

# Human Subjects Protection Program

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Some patients join clinical trials out of desperation. Others to help medicine advance. Whom do you blame if they get sick—or even die?

### Stories

- Human Guinea Pigs
- They're Dying to Get In
- Poisoning for Dollars
- Questions to Ask Your Doctor
- Clinical Trials Gone Wrong
- History: A Look at Past Abuse
- How Clinical Trials Are Supposed to Work

Human Research  
Protection Program

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IRB

# Human Research Protection Program (HRPP)

An integrated process where all the various components of an organization involved in the conduct of human research work together to protect the rights and welfare of participants

# Goals of a HRPP

- Improve the systems that protect the rights and welfare of individuals who participate in research
- Communicate to the public the strength of an organization's commitment to the protection of human research participants
- Improve the overall quality of research by consistently applying high standards and practices, raising the global benchmark for human research protection

# Domains

- **Organization**  
The entity that assumes responsibility for the Human Research Protection Program and applies for accreditation
- **Research Review Unit**  
Refers to the arrangements that the Organization has made for an independent review of ethical and scientific aspects of each research protocol involving human participants.
- **Investigator**  
Includes the various arrangements that the Organization has made for assuring that individuals who plan to conduct research — whether as a principal investigator, co-investigator, or other member of a research team — understand and fulfill their responsibilities.
- **Sponsored Research**  
Includes the Organization's arrangements for structuring its relationships with those who fund or initiate research external to the Organization, such as federal agencies, foundations, individual donors, and corporations
- **Participant Outreach**  
Refers to the arrangements the Organization has made for understanding the social, psychological, and physical needs and concerns of research participants and their communities

# Why an HRPP?

- Improves human research protection
- Improves research quality
- Assures regulatory compliance
- Better risk management programs
- Improved consistency
- Increases efficiency
- Builds public trust

# What is the role of Accreditation?

- Demonstrates the overall excellence by providing the most comprehensive protections for research participants
- Based on federal regulations and international guidance
- Not an audit
- Evaluates
  - » Structure: What you have
  - » Process: What you do
  - » Outcome: What you achieve
- Outcomes-based, collaborative learning experience

# Duke University Health System Human Subject Protection Program

## Conduct

- Duke University Hospital
- Durham Regional Hospital
- Duke Raleigh Hospital
- Duke Translational Medicine Institute (DTMI)
- Investigators and study staff
- DUMC Investigational Drug Service
- SBR
- Investigator and Study Staff

## Sponsorship and Finance

- Office of Research Administration (ORA)
- Office of Corporate Research and Collaboration (OCRC)
- Office of Sponsored Programs (OSP)
- Office of Research Support (ORS)
- Office of Finance & Resource Planning
- PRMO Clinical Trials Billing Office of Corporate
- Research Costing & Compliance (RCC)

## Review and Oversight

- Institutional Review Board (IRB)
- Institutional Bio-safety Committee (IBC)
- Radiation Safety
- Clinical Research Support Office
- Clinical Trials Quality Assurance (CTQA)
- Privacy Office
- Information Security

The moral test of any society is how it cares for the people in the dawn of life: the children; the twilight of life: the elderly; and the shadows of life: the sick and disenfranchised.

Hubert H. Humphrey