



UNIVERSITY of NEW HAMPSHIRE

Recombinant DNA/Infectious Agent Registration

*A Summary of the Registration Requirements Described in the
NIH Guidelines for Research Involving Recombinant DNA Molecules (<http://www4.od.nih.gov/oba/>)*

Level	Approval/Review	Requirements
III-A	NIH Director, RAC, IBC	A drug resistant gene transferred into a (new) microorganism.
III-B	NIH/OBA, IBC	The cloning of toxin molecules with LD ₅₀ < 100 ng/kg of body weight.
III-C	RAC, IRB, IBC	Recombinant DNA (or DNA or rDNA derived from rDNA) transferred into humans.
III-D	IBC†	Recombinant DNA transferred to or from whole animals, whole plants, transgenic rodents, experiments involving >10 Liters of culture, or agents listed in Risk Groups 1, 2, 3, or 4 (see below) at the appropriate Biological Safety Level (BSL).
III-E	IBC§	Recombinant DNA involving no more than 2/3 eukaryotic virus agents, whole plants, arthropods, or transgenic rodents.
III-F		Recombinant DNA not found in organisms or viruses, single monochromal or viral DNA sources, or host DNA transferred to the same host or related species.

† Approval required before initiation.

§ Notify IBC when project is initiated. IBC approval still required.

Risk Groups ^λ

Risk Group 1 (RG1)	Agents that are not associated with disease in healthy adult humans. (BSL-1)
Risk Group 2 (RG2)	Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available. (BSL-2)
Risk Group 3 (RG3)	Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available (high individual risk but low community risk). (BSL-3)
Risk Group 4 (RG4)	Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available (high individual risk and high community risk). (BSL-4)

^λ For a listing of agents, see “Appendix B – Classification of Human Etiologic Agents on the Basis of Hazard” in the NIH Guidelines For Research Involving Recombinant DNA Molecules, April 2002.