

**Where We've Been**

**Where We're Going**

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**U.S. Department of Health and Human Services**

Regional Research Community Forum

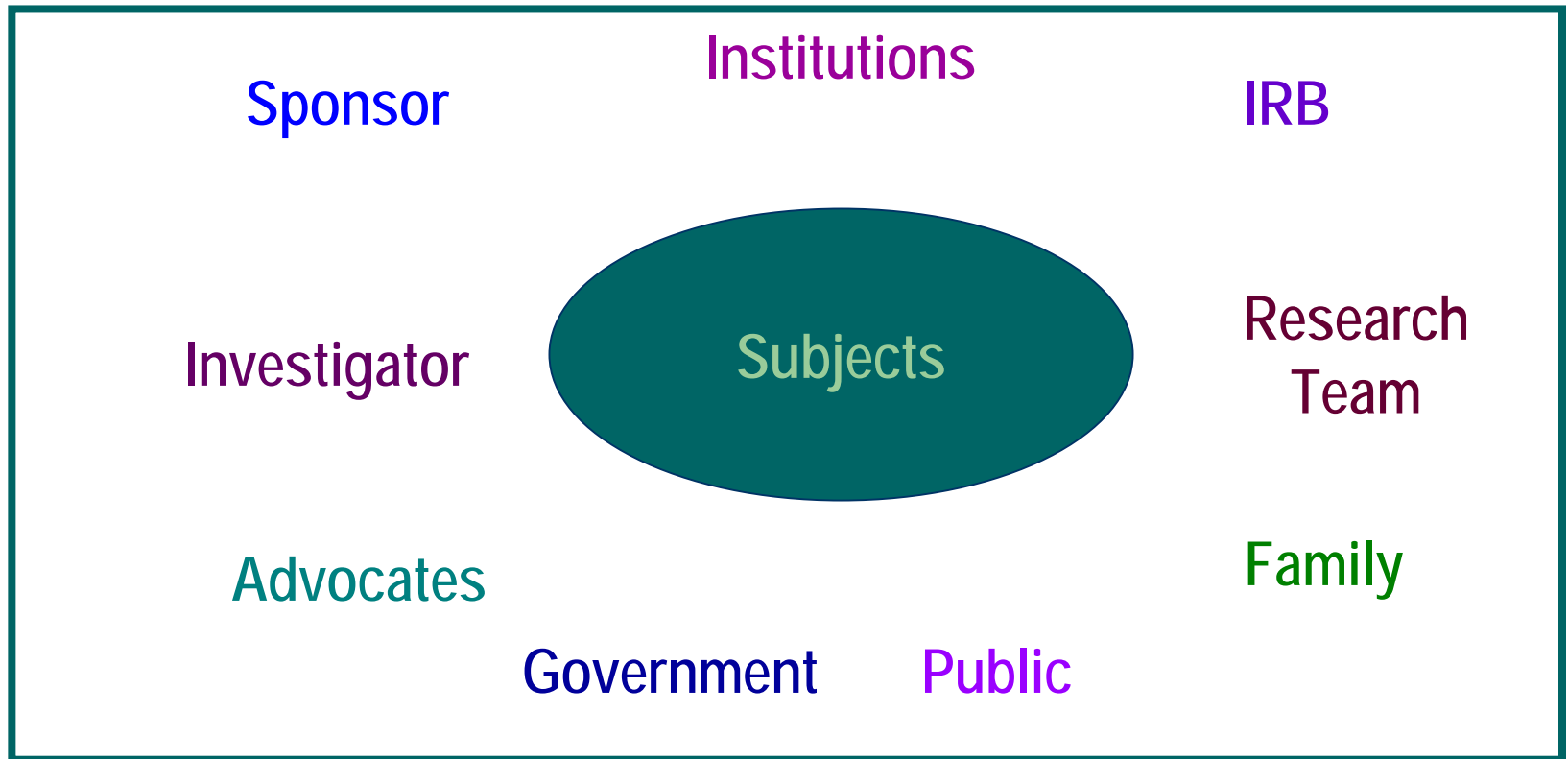
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# **“A Time for Reform”**

