Texas Tech University Health Sciences Center
Recombinant DNA Biosafety Committee

RECOMBINANT/SYNTHETIC NUCLEIC ACIDS (r/sNA) RESEARCH PROFILE

All recombinant/synthetic (r/s) RNA or DNA research at NIH-funded institutions must be performed according to the **NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules** (the "NIH Guidelines"). The Guidelines' purpose is to protect researchers and the environment from exposure to or release of harmful agents produced by recombinant/synthetic nucleic acid research. The Guidelines specify the kinds of r/sNA experiments subject to annual review by the institutional **Recombinant DNA Biosafety Committee (RDBC)**.

The Guidelines also identify some r/sNA experiments as exempt from annual review because they pose no significant risk to personnel or the environment when performed with good microbiological technique and lab hygiene. To determine if your research is **EXEMPT** from annual review according to the NIH Guidelines, please answer questions in *Section 1* (page 3). If your research is **NON-EXEMPT** from the NIH Guidelines as determined by your answers on *Section 1*, please complete *Sections 2-8* (pages 4-10).

Investigator [ ] RDBC# [ ]

Department [ ] Campus [Choose one.]

Email † [ ] Phone [ ]

Completion date of required CITI training course *NIH Recombinant DNA Guidelines* [**m/d/y**]

Titles of grants/projects in which you will conduct r/sNA research:

[ ]

Lab personnel who will perform r/sNA experiments:

[ ]

Please submit your completed form to beatriz.velez@ttuhsc.edu in the Research Integrity Office for review by the TTUHSC RDBC. Handwritten signature lines have been replaced with electronic signature lines. Do not convert this Word document to PDF.

DEFINITIONS:

Risk Group 1: Agents not associated with disease in healthy adult humans.

Risk Group 2: Agents associated with human disease that is rarely serious and for which preventive or therapeutic interventions are often available.

Risk Group 3: Agents associated with serious or lethal human disease for which preventive or therapeutic interventions may be available. (i.e. high individual risk but low community risk).

Risk Group 4: Agents likely to cause serious or lethal human disease for which preventive therapeutic interventions are not usually available. (i.e. high individual risk and high community risk).

BIOSAFETY LEVELS:

BSL-1 Eating and drinking are prohibited in laboratory areas. Experiments may be performed on open laboratory benches without use of special containment equipment. No mouth pipetting. Decontaminate potentially infectious material before disposal (physically e.g. by autoclaving or chemically e.g. with bleach and/or 70% alcohol). Clean and decontaminate work surfaces after use or at the end of the day. Immediately clean and decontaminate after spills. Wear personal protective equipment (PPE) when exposure to hazardous material is possible. Remove PPE and wash hands before exiting the lab. Dispose of sharps separately from general lab waste. Lab door must be lockable to limit access, but the lab need not be isolated from the general building

BSL-2 Observe all BSL-1 precautions, plus: Limit access to the laboratory when experiments are in progress. Specifically train personnel in handling pathogenic agents. Scientists with advanced training direct experiments done by lab personnel. Wear appropriate PPE at all times. Take extreme precautions with contaminated sharp items. Conduct experiments in biological safety cabinets or other physical containment equipment if infectious aerosols or splashes may be produced.

BSL-2+ Work conducted in a BSL-2 facility using BSL-3 practices. Persons entering the laboratory must be advised of the potential hazards. Laboratory personnel must demonstrate proficiency in microbiological practices before working with infectious agents. All manipulations of infectious materials must be in a biological safety cabinet. Incidents that may result in exposure to infectious materials must be immediately evaluated and treated.

BSL-3 There are currently no BSL-3 laboratories at TTUHSC Abilene/Amarillo/Lubbock/ Permian Basin.

ANIMAL BIOSAFETY LEVELS:

ABSL-1 Facilities should be separated from general traffic areas and restricted as appropriate. External doors should not be propped open and should be secured at all times. Personnel must be trained in animal facility procedures and have adequate knowledge of hazards and experimental animal procedures. Eating and drinking are prohibited in laboratory areas. Wear lab coat/gown/uniforms to prevent contamination of personal clothing and wear gloves when handling hazardous or infectious materials, and when handling animals. Remove all PPE and wash hands before exiting the laboratory. Dispose of all waste in the appropriate receptacle, e.g. needles in sharps container, biowaste in red bags, etc. Immediately clean and decontaminate spills. Clean work areas with appropriate disinfectants at the end of each day.

ABSL-2 Observe all ABSL-1 precautions, plus: personnel must be trained in the safe handling of infected animals and the manipulation of pathogenic agents. Biological safety cabinets are used when procedures involve the manipulation of infectious materials, or when aerosols or splashes may be created. Take extreme caution when handling sharps. Needles must not be recapped and all sharps must be disposed of in a hard-walled container. Substitute plastic for glassware, when possible. All biological waste must be deactivated before disposal. Workers wearing respiratory protection must be fit-tested and enrolled in the TTUHSC Respiratory Protection Program.

