Research Involving Human and Animal Subjects

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Human and Animal Subjects General Information

- See the April 2007 ATP booklet titled:

  "*Guidelines and Documentation Requirements for Research Involving Human and Animal Subjects*"

- Request a copy by calling: 1-800-ATP-FUND
- View it online: http://www.atp.nist.gov/atp/helpful.htm
- Contact Dr. Larry Uhteg: (301) 975-8779

Human and Animal Subjects Research Occurs in Many Areas

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

Human Subjects Regulations

- Protection of human subjects, "The Common Rule"
  - ✓ 15 CFR Part 27 Subpart A
- Protected classes of human subjects
  - ✓ 45 CFR Part 46 Subparts A, B, C and D
    - ➢ **Protected classes include: fetuses, pregnant women, gestational tissues, in vitro fertilization, prisoners, and children**
  - ✓ IRB approval for protected classes must satisfy requirements in the regulation
- Other applicable regulations

Human Subjects Special Issues

- ATP will not consider for funding new proposals or activities in ongoing ATP awards that involve human embryos or stem cells derived from human embryos.

- ATP rarely funds a portion of a Phase 1 clinical trial and does not fund Phase 2, Phase 3, or Phase 4 trials

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

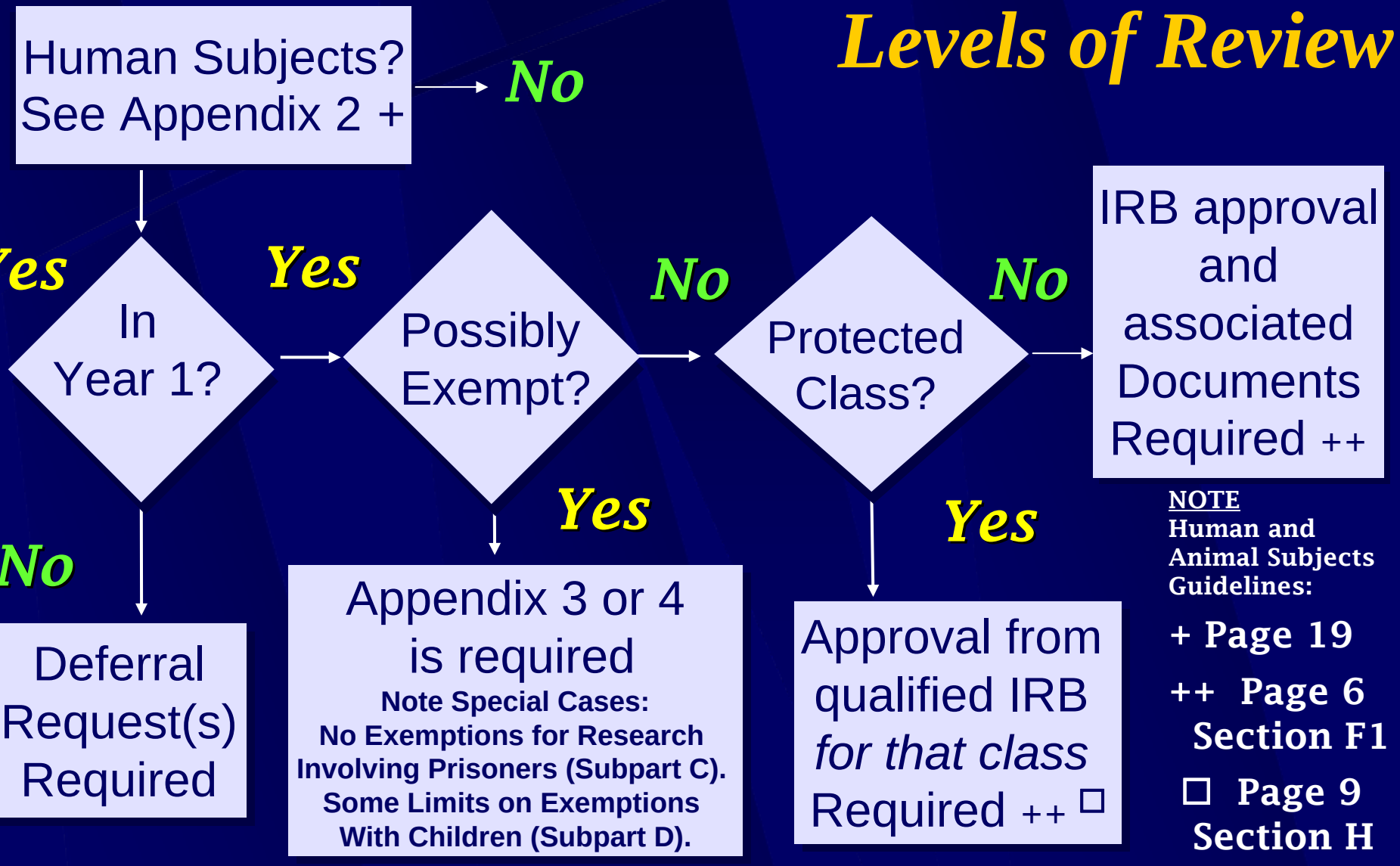
15 CFR Part 27 Section 102(f)

ADVANCED TECHNOLOGY PROGRAM

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

Human Subjects Levels of Review



NOTE
Human and Animal Subjects Guidelines:

+ Page 19

++ Page 6 Section F1

□ Page 9 Section H

Human Subjects Exempt Research

- Review the ATP “yellow kit”
- Use Appendix 2 – “the checklist”
- Complete Appendix 3 or 4 as necessary

