grants/policy/cloning_directive.htm).

Research Involving The Protected Classes

Research involving the protected classes of human subjects must be in compliance with the regulations found at 45 CFR Part 46 Subparts, B, C and D. Protected classes include pregnant women, human in vitro fertilization and fetuses (Subpart B), prisoners (Subpart C), and children (Subpart D). Some examples of research involving protected classes may include: medical test data from children, software usability test results involving prisoners, surveys with pregnant women as subjects, tissue and cell donations custom collected from fetal sources. The proposer is advised that NIST will require approval of all research involving the protected classes as described in Subpart B, **before** an initial award is issued, regardless of when the research is proposed to begin. NIST will not accept Institutional Review Board (IRB) deferred approvals of protocols for research that involves human subjects defined under Subpart B. In addition, **NIST applies 45 CFR Part 46, Subpart B to all types of gestational tissue, regardless of the source. Thus, any project involving human gestational tissue (including yolk sacs, non-full-term placentae, tissue or cells to be custom collected from a non-viable fetus or fetal tissues/cells by the applicant directly or through a third party) regardless of the source must meet the requirements in 45 CFR Part 46, Subpart B.**

General Information

Currently, ATP does not approve human subjects research that takes place in a foreign country as part of an ATP project. In addition, ATP typically does not accept foreign sources of human tissue, cells or data, even if the tissue, cells or data may qualify for an exemption under the 15 CFR Part 27. However, ATP will consider foreign sources of tissue, cells and data on a limited basis if the source is scientifically recognized as unique, an equivalent source is unavailable within the U.S., an alternative approach is not scientifically of equivalent merit, and the specific use qualifies for an exemption under the rule. In addition, proposers are reminded that ATP only rarely supports research as part of a Phase I clinical trial, and this type of research must be judged to be consistent with the ATP scientific and technological merit selection criterion.

Appendix 1: HUMAN SUBJECTS CHECKLIST

[This checklist may be used to determine if human subjects are involved in a research project and if the research may be exempt under the regulations on protection of human subjects (15 CFR Part 27).]

A proposal may contain more than one research activity involving human subjects that require different levels of review. This checklist should be used for each potential use of human subjects to help the proposer identify the level of documentation to be submitted to ATP with the proposal.

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: video taping people, observing children using new software, surveying manufacturing personnel during a pilot test of new equipment, gathering tissue or cells from human donors, etc.

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 item 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 CFR 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 CFR Part 27 or qualify for an exemption under 15 CFR 27.101 (b)? The following questions will help you evaluate whether or not to request an exemption determination by ATP, or provide documentation that the research may not be within scope of 15 CFR Part 27:

- a. Will the task involving human subjects only use 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 3.d.

No - Go to 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 3.d.

No - Go to 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 3.d.

No - Go to 5, this research is probably not exempt and will need an IRB review.

- 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 non-viable fetus or fetal sources of data, cells or tissue. Examples: testing educational software with children, surveys of obstetric patients.

Yes - Go to 5, this research is probably not exempt and will need an IRB review.

No - Go to 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 4, this research may be exempt under 15 CFR 27.101(b).

No - Go to 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 4, this research may not be within the scope of 15 CFR Part 27, or it may be exempt under 15 CFR 27.101(b).

No - Go to 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 5, this research is probably not exempt and will need an IRB review.

___ No - Go to 4, this research may be exempt under 15 CFR 27.101(b).

4. ___ Yes, an exemption under 15 CFR 27.101(b) may apply to the task, or the task may not be within the scope of 15 CFR Part 27. If the task is expected to take place during the first year of the project, follow the documentation requirements in **Appendix 2** of this booklet in order to request an evaluation by ATP. If the task is expected to take place during the out years of the project, follow the documentation requirements in **Appendix 2** of this booklet in order to request a deferred evaluation by ATP. The following areas are the most common exemptions typically granted for ATP proposals, additional exemption categories are listed in the regulation.

