MIT Biological Research Registration Categories and Experiments

Categories III-D to III-F (most common research):

Category	III-D	III-E	III-F
Definition	• Modifying pathogens or work with DNA from pathogens • DNA/RNA virus work • Viral vectors • Modifying animals or microorganisms going into animals • Modifying weeds, exotic plants, or plant pathogens • Certain influenza studies • Large scale GMO research (>10L volume)	• Eukaryotic virus work (<2/3 of viral genome) in tissue culture at BL1 containment • Modifying domestic, non-weed plants or non-pathogenic organisms in plants • Transgenic mouse work at BL1 containment • Anything else not covered by Categories III A-D or III-F	• Material that can't replicate in living cells or can't enter living cells • Low risk material already found in nature • Transposons found in nature • Work with specific non-pathogenic organisms
Examples	• Cloning GFP plasmid into *P. aeruginosa* • CrispR-Cas9 modification of *H. pylori* • Using modified *P. falciparum* purchased from ATCC • Cloning *S. typhimurum* genes into • *E. coli BL21* • Packaging a 3rd generation lentiviral vector in HEK cells • Using GFP to make fluorescent mice • Injecting modified HeLa cells into mice • Feeding mice *L. reuturi* containing GFP • Growing 11L of *E. coli K12* with YFP • Generating a new novel strain of influenza by combining fragments from different seasonal strains	• Modifying Arabidopsis • Adding *B. subtilis* with GFP to the soil of spinach • Creating transgenic mice requiring only BL1 containment • Cloning GFP in *E. coli BL21*	• Agents containing less than 1/2 of any eukaryotic virus propagated & maintained in cells in tissue culture • GMO of *E. coli K-12, S. cerevisiae, S. uvarum, K. lactis,* or *B. subtilis* strains
Approvals for amendments	• EHS Biosafety • CAB/ESCRO • Project initiation	• EHS Biosafety • Administrative approval***** • Project initiation • CAB/ESCRO • Project continuation	• EHS Biosafety • Administrative approval***** • Project initiation • CAB/ESCRO • Project continuation

***Administrative approval can give be given at discretion of Institutional Biosafety Officer.**

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Questions/Comments: MIT EHS Biosafety Program

MIT Biological Research Registration Categories and Experiments

Categories III-A to III-C (less common experiments that require additional approval):

Category	III-A	III-B	III-C
Definition	• Making a pathogen resistant to an antibiotic used as a primary method to treat the infection	• Adding toxin genes into an organism • Specific experiments considered "Major Actions" by the NIH	• Gene therapy or clinical studies with recombinant material in human subjects
Examples	• Making Staphylococcus aureus resistant to doxycycline • Making Clostridium difficile resistant to vancomycin	• Cloning botulinum toxin into Escherichia coli BL21Cloning tetanus toxin into Staphylococcus aureus • Please see the NIH guidelines for specific examples of Major Actions.	• Initiating a clinical research experiment to test the efficacy of a retroviral vector targeting a specific disease • Introducing CRISPR-Cas9 to human patients to target a cancer gene
Approval Process	• EHS Biosafety • CAB/ESCRO • NIH review • Project initiation	• EHS Biosafety • CAB/ESCRO • NIH review • Project initiation	• EHS Biosafety • CAB/ESCRO and COUHES • NIH review • Project initiation

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