# EHS Date Received:       Reg. Doc. No.:

**Kent State University**

# REGISTRATION DOCUMENT FOR RECOMBINANT & SYNTHETIC DNA RESEARCH

Principal Investigator:       Position Title:

School:       Department:

Mailing Address:

Telephone:       FAX:       E-mail:

Date of Request:       Location of lab(s):

**PROJECT INFORMATION**

1. Project Title:  Funding Agency
2. Names of individuals participating in this project:

|  |
| --- |
| **Name** |
|       |
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1. Description:
	1. Describe Research (Procedure, Outcome)
	2. Health Risks (Include BS rank)
	3. Precautions for Use Storage
	4. Emergency Response
	5. Disposal
	6. Transport
2. Include copy of grant abstract if funded.
3. DUAL USE RESEARCH QUESTIONS (apply to studies utilizing biological agents or toxins)

 If any categories below apply to your project please consult with a Biosafety Officer at 2-1957:

[ ] Enhance the harmful consequences of a biological agent or toxin.

[ ] Disrupt immunity or the effectiveness of immunization.

[ ] Add antibiotic resistance affecting response to a clinically useful drug **OR** facilitate ability to evade detection methodologies.

[ ] Increase the stability, transmissibility, or the ability to disseminate a biological agent or toxin.

[ ] Alter the host range or tropism of a biological agent or toxin.

[ ] Enhance the susceptibility of a host population.

[ ] Generate a novel pathogenic agent or toxin, or reconstitute an eradicated or extinct biological agent.

[ ] Check here if none of the above applies.

**TRAINING**

1. Have you read the most current NIH rDNA guidelines for research involving rDNA? Here is link for the most resent

[***NIH guidelines***](http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines). [ ]  Yes

Have the PI and ALL personnel participating in this research completed **Kent State Online CITI and Biosafey Training?**

 [ ] Yes

 What is the Biosafety Level(s) for this project: [ ]  BSL 1 [ ]  BSL 2 [ ]  BSL 3

**NIH GUIDELINES “SECTION III”**

This section describes experiments covered by the NIH Guidelines. Check 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) of the NIH guidelines).

[ ] 1a. Deliberate transfer of drug resistance trait to microorganisms that are unknown to acquire the trait naturally, 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/OBA 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 NIH/OBA Registration before Initiation**

[ ] 1. Experiments Involving the Deliberate Transfer of r∙s∙DNA or DNA or RNA Derived from r∙s∙DNA into One or More Human Subjects (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].)

[ ] 6. Experiments Involving More than 10 Liters of Culture.

[ ] 7. Experiments Involving Influenza Viruses. (Consult with EHRS 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 rDNA Molecules Containing No More than Two-Thirds of the Genome of any Eukaryotic Virus (In tissue culture ONLY).

[ ] 2. Experiments Involving Whole Plants

[ ] 3. Experiments Involving Creation of Transgenic Rodents (Housed at ABSL-1 ONLY).

This registration is for (check the one section that applies):

[ ]  **CROSSING** two different transgenic animals (not mice) requiring ABSL-1 or higher containment

Fill out Section “1”, **ONLY**

[ ]  **CROSSING** two different transgenic mice requiring ABSL-2 or higher containment

Fill out Section “1”, **ONLY**

[ ]  **CREATING** transgenic animals (rodent or not rodent)

Fill out Section “2”, **ONLY**

[ ]  **GENERATION** of rDNA

Fill out Section “3”, **ONLY**

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

Fill out Section “4”, **ONLY**

[ ]  Both **GENERATION and USE** of rDNA

Fill out Section “5”, **ONLY**

[ ]  **GENERATION and/or USE** of **WHOLE TRANSGENIC PLANTS**

Fill out Section “6”, **ONLY**

**SIGNATURE PAGE**

 Your signature below indicates that 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; that you accept responsibility for the safe conduct of the experiments conducted at this Biosafety Level; and that you have informed all associated personnel of the conditions required for this work.

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

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

**IBC ACTION**

[ ]  Acceptance [ ]  Exemption [ ]  Rejection

Comments:

Date:

Signature of IBC Representative:

Print Name:

**SECTION 1. CROSSING TRANSGENIC MICE OR OTHER TRANSGENIC ANIMALS**

*Complete this section if you are breeding two different transgenic mouse 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 or if you are crossing transgenic animals other than mice.*

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

**Transgenic Mice**: (must check off at least one of the following)

[ ]  Require BSL-2 or higher containment

[ ]  Contain a transgene under the control of a gamma retrovial promoter

[ ]  Contain a transgene encoding more than 50% of an exogenous eukaryotic virus

**Transgenic Animals**: (not mice)

[ ]  Require BSL-1 or higher containment

|  |  |  |  |
| --- | --- | --- | --- |
| **Existing Transgenic Line “A”** | **Existing Transgenic Line “B”** | **Newly Bred Line “C”** | **Genotype of New Transgenic** |
|       |       |       |       |
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**BIOSAFETY CONTAINMENT LEVEL**

1. This project will be conducted at Animal Biosafety Level: [ ]  1 [ ]  2 [ ]  3

**SECTION 2. CREATING TRANSGENIC ANIMALS**

*Complete this section if you are using rDNA ONLY to create transgenic animals. It is not necessary to fill out any of the other sections (DO NOT fill out any “generation” or “use” sections).*

*Example: Creating any transgenic animal.*

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

**TRANSGENE**

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

|  |  |  |  |
| --- | --- | --- | --- |
| **Promoter** | **Gene Name** | **Source of gene** (genus, species) | **Biological Activity of Sequence** |
|       |       |       |       |
|       |       |       |       |
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1. If any of the above genes are from a viral source, is it 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 rDNA or RNA?

