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

# penn_fulllogo

# REGISTRATION DOCUMENT FOR RECOMBINANT & SYNTHETIC

# NUCLEIC ACID (r∙s∙NA) RESEARCH

Principal Investigator:       Penn ID#:       Position Title:

School:       Department:

Mailing Address:

Telephone:       E-mail:

Date of Request:       Location of lab(s):

**PROJECT INFORMATION**

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

|  |  |
| --- | --- |
| **Name** | **Penn ID** |
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1. Provide a paragraph describing the goals and experimental approach of the proposed research. Include specific experimental details on your vector, transgenes, and target recipients. Explain how the registered work will address the goals and objectives of your research:

**TRAINING AND BIOSAFETY**

1. Have you read the most current ***NIH guidelines*** for research involving r∙s∙NA?  No  Yes
2. Have the **PI** and **ALL** personnel participating in this research completed **Penn Profiler** and **Penn’s Online r∙s∙NA Training**?  No  Yes
3. Are you knowledgeable about the appropriate Biosafety Level(s) for this project:  No  Yes
4. Is your research subject to the U.S. Government Policy for Institutional Oversight of Life Science Dual Use Research of Concern (DURC)?  No  Yes

**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∙NA 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].)

5. Experiments Involving Whole Plants.

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 r∙s∙NA 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).

**OTHER.**

1. Experiments Involving Genome Editing Technologies (i.e.: CRISPR/Cas9, TALENs, ZFNs)

2. Other, Describe:

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 r∙s∙NA

Fill out Section “3”, **ONLY**

**USE** of r∙s∙NA (including r∙s∙NA received from Vector Core, gifted, etc.)

Fill out Section “4”, **ONLY**

Both **GENERATION and USE** of r∙s∙NA

Fill out Section “5”, **ONLY**

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

Fill out Section “6”, **ONLY**

**GENOME EDITING TECHNOLOGIES** (new and/or novel gene editing approaches)

(i.e.: CRISPR/Cas9, TALENs, ZFNs)

Fill out Section “7”,

in **ADDITION** to the appropriate section above.

**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.

*Electronic signatures are accepted.*

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

Sponsorship (\* Required only if investigator is not a member of the Standing or Associated Faculty)

Faculty Sponsor\* (PRINT):

Faculty Sponsor\* (SIGNATURE):       Date:

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

**IBC ACTION**

Acceptance  Exemption  Rejection

Comments:

Date:

Signature of IBC Representative:

Print Name:

**SECTION 1. CROSSING TRANSGENIC / MUTANT ANIMALS**

*Complete this section if you are breeding two different transgenic or mutant mouse strains to generate a new strain, where either the parent strains or offspring require ABSL-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.*

*Examples: Crossing two different transgenic fruit fly lines; Breeding knockout mice from two different transgenic strains, one of which requires ABSL-2 containment.*

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

Require ABSL-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/Mutant Animals** (not mice)

Require ABSL-1 or higher containment

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

1. This project will be conducted at Animal Biosafety Level (ABSL):  1  2  3

**SECTION 2. CREATING TRANSGENIC / MUTANT ANIMALS**

*Complete this section ONLY if you are creating transgenic or mutant 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. New strain identification:
3. Identify who will be creating the transgenic animals

Your lab

Core Facility:

**TRANSGENE**

1. Specify the nature of the sequences being modified or inserted:

|  |  |  |  |
| --- | --- | --- | --- |
| **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 r∙s∙NA?

No Yes

1. Describe the method of gene transfer:

**BIOSAFETY CONTAINMENT LEVEL**

1. This project will be conducted at Biosafety Level (BSL):  1  2  3
2. This project will be conducted at Animal Biosafety Level (ABSL):  1  2  3

**SECTION 3. GENERATION OF r∙s∙NA**

*Complete this section if you are generating r∙s∙NA materials in your laboratory, but are NOT using them.*

*Example: You generate an r∙s∙NA vector for a collaborating researcher.*

**RECOMBINANT OR SYNTHETIC MATERIAL**

1. Name of material:
2. Type of material:

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

Retrovirus (not lentivirus)

Identify virus:

Identify envelope tropism:  Ecotropic  Amphotropic

Lentivirus

Identify generation of vector system:

Modified Microorganism Describe:

Other Describe:

1. Is the material propagated in your lab? No Yes, specify cells or organism:
2. If this is a viral vector:
3. Does this vector contain >2/3 of the viral genome?  No  Yes
4. Is this vector replication competent?  No  Yes
5. Is a helper virus required for replication? N/A  No  Yes, specify:
6. Identify cell line used for packaging (name, species):

**TRANSGENE**

1. Specify the nature of the sequences being used:

*NOTE: If using genome editing technology, identify the nuclease being used (i.e.: Cas9, Cpf1, ZFN, TALEN) in this table and identify gene targets in Section 7*

|  |  |  |  |
| --- | --- | --- | --- |
| **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:

**BIOSAFETY CONTAINMENT LEVEL**

1. This project will be conducted at Biosafety Level (BSL):  1  2  3
2. This project will be conducted at Animal Biosafety Level (ABSL):  1  2  3  N/A

**SECTION 4. USE OF r∙s∙NA**

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

*Example: The Vector Core, collaborator from Penn or another institution, or commercial vendor makes an r∙s∙NA construct for your lab and you will be using it in tissue culture, animals, etc.*

**RECOMBINANT OR SYNTHETIC MATERIAL**

1. Name of material:
2. Type of material:

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

Retrovirus (not lentivirus)

Identify virus:

Identify envelope tropism:  Ecotropic  Amphotropic

Lentivirus

Identify generation of vector system:

Modified Microorganism Describe:

Other Describe:

1. Is the material propagated in your lab? No Yes, specify cells or organism:
2. If this is a viral vector:
3. Does this vector contain >2/3 of the viral genome?  No  Yes
4. Is this vector replication competent?  No  Yes
5. Is a helper virus required for replication? N/A  No  Yes, specify:
6. Is this vector packaged in your lab?

