

# Recombinant DNA Categories vs. Review Bodies

As described in Section 3 of the [NIH Guidelines on recombinant DNA research](#), the Institutional Biosafety Committee functions on behalf of the Institution, with responsibility for overseeing all experimentation that involves the use of recombinant DNA.

Recombinant DNA experiments have been grouped into the following six categories by NIH. The first five (non-exempt) categories are subject to IBC oversight.

- 1. Experiments that Require Institutional Biosafety Committee Approval, RAC Review, and NIH Director Approval Before Initiation**
  - The deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture, will be reviewed by RAC.
  
- 2. Experiments That Require NIH/OBA and Institutional Biosafety Committee Approval Before Initiation**
  - Experiments Involving the Cloning of Toxin Molecules with LD50 of Less than 100 Nanograms per Kilogram Body Weight
  
- 3. Experiments that Require Institutional Biosafety Committee and Institutional Review Board Approvals and RAC Review Before Research Participant Enrollment**
  - Experiments Involving the Deliberate Transfer of Recombinant DNA or DNA or RNA Derived from Recombinant DNA into One or More Human Research Participants. *Note that RAC approval must be granted **before** the IBC can approve any such protocol*
  
- 4. Experiments that Require Institutional Biosafety Committee Approval Before Initiation**
  - Experiments Using Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents as Host-Vector Systems
  - Experiments in Which DNA From Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents is Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems
  - Experiments Involving the Use of Infectious DNA or RNA Viruses or Defective DNA or RNA Viruses in the Presence of Helper Virus in Tissue Culture Systems
  - Experiments Involving Whole Animals
  - Experiments Involving Whole Plants (involving use of pathogenic plant microorganisms/insects, or recombinant plants with potentially hazardous properties)
  - Experiments Involving More than 10 Liters of Culture

## 5. Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation

- Experiments not included in categories 1-4 or 6, are considered in category 5. All such experiments may be conducted at BL1 containment. *For example, experiments in which all components derived from non-pathogenic prokaryotes and non-pathogenic lower eukaryotes may be conducted at BL1 containment.*
- Experiments Involving the Formation of Recombinant DNA Molecules Containing No More than Two-Thirds of the Genome of any Eukaryotic Virus
- Experiments Involving Whole Plants (involving use of non-pathogenic plant microorganisms, or recombinant plants with non-hazardous properties)
- Experiments Involving Transgenic Rodents

## 6. Exempt Experiments

The following recombinant DNA molecules are exempt from the NIH Guidelines and registration with the IBC is **not required**:

- Those that are not in organisms or viruses.
- Those that consist entirely of DNA segments from a single nonchromosomal or viral DNA source, though one or more of the segments may be a synthetic equivalent. *Note that cloned DNA segments from eukaryotic viruses fall under category 5*
- Those that consist entirely of DNA from a prokaryotic host including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species), or when transferred to another host by well established physiological means.
- Those that consist entirely of DNA from an eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species).
- Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. A list of such exchangers will be prepared and periodically revised by the NIH Director with advice of the RAC.
- Those that do not present a significant risk to health or the environment, as determined by the NIH Director, with the advice of the RAC.