

**Duquesne University Institutional Biosafety Committee
Registration Document for Recombinant DNA Research**

Date _____ Protocol ID# (for IBC use only) _____

Principal Investigator _____
Department _____

Office (Bldg/Room) _____ Office Phone _____

Laboratory (Bldg/Room) _____ Lab Phone _____

Project Title _____

Project Period: Begin _____ End _____ (maximum approval 3 year, approval renewable)

Funding Source: _____

Funding Period: _____ To: _____

Is this a request for a modification of a previously approved protocol? Yes _____ No _____
If yes, what is the ID# of the previously approved protocol? _____
(NOTE: PIs who are requesting a modification should submit this cover page and attach a description of the changes.)

Is this a request for an extension of a previously approved protocol? Yes _____ No _____
If yes, what is the ID# of the previously approved protocol? _____
Project Dates Previously Approved: Begin _____ End _____
(NOTE: PIs who are requesting an extension of a previously approved project need only to submit this cover sheet.)

Brief Description of Project

Please note: The pages of this form have notes in parentheses which are meant to direct the reader to the appropriate NIH Guidelines (GL:) sections. These guidelines are available at the following website: <http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html>

I. Policy Statement.

A. Duquesne University requires that all research projects involving recombinant DNA (rDNA) molecules must be reviewed and approved by the Duquesne University Institutional Biosafety Committee (DUIBC).

B. The DUIBC shall assume its responsibility for meeting the conditions required by the NIH Guidelines for Research Involving Recombinant DNA Molecules as published in the Federal Register, Vol. 51, No. 88, Wednesday, May 7, 1986, and subsequent amendments (the latest of which was published in April, 2002) which may supersede earlier versions. The purpose of these guidelines is to specify practices for construction, manipulation and application of (1) rDNA molecules and (2) organisms and viruses containing rDNA molecules. The DUIBC will also assume its responsibility for other biosafety concerns by making recommendations to investigators regarding appropriate safety practices as outlined in Biosafety in Microbiological and Biomedical Laboratories, current edition, U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, Atlanta GA 30333, and National Institutes of Health, Bethesda, MD 20892. The directives presented in this policy document are in part based on the NIH Guidelines for Research Involving Recombinant DNA Molecules. This document is available at the following website:

<http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html>

The composition and specific responsibilities of the institutional biosafety committee are described in the NIH Guidelines (GL:IV-B-2).

C. In assuming their responsibilities, the DUIBC and Duquesne University intend to encourage the conduct of biological research while protecting the rights and welfare of those participating in the research, the University, and the community. University faculty, staff, and students conducting research involving rDNA under this policy are responsible for compliance with all federal regulations. University policy entrusts the investigator with primary responsibility for the protection of individuals using rDNA technology.

II. Implementation of Policy.

All individuals planning rDNA experiments in any form (including those applying for grant support) are required to complete the DUIBC registration document. NIH recognizes six categories of rDNA work (GL:III-A,B,C,D,E,F).

A. Experiments that require DUIBC approval, RAC review, and NIH director approval (GL:IIIA):

Experiments involving the deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally, where such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture.

B. Experiments which require DUIBC and NIH/OBA approval before initiation of work (GL:IIIB):

Experiments involving the cloning of toxin molecules with LD₅₀ of less than 100 nanograms per kilogram body weight. See GL:III-B-1 for details.

