

**REGISTRATION OF RECOMBINANT DNA RESEARCH**

**Instructions**

**To register recombinant DNA, please complete the appropriate forms on the following pages:**

**A) Complete ALL information in the RED section of the rDNA registration document.**

• Submit SEPARATE REGISTRATIONS for each vector. Different transgenes delivered with the same vector may be included in the same registration.

• If you are not sure which “NIH Guidelines [SECTION III](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457031)” covers your research, consult the following resources:

* NIH Guidelines for rDNA
* Exempt Experiments: [Section III-F](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457051)
* [APPENDIX A.](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457086) – Exemptions under Section III-F-6 -Sublists of Natural Exchangers
* [APPENDIX C.](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457086) – Exemptions under Section III-F-8

**B) Complete the one *additional* section that corresponds to your research:**

• Fill out **Part 1** (p. 5) ONLY if you are CROSSING \* transgenic rodents at ABSL 2 or higher containment, containing more than 50% of an exogenous eukaryotic viral genome, or carrying a transgene under the control of a gammaretroviral promoter. *Example*: Breeding of knockouts from two different transgenic strains under the above-mentioned conditions.

• Fill out **Part 2** (p. 6) ONLY if you are CREATING transgenic rodents. *Example*: Creating any transgenic rodent.

• Fill out **Part 3** (p. 7) ONLY for the GENERATION of rDNA. *Example*: You generate an rDNA vector for a collaborating researcher.

• Fill out **Part 4** (pp. 8-9) ONLY for the USE of rDNA (including rDNA received from Vector Core, gifted, etc.). This includes all rDNA constructs that you have received from another source. *Example*: The Vector Core or collaborator from another institution makes an rDNA construct for your lab and you will be using it in tissue culture, animals, etc.

• Fill out **Part 5** (pp. 10-11) ONLY for both the GENERATION and USE of rDNA. *Example*: You generate an rDNA construct and use it in tissue culture, animals, etc.

* Most generation of transgenic rodents by breeding is now exempt.
* See NIH Guidelines for rDNA for amendment.

C) To amend your existing rDNA registration, please contact the IBC Chairperson.

D) If you are working with DNA but believe your work to be exempt from rDNA registration requirements, you must still complete the RED section of the rDNA registration document.

**SUBMIT the document (including the RED bordered pages part and the ONE additional part corresponding to your research) to the chair of the Institutional Biosafety Committee by mail, by hand, or by email (using a locked, signed PDF).**

ALL FORMS MUST BE TYPED, NOT HANDWRITTEN.

INCOMPLETE OR HANDWRITTEN FORMS WILL BE RETURNED.

# IBC Date Received: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Reg. Doc. No.: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_



# REGISTRATION DOCUMENT FOR RECOMBINANT DNA RESEARCH

Principal Investigator:                       Position Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Department:      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Telephone:      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ E-mail:      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of Request:           \_\_\_\_\_\_ Location of lab(s):           \_\_\_\_\_\_\_\_\_\_\_

**PROJECT INFORMATION**

1. Project title:
2. Individuals participating in this project:

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| --- | --- | --- |
| **Name** | **Carleton email** | **Faculty, Staff, or Student** |
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1. Provide a brief description of proposed research, giving an overview of the recombinant DNA aspect of your project that can be understood by an educated but non-specialist audience.
2. If you have applied for grant funding of your research, attach a copy of the grant proposal abstract.
3. Does your research classify as [Dual Use Research of Concern](https://osp.od.nih.gov/biotechnology/dual-use-research-of-concern/) (that is, can work intended for beneficial purposes be directly misapplied)? If so, check the categories below that apply to your project or check the last box to indicate that no dual-use application is possible:   
    Renders a useful vaccine ineffective

Adds antibiotic resistance affecting response to a clinically useful drug

Enhances pathogen virulence

Increases pathogen transmissibility

Widens a pathogen’s host range

Lets a pathogen evade diagnostic or detection modalities

Weaponization (e.g., environmental stabilization of pathogens)

**Check here if none of the above apply**

**TRAINING**

1. Have you read the most current [National Institute of Health’s “Guidelines for Research Involving Recombinant DNA or Synthetic Nucleic Acid Molecules”](https://osp.od.nih.gov/biotechnology/nih-guidelines/) (as amended in April 2019) for research involving rDNA?

No Yes

1. Have the PI and all others participating in this research (faculty, staff, students, or others) completed Carleton’s Biosafety Training? No Yes (accessible via Carleton’s IBC [Training](https://apps.carleton.edu/governance/ibc/training/) page)
2. Please identify the appropriate Biosafety Level for this project:

Biosafety level guidelines can be found in the most recent CDC publication of “[Biosafety in Microbiological and Biomedical Laboratories](http://www.cdc.gov/biosafety/publications/bmbl5/index.htm)” (BMBL) 6th Edition.

