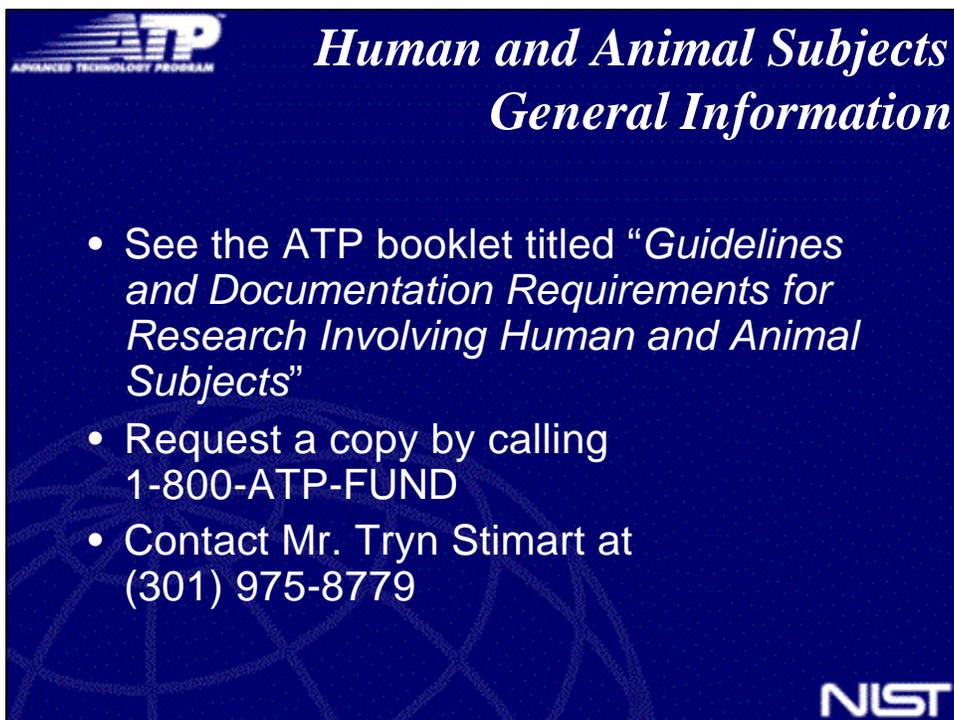


**ATP**  
ADVANCED TECHNOLOGY PROGRAM

# *Research Involving Human and Animal Subjects*

*Tryn Stimart, MS.  
ATP Human and  
Animal Subjects Advisor*

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



**ATP**  
ADVANCED TECHNOLOGY PROGRAM

# *Human and Animal Subjects General Information*

- See the ATP booklet titled “*Guidelines and Documentation Requirements for Research Involving Human and Animal Subjects*”
- Request a copy by calling  
1-800-ATP-FUND
- Contact Mr. Tryn Stimart at  
(301) 975-8779

**NIST**



## *Human and Animal Subjects Research Occurs in Many Areas*

- Biotechnology
- Chemistry
- Electronics/photonics
- Information Technology
- Manufacturing

NIST



## *Human Subjects Regulations*

- Protection of human subjects, “the common rule”
  - ✓ 15 CFR Part 27
- Protected classes of human subjects
  - ✓ 45 CFR 46 Subparts B, C and D
    - **Protected classes include: fetuses, pregnant women, gestational tissues, in vitro fertilization, prisoners, and children**
- Other applicable regulations

NIST



## *Human Subjects Regulatory Issues Human Embryonic Stem Cells*

- The Advanced Technology Program adheres to all Presidential orders, policies and Federal statutes, regulations and policies regarding the use of human embryonic stem cells. Until NIST and ATP have had opportunity to assess and implement necessary procedures, ATP will not consider proposals that propose to create, destroy, derive, characterize, or use human embryonic stem cells.

NIST



## *Human Subjects Regulatory Issues Human Embryonic Stem Cells*

- **During this competition, ATP will not consider any proposal that proposes to create, destroy, derive, characterize or use human embryonic stem cells.**