- a. Fill out **Appendix 3: “Request for Determination of No Human Subjects Involvement or Exemption from 15 CFR Part 27 for ATP Proposals Involving Information Technology Data, Manufacturing and Imaging Studies”** for the following possible exemption categories or other exemption categories that you believe apply:

- 1) Normal educational practices in an established or commonly accepted educational setting (15 CFR 27.101 (b) (1)).
- 2) Educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (15 CFR 27.101 (b)(2)).
NOTE: Data in the form of video or other images may fit into observation of public behavior if pre-existing publicly available video is used or the video is collected in a public setting.
- 3) Collection or study of existing data, documents, or records that are publicly available or stripped of all identifiers linked to the human subject (15 CFR 27.101 (b)(4)).
NOTE: This includes materials used as research controls. Data (e.g. video images, medical records, retail sales transactions etc.) from human sources that are not pre-existing DO NOT qualify for an exemption under 15 CFR 27.101 (b) (4). Existing means collected (i.e. on the shelf) prior to the research for a purpose other than the proposed research or excess material obtained through a procedure not related to the proposed project. (OPRR 10/1/98 Human Subjects Regulation Decision Charts).

- b. Fill out **Appendix 4: “Request for Determination of No Human Subjects Involvement or Exemption from 15 CFR Part 27 for ATP Proposals Involving Biological Studies”** for the following possible exemption category or other exemption categories that you believe apply:

Collection or study of existing data, documents, records, human cells, human tissues that are publicly available or stripped of all identifiers linked to the human subject (15 CFR 27.101 (b)(4)). NOTE: This includes materials used as research controls. Data (e.g. video images, medical records, retail sales transactions etc.) or specimens (e.g., cells, tissue, blood etc.) from human sources that are not pre-existing DO NOT qualify for an exemption

under 15 CFR 27.101 (b) (4). Existing means collected (i.e. on the shelf) prior to the research for a purpose other than the proposed research or excess material obtained through a procedure not related to the proposed project. (OPRR 10/1/98 Human Subjects Regulation Decision Charts).

5. ___ No, an exemption probably does not apply to the proposed research.
 - a. If research is expected to take place during the first year, the proposer should pursue obtaining an IRB review and approval. Follow the documentation requirements in **Appendix 2** of this booklet to request NIST institutional review of an IRB approval.
 - b. If the research is expected to take place during the out years of the project follow the documentation requirements in **Appendix 2** of this booklet to request a deferred NIST institutional review of an IRB approval. **This option does not apply to projects in which tasks in any year of the project involve the specific protected classes that are governed by 45 CFR Part 46, Subpart B (see item 5.a above) – NO EXCEPTIONS.**
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 or not human subjects are involved, or whether or not an exemption determination under the regulations is needed. If upon ATP/NIST review of your proposal we believe additional documentation is needed to reach a final determination, and your proposal is selected as a semifinalist, you will be asked to provide the additional documentation prior to an oral review.

Appendix 2: Human Subjects Documentation Requirements

If you answered “yes” on the form, NIST-1262 or 1263, item 14.E.vi found in the ATP Proposal Preparation Kit or if you are unsure whether or not the research tasks proposed involve human subjects, human tissue, data, or video collected about human subjects, you must submit one of the following types of documentation for each use of human subjects in the project. If you answered “no” on the form, NIST-1262 or 1263, item 14.E.vi., you are not required to submit any of the following documentation with the proposal. However, NIST reserves the right to make an independent determination of whether or not human subjects are involved in the research protocol and NIST may request documentation to complete the review process. A Timeline for Submission of NIST Required Documentation is provided at the end of Appendix 2 to aid in the submission of documentation. A proposal may contain more than one use of human subjects requiring different types of documentation for NIST review. For example, a project may have multiple exemptions, or one exemption and several deferrals, or an IRB review, a deferral and several exemptions. It is strongly recommended that the proposer complete Appendix 1 of this booklet to determine if human subjects are involved in the research proposal. Projects with human subjects research in the first year must supply item 1. Projects with human subjects in the out years of the project must supply item 3. **Projects with protected classes subject to Subpart B in ANY year of the project MUST provide item 2. by the time of the oral review; the other items do not apply.**