1. Do you believe your work with DNA to be exempt from the registration requirement? No Yes
2. If you answered “Yes” to D please explain why:

**RISK ASSESSMENT**

Provide a written risk assessment of your research and a biosafety plan that outlines how workers will be protected in the laboratory (attach as separate document).

See NIH Guidelines [Section II-A. Risk Assessment](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457026); the CITI module (instructions to access modules available on Carleton’s IBC [Training](https://apps.carleton.edu/governance/ibc/training/) page) “Biohazard Risk Assessment,” section “Initial Risk Assessment Should Address”; and Carleton’s [IBC FAQs page](https://apps.carleton.edu/governance/ibc/faqs/).

**CLASSIFICATION OF EXPERIMENTS** (as described in **Section III** of the NIH Guidelines)

Referring to [SECTION III](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457031) of the National Institute of Health’s “Guidelines for Research Involving Recombinant DNA or Synthetic Nucleic Acid Molecules,” identify and indicate in the list below the appropriate registration category(s) for your experiment (***Note***: No research may be initiated for categories A through D below until **ALL** required approvals are received.)

**III-A. Experiments that Require Institutional Biosafety Committee Approval, RAC Review, and NIH Director Approval Before Initiation.**

1. Major Actions (see [Section IV-C-1-b-(1)](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457073) of the NIH guidelines).

1a. Deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally (see [Section V-B](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457085)), if such acquisition could compromise use of the drug to control disease agents in humans, veterinary medicine or agriculture.

**III-B. Experiments that Require NIH OSP and Institutional Biosafety Committee Approval Before Initiation.**

1. Experiments Involving the Cloning of Toxin Molecules with LD50 of Less than 100 Nanograms Per Kilogram Body Weight.

**III-C. Experiments that Require Institutional Biosafety Committee and Institutional Review Board Approvals and RAC Review (if applicable) Before Research Participant Enrollment.**

1. Experiments Involving the Deliberate Transfer of Recombinant or Synthetic Nucleic Acid Molecults, or DNA or RNA Derived from Recombinant DNA or Synthetic Nucleic Acid Molecules, into One or More Human Research Participants (human gene transfer).

**III-D. Experiments that Require Institutional Biosafety Committee Approval Before Initiation.**

1. Experiments 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. (Do NOT check if ONLY generating transgenic rodents [III-E-3].)

5. Experiments Involving Whole Plants. (See NIH guidelines for experiments that fall under category D vs E)

6. Experiments Involving More than 10 Liters of Culture.

7. Experiments Involving Influenza Viruses. (Consult with IBC for guidance. BSL-3 containment may apply.)

**III-E. Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation.**

1. Experiments Involving the Formation of Recombinant DNA Molecules or Synthetic Nucleic Acid Molecules Containing No More than Two-Thirds of the Genome of any Eukaryotic Virus.

2. Experiments Involving Whole Plants (see NIH guidelines for experiments that fall under category D vs E)

3. Experiments Involving Transgenic Rodents

4. Other

**TYPE OF REGISTRATION**

Indicate the type of registration being sought here, noting the additional form that must be completed in each category:

**CROSSING** two different transgenic rodents requiring BSL-2 or higher containment

Fill out Part 1 **ONLY (p. 6)**

**CREATING** transgenic rodents

Fill out Part 2 **ONLY (p. 7)**

**GENERATION** of rDNA

Fill out Part 3 ONLY (p. 8)

**USE** of rDNA (including rDNA received from Vector Core, gifted, etc.)

Fill out Part 4 **ONLY (pp. 9-10)**

Both **GENERATION and USE** of rDNA

Fill out Part 5 ONLY (pp. 11-12)

**SIGNATURE PAGE**

Your signature below indicates that

1. you acknowledge all requirements and restrictions of the most current NIH guidelines for the Biosafety Level you have indicated above, unless modified by the IBC;
2. you accept responsibility for the safe conduct of the experiments conducted at this Biosafety Level; and
3. you have informed all associated personnel of the conditions required for this work.

**Signature of Principal Investigator:** **Date:**

Sponsorship (\*Required only if investigator is not a tenured or tenure-track faculty member at Carleton)

Faculty Sponsor\* (PRINT):

Faculty Sponsor\* (SIGNATURE):       Date:

***--APPLICANTS: DO NOT WRITE BELOW THIS LINE--***

**IBC ACTION**

Acceptance  Exemption  Rejection

Comments:

Date:

Signature of IBC Representative:

Print Name:

**Part 1. CROSSING TRANSGENIC RODENTS**

*Complete this section if you are breeding two different transgenic rodent strains to generate a new transgenic strain, where either the parent strains or offspring*

* *require BSL-2 or higher containment,*
* *contain a transgene encoding more than 50% of an exogenous eukaryotic virus, or*
* *contain a transgene under the control of a gamma retroviral virus.*

*Example: Breeding of knockouts from two different transgenic strains under the conditions mentioned above.*

**Which characteristics apply to either the parent or offspring strains of these transgenic rodents?**

They will require BSL-2 or higher containment.

