An Institutional Biosafety Committee (IBC) protocol for NIH guidelines must ensure compliance with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules. The protocol must provide detailed information so the IBC can assess potential risks to researchers, the public, and the environment. Below is a comprehensive template you can use for creating or submitting a protocol to your IBC under NIH guidelines.

IBC Protocol Submission Template

(Compliant with NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules)

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1. Principal Investigator (PI) Information

- Name:
- Department:
- Institution:
- Phone Number:
- Email:
- Office/Lab Location:

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2. Project Title and Summary

- Title of Research Project:
- Lay Summary (in plain language):

  Briefly describe the purpose and significance of the research.

- Scientific Summary:

  Detailed description of the project, including hypotheses, aims, and research approach.

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3. Funding Source

- Funding Agency (e.g., NIH, NSF, etc.):
- Grant Number (if applicable):
- Project Period:

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4. Biological Materials Involved

- Recombinant or Synthetic Nucleic Acids:

  (Yes/No)

  - Describe the constructs (e.g., plasmid vectors, viral vectors)
  - Source of DNA/RNA sequences
  - Genes inserted (with function and origin)
  - Host organism(s) or cells
- Other Biohazardous Agents (check all that apply):
  - Human/animal pathogens
  - Human or non-human primate cells or tissues
  - Biological toxins
  - Select agents or toxins
  - Transgenic animals or plants
  - Infectious agents (specify)

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5. Host and Vector Information

- Host Organism(s):

  (E.g., E. coli, yeast, mammalian cells, animals, plants)

- Vector(s):

  (E.g., plasmid name, viral backbone)

- Risk Group (RG) classification (NIH/CDC):
- Biosafety Level (BSL) required:

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6. Description of Laboratory Procedures

- Detailed Methods:

  Describe how rDNA/synthetic nucleic acids are introduced, expressed, or manipulated.

- Containment Procedures:

  Describe the physical and biological containment measures.

- Decontamination Procedures:
- Waste Disposal Methods:

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7. Personnel and Training

- List of all personnel involved in the project:

  Include names, titles, roles.

- Biosafety Training Completed:

  (Yes/No for each person + date)

- PPE Required and Training Provided:

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8. Risk Assessment and Management

- Potential Risks to Personnel and Environment:
- Risk Mitigation Strategies:
- Emergency Procedures (e.g., exposure response, spills):

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9. Animal or Human Subjects Involvement

- Does this project involve vertebrate animals? (Yes/No)
  - If yes, provide IACUC protocol # and status.
- Does this project involve human subjects or materials? (Yes/No)
  - If yes, provide IRB protocol # and status.

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10. NIH Guidelines Section Applicability

Indicate all applicable sections of the NIH Guidelines:

(Select and list any of the following, e.g., III-A through III-F)

- Section III-A (Deliberate transfer of drug resistance)
- Section III-B (Cloning of toxin molecules)

- Section III-C (Use of human gene transfer)
- Section III-D (BL2/BL3/BL4 experiments)
- Section III-E (BL1 exempt experiments)
- Section III-F (Exempt experiments – must still be registered)

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11. Certification and Signatures

- PI Signature:

  I certify that this protocol is accurate and that I will comply with all relevant biosafety policies, the NIH Guidelines, and any stipulations imposed by the IBC.

  Signature: _____

  Date: _____