ABSL-2+ Work conducted in an ABSL-2 facility using ABSL-3 practices. Observe all ABSL-2 precautions, plus contact the TTUHSC LARC for additional information on specific animal protocol(s).

1. **Will you introduce recombinant or synthetic RNA or DNA into live animals or human subjects?**
   ☐ YES ☐ NO If you answered "YES", skip ahead to **Section 2**. Your research is **NON-EXEMPT**.

2. **Will you use transgenic animals other than transgenic mice or rats?**
   ☐ YES ☐ NO If you answered "YES", skip ahead to **Section 2**. Your research is **NON-EXEMPT**.

3. **Will you generate transgenic mice or rats (including by crossing existing transgenic lines), or use transgenic mice or rats harboring more than 2/3 of the genome of viruses or organisms belonging to Risk Groups 2, 3, or 4 (as defined in DEFINITIONS at the beginning of this Questionnaire)?**
   ☐ YES ☐ NO If you answered "YES", skip ahead to **Section 2**. Your research is **NON-EXEMPT**.

4. **Will you work with nucleic acids from Risk Group 3 or 4 agents or restricted organisms, or with nucleic acids that code for biosynthesis of molecules toxic to vertebrates?**
   ☐ YES ☐ NO If you answered "YES", skip ahead to **Section 2**. Your research is **NON-EXEMPT**.

5. **Will recombinant or synthetic nucleic acids be deliberately introduced into any living cells or be modified to make them capable of penetrating into cells (e.g. for transformation or transfection)?**
   If you answered "NO", skip questions 6-9 and submit your **EXEMPT** *Profile*.
   ☐ YES ☐ NO If you answered "YES", please answer questions 6-9.

6. **Will recombinant or synthetic DNA be propagated or expressed using host-vector systems other than *Escherichia coli* K-12, *Saccharomyces*, *Bacillus subtilis* or *Bacillus licheniformis*, be shared between microorganisms of different species or strains that do not naturally exchange DNA, or be introduced into cultured eukaryotic cells other than existing cell lines?**
   ☐ YES ☐ NO If you answered "YES", skip ahead to **Section 2**. Your research is **NON-EXEMPT**.

7. **Will *E. coli* K-12 hosts contain conjugation-proficient plasmids or generalized transducing phages?**
   ☐ YES ☐ NO If you answered "YES", skip ahead to **Section 2**. Your research is **NON-EXEMPT**.

8. **Will cell culture experiments use infectious viruses (DNA or RNA), defective viruses in the presence of helper virus, or eukaryotic viral genome segments comprising more than 1/2 of the full viral genome?**
   ☐ YES ☐ NO If you answered "YES", skip ahead to **Section 2**. Your research is **NON-EXEMPT**.

9. **Will you culture organisms (including cells in culture) or viruses containing recombinant DNA in volumes exceeding 10L?**
   ☐ YES ☐ NO If you answered "YES", skip ahead to **Section 2**. Your research is **NON-EXEMPT**.

If you answered "NO" to questions 1-5 or to questions 1-4 and 6-9, your research is **EXEMPT** from annual review by the RDBC. So long as the nature of your research doesn't change, you will not need to complete this form again for another five (5) years.

I hereby attest that my lab's research is **EXEMPT** from annual review by the RDBC as determined by my answers to the recombinant/synthetic nucleic acid questions in *Section 1* above. I further attest that I will submit an updated *Research Profile* if the nature of my r/sNA research changes.

[ ] Principal Investigator (typed)

[ ] Department Chair (typed)

† **I acknowledge my typed name and submission of this *TTUHSC n/sNA Research Profile* via my ttuhsc.edu email constitutes my electronic signature, and my Department Chair will receive a copy of this *Research Profile*.**

Please check the boxes for all descriptions that apply to your NON-EXEMPT r/sNA research.

My lab's research will:

☐ Introduce recombinant or synthetic nucleic acids into human subjects.

If you checked this box, please contact the RDBC for further instructions on how to proceed.

☐ Introduce recombinant or synthetic nucleic acids into live animals.

☐ Use transgenic animals **other than** transgenic mice or rats.

☐ Generate transgenic mice or rats (including by crossing existing transgenic lines), or use transgenic mice or rats harboring more than 2/3 of the genome of viruses or organisms belonging to Risk Groups 2, 3, or 4 (as defined at the end of this Questionnaire).

☐ Work with nucleic acids from Risk Group 3 or 4 agents or restricted organisms, or with nucleic acids that code for biosynthesis of molecules toxic to vertebrates.

☐ Deliberately introduce recombinant or synthetic nucleic acids into living cells or modify r/sNAs to make them capable of penetrating into cells (e.g. as for transformation or transfection).

If you did not check this box, please skip ahead to the next page.

☐ Propagate or express recombinant or synthetic DNA using host-vector systems **other than** Escherichia coli K-12, Saccharomyces, Bacillus subtilis or Bacillus licheniformis, or transfer r/sDNA between microorganisms of different species or strains that do not naturally exchange DNA.

