

# What Requires an IBC Review at RU?

Work with the following materials will require IBC approval at Rutgers University before research may commence. IBC approval must be in place before IACUC and/or IRB approvals can be obtained. Any questions or concerns should be directed to the REHS Biosafety team at [biosafety@rutgers.edu](mailto:biosafety@rutgers.edu)

## Non-Recombinant Biological Materials/Agents

- Pathogenic Microorganisms at or above Risk Group 2 per the NIH Guidelines
  - Including: bacteria, viruses, parasites, fungi
- Microorganisms at Risk Group 1 per the NIH Guidelines if they pose a risk of infection to the researcher or biologicals in the research environment/community
- Biological Toxins
- Human, animal, & non-human primate: cells, tissues, body fluids, or other fluids/materials

## Recombinant and/or Synthetic Nucleic Acids

- Any recombinant and/or synthetic nucleic acid [or nucleic acid derived from recombinant and/or synthetic nucleic acid] with the potential to:
  - Be transcribed or translated
  - Be integrated into endogenous nucleic acids
    - Chromosomal DNA, mRNA
  - Influence pre- or post-
    - Transcription processes
      - siRNA, shRNA, antisense oligonucleotides, plasmids, chromatin
    - Translational processes
      - Chromatin modifiers, histone modification
- Gene Drives, viral vectors, CRISPR gene editing, TALEN editing, zinc finger nucleases, mega nucleases, etc.

## Recombinant and/or Synthetic Nucleic Acids with Cell Lines, Animals, and/or Plants

- Creation of a transgenic:
  - Plant
  - Cell Line – including immortalizing cell lines
  - Animals – excluding breeding and BSL1 transgenic rodents obtained from outside institutions/vendors
- Administration of recombinant and/or synthetic nucleic acids to a whole plant, cell line, and/or animal

## Genetically Modified & Recombinant Pathogens

- Viral vectors
  - Including but not limited to: AAV, AV, and Lentivirus
- Tools/Systems to genetically modify microbiological pathogens
  - Including: site-directed mutagenesis PCR, reverse genetics, etc.
- Genetically modified biological agents
  - At Risk Group 1 (and above) only if:
    - Tropism to humans
    - A harmful transgene is involved. Harmful defined as any of the following sequences or partial sequences:
      - A prion protein, prion-like protein, or protein involved in a misfolding pathways neuro-degenerative disease
      - Risk Group 2, 3, or 4 sequence
      - Any biological toxin
      - Oncogenes, tumor suppressors, or genes encoding proteins involved in chromatin modifications
      - Immunomodulatory genes known to suppress host immune function
      - Any sequence expected to increase the virulence, fitness, host-range/tropism
      - Human disease progression genes
        - Such as but not limited to: Liver disease, panniculitis, and Alpha-1 antitrypsin deficiency leading to emphysema
  - At Risk Group 2,3, and 4