

# Ethics of Nanobiotechnology Oversight

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**NIRT: Evaluating Oversight Models for Active  
Nanostructures and Nanosystems:  
Learning from Past Technologies in a Societal Context**  
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# NIRT Research Goals

1. Assessment of oversight in 6 historical case studies utilizing criteria schooled by consensus (lit. collection & analysis, expert elicitation, consensus):
  - drugs
  - medical devices
  - chemicals in the environment
  - chemicals in the workplace
  - gene transfer research (“gene therapy”)
  - genetically engineered organisms in the food supply
2. Application of oversight lessons to nanobio (mapping, consensus)
3. Development of oversight models for nanobio products and research (scenarion analysis, consensus)

# Work on ethical issues--outline

1. The ethics of oversight assessment
2. Ethics criteria in evaluating oversight models
3. Case study: gene transfer research (“gene therapy”)
4. Moving to ethics issues in nanobio oversight

# 1. Ethics of oversight assessment

- Bioethics has traditionally focused on dyadic relationships (e.g., Doctor-Patient)
- Evolution to encompass ethics of organizations, systems, governance, e.g.:
  - Oversight system for human subjects research (IRBs, DSMBs, NIH, OHRP)
  - Systems for health care delivery (private & governmental)
  - Cross-institutional systems (QI, patient safety)
  - Regulatory & governance approaches (for GMOs, gene therapy, embryo research, rerogenetics; PCB, RAC)

# Ethics of oversight assessment (cont'd)

- Our project examines 6 oversight case studies (mixing public & private oversight approaches), using ethics, law, and policy to evaluate & dev't nanobio oversight approaches
- Relevant work on the ethics of oversight includes:
  - S.M. Wolf, *Law & Bioethics: From Values to Violence*, 32 *Journal of Law, Medicine & Ethics* 293 (2004)
  - S.M. Wolf, *Toward a Theory of Process*, 20 *Law, Medicine & Health Care* 278 (1993)
  - R.A. Charo, *The Hunting of the Snark: The Moral Status of Embryos, Right-to-Lifers, and Third World Women*, 6 *Stanford Law & Policy Review* 11 (1995)

## 2. Ethics criteria in oversight assessment

Our project uses case studies, expert elicitation, and lit. review to establish criteria for oversight assessment, including criteria of ethical significance, e.g.:

1. Development of oversight system (sample criteria):
  - Public input
  - Transparency
  - Empirical basis
2. Attributes of system (sample criteria):
  - Treatment of uncertainty
  - Empirical basis
  - Public input
  - Transparency
  - Conflicts of interest
  - Informed consent
3. Evolution of system
4. Outcomes



### 3. Case study: Gene therapy (1971-now) (S.M. Wolf & Rishi Gupta)

- Period I: Establishing NIH & FDA Oversight Mechanisms (1971-1986)
- Period II: Oversight of Gene Therapy Clinical Trials by RAC & FDA (1986-1996)
- Period III: Decline of the RAC & Emergence of Adverse Events (1996-now)



# Case study (cont'd):

Why study gene therapy oversight?

1. **Current research** on nano-vectors for gene therapy
2. Exemplifies human subjects **research oversight**
3. Coordination/conflict among **multiple agencies** (FDA, NIH)
4. Oversight by appointed expert advisory body (RAC) vs. executive agency (FDA) vs. elected officials (**ethics/politics** relationship)
5. Debate on **enhancement**
6. Debate on **multi-generational** effects (germ-line)
7. Use of **moratorium** (on germ-line)
8. Issues of secrecy & **proprietary info** vs. transparency (FDA vs. RAC at NIH)
9. Burden of proof=on researchers, evidence of safety required, high level of **regulatory prophylaxis**
10. Preventing harm vs. **retarding science** (RAC's role)

# 4. Moving to ethics issues in nanobio oversight

- Nanoethics draws on bioethics, engineering ethics, business ethics, environmental ethics,...“technopolitics”—differing degrees of attention to ethics of oversight systems
- Debate on nanobio oversight (e.g., EPA, OSHA, NIOSH, FDA, NIH, industry) has not yet specified the ethics components
- Comparing historical case studies featuring ethics debate on oversight design can surface ethics of nanobio oversight
- Can also offer oversight design options while revealing the ethical values served & trade-offs presented

# Ethics of nanobio oversight (cont'd)

Project outcomes include:

- 6 historical oversight case studies
- Comparison across case studies
- Methodology papers
- Consensus report on lessons for nanobio oversight
- Individual papers on specific problems in nanobio oversight (symposium)
- Public conference
- Website development