[ ] No [ ] Yes

1. Describe the method of gene transfer:

**BIOSAFETY CONTAINMENT LEVEL**

1. This project will be conducted at Biosafety Level: [ ]  1 [ ]  2 [ ]  3
2. This project will be conducted at Animal Biosafety Level: [ ]  N/A [ ]  1 [ ]  2 [ ]  3

**SECTION 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:

|  |  |  |  |
| --- | --- | --- | --- |
| **Promoter** | **Gene Name** | **Source of gene** (genus, species) | **Biological Activity of Sequence** |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |

1. If any of the above genes are from a viral source, is it 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

[ ]  Viral Vector

 [ ]  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**

1. This project will be conducted at Biosafety Level: [ ]  1 [ ]  2 [ ]  3
2. This project will be conducted at Animal Biosafety Level: [ ]  N/A [ ]  1 [ ]  2 [ ]  3

**SECTION 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, collaborator from KSU 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 only (specify species and if mouse, strain):

 [ ]  Tissue Culture only (specify cell line name and source):

 [ ]  Modified tissue culture cell lines into animals

 Specify cell line name and source:

 Specify animal species/mouse strain:

 [ ]  Plant cells:

 [ ]  Plants:

 [ ]  Gene therapy, specify target host (s): [ ]  Human [ ]  Animal –

 species/mouse strain:

 [ ]  Eukaryotes, Prokaryotes, Fungi (List below)

 [ ]  DNA vaccine, specify target recipients (s): [ ]  Human [ ] Animal –

 species/mouse strain:

**RECOMBINANT MATERIAL**

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

[ ]  Naked DNA or RNA

[ ]  Bacterial Plasmid

[ ]  Viral Vector

 [ ]  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:

|  |  |  |
| --- | --- | --- |
| **Gene Name** | **Source of gene** (genus, species) | **Biological Activity of Sequence** |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |

* + 1. If any of the above genes are from a viral source, is it 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 r∙s∙DNA or RNA?

 [ ] No [ ] Yes

**BIOSAFETY CONTAINMENT LEVEL**

1. This project will be conducted at Biosafety Level: [ ]  1 [ ]  2 [ ]  3
2. This project will be conducted at Animal Biosafety Level: [ ] N/A [ ]  1 [ ]  2 [ ]  3

**SECTION 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:

|  |  |  |  |
| --- | --- | --- | --- |
| **Promoter** | **Gene Name** | **Source of gene** (genus, species) | **Biological Activity of Sequence** |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |

1. If any of the above genes are from a viral source, is it 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 r∙s∙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 only (specify species and if mouse, strain):

 [ ]  Tissue Culture only (specify cell line name and source):

 [ ]  Tissue culture cell lines into animals

 Specify cell line name and source:

 Specify animal species/mouse strain:

 [ ]  Plant cells:

 [ ]  Plants:

 [ ]  Gene therapy, specify target host (s): [ ]  Human [ ]  Animal –

 species/mouse strain:

 [ ]  DNA vaccine, specify target recipients (s): [ ]  Human [ ] Animal –

 species/mouse strain:

**BIOSAFETY CONTAINMENT LEVEL**

1. This project will be conducted at Biosafety Level: [ ]  1 [ ]  2 [ ]  3
2. This project will be conducted at Animal Biosafety Level: [ ] N/A [ ]  1 [ ]  2 [ ]  3

**SECTION 6. GENERATION and/or USE** of **WHOLE TRANSGENIC PLANTS**

*Complete this section if you are using rDNA to create transgenic plants or use transgenic plants. It is not necessary to fill out any of the other sections (DO NOT fill out any “generation” or “use” sections).*

1. Genus, species, of parent strain:
2. Transgenic strain identification:
3. Is a USDA permit required for transport or use of these plants? [ ]  **YES** [ ]  **NO**

 If YES, Please provide your:

 Permit Number:       **OR** Application Number:

**TRANSGENE**

1. Specify the nature of the gene sequence modified and/or inserted into the recombinant plant:

|  |  |  |  |
| --- | --- | --- | --- |
| **Promoter** | **Gene Name** | **Source of gene** (genus, species) | **Biological Activity of Sequence** |
|       |       |       |       |
|       |       |       |       |
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**HOST-VECTOR SYSTEM**

1. Describe the method of gene transfer:
2. Identify name of vector:
3. Identify vector system (example: Rhizobium spp. and Agrobacterium spp.):
4. Will a deliberate attempt be made to obtain expression of foreign gene encoded in r∙s∙DNA or r∙s∙RNA?

 [ ]  **YES** [ ]  **NO**

**BIOSAFETY CONTAINMENT LEVEL**

1. This project will be conducted at Biosafety Level: [ ]  **BSL-1-P**

 [ ]  **BSL-2-P**

 [ ]  **BSL-3-P**

 Housed in:

* + 1. Greenhouse [ ]
		2. Growth Chamber [ ]
		3. Other [ ]  DESCRIBE: