

# **Synthetic Nucleic Acids and the *NIH* *Guidelines for Research Involving* *Recombinant DNA***

## **Panel I**

### **Basic Research with Recombinant and Synthetic Nucleic Acids**



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# **Panel I Basic Research with Recombinant and Synthetic NAs**

## **Moderators**

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## **Panelists**

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# Section I-B. Proposed Definition of Recombinant DNA Molecules

In the context of the *NIH Guidelines*, recombinant and synthetic nucleic acids are defined as:

- (i) Recombinant nucleic acid molecules that are constructed by joining nucleic acid molecules and that can replicate in a living cell,
- (ii) **Synthetic nucleic acid molecules that are chemically, or by other means, synthesized or amplified and that may wholly or partially contain functional equivalents of nucleotides, or**
- (iii) molecules that result from the replication of those described in (i) or (ii) above.

# Section III-F. Exempt Experiments

## **Section III-F-1:**

**Synthetic nucleic acids that can not replicate, and that are not deliberately transferred into one or more human research participants (see Section III-C and Appendix M).**

# Section III-F. Exempt Experiments

## **Section III-F-2:**

**Recombinant or synthetic nucleic acids that are not in organisms, cell or viruses and that have not been modified or manipulated (e.g., encapsulated into synthetic or natural vehicles) to render them capable of penetrating cellular membranes.**

# Discussion Questions

- **Is there a sufficient distinction between the risks of basic and preclinical research with replicating vs. non-replicating synthetic nucleic acid molecules to warrant the exemption?**
  - **What are the risks with the use of synthetic replication-incompetent, integrating vectors in the laboratory?**
  - **At the lower doses typically used in laboratory experiments, are the risks to the laboratory worker of such non-replicating, synthetic nucleic acids sufficiently low to warrant exemption from the *NIH Guidelines*?**

# Discussion Questions

- ❑ **Since the increased risk associated with human gene transfer is in part related to the administration of higher doses, should the exemption be limited to experiments involving the handling of low quantities or doses of nucleic acids?**
- ❑ **What quantity would be expected not to pose a biosafety risk?**
- ❑ **Are there examples of non-replicating, synthetic nucleic acid research that should not be exempt due to greater potential risks, in particular expression cassettes for oncogenes or toxins?**