1. **Documentation for No Human Subjects Involvement or Exempt Research.** To allow NIST to determine if there are any identifiable human subjects, human tissue, cells/cell lines, data or recordings involved in the proposed research that may not be within the scope of 15 CFR Part 27 or that may qualify for an exemption from 15 CFR Part 27, the proposer should provide specific responses to Appendices 3 and/or 4 in this booklet and submit the responses with the proposal. If an IRB has reviewed the research project and made a determination that the research qualifies for an exemption, the proposer **must** provide a copy of the IRB approval of the exemption with the proposal. In most cases, exemptions do not apply to research involving protected classes of human subjects. **NOTE:** Data (e.g., video images, medical records, retail sales transactions etc.) or specimens (e.g., cells, tissue, blood etc.) from human sources that are not pre-existing **DO NOT** qualify for an exemption under 15 CFR 27.101 (b) (4). Existing means collected (i.e. on the shelf) prior to the research for a purpose other than the proposed research or excess material obtained through a procedure not related to the proposed project (OPRR 10/1/98 Human Subjects Regulation Decision Charts). If NIST questions the determination provided, NIST will request appropriate documentation to complete the review process.
2. **Documentation for Non-Exempt Research.** If NIST determines that the research project involves human subjects and does not qualify for an exemption, and the tasks involving human subjects are anticipated to begin in the first year of the project, the documentation outlined below is required.
 - a. **IRB Assurance Documentation**

SPECIAL REQUIREMENTS FOR PROTECTED CLASSES: Research projects involving protected classes of human subjects as defined in 45 CFR Part 46, Subparts B, C, and D including pregnant women, human in vitro fertilization, fetuses, prisoners, and

children) MUST be reviewed and approved by an IRB that possesses a current MPA appropriate for the research in question, or another type of assurance that has been approved by Office of Human Research Protection (OHRP)/ DHHS for federal- wide use. **No award involving protected classes as defined under 45 CFR Part 46, Subpart B, will be issued until the proposer has certified that an appropriate IRB has made the determinations required under Subpart B, and all other NIST approvals have been completed. This applies to involvement of protected classes under Subpart B in ANY year of the project, not just the first year.** Therefore, IRB approval for any tasks involving protected classes of human subjects under Subpart B at any time during the proposed ATP award period must accompany the proposal, or be supplied at oral review if the proposal is selected as a semifinalist. **Research activities regulated under Subpart B will not be added to any proposal once the award is issued.**

Documentation of an applicable IRB assurance is REQUIRED as outlined below:

- 1) **An IRB With a Multiple Project Assurance (MPA).** If your organization uses an IRB with an MPA on file with OHRP to approve your research projects, the proposer **must** provide the IRB's MPA number (or the number and type of assurance approved for federal-wide use) and its associated expiration date with the proposal. A listing of institutions that have an MPA on file with OHRP can be found at <http://ohrp.osophs.dhhs.gov/polasur.htm>.
- 2) **An IRB Within an Organization Without an MPA.** If the proposing organization is using an IRB that has been created by and within the proposing organization and does not have an MPA on file with OHRP, a Single Project Assurance (SPA) granted by NIST is required. An SPA is required by NIST to document that the proposing Organization's IRB was created according to the requirements of 15 CFR Part 27 and that all research involving human subjects will comply with the requirements of 15 CFR Part 27 and the ethical principles set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled, "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," which is commonly referred to as the "Belmont Report" (<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm>). NIST will not grant an SPA for research that involves any of the following categories:
 - a) Any research involving the protected classes as defined at 45 CFR Part 46 Subparts B, C and D.
 - b) Any research involving pre-clinical or clinical trials,
 - c) Any research that involves invasive administration of any drug or agent,
 - d) Any research that involves invasive surgical procedures,
 - e) Any research that NIST determines may place research subjects at greater than minimal risk.

On a case by case basis, NIST will determine whether or not the proposed research falls within one of the categories mentioned above. For all categories of research not mentioned above, NIST will determine, on a case by case basis, whether or not an SPA will be

granted. If NIST determines that an SPA will not be granted, NIST will require that an IRB with an MPA on file with OHRP review and approve the research protocol.

Information on drafting an SPA, submitting an SPA and other SPA-related issues may be found on the ATP website <http://www.atp.nist.gov>.

NOTE: For research involving protected classes, the IRB reviewing and approving the research protocol MUST have an MPA on file with OHRP. NIST will not accept IRB approval for research involving protected classes from any IRB without an MPA on file with OHRP.

