

# NIH *Guidelines for Research Involving Recombinant DNA Molecules*

*RAC Meeting*  
*September 12, 2012*

Impact of Recent Amendments on Local Institutional Biosafety Committees (IBCs)

- 1. Research with synthetic nucleic acids.**
- 2. Transfer of drug resistance traits to microorganisms (Section III-A-1-a)**



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# Research with synthetic nucleic acids.

- Objective: provide a mechanism whereby appropriate biocontainment and biosafety are applied to research involving synthetic nucleic acids.
- Goal is to be consistent with current risk assessment processes associated with rDNA research.



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# Scope of *Guidelines* expanded

- Primary challenge to IBCs is that the inclusion of synthetic nucleic acids potentially expands the applicability of the NIH *Guidelines* beyond the Life Sciences to include the Physical Sciences.
- Community unfamiliar with Federal and local oversight mechanisms and requirements related to rDNA.
  - Will require a significant outreach and education campaign at the local level.



# Importance of NSABB recommendations

- Establishment of mechanisms to establish and promote an institution-wide culture of responsibility (safety and security)
  - Establishment of a formal code of conduct



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# Scope of *Guidelines* expanded

- However, exemptions to the applicability of the NIH Guidelines to synthetic nucleic acids is largely mitigated in that:
  - Exemptions parallel those already existing for rDNA.
  - Chemical synthesis of nucleic acids is excluded.
    - Only applicable if synthetic nucleic acids are placed in a biological system.
    - Risks from chemical synthesis alone are considered low.



# Impact on Human Gene Transfer

- Negligible as risk assessments for synthetic molecules expressed by a molecular vector are similar to those involving rDNA.
- Oligos are excluded.



# Risk Assessment Paradigm

- Largely unchanged relative to standard rDNA risk assessment.
- However, chimeras will require very close scrutiny as outcomes may not be predictive.
- Potentially may require additional IBC expertise (physical sciences, computational biology)



# Transfer of drug resistance traits to microorganisms

- Criteria for Major Actions remain unchanged.
- Additional language clarifying therapeutic utility of a particular drug is helpful.
- Review process streamlined via delegated authority to OBA to approve requests similar to those previously-approved.
- Net impact is favorable to research community.



**Thank you!**



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