rDNA USE AT UCSC

UC Requirements

The University of California follows the National Institutes of Health (NIH) Guidelines for all research involving recombinant DNA molecules (rDNA) for which the University is responsible, and not just for research funded by NIH. These Guidelines are published in the Federal Register and are periodically updated. The most recent Guidelines are available from the NIH

WHO NEEDS APPROVAL?

The NIH Guidelines sets out review requirements for rDNA research. Without obtaining required Institution Biosafety Committee (IBC) approval, research cannot be conducted.

The NIH Guidelines for Research Involving Recombinant DNA Molecules defines four categories of review requirements for rDNA research:

(a)Exempt research, which does not require IBC approval

(b)Research Requiring IBC Notice-experiments requiring registration with the IBC at the time the experiment is initiated, and subsequent IBC review and approval

(c)Research Requiring IBC review and approval

(d)Research requiring NIH, RAC, IBC and other approvals

These categories are detailed further on the next two pages.

The NIH Guidelines for Research Involving Recombinant DNA Molecules is the primary source of information regarding review requirements for recombinant DNA research.

CATEGORIES OF rDNA RESEARCH

Exempt Research

Experiments using the following recombinant DNA molecules do not require IBC registration or approval:

(a)Those that are not in organisms or viruses.

(b)Those that consist entirely of DNA segments from a single non-chromosomal or viral DNA source, though one or more of the segments may be a synthetic equivalent.

(c)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.

(d)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).

(e)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. [1]

(f)Those that do not present a significant risk to health or the environment [3]

Experiments in this category can generally be conducted using Risk Group 1 (RG1) level containment.

Research requiring NIH, RAC, IBC and other approvals

Research falling in this category include:

(a)Research defined as a Major Action under the NIH Guidelines.

(b)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 or in veterinary medicine.

(c) Experiments Involving the Cloning of Toxin Molecules with LD50 of Less than 100 Nanograms per Kilogram Body Weight.

(d) Experiments Involving the Deliberate Transfer of genes providing information necessary to produce Recombinant DNA, or DNA or RNA Derived from Recombinant DNA, into One or More Human Research Participants.

Research Requiring IBC review and approval

Experiments using the following recombinant DNA molecules require IBC registration and approval prior to initiation:

(a)Experiments involving most exotic infectious agents with recognized potential for serious detrimental impact on managed or natural ecosystems when recombinant DNA techniques are associated with whole plants.

(b)Experiments involving plants containing cloned genomes of readily transmissible exotic infectious agents with recognized potential for serious detrimental effects on managed or natural ecosystems in which there exists the possibility of reconstituting the complete and functional genome of the infectious agent by genomic complementation in planta.

(c)Experiments with a small number of readily transmissible exotic infectious agents that have the potential of being serious pathogens of major U.S. crops.

(d)Most experiments involving sequences encoding potent vertebrate toxins introduced into plants or associated organisms. [2]

(e)Experiments with microbial pathogens of insects or small animals associated with plants if the recombinant DNA-modified organism has a recognized potential for serious detrimental impact on managed or natural ecosystems.

(f)Experiments Involving More than 10 Liters of Culture

Experiments in this category can generally be conducted using Risk Group 1 (RG1) level containment.

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[1] A list of such exchangers will be prepared and periodically revised by the NIH Director with advice of the RAC after appropriate notice and opportunity for public comment.

[2] Recombinant DNA containing genes for the biosynthesis of toxin molecules lethal for vertebrates at an LD50 of <100 nanograms per kilogram body weight require NIH/OBA and Institutional Biosafety Committee approval before initiation.

CATEGORIES OF rDNA RESEARCH

Research Requiring IBC Notice

rDNA experiments which are not exempt and which do not require IBC review and approval under the NIH guidelines require registration with the IBC at the time the experiment is initiated. The Institutional Biosafety Committee reviews and approves all such proposals.

These experiments include:

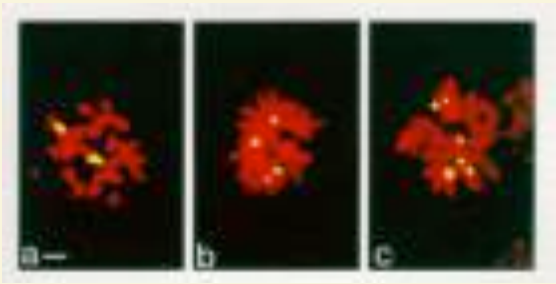
(a) Experiments Involving the Formation of Recombinant DNA Molecules Containing No More than Two-Thirds of the Genome of any Eukaryotic Virus: Recombinant DNA molecules containing no more than two-thirds of the genome of any eukaryotic virus (all viruses from a single Family being considered identical)

(b)Experiments Involving Whole Plants:

(c)This section covers experiments involving recombinant DNA-modified whole plants, and/or experiments involving recombinant DNA-modified organisms associated with whole plants, except those that fall under Exempt Research or Research Requiring IBC review and approval .

(d)Experiments Involving Transgenic Rodents: This section covers experiments involving the generation of rodents in which the animal's genome has been altered by stable introduction of recombinant DNA, or DNA derived therefrom, into the germ-line (transgenic rodents).

Experiments in this category must generally be conducted using Risk Group 2 (RG2) or higher level containment.



How do I get approval?

To obtain approval for your rDNA experiment, please fill out the IBC rDNA application available on the UCSC EH&S web site (http://ehs.ucsc.edu/lab_research_safety/biosafety.php) and submit it to the IBC for review. Please allow sufficient time for review prior to your experiment's scheduled start date. This is in addition to any Biological Use Authorization which may be required. To facilitate processing, please check that:

- *Your application contains sufficient detail about the recombinant DNA work that will be performed, so that IBC reviewers can adequately assess the procedures to be performed and the containment required.*
- *All decontamination and disposal procedures have been adequately described.*
- *The application contains an appropriate description of what will be done if research personnel are accidentally exposed to a potential human pathogen.*

Who to contact

The UCSC biological safety program is administered through the Institutional Biosafety Committee.
For more information or to submit applications for rDNA use, contact:
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