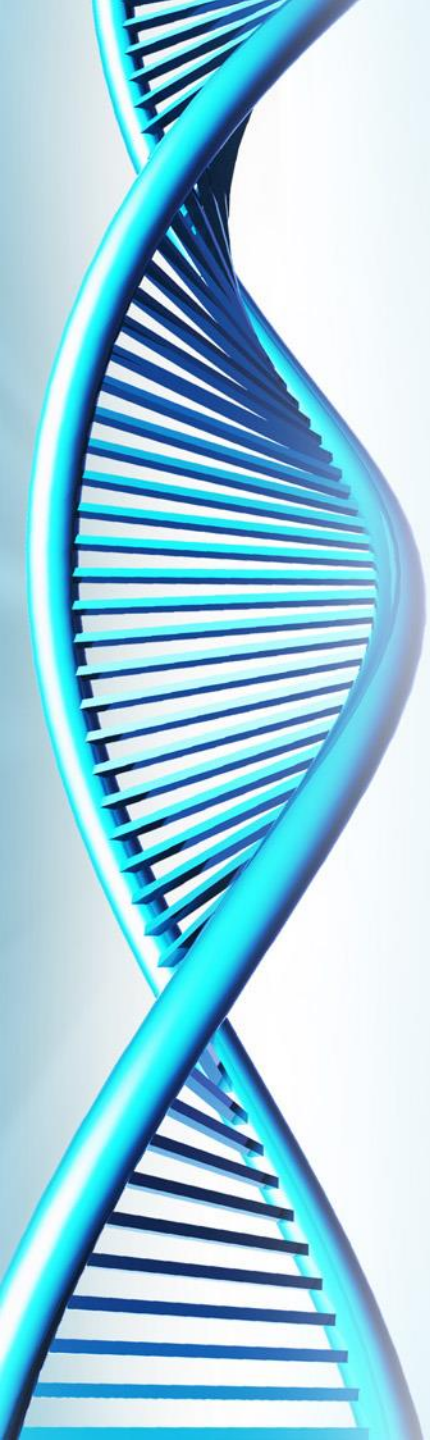


Biosafety and the *NIH Guidelines*

This section will explore:

- Why the *NIH Guidelines* are important
- The definition of recombinant or synthetic nucleic acid research
- ✓ **Content of the *NIH Guidelines***
  - **Notable Appendices of the *NIH Guidelines***
- 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**

Appendices of the *NIH Guidelines*

There are currently 17 appendices in the *NIH Guidelines*

The following six appendices are most commonly referenced by the Pitt IBC:

- **Appendix B** – Risk Groups and BSL
- **Appendix C** – Exemptions/exceptions
- **Appendix G** – Physical containment
- **Appendix K** – Large scale (10+L volume)
- **Appendix M** – Human gene transfer
- **Appendix Q** – Large animal containment

Appendix B

Classification of Human Etiologic Agents on the Basis of Hazard (Risk Groups)

- Reflects the current state of knowledge and is not meant to be all-inclusive
- Considered to be a resource document
- Additional guidance for agents that are *not* listed in ***Appendix B*** may be obtained through:
  - Centers for Disease Control (CDC)
  - NIH, Division of Safety
  - National Animal Disease Center, USDA

Appendix C-VIII

Generation of Transgenic Rodents via Breeding

The breeding of two different transgenic rodents or the breeding of a transgenic rodent with a non-transgenic rodent with the intent of creating a new strain to be housed under ABSL-1 containment may qualify for **IBC Registration status** with the IBC ***if***:

1) **Both parental rodents can be housed under BL1 containment;**

and

2) **neither parental transgenic rodent contains the following genetic modifications:**

   a) **incorporation of more than one-half of the genome of an exogenous eukaryotic virus from a single family of viruses;**

   OR

   b) **incorporation of a transgene that is under the control of a gamma-retroviral long terminal repeat (LTR);**

and

3) **the transgenic rodent that results from this breeding is *not* expected to contain more than one-half of an exogenous viral genome from a single family of viruses.**

Appendix G

Physical Containment and Good Microbiological Practices

This appendix specifies containment for standard laboratory experiments

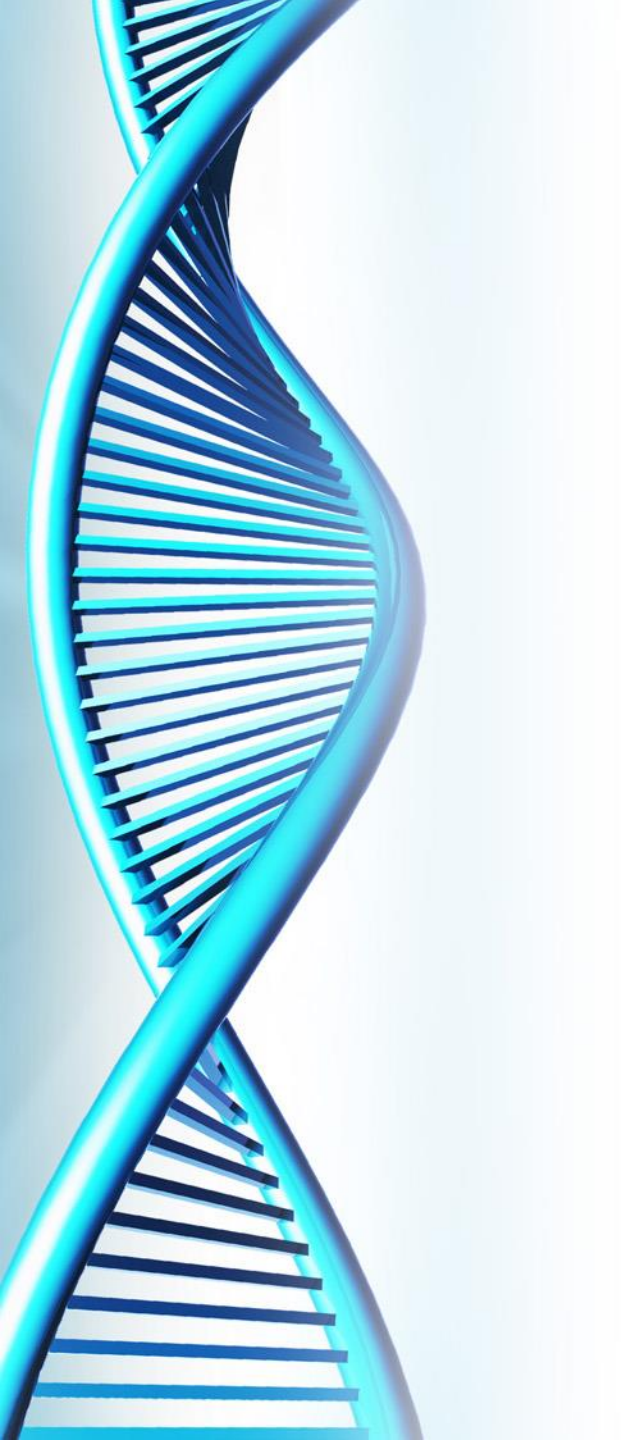
- Biosafety levels BSL-1 through BSL-4 are defined
- Containment appropriate to ***most*** research projects
- Specific containment requirements are addressed in other Appendices:
  - **Appendix K** - Large scale volumes (over 10 liters)
  - **Appendix P** – Plant research containment
  - **Appendix Q** – Large Animal ***or*** non-standard laboratory animal housing containment

Appendix M

Human Gene Transfer/Clinical Trials

- Protocol submission requirements
- Will be for NIH registration purposes
- Exempt RAC discussion/public review
- IBC approval required for HGT administration*
- Section M-I-C: Reporting requirements
- Section M-VI: Vaccine exemption

Exempt RAC review** or **Vaccine Exemption
*does **NOT** mean that the clinical study is exempt from IBC review!*



End of Chapter 4