- b. **IRB Protocol.** A signed copy of the final approved IRB protocol for each of the specific research tasks in the ATP proposal must be submitted to NIST.
 - c. **Informed Consent Forms.** All informed consent forms reviewed and approved by the IRB must be submitted to NIST. All informed consent forms must clearly state that the cognizant IRB, NIST, and other appropriate Federal officials may review any records associated with the protocol.
 - d. **IRB Approval Documentation.** A signed and dated approval letter from an IRB with an appropriate assurance for each approved protocol, along with any pertinent comments from the IRB concerning interim review requirements or other restrictions must be submitted to NIST.
 - e. **IRB Education Documentation.** A signed and dated letter is required from the Organizational Official who is authorized to enter into commitments on behalf of the organization documenting that appropriate IRB education has been received by the Organizational Official, the IRB Coordinator or such person that coordinates the IRB documents and materials if such a person exists, the IRB Chairperson, all IRB members and all key personnel associated with the proposal. The NIST requirement of documentation of education is consistent with NIH notice OD-00-039 (June 5, 2000). Although NIST will not endorse an educational curriculum, there are several curricula that are available to organizations and investigators which may be found at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.
3. **Documentation for Deferrals. (This option does not apply to research governed by 45 CFR Part 46, Subpart B, see item 2.a. above.)** If there are no research tasks involving human subjects or tissue in the first year, but some are anticipated beyond the first year of the project, the proposer should provide a detailed request for a deferred IRB approval or exemption as appropriate under 15 CFR 27.118. The documentation as outlined in items 1. and 2. above must be submitted for review and written approval by the NIST Grants Officer prior to releasing funds for the research tasks requiring an exemption determination or an IRB approval for tasks involving human subjects in the out-years of the project. It is strongly encouraged that this documentation be provided well in advance (3-6 months) of the planned start of the tasks involving human subjects. Deferral requests should include the following documentation:

- a. A projected date when the research tasks involving human subjects, tissue, data or recordings involving human subjects are planned. For example: second quarter of Year 3.
- b. A schedule of when documentation is expected to be submitted to NIST for either an exemption determination, item 1. above, or for documentation of an IRB approval for non-exempt research, item 2. above. NOTE: The NIST IRB is not authorized to perform IRB reviews for ATP proposers or funded projects.

Timeline for Submission of NIST Required Human Subjects Documentation (*Before submitting any documentation to NIST, the proposer is advised to read this booklet and the ATP Proposal Preparation Kit in their entirety*). **NOTE:** As required in Exhibit 2 of the ATP Proposal Preparation Kit, please incorporate the required documentation listed below in the initial proposal (**see GATE 1 column below**) and submit the required 16 copies, i.e., an original signed bound and 15 copies (1 unbound and 14 bound).

Determination of Human Subjects Use	Gate 1 (Initial Proposal)	Gate 3 (Prior to Oral Review)
Year 1 No Human Subjects or Exempt	Completed Appendix 3, “Request for Determination of No Human Subjects Involvement or Exemption from 15 CFR Part 27 for ATP Proposals Involving Information Technology Data, Manufacturing and Imaging Studies,” and/or Appendix 4, “Request for Determination of No Human Subjects Involvement or Exemption from 15 CFR Part 27 for ATP Proposals Involving Biological Studies,” as required	All other NIST required materials or clarifications as requested in pre-orals questions
Year 1 Non-exempt; IRB with MPA	The name of the IRB that will be reviewing the protocol; the MPA number of the IRB and the expected date of IRB review	A protocol summary of the research approved by the IRB; a signed and dated approval letter from the IRB; all IRB approved consent forms and a signed and dated letter documenting appropriate IRB education
Year 1 Non-exempt; IRB without MPA	The approved IRB protocol; all approved consent forms; a roster of the IRB; a completed and signed SPA and a signed and dated letter from the organization documenting appropriate IRB education	All other NIST required materials or clarifications as requested in pre-orals questions
After Year 1 Deferred	No documents are required to be submitted with the initial proposal	A projected date of human subjects usage and a schedule of when NIST required materials will be submitted in accordance with the categories listed above

NOTE: For research involving the protected classes under 45 CFR Part 46, Subpart B, in ANY year of the project, IRB approval is required for each involvement of human subjects in the project BEFORE an award can be issued.

