

Emerging Issues and the Role of OHRP



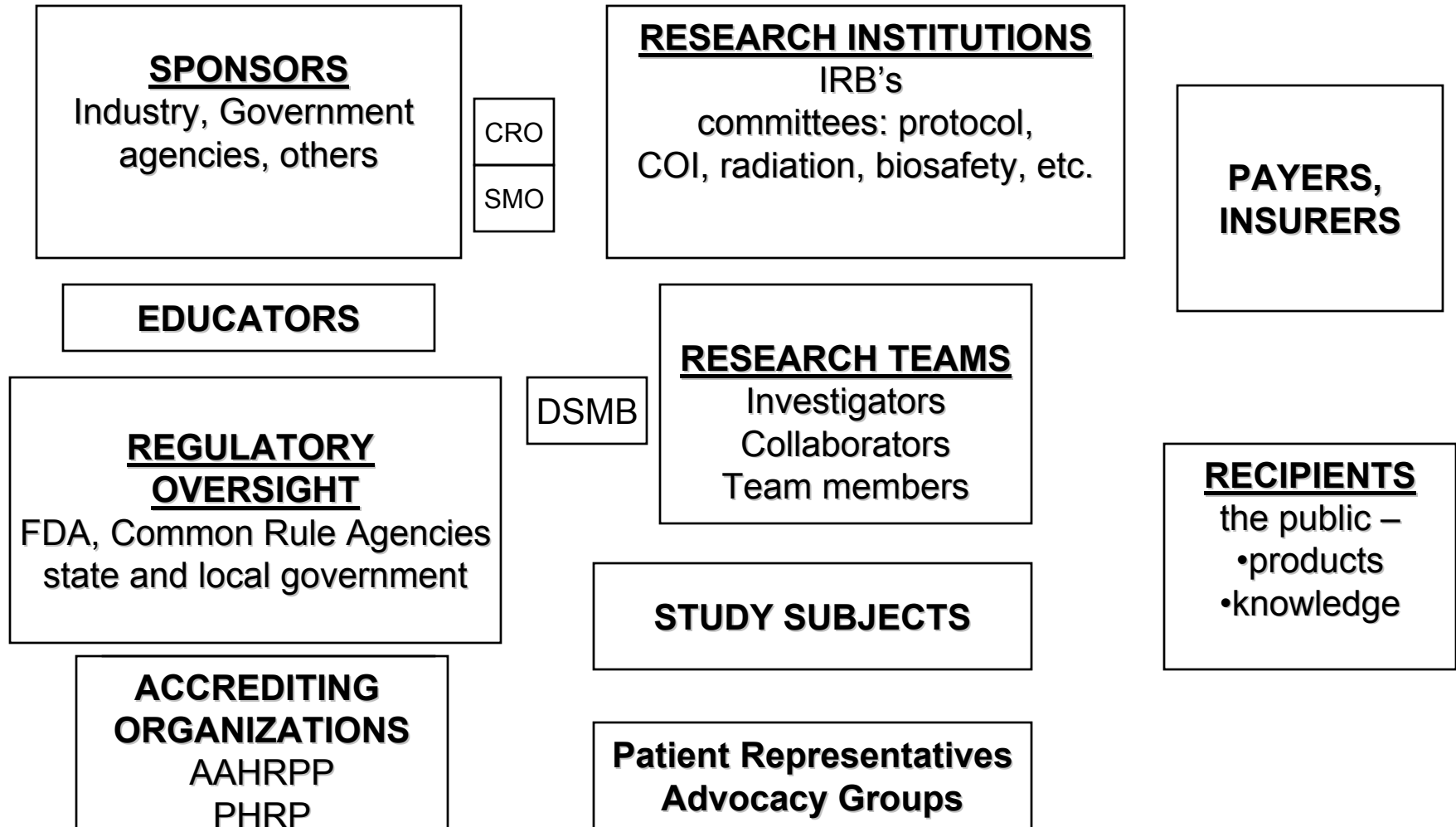
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Topics

- ❖ Focus on the enterprise
- ❖ Burden vs. Protection
- ❖ Effectiveness/efficiency of IRBs
- ❖ Accreditation of institutions
- ❖ Preventing another HSP tragedy

Human Research Enterprise



The Enterprise

- ❖ Where are risks to subjects?
- ❖ Risks to subjects determine risks to the enterprise

Burden To The Enterprise Vs. Risks To Subject

Burdens represent protection of

1. Research subjects
2. Institutions, sponsors
3. Both
4. Neither

Burdens That Protect

- ❖ Research subjects
 - informed consent focused on HSP
- ❖ Institutions, sponsors
 - informed consent focused on limiting liability

Burdens (con't)

- ❖ Both

- Well trained investigators

- ❖ Neither

- Most AE reports in multi-site studies

Burdens (con't)

Let's be more clear about

- ❖ What's being protected
- ❖ Sources of burden

Sources of Burden

- ❖ Regulations - Federal, State
- ❖ Over-interpretation of regs
- ❖ Fear of litigation
- ❖ Duplicative requirements of sponsors

Effectiveness of IRBs

- ❖ Overall very good, but not consistently so
- ❖ Diversity greater than local needs dictate
- ❖ What is the role of IRBs today?
 - interface with partners
- ❖ Reluctance to serve
 - workload, liability (public member)
- ❖ Institutional culture of indifference

Efficiency of IRBs

- ❖ Moving the freight vs. doing well
- ❖ Range is disturbing
 - 10 min to days/ protocol
- ❖ inadequate IT support
- ❖ Excessive behaviors
- ❖ Lack of training, understanding
- ❖ Inadequate resources
- ❖ Lack of info on best practices

Accreditation of Institutions

- ❖ OHRP supports the concept
- ❖ Potentially very beneficial
- ❖ We must be patient!

Preventing Another HSP Tragedy

- ❖ Not likely a simple cause
- ❖ Two elements
 - permissive infrastructure
 - last opportunity to prevent
- ❖ The enterprise is fragile!

Permissive Infrastructure

- ❖ Error of IRB approval
- ❖ Indifference to regulations
- ❖ Poor quality management
- ❖ Lack of accountability
- ❖ Studies by-passed the IRB
- ❖ Focus is on IRBs

Last Opportunity To Present

- ❖ Somebody fell asleep at the wheel!
- ❖ No redundant step to detect a problem in time
- ❖ Fear of being caught, hope beyond reason
- ❖ May not be the person originally at fault
- ❖ "blinded" by C of I
- ❖ Focus is on investigators

Closing Thoughts

- ❖ Focus on the whole enterprise
- ❖ Balance burden & protection
- ❖ Need to review function of IRBs
- ❖ Accreditation would be progress
- ❖ How do we prevent another HSP tragedy?
- ❖ Public trust is essential