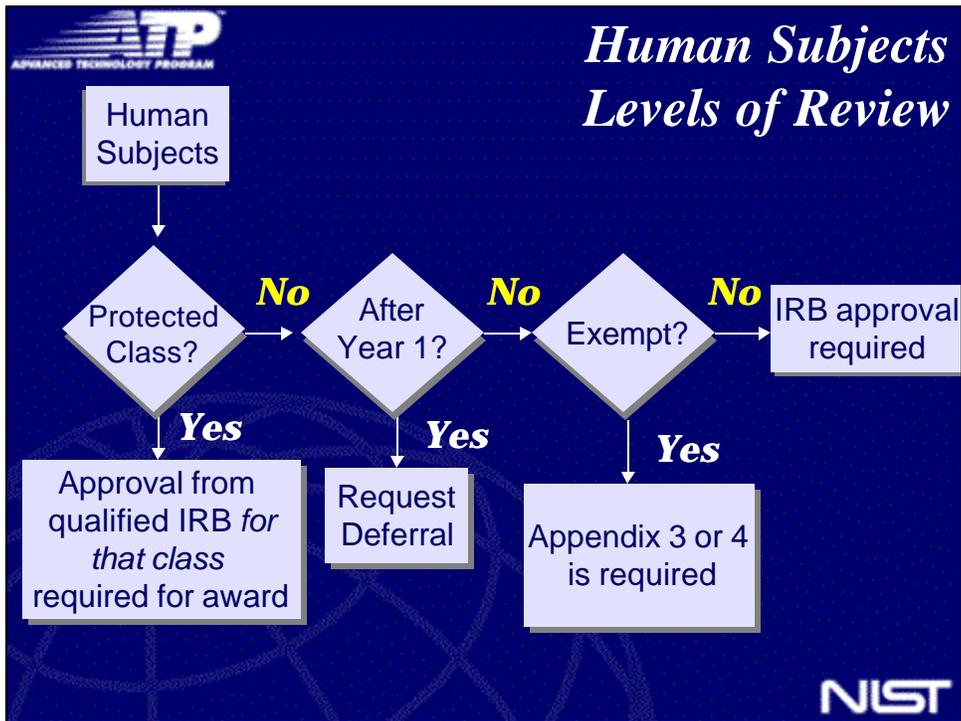
NIST

## *Human Subjects Definition*

- A human subject is a living individual about whom an investigator obtains:
  - (1) data through intervention or interaction with the individual or
  - (2) identifiable private information

## *Human Subjects Research Examples*

- **Bodily materials** such as cells, blood, urine, tissues, hair, organs, even if you did not collect the materials
- **Humans to test research output** such as products, software usability, human-machine interfaces or materials
- **Data collected** through intervention or interaction with individuals, including data from voice, video, digital or image recordings made for research purposes
- **Private information or data** that can be readily identified with an individual, including genetic information, medical records, worker surveillance studies, even if you did not collect the information
- **Human studies** involving categories or classes of subjects such as certain types of workers in an organization



**ATP**  
ADVANCED TECHNOLOGY PROGRAM

## Human Subjects Exempt Research

- Review the ATP booklet
- Use the checklist and complete Appendix 3 or 4 as necessary

**NIST**



## *Human Subjects Non-Exempt Research*

- NIST requires IRB review and approval
- The IRB must have an assurance
  - ✓ **FWA on file with OHRP**
  - ✓ **MPA on file with OHRP**
- The NIST IRB cannot perform this review
- NIST must perform an Agency review and approve all non-exempt research prior to the use of human subjects

NIST



## *Human Subjects Deferred Research*

- A deferral request for the use of human subjects after Year 1 may be granted
- Research using human subjects may not begin until NIST has reviewed and approved the research
- **Members of the protected class as defined under 45 CFR 46 Subpart B ARE NOT eligible for a deferral**

NIST



## *Animal Subjects Assurances/Certifications*

- All research must be in compliance with “*The Guide for the Care and Use of Laboratory Animals*” and all other applicable regulations
- Each Institution housing and caring for animals must have and maintain an appropriate certification for animal welfare throughout the research involving animals:
  - ✓ USDA Certification
  - ✓ AWA Assurance
  - ✓ AAALAC Accreditation

NIST



## *Animal Subjects Approvals*

- All Animal Study Protocols (ASPs) must have IACUC review and approval before beginning
- A copy of the approved ASP, the IACUC approval letter and assurance/certification documentation must be submitted to ATP and approved in advance of using animals

NIST



## *Animal Subjects Deferred Research*

- A deferral request for the use of animal subjects after Year 1 may be granted
- Research using animal subjects may not begin until all required documents have been received and approved by NIST

NIST



## *Human Subjects Submission GATE 1*

- **Exempt**
  - ✓ Completed Appendix 3 or 4
- **Non-exempt; IRB with Assurance**
  - ✓ Name of IRB, Assurance number and expiration date, and expected date of IRB review
- **Deferred**
  - ✓ Nothing required beyond what is presented in the technical plan

NIST



## *Human Subjects Submission GATE 3*

- **Exempt**
  - ✓ All other NIST required information
- **Non-exempt; IRB with Assurance**
  - ✓ IRB protocol summary, IRB approval letter, all IRB approved consent forms and advertisements
- **Deferred**
  - ✓ Projected start date, schedule of IRB review or date exemption is anticipated

NIST



## *Animal Subjects Submission GATE 1*

- **Year 1 Use**
  - ✓ Name of IACUC, location of housing for all animals, appropriate USDA, OLAW or AAALAC number and expiration date
- **After Year 1**
  - ✓ Nothing required beyond what animal use is already presented in the technical plan

NIST



## *Animal Subjects Submission GATE 3*

- **Year 1 use**
  - ✓ IACUC approved ASP, IACUC approval letter, copy of the appropriate USDA, OLAW or AAALAC assurance document
- **After Year 1**
  - ✓ Name of IACUC, copy of the appropriate USDA/OLAW/AAALAC assurance document, timeline for submission to NIST for review

**NIST**