

University of Delaware

Department of Environmental Health & Safety

Procedures for Approval of Recombinant DNA Research

Any research involving work with recombinant DNA must be registered with the University Biosafety Committee (UBC) according to the NIH and University Policy. To register your work and receive the approvals that may be required for your grant applications, please complete the *Recombinant DNA Registration Form*. A copy of the current NIH *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* is available at our website (<http://www.udel.edu/ehs>).

Upon completion of the registration form, a UBC member must review the project. Each college has at least one UBC member who can review projects. If your college's member is not available, please contact another member for approval. Any UBC member may request additional members review the proposal, or may request full committee review. When the committee member completes the review, the forms are sent to the Biosafety Officer at EHS. A copy of the signed registration form will be sent to the researcher as provisional approval of the project for grant applications. For non-exempt projects, the UBC must review the protocol in order to obtain final approval, thus permitting work to begin. For non-exempt projects allow sufficient lead time for the review process to be completed prior to the start of the project. The project must be reviewed and updated on an annual basis. Every three years a new *Registration Form* must be submitted. The Biosafety Officer will contact you to initiate this.

A researcher may apply for a single approval of all related work that meets the **exempt** definition under the NIH *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*, rather than be approved on a project-by-project basis. To receive approval, the Principal Investigator (PI) must complete the *Recombinant DNA Registration Form*. Section I must be completed, using the "General Work Description" option to describe the type of procedures to be done by the lab group. "Project Title" is left blank. In Section II, Category A is marked. A description of the types of recombinant DNA procedures to be performed by the lab group is attached. The *Registration Form* is then submitted to a UBC member for approval, followed by the Biosafety Officer. This approved form is valid for one year from the date of the Biosafety Officer's signature. After one year, the *Recombinant DNA Registration Form* must be resubmitted and approved. It is the PI's responsibility to assure that the work being submitted with the grant complies with the submitted and approved procedures. If it is found that the grant was not under the exempt status, or the work procedures differed from what had been approved, the approval and funding for the project may be jeopardized. If a PI wishes to perform work that varies from what has been approved, he or she must complete a new registration form. These procedures apply to exempt work ONLY. All non-exempt work must be approved on a project-by-project basis.

Note: Large Scale (>10 liters) work with rDNA does **NOT** meet the criteria for exempt category work. You must complete a registration form for non-exempt work for this. A customized form for large scale research has been developed and is available on

the EHS website.

If you are performing related rDNA projects in your research program, consider using the registration form as a ‘blanket’, to cover more than one related rDNA project. This will decrease the number of forms you have to fill out, as well as enable you and your researchers to embark on new, yet related, projects immediately, without having to wait for a new approval. This can be done if your rDNA work **does not** result in different gene functions of the recombinant DNA, relative to what is native in the genome.

An example of related projects includes analysis of gene function through targeted deletions of genes in one organism; if you know that you will be doing this for a handful of genes, then you may wish to describe your project in the registration form as “Targeted deletion of genes in the genome of organism X, in order to study gene function”. This will eliminate the need for you to fill out a new form and get a new approval for each gene being deleted. A second example is if your rDNA work involves fusion proteins with reporter genes, you may also write a blanket rDNA form as “Analysis of multiple gene functions in organism X, using reporter constructs”.

Blanket registration forms may not be written for anything where the gene function is going to be altered or increased. Examples include, but are not limited to, over-expression of genes, and placing a gene from one organism into another.

If you choose to write your registration form as a ‘blanket’, it will be up to the discretion of the UBC to determine whether this is acceptable and fits into the preceding guidelines. It might be best to first consult with a member of the UBC or the Biosafety Officer. Considering the relatedness of your rDNA projects and whether they could be written up in one blanket form may save you significant time as well as expedite the initiation of new experiments.

Questions regarding these procedures may be addressed to Krista Murray at klmurray@udel.edu or call 302-831-1433.