They contain a transgene under the control of a gamma retrovial promoter.

They contain a transgene encoding more than 50% of an exogenous eukaryotic virus.

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| **Existing Transgenic Line “A”** | **Existing Transgenic Line “B”** | **Newly Bred Line “C”** | **Genotype of New Transgenic Line** |
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**BIOSAFETY CONTAINMENT LEVEL** [description of biosafety levels found in [Appendix G-II. Physical Containment Levels](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457151) and [Appendix G-III Footnotes and References of Appendix G](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457178)]

1. This project will be conducted at Animal Biosafety Level:  1  2
2. Summarize any threat posed to humans and briefly outline your procedures to ensure safe use and any relevant containment procedures:

**Part 2. CREATING TRANSGENIC RODENTS**

*Complete this section if you are using rDNA* ***ONLY*** *to create transgenic rodents. In this case, you do not need to fill out any of the other sections (e.g., the “generation” or “use” sections).*

*Example: Creating any transgenic rodent.*

1. Genus, species, of parent strain:
2. Transgenic strain identification:

**TRANSGENE**

1. Specify the nature of the gene sequence inserted into the recombinant vector:

|  |  |  |  |  |  |  |
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| **Gene Name** | **Promoter**  (if other than gene’s own) | **Vector**  (to carry gene / integrate gene into genome) | **Source of gene** (genus, species) | **Risk Group\*** | **Biological Activity of Sequence** | **Host**  (genus, species) |
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\*Risk group categories can be found in the NIH *Guidelines* [APPENDIX B](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457093).

1. If any of the above genes are from a viral source, are they more than 2/3 of the viral genome?

No Yes, specify:

1. Will a deliberate attempt be made to obtain expression of the foreign gene encoded in the recombinant DNA or RNA? No Yes
2. Describe the method of gene transfer:

**BIOSAFETY CONTAINMENT LEVEL** [description of biosafety levels found in [Appendix G-II. Physical Containment Levels](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457151) and [Appendix G-III Footnotes and References of Appendix G](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457178)]

1. This project will be conducted at Biosafety Level:  1  2
2. This project will be conducted at Animal Biosafety Level:  1  2

C. Summarize any threat posed to humans and briefly outline your procedures to ensure safe use and any relevant containment procedures:

**Part 3. GENERATION OF rDNA**

*Complete this section if you are generating rDNA materials in your laboratory, but are NOT using them.*

*Example: You generate an rDNA vector for a collaborating researcher.*

**TRANSGENE**

1. Specify the nature of the gene sequence inserted into the recombinant vector:

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| --- | --- | --- | --- | --- | --- | --- |
| **Gene Name** | **Promoter**  (if other than gene’s own) | **Vector**  (to carry gene / integrate gene into genome) | **Source of gene** (genus, species) | **Risk Group\*** | **Biological Activity of Sequence** | **Host**  (genus, species) |
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\*Risk group categories can be found in the NIH *Guidelines* [APPENDIX B](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457093).

1. If any of the above genes are from a viral source, are they more than 2/3 of the viral genome?

No  Yes, specify:

**HOST-VECTOR SYSTEM**

1. Identify name of vector:
2. Identify vector system:

Naked DNA or RNA

Bacterial Plasmid PLEASE ATTACH MAP(S) OF PLASMID.

Viral Vector PLEASE ATTACH MAP(S) OF EXPRESSION CASSETTE.

Adeno-associated virus (AAV);  Adenovirus;  Lentivirus (identify generation of vector system:      ;  Retrovirus;  Other (Describe:                )

1. List host cell line or packaging cells for recombinant vector propagation:
2. If this is a viral vector system,
   1. What % of the viral genome remains?
   2. Is this vector replication competent? No Yes
   3. Is a helper virus required for replication? No Yes, specify:

**BIOSAFETY CONTAINMENT LEVEL** [description of biosafety levels found in [Appendix G-II. Physical Containment Levels](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457151) and [Appendix G-III Footnotes and References of Appendix G](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457178)]

1. This project will be conducted at Biosafety Level:  1  2
2. This project will be conducted at Animal Biosafety Level:  N/A  1  2

C. Summarize any threat posed to humans and briefly outline your procedures to ensure safe use and any relevant containment procedures:

**Part 4. USE OF rDNA**

*Complete this section if you are using rDNA materials in your laboratory. This includes all rDNA constructs that you have received from another source.*

*Example: The Vector Core or collaborator from another institution makes an rDNA construct for your lab and you will be using it in tissue culture, animals, etc.*

**TARGET RECIPIENT**

Indicate the recipient(s) of the rDNA (check all that apply).

