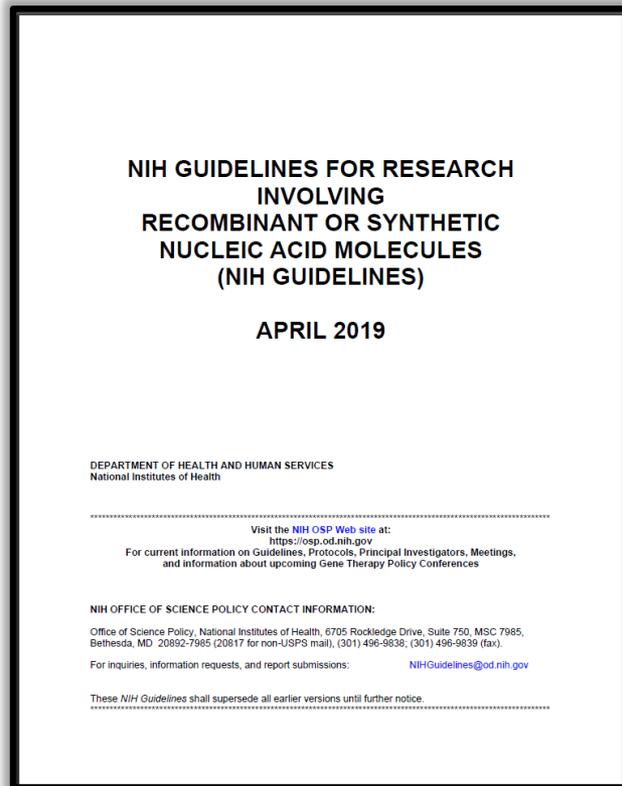


Overview:
*NIH Guidelines for Research Involving Recombinant or
Synthetic Nucleic Acid Molecules*
and
**Biosafety in Microbiological and Biomedical
Laboratories (BMBL)**

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules

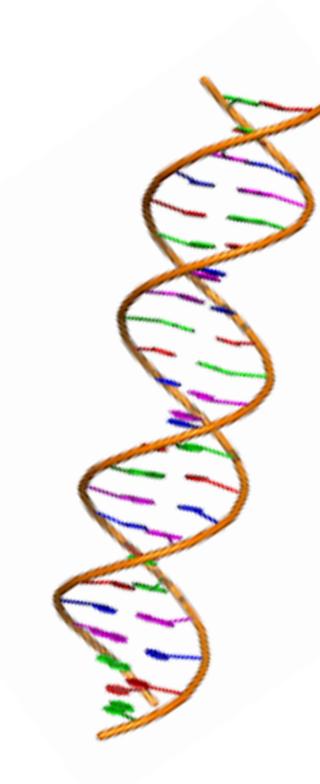


- **Evolving, scientifically-responsive document**
 - **Multiple revisions since 1976**
 - **Latest version – April 2019**

https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm

NIH Guidelines - Scope

- **Specifies 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



The *NIH Guidelines* - Applicability

- Research with recombinant or synthetic (or both) nucleic acid molecules that is
 - Conducted at or sponsored by an institution that receives any support for recombinant or synthetic nucleic acid research from NIH
- Other Federal agencies and some private funders of research also make adherence to the *NIH Guidelines* a term and condition of their funding
- A number of institutions also voluntarily adhere to the requirements of the *NIH Guidelines*
- Specifically addresses contained research

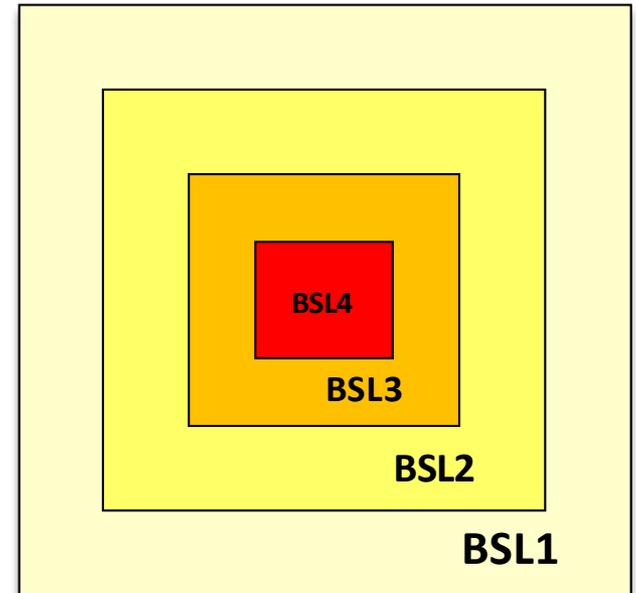
Institutional Biosafety Committees

- **Established under the *NIH Guidelines* specifically for the review of research involving recombinant or synthetic nucleic acid molecules**
 - **Potential risk to environment and public health**
 - **Biological Containment levels per *NIH Guidelines***
 - **Adequacy of facilities, SOPs,**
 - **Research personnel training**

NIH Guidelines – Containment

- **Physical (Appendix G)**
 - **Work Practices**
 - **Safety Equipment**
 - **Facilities**

- **Biological (Appendix I)**
 - **Survival**
 - **Transmission**



NIH Guidelines Section III - Levels of Review

Level of review	Example of types of research covered	Relevant section(s) of the <i>NIH Guidelines</i>
IBC and NIH Director review and approval	Experiments that compromise the control of disease agents in medicine through deliberate transfer of a drug resistance trait	III-A
IBC approval and NIH review for containment determinations	Experiment involving the cloning of toxin molecules with LD50 of less than 100 nanograms per kilogram of body weight	III-B
IBC and IRB approval and NIH review before research participant enrollment	Experiments involving the deliberate transfer of recombinant or synthetic nucleic acid molecules into a human research participant	III-C
IBC approval before initiation	Creating stable germline alterations of an animal's genome, or testing viable recombinant or synthetically modified microorganisms on whole animals, where BL-2 containment or greater is necessary	III-D
IBC notice at initiation	Creating stable germline alterations of rodents by introduction of recombinant or synthetic nucleic acid molecules when these experiments require only BL-1 containment	III-E
Exempt from the <i>NIH Guidelines</i> . IBC registration not required if experiment not covered by Sections III-A, III-B, or III-C	Purchase or transfer of transgenic rodents	III-F

Key Sections:

Section III-D-4: Experiments Involving Whole Animals

- **Experiments Require IBC Approval Before Initiation**
 - **Includes experiments in which:**
 - **The animal's genome has been altered by stable introduction of recombinant or synthetic nucleic acids into germline (transgenic animals)**
 - **Viable recombinant or synthetic nucleic acid molecule-modified microorganisms are tested on whole animals**

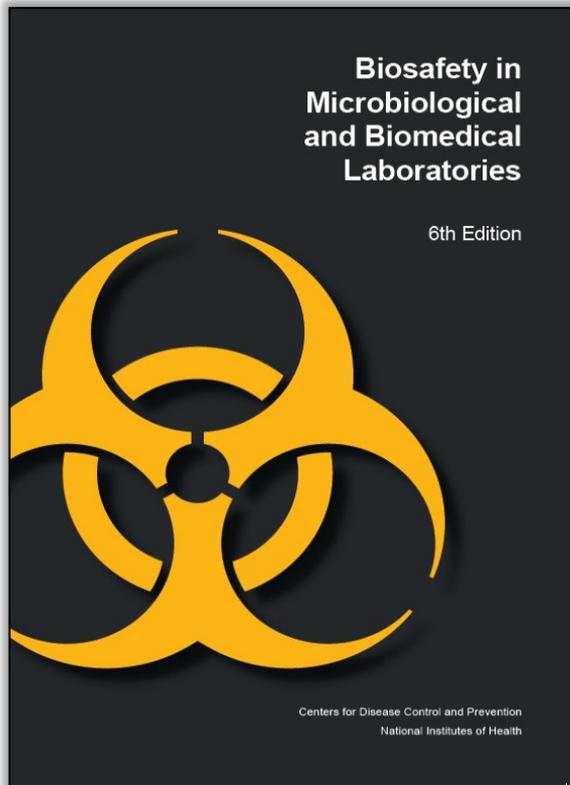


Key Sections: Section III-E-3

- **Experiments Involving the Generation of Transgenic Rodents**
 - **Experiments in which:**
 - **Rodent's genome has been altered by stable introduction of recombinant or synthetic nucleic acid molecules into germline**
 - **BL1 containment is appropriate**



Biosafety in Microbiological and Biomedical Laboratories (BMBL)



■ Applicability

- ❑ Code of practice and an authoritative reference.
- ❑ The preamble to the BMBL specifically states its purpose is to articulate “*best practices and is not intended as a regulatory document*”.

BMBL - Key Sections

- **Section II – Biological Risk Assessment**
Approaches to assessing risks and selecting appropriate safeguards.
- **Section IV – Laboratory Biosafety Level Criteria**
Requirements for biosafety levels including facility design criteria, safety equipment and work practices for physical containment and prevention of exposure and/or releases.
- **Section V - Vivarium Facilities for Animal Research**
- **Agent Summary Statements**
Identify the primary agent and procedure hazards for specific pathogens and recommend precautions for their control
- **Agricultural Pathogen Biosafety**
- **Arthropod Containment Guidelines**
Incorporated by reference