C. Experiments that Require Institutional Biosafety Committee and Institutional Review Board Approvals and RAC Review Before Research Participant Enrollment (GL:IIIC):

Experiments involving the deliberate transfer of recombinant DNA, or DNA or RNA derived from recombinant DNA, into one or more human research participants

D. Experiments that require DUIBC approval before initiation of work (GL:IIID):

1. Experiment using risk group 2, risk group 3, risk group 4, or restricted agents as host-vector systems.

2. Experiments in which DNA from risk group 2, risk group 3, risk group 4, or restricted agents is cloned into nonpathogenic prokaryotic or lower eukaryotic host-vector systems.
3. Experiments involving the use of infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper virus in tissue culture systems.
4. Experiments involving whole animals in which the animal's genome has been altered by stable introduction of recombinant DNA, or DNA derived therefrom, into the germ-line (transgenic animals) and experiments involving viable recombinant DNA-modified microorganisms tested on whole animals.
5. Experiments to genetically engineer plants by recombinant DNA methods, to use such plants for other experimental purposes (e.g. response to stress), to propagate such plants, or to use plants together with microorganisms or insects containing recombinant DNA. See NIH Guidelines for details.
6. Experiments involving more than 10 liters of culture.

E. Experiments that require DUIBC notice simultaneous with initiation (GL:IIIE):

1. Experiments involving the formation of recombinant DNA molecules containing no more than two-thirds of the genome of any eucaryotic virus.
2. Other experiments, not covered in D-5, involving whole plants. See guidelines for details.
3. Experiments involving transgenic rodents at BSL1 containment.

F. Exempt experiments (GL:IIIF): The following recombinant DNA molecules are exempt. It is the DUIBC policy to register these experiments.

1. Those that are not in organisms or viruses.
2. Those that consist entirely of DNA segments from a single nonchromosomal or viral DNA source, though one or more of the segments may be a synthetic equivalent.
3. 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.
4. Those that consist entirely of DNA from a eucaryotic 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).
5. 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. See GL: appendices A-I through A-VI, *Exemptions Under Section III-D-5--Sublists of Natural Exchangers*, for a list of natural exchangers that are exempt from the NIH Guidelines.
6. Those that do not present a significant risk to health or the environment (GL: Appendix C).

The information provided on this form allows the DUIBC to assess the proposed research with regards to 1) determining of the appropriate biosafety level and standard containment practices; 2) assurance that lab personnel will be informed of the level of biohazard and adequately trained in microbiological and containment techniques, and emergency plans for accidental spills and personnel contamination; 3) assurance of compliance with the NIH Guidelines, including shipping requirements for recombinant molecules. This document serves as the registration document for recombinant DNA research as per guidelines given in GL: IVB.

III. Questionnaire (attach extra pages if necessary):

A. Is the proposed work exempt from the NIH Guidelines? Yes _____ No _____.

Using the criteria of part F of the previous section, indicate why your work is exempt.

If proposed research is not exempt, answer the questions remaining. If work is exempt, sign and submit this form.

B. List source(s) of all DNA in the proposed work.

C. Identify hosts and vectors to be used.

D. Will your work involve deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally? Yes _____ No _____. If the answer is yes please, on a separate sheet, answer the following questions.

1. Which drug resistance trait is to be transferred?
2. What microorganism will this trait be transferred to?
3. Would acquisition of such a trait by the microorganism compromise the use of the drug to control disease agents in human or veterinary medicine or agriculture?

E. Does your work involve experiments in which the cloning of genes coding for toxin molecules with LD₅₀ of less than 100 nanograms per kilogram body weight? Yes _____ No _____. If yes, what is the toxin? Experiments involving formation of recombinant DNAs for genes coding for certain molecules toxic to vertebrates require RAC review and NIH approval and must be carried out under NIH specified conditions described in GL:Appendix F.

F. Does your work involve experiments using risk group 2, risk group 3, risk group 4, or restricted agents as host-vector systems? Yes _____ No _____. Work with restricted agents requires a special USDA permit and determination of containment conditions by OBA review.

G. Does your work involve experiments in which DNA from risk group 2, risk group 3, risk group 4, or restricted agents is cloned into nonpathogenic prokaryotic or lower eukaryotic host-vector systems? Yes _____ No _____. If yes, answer the following questions on a separate sheet.

1. From what source will the DNA be obtained?
2. Is it a Class 1,2,3,4 or restricted agent? Work with restricted agents requires a special USDA permit and determination of containment conditions by OBA review.