## **June 1998 Report - OIG**

- The challenge of the modern research environment
- Relying only on overburdened Institutional Review Boards (IRBs)

# Enhance Human Subject Protections: Whole Human Research Enterprise



# **New Focus**



## **Human Research Protection Program**

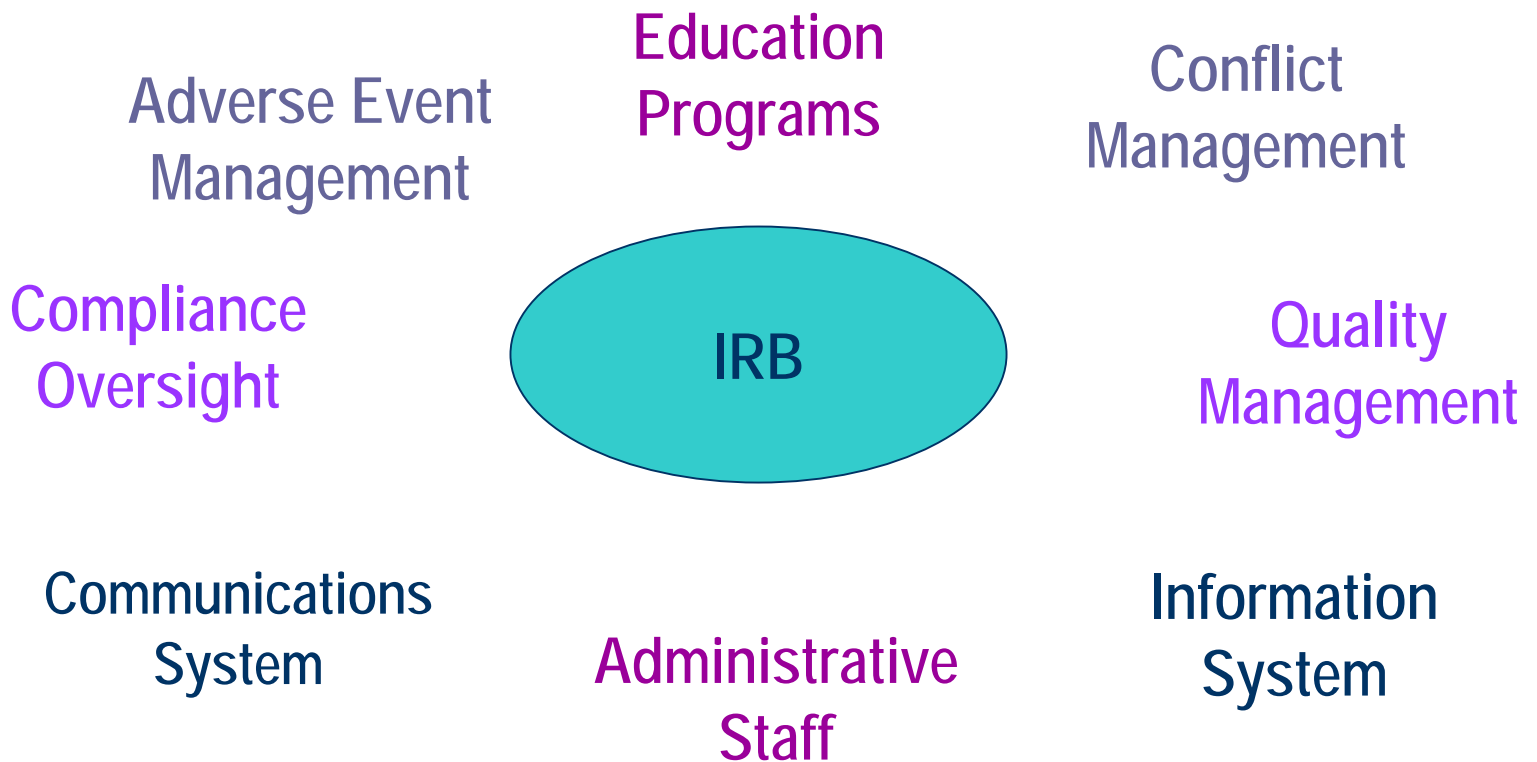
# Changes in the Human Subject Protection System

