Biosafety and the *NIH Guidelines*

This section will explore:

- ✓ **Why the *NIH Guidelines* are important**
- ✓ **The definition of recombinant or synthetic nucleic acid research**
- ✓ **Contents of the *NIH Guidelines***
  - **Sections I and II (Scope and Safety)**
- What is an IBC and its function?
- How to submit a research proposal to the IBC for review

Content of the *NIH Guidelines*

- **Section I – Scope**
- **Section II – Safety Considerations**
- Section III –Experimental Classifications
- Section IV – Roles and Responsibilities
- Appendices

The *NIH Guidelines* apply to…

- Research involving recombinant or synthetic (or both) nucleic acid molecules that is
  - **Performed at *or* sponsored by an institution that receives *any* NIH funding**
- Rationale: For biosafety to be meaningful, it has to be observed by all investigators at an institution

This applicability is broader than many NIH grant and contract requirements

The Importance of the *NIH Guidelines*

- **Federal funding** – it is a mandate for institutional compliance by the NIH
- **Public Transparency** - to increase public trust of science and research:
  - IBC meetings are Open to the public
  - IBC Minutes are available to the public

    see: Freedom of Information Act FOIA 1967
- **Based on Investigator integrity** established at Alisomar, CA in 1975

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Federal funding is the threshold requirement for institutional compliance

NIH Guidelines – **Section I**

Scope and Applicability

Specifies the practices for constructing *and* handling:

(i) recombinant nucleic acid molecules,

(ii) synthetic nucleic acid molecules, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, and

(iii) cells, organisms and viruses containing such molecules

NIH Guidelines – **Section I**

Definition

In the context of the *NIH Guidelines,* Recombinant and Synthetic Nucleic Acids are:

(i) molecules that:

a) are constructed by joining nucleic acid molecules *AND*

b) can replicate in a living cell

(i) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e. synthetic nucleic acids; *OR*

(ii) molecules that result from the replication of those described in (*i*) or (*ii*) above.

NIH Guidelines – **Section II**

Safety Considerations

NIH Guidelines – Section II

Safety Considerations

Risk assessments: (*Appendix B*)

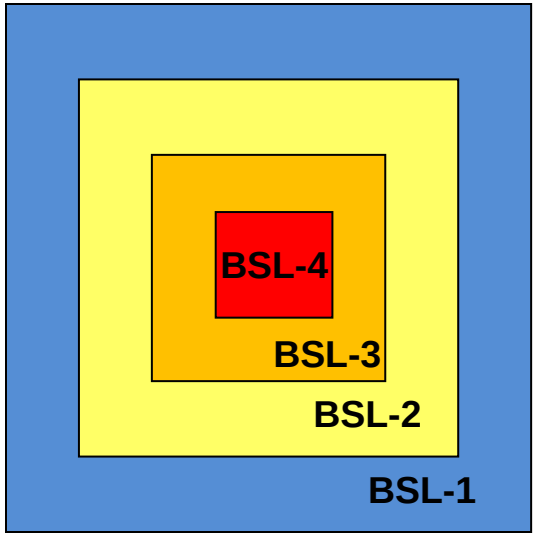
Risk Groups 1 - 4

RG 1	RG 2	RG 3	RG 4
Agents that are not associated with disease in healthy adult humans	Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are *often* available	Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions *may be* available (high individual risk but low community risk)	Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are *not usually* available (high individual risk and high community risk)

NIH Guidelines – Section II Safety Considerations

Containment; 2 types:

- **Physical** (Appendix G)
  - Practices
  - Equipment
  - Facilities
- **Biological** (Appendix I)
  - Survival
  - Transmission



End of Chapter 1