Animal (specify species and if mouse, strain):

Tissue culture (specify cell line name and source):

Modified tissue culture cell lines into animals

Specify cell line name and source:

Specify animal species/mouse strain:

Bacteria (specify organism and source):

Plant cells:

Plants:

Other:

**RECOMBINANT MATERIAL**

1. Identify name of vector:
2. Type of vector:

Naked DNA or RNA

Bacterial Plasmid PLEASE ATTACH MAP(S) OF PLASMID.

Viral Vector PLEASE ATTACH MAP(S) OF EXPRESSION CASSETTE.

Adeno-associated virus (AAV)

Adenovirus

Lentivirus Identify generation of vector system:

Retrovirus

Other Describe:

1. List host cell line or packaging cells for recombinant vector propagation:
2. If this is a viral vector:
   1. What % of the viral genome remains:
   2. Is this vector replication competent? No Yes

**TRANSGENE**

* + 1. Specify the nature of the gene sequence inserted into the recombinant vector:

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| --- | --- | --- | --- | --- | --- | --- |
| **Gene Name** | **Promoter**  (if other than gene’s own) | **Vector**  (to carry gene / integrate gene into genome) | **Source of gene** (genus, species) | **Risk Group\*** | **Biological Activity of Sequence** | **Host**  (genus, species) |
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\*Risk group categories can be found in the NIH *Guidelines* [APPENDIX B](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457093).

* + 1. If any of the above genes are from a viral source, are they more than 2/3 of the viral genome?

No Yes, specify:

* + 1. Will a deliberate attempt be made to obtain expression of the foreign gene encoded in the recombinant DNA or RNA? No Yes

**BIOSAFETY CONTAINMENT LEVEL** [description of biosafety levels found in [Appendix G-II. Physical Containment Levels](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457151) and [Appendix G-III Footnotes and References of Appendix G](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457178)] (-M, -N, -P)]

1. This project will be conducted at Biosafety Level:  1  2
2. This project will be conducted at Animal Biosafety Level: N/A  1  2
3. Summarize any threat posed to humans and briefly outline your procedures to ensure safe use and any relevant containment procedures:

**Part 5. Both GENERATION and USE OF rDNA**

*Complete this section if you are both generating and using rDNA in your laboratory.*

*Example: You generate an rDNA construct and use it in tissue culture, animals, etc.*

**TRANSGENE**

1. Specify the nature of the gene sequence inserted into the recombinant vector:

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| --- | --- | --- | --- | --- | --- | --- |
| **Gene Name** | **Promoter**  (if other than gene’s own) | **Vector**  (to carry gene / integrate gene into genome) | **Source of gene** (genus, species) | **Risk Group\*** | **Biological Activity of Sequence** | **Host**  (genus, species) |
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\*Risk group categories can be found in the NIH *Guidelines* [APPENDIX B](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457093).

1. If any of the above genes are from a viral source, are they more than 2/3 of the viral genome?

No Yes, specify:

1. Will a deliberate attempt be made to obtain expression of the foreign gene encoded in the recombinant DNA or RNA? No Yes

**HOST-VECTOR SYSTEM**

1. Identify name of vector:
2. Identify vector system:

Naked DNA or RNA

Bacterial Plasmid …..PLEASE ATTACH MAP(S) OF PLASMID.

Viral Vector …………PLEASE ATTACH MAP(S) OF EXPRESSION CASSETTE.

Adeno-associated virus (AAV)

Adenovirus

Lentivirus Identify generation of vector system:

Retrovirus

Other Describe:

1. List host cell line or packaging cells for recombinant vector propagation:
2. If this is a viral vector system:
   1. What % of the viral genome remains:
   2. Is this vector replication competent? No Yes
3. Is a helper virus required for replication? No Yes, specify:

**TARGET RECIPIENT**

Indicate the recipient(s) of the rDNA (check all that apply).

Animal (specify species and if mouse, strain):

Tissue culture (specify cell line name and source):

Tissue culture cell lines into animals

Specify cell line name and source:

Specify animal species/mouse strain:

Bacteria (specify organism and source):

Plant cells:

Plants:

Other:

**BIOSAFETY CONTAINMENT LEVEL**

1. This project will be conducted at Biosafety Level:  1  2
2. This project will be conducted at Animal Biosafety Level: N/A  1  2
3. Summarize any threat posed to humans and briefly outline your procedures to ensure safe use and any relevant containment procedures: