RUTGERS
Office for Research

Human Subjects Research:

Overview to Protecting People in Research

Graduate School of Applied & Professional Psychology

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Overview

Orientation to Human Subjects Protections

[40 minutes]

- **Rutgers HSPP Mission**
- **Changes within the HSPP/IRB- I,II**
- **IRB Staff vs. IRB Committee Role**
- **Research Requiring IRB Oversight**
- **Levels of IRB Review**
- **Vulnerable Populations**
- **Criteria for IRB Approval**

The mission of the Human Subjects Protection Program (HSPP)/IRB is to support the University's research enterprise by:

- ensuring the protection of individuals who participate in research;
- ensuring compliance with all pertinent federal and state laws and regulations;
- fostering the ethical conduct of human subjects research;
- providing education and other services to the University's researchers regarding regulatory requirements and best practices.

Changes within the HSPP/IRB

I. HSPP/IRB STAFF REORGANIZATION

- Co-location of Entire HSPP Team
- One set of Standard Operating Procedures
- New Education & Training Program
- Pre-Review Team Consultation Services

Changes within the HSPP/IRB

II. IRB Committees Restructuring Plan

Benefits of IRB Board Restructuring

- Allows for greater efficiency and effectiveness
- Easier to call quorums
- Greater Representation: Other academic disciplines, RWJ Barnabas
- Positioned for future growth: RWJ Barnabas, NJIT, Clinical Trials

HSPP Team

HSPP Leadership Team:

Executive Director, HSPP - Carlotta Rodriguez, MS, CIP, CHRC
Assistant IRB Director - Malica Dock, CHRC, CIP
Assistant IRB Director - Swapnali Chaudhari, MBBS, MS, CIP
Sr. Reliance Manager - Claribel Vega, BA
Sr. IRB Manager - Angela Cartmell-McGlyn, PhD, CIP
Training and Communication Manager - Michelle Watkinson, BA, CIP
Pre-Review Team Manager - Donna Hoagland, BSN, CIP, CCRC, CHRC
Sr. Human Subject Protocol Analyst - Niem-Tzu “Rebecca” Chen, MS, MEd, CCRP
Director, Human Subject Protocol Analyst - Cheryl Forst, RN, BSN, CCRP

Need to Contact a Team member? Please see our online directory:
https://research.rutgers.edu/staff-directory/1275

HSPP Services

- **Training & Communication**
  - **Monthly eIRB Workshops**
  - **Department Reviewer Approval Trainings**
  - **Committee & Staff Education**
  - **Human Subjects Research Ethics**
- **Pre-Review Team Email**
  - **IRBprereview@research.rutgers.edu**
- **IRB General Inquiry Email**
  - **IRBoffice@research.rutgers.edu**
- **Monthly HSPP Bulletin**
- **Other Services**
  - **External IRB & Reliance Agreements: Pre-Consultation Assistance Available**
  - **Quality Assurance Program**
  - **Clinical Trials (CTG) Registration and Results Reporting**
  - **Non-Human Research Self-Certification Tool (HRP-310b)**

Understanding our Distinct Roles

Your Resource in the Responsible Conduct of Research

- **IRB Office Administrative Function:**
  - IRB Administrators
  - ✓ Research Resource/SME
  - ✓ Pre-Reviews & Pre-Administrative review
  - ✓ eIRB training
  - ✓ Pre-reviews
  - ✓ Reliance Agreements

- **IRB Committee Review Function**
  - IRB Members
    - ✓ Mission is to protect the rights and welfare of subjects
    - ✓ Approve, disapprove, and require modifications to secure approval
    - ✓ Provide Recommendations/SME

Research Requiring IRB Oversight

Human Subject:

Living individual about whom an investigator conducting research:

- **Obtains/uses/studies/analyzes information or biospecimens through intervention or interaction;**

OR

- **Obtains/uses/studies/analyzes or generates identifiable private info or identifiable biospecimens.**

Research:

Systematic investigation designed to develop or contribute to generalizable knowledge.

Definitions as per 45CFR46.102(e)(1) and (l)

What's the IRB Member's role in the review of research?

Ensures that the 45 CFR 46.111 & 21 CFR 56.111 Criteria for Approval of research are satisfied:

- Risks to subjects are minimized
- Risks are reasonable in relation to anticipated benefits
- Selection of subjects is equitable
- Informed consent is sought from each subject
- Informed consent is appropriately documented
- Data collection is monitored to ensure subject safety
- Privacy and Confidentiality of subjects is protected
- Additional safeguards are included for vulnerable populations

Criteria for IRB Approval – Respect for Persons (Autonomy)

Principle

Research should:

- Protect subjects from harm
- Benefit subjects directly, or benefit the wider population from the knowledge gained by its conduct
- Benefits of the research should outweigh potential harms to subjects

Application: *Operationalized by Consent*

Informed Consent:

1. Will be sought from subject or legally authorized representative.
2. Process: Adequate info about study to make informed decision in own best interest
3. Info is comprehensible
4. Individual not coerced or unduly influenced to enroll
5. Consent will be documented

Criteria for Approval - Beneficence

Principle: Do NO HARM

Research :

- Protect from harm
- Benefit subjects directly, or benefit the wider population from the knowledge gained
- Benefits of the research should outweigh potential harms

Application:

Risks of harm are minimized by:

- Using procedures consistent with sound research design
- Using procedures already being performed for diagnostic or treatment purposes
- Possessing resources adequate to conduct the research as planned, complete it and publish it!

Favorable risks of harms-to-potential-benefit ratio

Adequate plan to monitor data collected exists to ensure subject safety.

Criteria for Approval - Justice

Principle

Justice is concept of moral rightness in our dealings with other individuals and groups of people in society.

Distributive justice requires fair dealings in the selection of individuals in research and that its harms and benefits are distributed fairly.

Application:

Selection of subjects is equitable.

- Scientific goals of the study, not convenience, privilege, or other factors unrelated to the research, must be the primary basis for inclusion/exclusion.
- Fair subject selection—persons/groups who bear burdens of research are able to enjoy to its benefits.
- Subjects who are eligible based on scientific objectives of a study, but higher risk of being harmed, should be excluded.

Research Materials Reviewed by the IRB

Initial Application:

- Protocol Plan
- Investigator brochure, if any
- Scientific Evaluations
Recruitment Materials
- Consent Documents & Scripts
- Data Collection Tools
- Planned Communications w/Subjects
- Institutional Authorization Agreements
- Site Permissions
- Data Use or Material Transfer Agreements

Periodically:

Progress Reports (New Flexibility)

Modifications to approved research

Unanticipated Problems

Protocol Deviations

Significant new findings

Data Safety Monitoring Reports

Initial & Periodically Thereafter

Investigator/Study Staff Training Records

Conflicts of Interest Disclosures

What Regulations Do IRBs Follow?

Federal Regulations

- **Title 45 CFR Part 46 Common Rule (OHRP)**
- **Title 21 CFR Part 50 FDA**
- **HIPAA** (Health Insurance Portability and Accountability Act)

State Regulations/Statutes

- **New Jersey Survey Law**
- **Access to Medical Research Act**

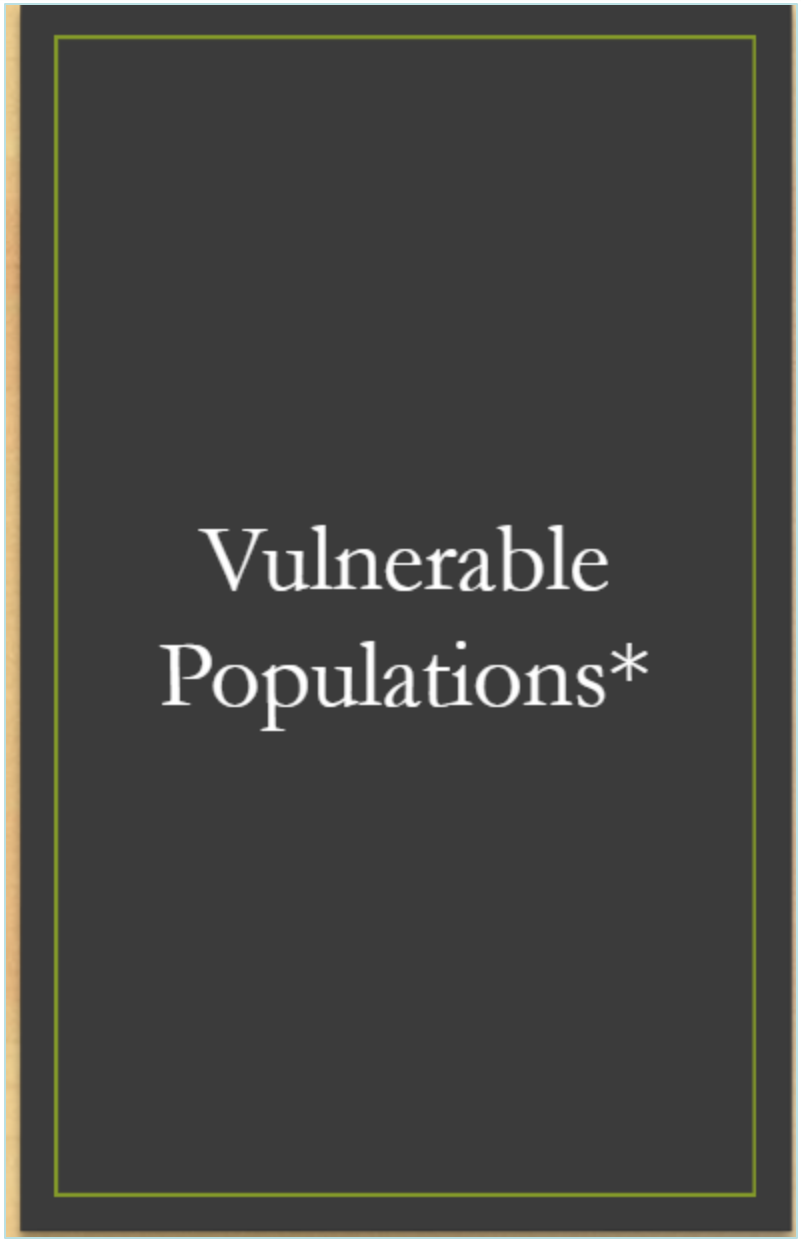
Institutional Policies

- **Rutgers IRB Authority**
- **Conflicts of Interest**
- **UEC's General Data Protection Regulation (GDPR) Compliance**
- **OIT's Minimum Security Standards for Data Protection**
- **Departmental Policies**

Exempt Research	Expedited Research
Minimal Risk	Minimal Risk
8 Categories	9 Categories (7 apply to initial review)
Review of Research plan	Review of Research plan
• Deception under Cat. 3 with prospective consent per rCR • No Prisoners • Children as Subjects (Cat.1, 2,4 or 6) • No PHI • May Include Identifiable Data w/ Limited IRB Review • Can include International Research	• Vulnerable populations: children, prisoners, pregnant women • Deception • PHI • Identifiable or Restricted Access Datasets • Can include International Research
Chair or Designee (may include department approved reviewer(s) and/or HSPP/IRB staff) approval	Chair or designee) or Full Committee approval for prisoner research
No Annual Review	Requires: Annual Review or Status Report

Full Board Research

Risk level cannot be determined under expedited procedures or Might be a minor increase over MR May already be Greater than Minimal Risk	Full Board Review at a Weekly Meeting
Sensitive Topics and/or Data Collections ❖ Drug or Device Studies ❖ Illegal Behaviors, including Alcohol use ❖ Sexual Behaviors	Vulnerable Populations ❖ Prisoners ❖ Cognitively Impaired Individuals ❖ Access to Restricted Data, if data holder requires
Data Security	International Research –Evaluation of Local Context
Clinical Trials/Interventions	Unanticipated Problems
DSMB/Follow-ups	At Least Annual Review Required at Full Board Meeting. Note: The Board might require more frequent, when deemed appropriate, re-review such as every 6 months.
Certificate of Confidentiality	

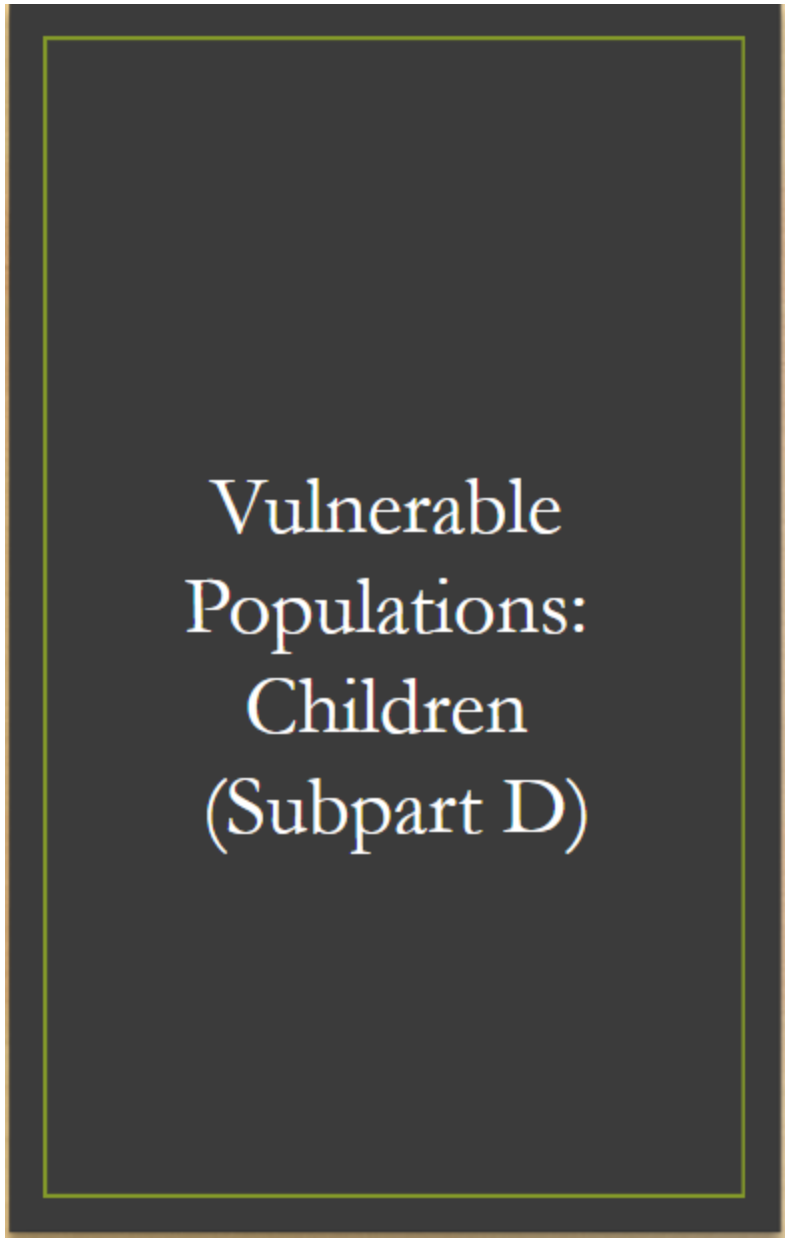


- Regulatory Defined- Federal regulations categorized certain groups of human subjects as "*vulnerable populations*", of which the regulations require special treatment with respect to safeguards of their well-being:
  - Pregnant Women (Subpart B)
  - Prisoners (Subpart C)
  - Children (Subpart D), including wards of the state

- Non-Regulatory Protected Populations:
  - Students & Employees
  - Cognitively Impaired Persons: Surrogate (NJ Access to Medical Research)
  - Elderly
  - Non-English Speakers
  - Undocumented Individuals
  - Minorities

*****The mere presence of the appearance of vulnerability should not lead to a presumption that a person is incapable of deciding regarding participation in research and of giving valid informed consent.

Special Considerations: Restricted Level Data



Research with Minors **requires:**

- **Process for permission from** Parents/Guardians AND **Assent Process**;

- **Assent Process** with Minor Subject:
  - Out of respect for children as developing persons, children should be asked whether they wish to participate in the research.
  - If the child dissents from participating in research, even if his or her parents or guardian have granted permission, the child's decision prevails for a minimal risk research with no direct benefits to the subjects.
  - Waiver of parental consent, (in limited research areas: e.g., Child Abuse, Substance Use, Online Behaviors) might be approvable.
  - There might be additional requirements to include a minor in research. For example, a pregnant minor requires parental permission to participate.

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Resource Guide

- **Policies & Regulations:** https://research.rutgers.edu/researcher-support/research-compliance/human-subjects-protection-program-irbs/policies-and
- **Templates & Forms:** https://research.rutgers.edu/researcher-support/research-compliance/human-subjects-protection-program-toolkit
- **Department Approver list:** https://research.rutgers.edu/researcher-support/research-compliance/human-subjects-protection-program-irbs/electronic-irb
- **Guidance Topics:** https://research.rutgers.edu/researcher-support/research-compliance/human-subjects-protection-program-irbs/hspp-guidance-topics
- **SIRB/External IRB:** https://research.rutgers.edu/node/1575
- **IRB Fees:** https://research.rutgers.edu/researcher-support/research-compliance/human-subjects-protection-program-irbs/irb-fees

Interested in Becoming an IRB Member?

We are always in need of additional members of our research community to provide their expertise. The onboarding process includes:

1. The initial process begins by emailing your expressed interest along with sending a copy of your current C.V. or resume.
2. Observation of 1 (or 2) full board meetings prior to serving as a member on the IRB committee.
3. Virtual training: CITI IRB Member modulates along with a new IRB Member orientation session (scheduled at your convenience).We provide New Member Handbook, eIRB IRB Member manual and regulatory guidance.
4. An appointment letter from the Vice President for Research, Dr. Zwick.

- **If you are interested in becoming an IRB committee member, please contact Michelle Watkinson (michelle.watkinson@research.rutgers.edu).**

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Questions?

Rutgers IRB

Human Subjects Protection Program website:
https://research.rutgers.edu/researcher-support/research-compliance/human-subjects-protection-program-irbs

Got More Questions?
Email our general inbox:
irboffice@research.Rutgers.edu

Need specific Guidance?
Contact our Pre-Review Team:
Requests can be made by sending an email to irbprereview@research.rutgers.edu

Want to learn more about eIRB?
Attend an eIRB Workshop-please see https://research.rutgers.edu/node/1336 for more information & registration