No Identify source providing vector:

Yes List cell line (name, species):

**TRANSGENE**

* + 1. Specify the nature of the sequences being used:

*NOTE: If using genome editing technology, identify the nuclease being used (i.e.: Cas9, Cpf1, ZFN, TALEN) in this table and identify gene targets in Section 7*

|  |  |  |  |
| --- | --- | --- | --- |
| **Promoter** | **Gene Name** | **Source**  (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 sequence(s)?

No  Yes

**TARGET RECIPIENT**

Indicate the recipient(s) of the r∙s∙NA (check all that apply).

Animal only (specify species and if mouse, strain):

Cells only (specify cell type, name, and species):

Modified cells into animals

Specify cell type, name, and species:

Specify animal species / mouse strain:

Microorganism only (specify genus, species):

Modified microorganism into animals

Specify microorganism genus, species:

Specify animal species / mouse strain:

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 (BSL):  1  2  3
2. This project will be conducted at Animal Biosafety Level (ABSL):  1  2  3  N/A

**SECTION 5. Both GENERATION and USE OF r∙s∙NA**

*Complete this section if you are both generating and using r∙s∙NA in your laboratory.*

*Example: You generate an r∙s∙NA construct and use it in tissue culture, animals, etc.*

**RECOMBINANT OR SYNTHETIC MATERIAL**

1. Name of material:
2. Type of material:

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

Retrovirus (not lentivirus)

Identify virus:

Identify envelope tropism:  Ecotropic  Amphotropic

Lentivirus

Identify generation of vector system:

Modified Microorganism Describe:

Other Describe:

1. Is the material propagated in your lab? No Yes, specify cells or organism:
2. If this is a viral vector:
3. Does this vector contain >2/3 of the viral genome?  No  Yes
4. Is this vector replication competent?  No  Yes
5. Is a helper virus required for replication? N/A  No  Yes, specify:
6. Identify cell line used for packaging (name, species):

**TRANSGENE**

1. Specify the nature of the sequences being used:

*NOTE: If using genome editing technology, identify the nuclease being used (i.e.: Cas9, Cpf1, ZFN, TALEN) in this table and identify gene targets in Section 7*

|  |  |  |  |
| --- | --- | --- | --- |
| **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 sequence(s)?

No Yes

**TARGET RECIPIENT**

Indicate the recipient(s) of the r∙s∙NA (check all that apply).

Animal only (specify species and if mouse, strain):

Cells only (specify cell type, name, and species):

Modified cells into animals

Specify cell type, name, and species:

Specify animal species / mouse strain:

Microorganism only (specify genus, species):

Modified microorganism into animals

Specify microorganism genus, species:

Specify animal species / mouse strain:

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 (BSL):  1  2  3
2. This project will be conducted at Animal Biosafety Level (ABSL):  1  2  3  N/A

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

*Complete this section if you are using r∙s∙NA 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).*

*Example: Creating any transgenic plant.*

1. Genus, species, of parent strain:
2. Transgenic strain identification:
3. Is a USDA permit required for transport or use of these plants?  No  Yes

If YES, Provide permit number or application number:

**TRANSGENE**

1. Specify the nature of the gene sequence modified, knocked-out, and/or inserted into the plant:

*NOTE: If using genome editing technology, identify the nuclease being used (i.e.: Cas9, Cpf1, ZFN, TALEN) in this table and identify gene targets in Section 7*

|  |  |  |  |
| --- | --- | --- | --- |
| **Promoter** | **Gene Name** | **Source of gene** (genus, species) | **Biological Activity of Sequence** |
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1. Will a deliberate attempt be made to obtain expression of the foreign sequence?

No  Yes

1. Describe the method of gene transfer and/or modification:

**BIOSAFETY CONTAINMENT LEVEL**

1. This project will be conducted at Biosafety Level (BSL):  1  2  3
2. This project will be conducted at Plant Biosafety Level (BSL-P):  1  2  3
3. Plants will be housed in:

Greenhouse, Location:

Growth Chamber, Location:

Other, Describe:

1. Describe method of inactivation and disposal:

**SECTION 7. GENERATION and / or USE of GENOME EDITING TECHNOLOGY**

*Complete this section if you are generating and/or using genome editing technology including CRISPR/Cas9, Zinc Finger Nucleases (ZFNs), and TALENs.*

**GENE TARGETS**

1. Specify the genes to be targeted for editing

*NOTE:* *Identify the nuclease (i.e.: Cas9, Cpf1, ZFN, TALEN) being used in the transgene table of Section 3-6*

|  |  |  |
| --- | --- | --- |
| **Gene Name** | **Target Species** | **Biological Activity of Sequence** |
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1. Identify the functional consequence of the genome editing

Deletion

Insertion

Mutation

Transcriptional regulation

Other, describe:

**CRISPR/Cas9 DELIVERY**

1. Are the nuclease (i.e.: Cas9, Cpf1, etc.) and guide RNA on the same plasmid, vector, or delivery vehicle?

No  Yes

1. Identify how the nuclease is delivered

RNA

Protein

Plasmid

Viral Vector, type:

Other, describe:

1. Identify how guide RNA is delivered

RNA

Plasmid

Viral Vector, type:

Other, describe: