Experiment involves the transfer of unnatural drug resistant trait to microorganisms that compromises disease control efforts

- Yes: Requires Institutional Biosafety Committee Approval, RAC Review, and NIH Director approval before Initiation
- No

Experiment involves cloning of toxin Molecules with LD$_{50}$ of Less than 100 ng/kg Body Weight (e.g., botulinum, tetanus, diphtheria, Shigella dysenteriae)

- Yes: Require NIH/OBA and Institutional Biosafety Committee Approval prior to Initiation
- No

Experiment Involves the Deliberate Transfer of Recombinant DNA or derived Recombinant DNA, into One or More Human Research Participants (e.g., Human Gene Transfer)

- Yes: Require IBC and Institutional Review Board Approvals and RAC Review Before Research Participant Enrollment
- No

Experiment Involves Using:
- Risk Groups 2-4/Restricted Agents as Host-Vector Systems
- Risk Groups 2-4/Restricted Agents cloned into Nonpathogenic Prokaryotic/Lower Eukaryotic Host-Vector System
- Infectious DNA/RNA in Tissue Culture
- Whole Animals
- Whole Plants
- More than 10 Liters of Culture

- Yes: Require Institutional Biosafety Committee Approval Before Initiation
- No

Experiment involves Recombinant DNA with no more than two thirds of an eukaryotic viral genome

- Yes: Require IBC Notice Simultaneous with Initiation
- No

Exempt: Register with the IBC
Risk Assessment Factors

When evaluating your experiment’s risk, the level of risk involves your agent and the process of manipulation in terms of the following conditions?

- Virulence
- Pathogenticity
- Infectious Dose
- Environmental Stability
- Route of Spread
- Communicability
- Operations
- Quantity
- Availability of Vaccine or Treatment
- Gene Product Effects
  - Toxicity
  - Physiological Activity
  - Allergenicity

For the Risk Group Level of your agent, consult Appendix B “Classification of Human Etiological Agents on the Basis of Hazard” of the NIH Guidelines