

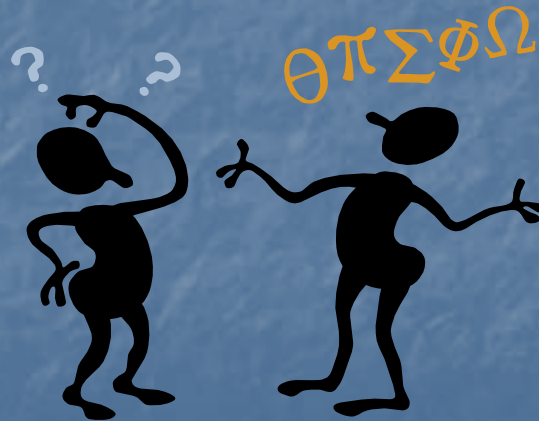
# New Jersey Institute of Technology's Program for the Protection of Human Research Subjects

Dawn Hall Apgar, PhD, LSW, ACSW  
Center for Architecture and Building Science Research  
Developmental Disabilities (DD) Planning Institute  
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# Overview of Presentation

- WHAT IS THE INSTITUTIONAL REVIEW BOARD (IRB)?
- WHO IS ON THE IRB?
- WHAT ISSUES MUST BE CONSIDERED IN HUMAN SUBJECT RESEARCH PROTECTION?
- WHAT IS THE PROCESS FOR APPROVAL?

# Why Does NJIT Have an IRB and What Does It Do?



# Purpose of IRB

Protection of the rights of human subjects in NJIT-affiliated research studies

- Review all research activities done by NJIT faculty, staff, and/or students with human subjects
  - Research located on campus
  - Done in collaboration with other universities
  - Funded and non-funded

MYTH: The IRB is only concerned with medical or drug testing.

# Covered Activities

According to the United States' Department of Health and Human Services:

- Human Subjects are living individuals about whom an investigator conducting research obtains (1) data from an intervention or interaction with the individual, or (2) identifiable information.

MYTH: IRB approval is only needed if sensitive information is collected.

- Research is defined as systematic investigation, including research development, testing and evaluation, designed to develop or contribute to new knowledge.

MYTH: IRB approval is needed for all data collection with humans.

# Activities That Do Not Require IRB Review

- Student class evaluations to provide instructor feedback
- Satisfaction surveys to guide administrative decisions
- Marketing outreach to guide development of university materials

# Value of IRB for Researchers

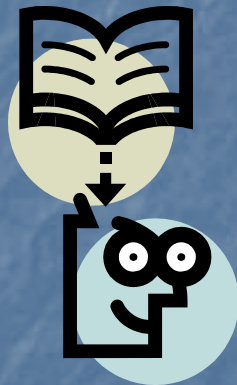
- An extra set of “eyes” to ensure human subjects’ protection are considered
- Collaboration between IRB and PIs
- Resource for faculty and students
  - Development of policies and educational materials

Who is on the IRB?

# IRB Membership

- A Minimum of 5 Members with Varying Backgrounds
- Appointed by the Senior VP for Research and Development
  - NJIT Faculty and Staff
    - Tara Alvarez, Biomedical Engineering
    - Roxanne Hiltz, Information Systems
    - Maxine Kahn, Sponsored Research Administration
    - Judith Sheft, Office of Research and Development
    - Laurent Simon, Chemical Engineering
    - Brian Tierney, University Counsel
  - Faculty at Other Institutions
    - Phylis Peterman, Rutgers – Newark
  - Community Members
    - Ashutosh Sharma, Vyteris, Inc.
  - Outside Consultants (as needed)

# What Does the IRB Consider When Making Decisions?



# Guiding Ethical Principles

- Respect for Persons

Consent, Privacy, Confidentiality

- Beneficence

Risks Versus Benefits

- Justice

Equity

# Criteria for Approval

- Risks to Subjects are Minimized & Reasonable.
  - Definition of Minimal Risk:
    - The probability and magnitude of harm or discomfort anticipated in the research are **not greater** in and of themselves from those ordinarily encountered in **daily life** or during the performance of routine physical or psychological examination or tests.
  - Minimal Risk: Expedited Review (1 Member)
  - More than Minimal Risk: Full Review (Entire Committee)

The IRB decides what can be expedited and what needs full review.

# Criteria for Approval

- Selection of Subjects is Equitable.
  - Stricter standards are not imposed on certain groups of people.
  - Individuals know how and why they were selected.

# Criteria for Approval

- Informed Consent of Subjects is Obtained.
  - Informed consent is the voluntary choice of an individual to participate in research.
    - Must understand its purposes, procedures, risks, benefits, compensation, alternatives, etc.
    - Must get assent of children.