☐ Use E. coli K-12 hosts that contain conjugation-proficient plasmids or are infected with transducing phages.

☐ Introduce r/sNAs into cultured eukaryotic cells **other than** existing cell lines.

☐ Conduct cell culture experiments using infectious viruses (DNA or RNA), defective viruses in the presence of helper virus, or eukaryotic viral genome segments comprising more than 1/2 of the full viral genome.

☐ Culture organisms (including cells in culture) or viruses containing recombinant DNA in volumes exceeding 10L.

For each of the checked boxes above, please provide additional information about the research in **SECTIONS 3 - 8**. Complete only the sections applicable to your research, or check **N/A**.

Introduction of r/s nucleic acids into live animals ☐ N/A

List animal information:

Species	Strain	Sex	IACUC protocol #

Which of the following r/sNAs will be introduced into animals?

☐ Naked DNA or RNA

☐ Bacterial plasmid

☐ Viral vector

- ☐ Adenovirus
- ☐ Adeno-associated virus (AAV)
- ☐ Lentivirus Vector generation system: Click here to enter text.
- ☐ Retrovirus
- ☐ Other List: Click here to enter text.

If you will use viral vectors:

1. What percent of the original viral genome remains? Click here to enter text.%
2. Is the vector replication competent? ☐ NO ☐ YES
3. What host cell line or packaging cells will be used for vector propagation?

Click here to enter text.

Please briefly describe any encoded gene products, promoters, replication origins, and other regulatory elements of the r/sDNAs you will introduce into animals.

Non-exempt use of transgenic animals ☐ N/A

If you will use transgenic animals **other than** mice and rats, please list the animal species and strain and relevant IACUC protocol #s, and describe the transgene (DNA source, gene product, regulatory elements, insertion site if known), and the transgenic phenotype (if known).

If you will generate transgenic mice or rats (including by crossing different existing transgenic lines), or use transgenic mice or rats harboring more than 2/3 of the genome of viruses or organisms belonging to Risk Groups 2, 3, or 4, please describe the host animals (species, strain, genotype if known) and the transgene (DNA source, gene product, regulatory elements, insertion site if known), and the transgenic phenotype if known. Please also list relevant IACUC protocol #s.

Research with nucleic acids from Risk Group 3 or 4 agents or restricted organisms, or with nucleic acids encoding molecules toxic to vertebrates

☐ N/A

Please describe research with nucleic acids from Risk Group 3 or 4 agents or restricted organisms, including the names of the agents/organisms, and the nature of the nucleic acids (genes encoded, regulatory elements, etc., and whether associated with virulence or infectivity).

Please describe research with nucleic acids that encode molecules toxic to vertebrates. Include a description of the source and biological activity of the toxin.

Non-exempt introduction of r/sDNA into bacteria ☐ N/A

Please describe research involving propagation or expression of recombinant or synthetic DNA using host-vector systems **other than** *Escherichia coli* K-12, Saccharomyces, *Bacillus subtilis* or *Bacillus licheniformis*, or transfer r/sDNA between microorganisms of different species or strains that do not naturally exchange DNA. List the bacterial species and strains, and the nature of the DNA to be introduced (source, encoded genes, regulatory elements, etc.).

Please describe research using *E. coli* K-12 hosts that contain conjugation-proficient plasmids or are infected with transducing phages.

Non-exempt introduction of r/sNA into eukaryotic cells ☐ N/A

Please describe research involving introduction of r/s nucleic acids into cultured eukaryotic cells **other than** existing cell lines. Include a description of the cells and the nature of the DNA to be introduced (source, encoded genes, regulatory elements, etc.)

Please describe cell culture experiments using infectious viruses (DNA or RNA), defective viruses in the presence of helper virus, or eukaryotic viral genome segments comprising more than 1/2 of the full viral genome. Please identify the cell lines and viruses, and describe any defective virus/helper combinations or large viral genome segments.

Culture of organisms (including cells in culture) or viruses containing recombinant DNA in volumes exceeding 10L

☐ N/A

Please identify organisms, cells, viruses, and describe the rDNA used (source, genes encoded, regulatory elements, etc.)

I hereby attest that this Profile accurately describes my lab's r/sNA research, and the described research will be conducted at a biosafety level and with physical containment meeting or exceeding that stipulated by the RDBC. I further attest that I will submit updated Profiles if/as my lab's r/sNA research changes.

Principal Investigator (typed)

Department Chair (typed)

† **I acknowledge my typed name and submission of this *TTUHSC n/sNA Research Profile* via my ttuhsc.edu email constitutes my electronic signature, and my Department Chair will receive a copy of this *Research Profile*.**

Reviewed by the RDBC on	Risk Group	Biosafety Level	Animal Biosafety Level
Click here to enter a date.	Choose an item.	Choose an item.	Choose an item.

Reviewer Comments: (optional)