UCM IBC Categories of Research

Research that involves any of the components listed below will require one of the following levels of approval: (a) Institutional (b) Institutional with adherence to NIH Guidelines (c) Institutional and NIH OSP **or** (d) Institutional and NIH Director.

a) **Recombinant or synthetic nucleic acid molecules:** molecules capable of replicating in living cells that are constructed outside of living cells by joining DNA segments (natural or synthetic) to DNA molecules. Including molecules that are produced from replication of these cells, transgenic animals, plants, mutagenesis and/or cloning in microorganisms.
b) Microorganisms (non-pathogenic and pathogenic)
c) Toxins
d) Biological samples
e) Animal-derived materials
f) Human-derived materials

Research for each level of approval:

1. **Institutional approval**: Experiments that fall under the Exempt experiments (NIH Exempt) in the NIH Guidelines but include one of the categories listed above.

2. **Institutional with adherence to NIH Guidelines** (NIH Guidelines)**:** Includes both BSL-1 and BSL-2 level research:
    a. Any research or experiments involving Risk Group 2 agents:
        i. When used as host-vector systems.
        ii. DNA is cloned into nonpathogenic prokaryotic or lower eukaryotic host-vector systems.
        iii. Use of infectious or defective viruses in presence of helper virus.
    b. Research involving transgenic animals (alteration of genome by stable introduction of recombinant or synthetic nucleic acid molecules or nucleic acids derived therefrom into the germline)
    c. Experiments involving viable recombinant or synthetic nucleic acid molecule modified microorganisms tested on whole animals
    d. Experiments to genetically engineer plants by recombinant or synthetic nucleic acid molecule methods, to use for experimental purposes, propagate such plants, or use plants with microorganisms or insects containing recombinant or synthetic nucleic acid molecules.

3. **Institutional and NIH OSP** (NIH OSP):
    a. Cloning of toxin molecules with LD_{50} of less than 100 nanograms per kg of body weight.
    b. Experiments approved as Major Actions under NIH Guidelines (Major Actions)
    c. Experiments involving human gene transfer.

4. **Institutional and NIH Director** (NIH Director):
    a. Transfer of a drug-resistant trait into a microorganism not known to acquire the trait naturally, if the ability to control the disease agents in humans, veterinary medicine, or agriculture is compromised due to acquisition of the drug-resistant trait.