- **Institutions**
- **Private Sector**
- **Federal Government**
- **Office for Human Research Protections (OHRP)**



# **Institutions**

# The Institution: Elements of An Effective Human Research Protection Program



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# Private Sector

# Private Sector

- Certification
- Accreditation



# **Federal Government**

# The Government: An Integrated Approach

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President's  
Council on Bioethics

Human Subjects  
Research  
Subcommittee

Secretary's Advisory  
Committee on Human Research  
Protections

Office for Human  
Research  
Protections

# SACHRP

First meeting July 2003

- Subcommittees

Subpart D – Research involving Children

Subpart C – Research involving Prisoners

Subpart A – The Common Rule

# SACHRP

- Other Topics:
  - Subpart B
  - Social & Behavioral
  - Research vs. Non–Research
  - Adverse Event Reporting
  - Accreditation



# **Office for Human Research Protections (OHRP)**

# OHRP

- 1974 – Office for Protection from Research Risks (OPRR)
- 2000 – Office for Human Research Protections (OHRP) established within the Office of the Secretary, Department of Health and Human Services (HHS)

# OHRP Organization

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Office of the Director



Division of Policy and Assurances

Division of Compliance Oversight

Division of Education and Development

# OHRP Activities

- IRB Registration
- Federalwide Assurance
- New Guidance
- Not For Cause Evaluations
- Quality Improvement Program
- Education



# **IRB Registration**



# **Federalwide Assurance**



# **New Guidance**



# **Not-For-Cause Evaluations**



# **Quality Improvement Program**

# OHRP's QI Program (QIP)

- OHRP initiated QIP 2002
- QIP includes two separate components:
  - A Guided Self Assessment Tool
  - OHRP QA Consultation conducted by the Division of Education & Development staff
- Voluntary participation
- No Cost

# Goals of OHRP's QIP

- Provide tools to help an institution identify strengths and areas for improvement
- Provide detailed review of IRB written procedures and meeting minutes
- Clarify regulatory requirements

continued

# Goals of OHRP's QIP

- Explore ways to improve the quality, efficiency, and effectiveness of the human research protection program
- Foster partnerships and collaborations among institutions
- Identify “best practices”

# Status of OHRP's QIP Program

- Approximately 80 consultations completed
- QIP continues to grow as a result of positive endorsements from institutions
- OHRP is currently scheduling consultations about 60 days in advance

# How the OHRP QA Team Handles Noncompliance

- Procedural non-compliance
  - QA team clarifies regulatory requirement(s) and works with institution to develop its corrective action plan
  - QA team may offer a follow-up interaction
- Serious or systemic noncompliance that has or may put the rights and welfare of subjects at risk
  - Same Steps as above
  - Recommend self-reporting to OHRP
  - Notification of Institutional Official & OHRP Director



# Education

# Educational Resources

- Investigator 101 CD ROM
- Videotape Series
- IRB Guidebook
- OHRP National & Regional Conferences
- Presentations
- Public Outreach

# OHRP Electronic Access

- **Web Site: <http://www.hhs.gov/ohrp>**
  - IRB Registration & Assurance Filing
  - Quality Improvement Program
  - Policy Guidance
  - Compliance Oversight
  - Educational Materials/Workshops
  - SACHRP
- **Listserv**
- **Email: [ohrp@osophs.dhhs.gov](mailto:ohrp@osophs.dhhs.gov)**