

A Multi-Layered Model of the System of Regulation in Research

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Shifts in Approaches to Guidelines for Ethical Scientific Conduct

- **Pre 1975: Following ‘normal’ practice of science**
 - Passive: implicit ‘learning by doing’, normative
- **~ 1975-1990: Preventing scientific misconduct**
 - Active: administrative oversight, IRBs, sanctions
- **~1990-present: Promoting research integrity**
 - Proactive: diffusion of norms and return to professional norms + regulatory oversight

ORI's Evolving Research Agenda

- **Definitional Issues**
 - From FFP to RCR, defining 'research integrity'
- **Prevalence Issues**
 - How widespread is scientific misconduct?
 - What factors are associated with misconduct?
- **Preventative Issues**
 - Educational approaches
 - Regulatory approaches
- **Effectiveness Issues**

Effectiveness Issues: Conceptual Requirements

- **Studies of regulatory effectiveness demand clarity about:**
 - The *meaning* of regulation
 - The *distinction* between regulation and self-regulation
 - The *appropriate bodies* who should be involved
 - The *stages* in the research process that call for regulation

Q1: What does regulation mean?

- **Regulation in general means ‘controlling human behavior by rules or restrictions’**
 - Governmental laws and dictates
 - Organizational policies
 - Professional guidelines
 - Group norms
 - Individual values

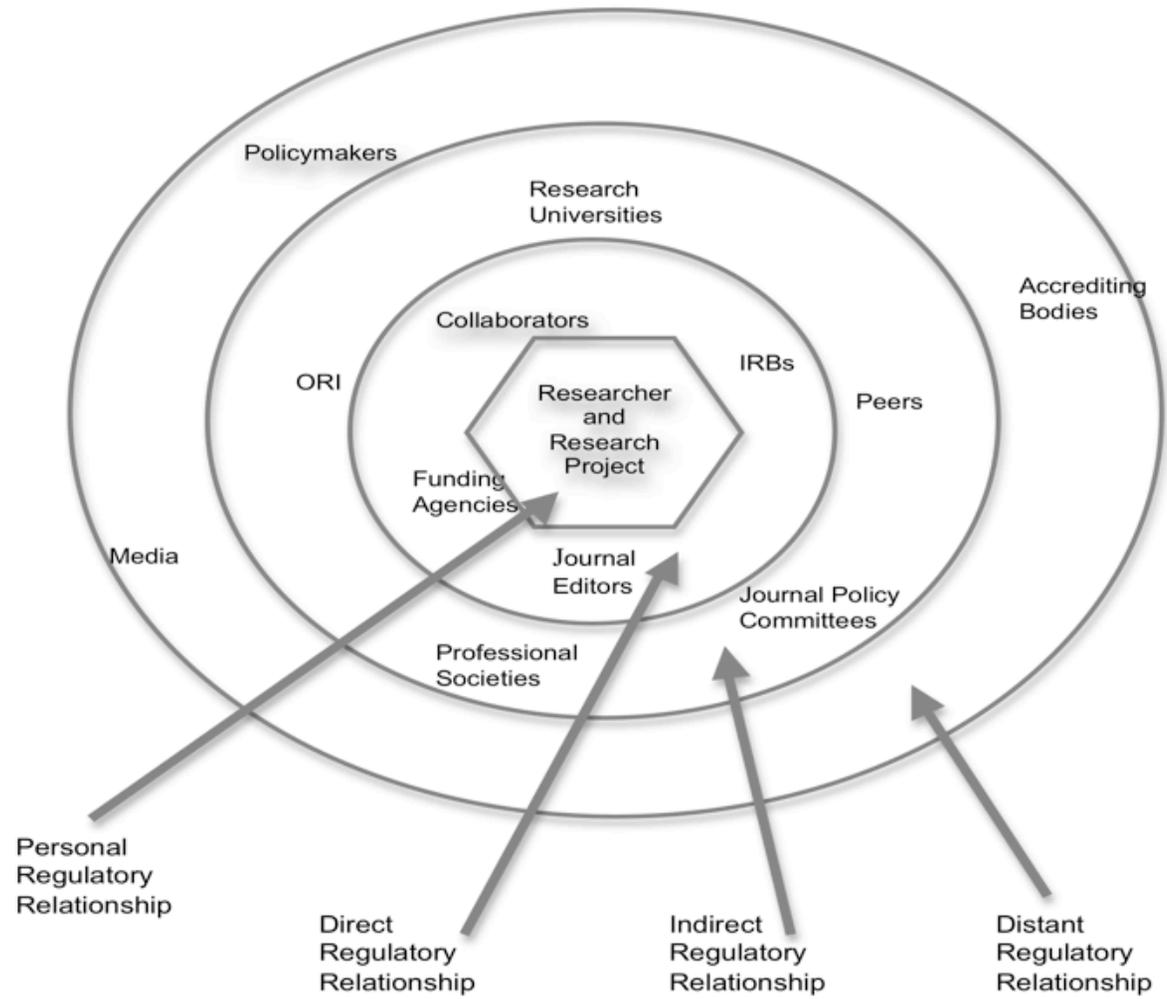
Q2: What is the distinction between regulation and self-regulation?

- **Related to the debate about who makes and enforces the rules or restrictions**
- **At what level of analysis does self-regulation cease being self-regulation?**
 - **Individual**
 - **Research group**
 - **Profession**
 - **University**

Q3: Who are the relevant actors, and what is their connection to the research?

- **The focal entity: A specific researcher linked to a specific research project**
- **Four types of regulatory relationships to the focal entity**
 - Personal regulatory relationship
 - Direct regulatory relationship
 - Indirect regulatory relationship
 - Distant regulatory relationship

Relational Map of Actors in the System of Regulation



Relational map reveals complexity of regulatory system

- **Subsystems can exist among actors**
 - Actors are connected to one another as well as to a particular project
 - Through development, diffusion, oversight, and investigation of research practices
- **Layers may be porous**
 - Indirect and distant actors can be drawn more closely to a particular project or researcher
 - During investigation of scientific misconduct
 - If an investigation triggers the need for policy changes

Q4: When can (should) regulation occur?

- Relational map addresses the WHO question
- Need also to examine the WHEN question
 - *Moments* in the research process when regulatory review may occur

Moments in the Research Process for Potential Regulation

		Timing of Regulatory Review		
		A Before	B During	C After
Research Stage				
1	Design	1-A	1-B	1-C
2	Data collection	2-A	2-B	2-C
3	Data processing	3-A	3-B	3-C
4	Data analysis	4-A	4-B	4-C
5	Writing	5-A	5-B	5-C
6	Presentation	6-A	6-B	6-C
7	Publication	7-A	7-B	7-C

Potential questions about regulation for each 'moment' of the research

- **At what level does the regulation take place?**
 - Personal, direct, indirect, distant
- **Are the guidelines implicit or explicit?**
 - What actors promulgated the guidelines?
 - What actors enforce the guidelines?
- **Is the regulation mandatory or voluntary?**
- **Are the regulatory actors members of the same discipline as the researcher?**
 - Which actors predominate when the research is interdisciplinary?

Contextual Considerations

- **Disciplinary differences**
 - Research questions
 - Modes of inquiry
 - Sources of data
 - Methods of data collection
 - Professional norms
 - Nature and role of professional societies
 - Sources of funding

The Effectiveness of Research Regulation

**A critically important issue that is
exceedingly difficult to assess with
rigor!**

Questions? Comments?

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