Appendix 3: Request for Determination of No Human Subjects Involvement or Exemption from 15 CFR Part 27 for ATP Proposals Involving Information Technology Data, Manufacturing and Imaging Studies

Responses to the following questions must be supplied along with the initial proposal submission (**Gate 1**) to allow NIST to perform an independent determination if no human subjects are involved in the research proposal or to determine if the use of human subjects qualifies for an exemption from 15 CFR 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. No other way to achieve equivalent technical outcome? Why?).
3. Are the data/images stripped of any identifiable information (e.g. personal identifiers such as names or codes which 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 #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 pre-existing, being collected for the express purpose of the research, or obtained by some combination of the two?
6. What is the source of the data/image/recording (e.g. video archives, proprietary database, security systems/records, medical records, video conference records, etc.)?
7. What is the extent of data/image/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, etc.?
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 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 #10 disqualifies the project from exemption under 15 CFR 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, on file with the OHRP, and which has been approved by OHRP for federal wide use. This IRB approval **MUST** be submitted by the time of oral review (**Gate 3**). Please follow the instructions for research involving the protected classes in Appendix 2.
11. Is the image/recording being recorded in fact “public behavior”? Some indicators of public behavior would be:
 - a. Image of behavior does NOT give rise to any cause of action under ANY legal theory protecting personal privacy;
 - b. There are NO trade secrets or OTHER CONFIDENTIAL INFORMATION of any person contained in the image or recording;
 - c. There are NO copyright restrictions OR, the copyright holder has granted written

- permission to the proposer;
 - d. Any other matter the proposer deems germane to this issue.
12. If answer to #11 is “yes”:
- a. Can the human subjects be identified directly or through identifiers?
 - b. If the human subjects can be identified, any disclosure would NOT reasonably place the subjects at risk of criminal or civil liability, 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 prior to notification of ATP award decisions.

Name and Signature of Principal Investigator

Date

Appendix 4: Request for Determination of No Human Subjects Involvement or Exemption from 15 CFR Part 27 for ATP Proposals Involving Biological Studies

Responses to the following questions must be supplied along with the initial proposal submission (**Gate 1**) to allow NIST to perform an independent determination if no human subjects are involved in the research proposal or to determine if the use of human subjects qualifies for an exemption from 15 CFR 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 the collection of data or 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. No other way to achieve equivalent technical outcome? Why?).
3. Are the samples stripped of any identifiable information (e.g. personal identifiers such as names or codes which 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 #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, etc.)
6. What is the extent of tissue handling by the Principal Investigator: collecting, receiving, and/or sending specimens?
7. Are the samples pre-existing, being collected for the express purpose of the research, or obtained by some combination of the two?
8. Do the samples come 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 CFR 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, on file with the OHRP, and which has been approved by OHRP for federal wide use. This IRB approval **MUST** be submitted by oral review (**Gate 3**). Please follow the instructions for research involving the protected classes in Appendix 2.

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 the ATP prior to notification of ATP award decisions.

Name and Signature of Principal Investigator

Date

Research Involving Vertebrate Animals

This part of the booklet outlines the regulations and policies NIST applies to research proposals that intend to use live vertebrate animals. Research involving live vertebrate animals under an ATP project must be in compliance with the Animal Welfare Act (7 U.S.C. §§ 2131 et. seq.) and the National Research Council's "Guide for the Care and Use of Laboratory Animals" (<http://www.nap.edu>.) In addition, NIST requires certain assurances or institutional certifications depending on the type of research proposed as described below. If institutional assurances or certifications are not obtainable for research proposed to begin within the first year, the proposer is advised that it is unlikely that an award can be issued. NIST requires Institutional Animal Care and Use Committee (IACUC) approval of any live vertebrate animal research prior to beginning the research. The IACUC associated with the organization(s) where animals will be manipulated, housed and cared for must approve all Animal Study Proposals (ASPs) detailing all research involving vertebrate animals. NIST will also make an independent review of the ASP before the NIST Grants Officer approves release of funds for animal studies.

If you answered “yes” on form, NIST-1262 or 1263, item E.vii. found in the ATP Proposal Preparation Kit, and there are research tasks proposed that involve animal subjects, the proposer must submit the following documentation for each use of animal subjects in the project. If you answered “no” on the form, NIST-1262 or 1263, item 14.E.vii., you are not required to submit any of the following documentation with the proposal. A timeline for Submission of NIST Required Documentation is provided at the end of this part of the booklet to aid in the submission of documentation. The documents described below do not apply to proposed research using pre-existing images of animals (e.g. a wildlife documentary, or pictures of animals in newscasts, etc.), 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 documents also do not apply to obtaining animal materials from commercial processors of animal products, or to animal cell lines or tissues from tissue banks.