H. Does your work involve experiments where the use of infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper virus in tissue culture systems occurs?

Yes _____ No _____. If yes, please answer the following questions on a separate sheet of paper.

1. Are the proposed experiments likely to enhance the pathogenicity (e.g., insertion of a host oncogene) or to extend the host range (e.g., introduction of novel control elements) of a viral vector under conditions which permit a productive infection? If so, the IBC may increase the containment level.
2. Is the virus or defective virus a Class 1,2,3,4 or restricted agent? Work with restricted agents requires a special USDA permit and determination of containment conditions by ORDA review.
3. Does defective nucleic acid represent less than 2/3 of the viral genome? If so, has it been shown that the cells in which this defective nucleic acid will be propagated and maintained are free of helper virus for the specific family of viruses being used?

I. Does your work involve the use of whole animals in which the animal's genome has been altered by stable introduction of recombinant DNA, or DNA derived therefrom, into the germ-line (transgenic animals) and experiments involving viable recombinant DNA-modified microorganisms tested on whole animals? Yes _____ No _____. If yes, present details of this work on an attached page. Consult Appendix Q of the guidelines for details.

J. Does your work involve experiments to genetically engineer plants by recombinant DNA methods, to use such plants for other experimental purposes (e.g., response to stress), to propagate such plants, or to use plants together with microorganisms or insects containing recombinant DNA? Yes _____ No _____. If yes, present details of this work on an attached page. Consult Appendix P of the guidelines for details.

K. Does your work involve experiments involving more than 10 liters of culture? Yes _____ No _____. If yes, present details of this work on an attached page. Consult Appendix K of the guidelines for details.

L. Does your work involve experiments in which the formation of recombinant DNA molecules containing no more than two-thirds of the genome of any eucaryotic virus occurs? Yes _____ No _____. If yes, present details of this work on an attached page.

M. Is the release of any organism containing recombinant DNA into the environment being proposed? Yes _____ No _____. If yes, present details of this work on an attached page.

N. In the proposed research, will any recombinant DNA, DNA, or RNA be deliberately transferred into human subjects? Yes _____ No _____. If yes, present details of this work on an attached page. Refer to Appendix M of the Guidelines.

O. What Biosafety (containment) Level have you determined is appropriate for conducting the proposed work? _____. Do you have access to facilities that will allow you to adhere to the standard containment practices at this Biosafety Level? Yes _____ No _____.

P. Will all personnel participating in this research be apprised of the biohazard involved and trained appropriately in microbiological techniques and precautions necessary for them to maintain the appropriate containment level, and will they be instructed in emergency plans for accidental spills or personnel contamination? Yes _____ No _____.

Q. Will shipping of any recombinant or infectious materials to other sites be done in the course of this project? Yes _____ No _____. The NIH Guidelines for shipping of etiologic agents must be strictly followed. The IATA, DOT, CDC and USDA regulations must also be followed when shipping etiologic agents, which includes the requirement that the individual shipping the material receive formal training.

R. Briefly, but specifically, give physical dimensions and location of the laboratory where this work will be done, and any special containment equipment and laboratory facilities (lab exits, sinks available for handwashing, biosafety cabinets [number, class, certified annually?, date of last certification], negative airflow animal facilities, autoclaves) which will be used to adhere to the appropriate Biosafety Level:

S. Briefly indicate on a separate sheet how the laboratory space where the proposed work will be done will comply with the containment level required. See Appendix G of the NIH Guidelines.

T. Does the proposed work involve the use of animals? Yes _____ No _____. If so, has institutional animal committee approval been obtained? Yes _____ No _____.

IV. Certification.

I have read and become familiar with the sections of the NIH Guidelines for Research Involving Recombinant DNA Molecules which pertain to the experiments I will be conducting.

Yes _____ No _____

Date _____

Principal Investigator Signature _____

V. DUIBC Action.

Date Received _____

By _____

DUIBC recommendation: _____

May, 2005