Research Involving Human Subjects

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TIP Human and Animal Subjects Advisor

Human and Animal Subjects General Information

- See the June 2008 TIP booklet titled:

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

- Request a copy by calling: 1-800-TIP-NIST
- View it online or print as a .pdf file: http://www.nist.gov/tip/helpful.htm
- Contact Dr. Larry Uhteg: (301) 975-8779

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 B, C and D
    - ➢ **Protected classes include: fetuses, pregnant women, gestational tissues, in vitro fertilization, prisoners, and children**
  - ✓ IRB must be qualified to review and approve protocols involving protected classes
- Other applicable regulations

Human Subjects

- 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)

Human Subjects Research Occurs in Many Areas

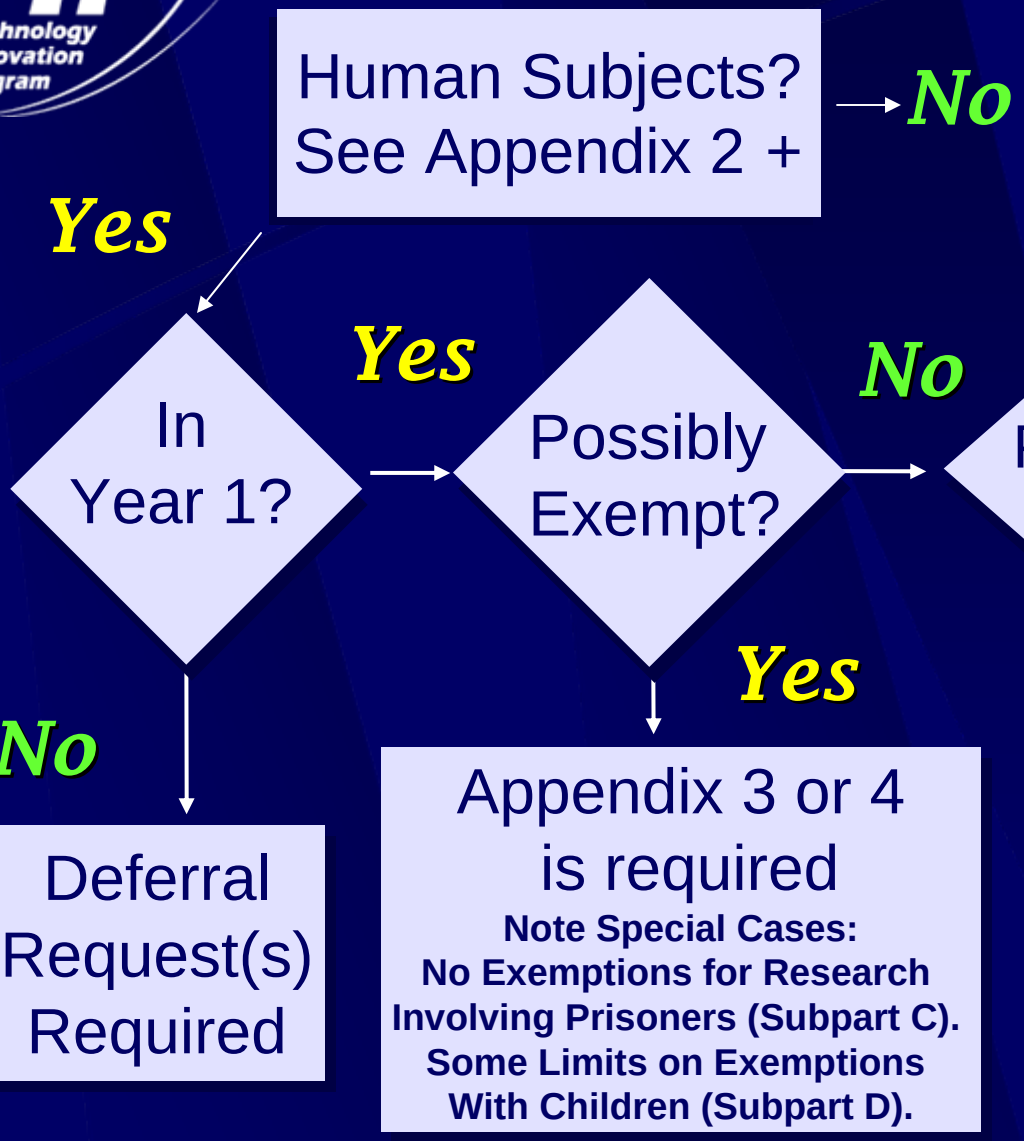
- Biotechnology
- Chemistry
- Electronics/photonics
- Information Technology
- Manufacturing

A human subject may be used in almost any capacity to test or evaluate technology

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 or data collected through surveys
- **Human studies** involving categories or classes of subjects such as certain types of workers in an organization
- Human studies involving material testing outside of the development location
- **Private information or data** that can be readily identified with an individual, including worker surveillance studies, even if you did not collect the information

Human Subjects Levels of Review



NOTE
Human and Animal Subjects Guidelines:

+ Page 21

++ Page 5 Section F1

□ Page 10 Section H

Human Subjects Exempt Research

- Review the TIP "Guidelines and Documentation Requirements for Research Involving Human and Animal Subjects"
- Use Appendix 2 – "Human Subjects Determination 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 the Office of Human Research Protections (OHRP), have a registration number, and be linked to applicable Federalwide Assurances (FWA) of the human study participants
- 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

- The technical plan should include this study and the expected time it will be carried out.
- Research using human subjects may not begin until the IRB and NIST have reviewed and approved the research.

Human Subjects Information Submitted in the Proposal

- **Complete form SF-424 R&R. The following information is requested on the form:**
- **For Exempt Activity in Year 1**
  - ✓ Proposed or IRB approved exemption number or leave blank
  - ✓ Completed Appendix 3 or 4 as part of the project narrative
- **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 R&R allows only one study to be described. If additional studies are planned, include information on these studies as part of the technical plan**
- **For Deferred or Later Year of an Award**
  - ✓ Technical Plan should clearly indicate future activity
    - – Exempt
    - – Non-Exempt

Human Subjects Submission in Proposals Under Review

- **Exempt – Year 1**
  - ✓ Completed Appendix 3 or 4 if not submitted with the proposal
  - ✓ All other NIST required information
- **Non-exempt – Year 1**
  - ✓ NIST required information
    - – Expected date of submission to IRB if proposal funded
- **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

Animal Studies

- If studies using vertebrate animals are anticipated, refer to the “Guidelines and Documentation Requirements for Research Involving Human and Animal Subjects” and contact the Human and Animal Subjects Advisor for help.

Common Documentation Issues

Appendix 7: Human and Animal Subjects Guidelines

- **Protocols**
  - *Protocol is complete with sufficient detail for reviewer to fully understand the study design*
  - *Content consistent with TIP proposal submission*
  - *Risks to subjects clearly explained*
  - *All data to be collected and analyzed is clearly described and links appropriately to the TIP proposal*

- **Consent Forms**
  - *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*
- *Documents must be signed by the person indicated or required by approving committee:*
  - ✓ *Principal Investigator*
- *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