# The Consent Process

Subjects must sign a consent form. The information contained in the consent form must:

- Make clear that the activity involves research and describe the overall experience that will be encountered;
- Explain the procedures, including any parts that are experimental (e.g., a new drug, extra tests, separate research records, or flipping a coin for random assignment);
- Identify the total number of study participants;

# The Consent Process

- Include the expected length of time it will take for study visits or scheduled procedures, as well as, the total expected length of participation;
- Inform participants that participation may be discontinued at any time without penalty or loss of benefits for refusing to participate or discontinuing participation.
- Disclose whether participation is going to be either anonymous or confidential.
  - **Anonymous** - Data that is recorded such that no identifier whatsoever exists to link a subject's identity to their response.

**MYTH:** If participants are not asked their names, research is anonymous.

- **Confidential** - There exists a documented link between a subject's identity and his/her response in the research.

# Criteria for Approval

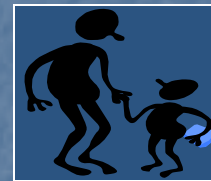
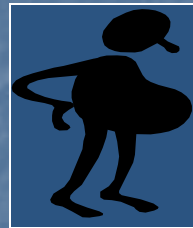
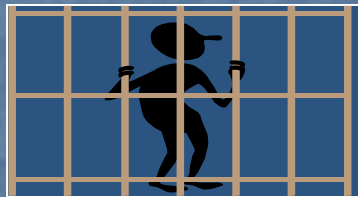
- Safety of Subjects is Monitored.
  - Must have procedures for handling adverse effects or unintended consequences.
  - Must document the training of all research staff in these procedures.

# Criteria for Approval

- Privacy and Confidentiality are Protected.
  - Study records are kept in a locked file cabinet.
  - Study records do not have participants' names, but use research identification numbers.
  - Names of subjects are not included in study reports.
  - Photo releases are obtained if necessary.
  - Guidelines for web-based surveying are followed.

# Criteria for Approval

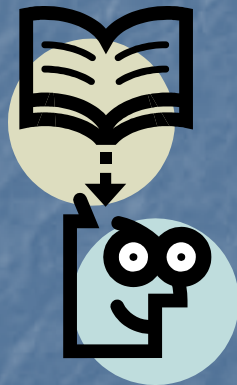
- Additional Safeguards are Implemented for Vulnerable Populations (children, prisoners, women who are pregnant, persons with cognitive impairments or those who are economically or educationally disadvantaged).



# Students are Vulnerable Subjects

- There is an Inherent Power Differential Between Students and Faculty.
- Students Should Not Be Used Just as They are Convenient.
- Additional Safeguards Needed:
  - Research faculty should not use current students.
  - Students must be 18 years old.
  - Base grades points cannot be used as incentives.
  - Limits are placed on use of extra credit as incentives.
  - Research for extra credit must be related to course content.
  - Alternate assignments must be available and equivalent.
  - Participation should not be graded.
- Researchers should consult NJIT IRB Guidelines for Using Students as Subjects (11/07/06).

# What is the Process for Getting Approval?



# Important

- Must contact the IRB and get approval BEFORE human subjects' research begins (including pretesting)
  - The IRB may impact protocols and/or forms so do not want to wait till they are finalized or printed
- Must allow ample time for process
  - Full reviews only occur once per month and may take several meetings

# Helpful to consult IRB prior to completing the application

Expedites review time

Reduces need for revisions

Reduces miscommunications



# Application Process

- Get application materials from website to make sure using current forms.
- Faculty must be co-PIs (for expedited reviews) or PIs for research (for full reviews).
  - Faculty contact information must be listed on consent form.
  - Faculty must submit documentation that supervising students.

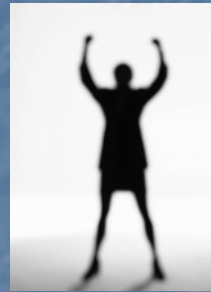
# Application Process

- All members of the research team must sign conflict of interest statements.
  - Do not get incentives for subject recruitment or study outcomes.
  - Do not have substantial financial investment in drugs, products, etc. which may interfere with judgment.

# Application Process

- Human subjects' protection training is required for all members of the research team.
  - Office for Human Research Protection (OHRP) at <http://hhs.gov/hrp>
  - Researchers must keep copies of their training certificates.
- IRB applications must contain consent forms, advertising materials, questionnaires or surveys.

# What is My Responsibility Once My Research is Approved?



# Investigator Responsibilities

- All Projects are Approved for One Year
  - Can be Renewed – Must Fill Out Continuation Application and Self-Audit
  - Cannot Change Forms or Protocols without IRB Approval
    - Must Comply with All Approved Protocols
  - Must Notify IRB When Research Completed
  - Must Notify IRB if Adverse Consequences Occur

THANK YOU  
Questions and Answers