If you have any questions regarding research projects involving vertebrate animals, please contact the ATP Human and Animal Subjects Advisor, Mr. Tryn Stimart at 301-975-8779 for additional guidance.

Documentation Requirements

1. For research involving vertebrate animals during the first year of the research proposal, a copy of the following documentation is required.
 - a. **Certifications/Assurances** (NIST will require at least one of the following in order to approve the use of animal subjects)
 - 1) **The U.S. Department of Agriculture (USDA) Animal Welfare Act registration certificate.** A USDA registration is required for large animal studies (e.g. bovine). General information about applying for this registration is available at <http://www.aphis.usda.gov/ac/awainfo.html>.

- 2) **The Animal Welfare Assurance issued by the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH).** An assurance from OLAW can only be obtained if your organization is receiving funding from the NIH. General information regarding animal welfare policies and regulations is available at <http://grants.nih.gov/grants/olaw/olaw.htm>.
 - 3) **The Association for Assessment and Accreditation of Laboratory Animals Care International (AAALAC) accreditation.** Applicable to organizations using **only** rodents, birds, or fish. AAALAC accreditation alone is insufficient for large animal studies. General information about applying for this accreditation is available at <http://www.aaalac.org/html/application.html>.
- b. **Animal Study Proposals (ASP).** A copy of all approved ASPs including all signatures as required by the organizational IACUC must be submitted to NIST. In addition to the necessary information required by the organizational IACUC, NIST requires that all approved ASPs contain the following information:
- 1) The name, degree and experience of all personnel involved with the care and use of the animals.
 - 2) A determination of the pain category for all animals associated with the research.
 - 3) Certification by the Principal Investigator of the ASP that a literature search has been completed to determine if there are any alternative procedures which would involve less pain or distress to the animals proposed in the research and that the research proposed is not unnecessarily duplicative.

An example of an ASP or a similar ASP to what may eventually be submitted to an IACUC for review is NOT acceptable. If the ASP includes tasks not applicable to the ATP project, or if the ASP is supported by multiple sources of funding, include a brief description of what portions of the ASP apply specifically to the ATP project.

- c. **IACUC Approval Memos.** A copy of all approval memos issued by the organizational IACUC for the animal study proposals in item 1b. above must be submitted to NIST. The approval memos must be signed by the approving official for the IACUC approving the ASP and include expiration dates and interim reporting requirements or restrictions for each study.
2. For research involving live vertebrate animals beginning **after** the first year of the proposal, the following information is required by the time of oral review:
- a. The name of the organization(s) that may be performing the animal studies.
 - b. An indication whether or not the organization(s) has certifications or assurances as described in 1.a. If the organization(s) does not have the required certifications or assurances, provide a time line anticipated for obtaining certification or assurance prior to performing the animal studies.
 - c. A time line for when the ASPs will be submitted to the appropriate IACUC, and when NIST

can expect to receive all required documentation as outlined above for each ASP.

Timeline for Submission of NIST Required Animal Subjects Documentation: *(Before submitting any documentation to NIST, the proposer is advised to read this booklet and the ATP Proposal Preparation Kit in their entirety).*

NOTE: As required in Exhibit 2 of the ATP Proposal Preparation Kit, please incorporate the required documentation listed below in the initial proposal (**see GATE 1 column below**) and submit the required 16 copies, i.e., an original signed bound and 15 copies (1 unbound and 14 bound).

Date of Animal usage	Gate 1 (Initial ATP Proposal)	Gate 3 (Prior to Oral review)
Year 1	The name of the IACUC that will be reviewing and approving each ASP; the location of use and housing for ALL animals; the appropriate USDA, OLAW, AAALAC assurance or certification number	An IACUC approved ASP; a signed and dated approval letter for the ASP from the approving official for the IACUC and a copy of the appropriate assurance or certification document
After Year 1 Deferred	No documents are required to be submitted with the initial proposal	The name of the IACUC that may be reviewing and approving each ASP; a copy of the appropriate assurance or certification document for the IACUC, or a timeline for obtaining such an assurance; a timeline for submission of the approved ASP to NIST for review