

Policy: IBC Review and approval of BUAs

Please note that all projects including those expedited will be reviewed and approved at the monthly IBC meetings by the USC IBC.

Expedited Review by Biosafety Officer (BSO)

1. Use of human or non-human primate blood, specimens, clinical samples, cells, or established cell lines
2. Addition of personnel
3. Addition of research locations
4. Addition or change of grant title to match IACUC approval
5. Simultaneous notification rDNA experiments (Section III-E)
6. Exempt experiments (Section III-F)
7. Addition of carcinogenic, mutagenic, toxic chemicals and toxins of biological origin to a previously approved project if the additions are similar to that which is previously approved.
8. Any combination of the above

Full IBC Review and Approval

1. The use of recombinant and/or synthetic nucleic acid molecules according to the following sections of the NIH Guidelines.
 - a. III-A Experiments that require IBC approval, RAC review, and NIH Directors approval prior to initiation
 - i. Deliberate transfer of drug resistance to microorganisms not known to acquire the trait naturally if such acquisition could compromise the ability to control disease agents in humans, veterinary medicine, or agriculture
 - b. III-B Experiments that require NIH/OBA and IBC approval prior to initiation
 - i. Cloning genes that encode toxins with an LD₅₀ of less than 100 ng per kg body weight
 - ii. Experiments that are equivalent to experiments that have been previously approved as a major action
 - c. III-C Experiments that require IBC and IRB approvals and possibly RAC approval (RAC may or may not require a public review and discussion)
 - i. Human gene therapy
2. Use of Risk Group 2 or 3 agents
3. Use of select agents and toxins as defined under the Federal Select Agent Program
4. Use of potential dual use research of concern (DURC) agents
5. Use of carcinogenic, mutagenic, toxic chemicals and toxins of biological origin
6. Any biohazardous research performed by a PI new to USC
7. Research that the IBC Chairs or the BSO believe requires review due to the risk assessment