Human Subjects Non-Exempt Research

- NIST requires IRB review and approval
- The IRB must be registered with OHRP, have a registration number, and be linked to applicable Federal Wide assurances (FWA)
- All institutions engaged in research must have an FWA on file with OHRP
- The NIST IRB does not perform this review
- ***NIST policy requires an administrative review of IRB approvals and approval of all research prior to the use of human subjects being approved in writing by the NIST Grants Officer.***
- ***Submission of materials to NIST prior to IRB review is encouraged to allow NIST questions or concerns to be addressed early in the review process.***

Human Subjects Deferred Research

- A deferral request for the use of human subjects is submitted with the proposal.
- Research using human subjects may not begin until the IRB and NIST have reviewed and approved the research.
- **Companies are encouraged to submit drafts in advance of seeking IRB approval. Submission of study materials in advance can be critical to meeting your R&D timeline.**

Human Subjects Submission At Proposal Stage

- **Complete form SF-424. The following information is requested on the form:**
- **For Exempt Activity in Year 1**
  - ✓ Proposed or IRB approved exemption number
  - ✓ Completed Appendix 3 or 4 as an attachment
- **For Non-exempt Activity in Year 1**
  - ✓ Name of IRB, registration number
  - ✓ Expected date of IRB review and approval
  - ✓ FWA of proposing organization and all institution(s) engaged in the research
- **Form SF-424 allows only one study to be described. If additional studies are planned, submit information on these studies as attachments**

- **For Deferred or Later Year of an Award**
  - ✓ Technical Plan should clearly indicate future activity
    - – Exempt
    - – Non-Exempt

Human Subjects Submission At Semifinalist Stage

- **Exempt – Year 1**
  - ✓ All other NIST required information
- **Non-exempt – Year 1**
  - ✓ NIST required information
    - – Signed copy of IRB approved protocol
    - – Signed approval memo for protocol with expiration date
    - – Copy of all other documents approved by the IRB, such as consent forms, advertisements, screening scripts etc.
    - – Any clarifications requested by NIST
- **Deferred**
  - ✓ NIST required information
    - – Projected date of human subjects activity – exempt or non-exempt
    - – Schedule when documentation will be submitted
    - – Dates for obtaining FWAs and agreements with IRBs, if not in place
    - – Any clarifications requested by NIST

Vertebrate 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 Registration http://www.aphis.usda.gov/ac/publications.html
  - ✓ OLAW Certification http://grants.nih.gov/grants/olaw/olaw.html
  - ✓ AAALAC Accreditation http://www.aaalac.org

Vertebrate Animal Subjects IACUC Approvals

- All Animal Study Protocols (ASPs) must have Institutional Animal Care and Use committee (IACUC) review and approval
- A copy of the approved ASP, the IACUC approval letter and identification of the type of assurance/certification must be submitted to ATP for review.
- Written approval from the NIST Grants Officer prior to using animals is required.

Animal Subjects Deferred Research

- A deferral request for the use of animal subjects after Year 1 needs to be requested
- Research using animal subjects may not begin until all required documents have been received by ATP, reviewed by NIST, and approval in writing by the NIST Grants Officer

Animal Subjects Submission At Proposal Stage

- **Animal Subjects Activity in Year 1**
  - ✓ Indicate on Form SF-424 that animal studies are part of study
  - ✓ Indicate why animal studies required (technical plan or attachment)
  - ✓ Location and name of organizations for housing and use for all animal studies
  - ✓ Name of IACUC reviewing proposal
  - ✓ Date of approval (if currently approved)
  - ✓ Type of assurance:
    - OLAW,
    - USDA, or
    - AAALAC
- **Deferred or Later Year of an Award**
  - ✓ Technical Plan should clearly indicate future activity involving vertebrate animals

Animal Subjects Submission At Semifinalist Stage

- **Animal Subjects Activity in Year 1**
  - ✓ IACUC approved ASP
  - ✓ IACUC approval letter with expiration date
  - ✓ Type of assurance:
    - OLAW,
    - USDA, or
    - AAALAC
  - ✓ Any clarifications requested to facilitate evaluation by ATP or NIST
- **Deferred**
  - ✓ NIST required information
    - Projected date of animal subjects activity
    - Schedule when documentation will be submitted
    - Dates for obtaining agreement with facility with IACUC, or establishing assurance and IACUC, if not in place
    - Any clarifications requested by NIST

Common Documentation Issues

Appendix 7: Human & Animal Subjects Guidelines

- **Protocols** *(human and animal subjects activities)*
  - *Content consistent with ATP proposal submission*
  - *Risks to subjects clearly explained*
  - *All data to be collected and analyzed is clearly described and links appropriately to the ATP proposal*

- **Consent Forms** *(human subjects activities)*
  - *Consent forms are consistent with protocol*
  - *Who to notify in event of problems is clear*
  - *Who has access to data is outlined*
  - *How confidentiality is assured is clear*
  - *Withdrawal process is clearly explained*
  - *Payment terms are clear, if applicable*

Common Documentation Issues

Appendix 7: Human & Animal Subjects Guidelines

- *NIST requires copies of all materials that are submitted for approval to an IRB or IACUC*
- *Documents must be signed by the person indicated or required by approving committee:*
  - ✓ *Principal Investigator*
  - ✓ *Veterinarian for animal studies, etc.*
- *All approved forms should be clearly marked*
- *All institutions engaged in human subjects research activities need an FWA which is linked to the reviewing IRB*
- *Identify personnel affiliations and any potential conflicts of interest*
- *PI is not a voting member of the reviewing committee*

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We are here to answer any questions you may have about Human & Animal Subjects in Research