Hampton University
EXPERIMENTATION INVOLVING RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULE RESEARCH - PLANT, ANIMAL, HUMAN AND LAB BENCH PROJECTS

This form is to be used when requesting authorization for experimentation involving recombinant or synthetic nucleic acid molecules. This form will cover human gene transfer, plant, animal, and lab bench projects. Completed forms must be submitted to the Office of Research. For relevant regulations, see *NIH Guidelines*.

Please email this form as an attachment to: IBCCHAIR@hamptonu.edu

Recombinant or Synthetic Nucleic Acid Molecule Research Protocol

IBC OFFICE USE	
Protocol Number:	
Protocol status:	
Initial Submission Date:	
Approval Period:	
NIH Guideline Classification:	☐ III-A ☐ III-B ☐ III-C ☐ III-D ☐ III-E ☐ III-F
Biosafety Level	☐ BSL-1 ☐ BSL-2 ☐ BSL-3

Section A: Title & PI

A1. Protocol Title:

A2. Principal Investigator	
Name	
ID#	
Email	
Phone #	

A2. Principal Investigator

Department	
Room #	
Degree & Awarding Institution	
Number of years of experience as related to the project	

☐ (Check if applicable)	The Principal Investigator is adequately trained in: • Proper aseptic techniques; • Knowledge of the biology of the organisms used in the experiments; and • Procedures for dealing with accidents.

A3. Administrative Contact

Name	
Email	

A4. Institution(s) where work will be performed

Check all applicable institutions.

Hampton University Main campus: ☐
Off campus location: ☐
Specify exact address and location:

A5: COLLABORATORS FROM OTHER INSTITUTIONS

Copy and complete the table for each institution that will participate in this study.

Are collaborations involving other institutions proposed? ☐ YES ☐ NO

Name of collaborator:	
Name of institution:	
Has this project been approved by that institution?	☐ YES ☐ NO If yes, provide the IBC approval date:

A6: Funding Source

Copy and complete the table for each funding source that will support this study.

Name of funding source:	
Grant number:	

Approval period	
Is the PI or research funded by Hampton University internal funds? ☐ YES ☐ NO	

Section B: ASSOCIATED PERSONNEL & TRAINING

Copy and complete the table for each individual who will work with and/or handle the recombinant or synthetic nucleic acid molecules described in this study.

Name	
Hampton ID#	
Email	
Degree & Awarding Institution	
Number of years of experience as related to the project.	

Name	
Hampton ID#	
Email	
Degree & Awarding Institution	
Number of years of experience as related to the project.	

☐ (Check if applicable)	The PI certifies that before experiments involving recombinant or synthetic nucleic acid molecules begin the experimenters will be adequately trained in at least: • Proper aseptic techniques; • Knowledge of the biology of the organisms used in the experiments so that the potential biohazards can be understood and the appropriate precautions can be taken; and • Procedures for dealing with accidents.

Section C: PROJECT DESCRIPTION

Please provide a brief description and rationale of the project. (Provide a concise description of all proposed activities involving recombinant or synthetic nucleic acid molecules; use language that is understandable to those with a general knowledge of biology; define all acronyms.)

Section D: PROJECT LOCATION & CONTAINMENT

D1. Building & Room Number:

D2. Biological Safety Cabinet: ☐ YES ☐ NO
Serial Number:
Certification Date:

Serial Number:
Certification Date:

D3. Fume Hood: ☐ YES ☐ NO

D4. Additional room features or equipment to be used (such as cell sorters, sonicators, UV lights)?
☐ YES ☐ NO
If yes, describe the room feature:

D5. Biosafety Level (Check One)
Will you use human cells or cell lines in your research using recombinant or synthetic nucleic acid molecules? ☐ YES (Check at BSL-2) ☐ NO
☐ BSL-1 ☐ BSL-2 ☐ BSL-3

D6. What methods of decontamination will be used for lab benches, equipment, etc?
☐ 70% Alcohol
☐ 10% Bleach
☐ Other
Describe other method:

D7. How will the following waste be deactivated for disposal? (Check all applicable methods)
a. Solids
☐ Biological - Autoclave
☐ Biological – Collect in Stericycle Boxes for OES (must be approved)
☐ Chemical – Collect in separate container for OES pick up
☐ Other
Describe other method:

b. Liquids

☐ Treat with 10% bleach and flush down drain
☐ Autoclave and flush down drain
☐ Chemical – Collect in separate container for OES pick up
☐ Other
Describe other method:

D8. What personal protective equipment will be used (check all applicable boxes)?

☐ Lab coat
☐ Gown

☐ Latex gloves
☐ Nitrile gloves
☐ Gloves: other (describe):

☐ Safety goggles
☐ Surgical/Dust mask
☐ N95 mask
☐ Face shield

☐ Other
Describe other method:

D9. Recombinant or Synthetic Nucleic Acid Molecules Construct Chart – list all constructs to be worked with (including viral vectors)

Provide information for each gene or class of genes you will work with. Add more rows if needed.

Source of Nucleic Acid to be Cloned	Gene	Function/Anticipated Function	Prokaryotic Vector	Point of Use*	Eukaryotic and Viral Vector	Point of Use (specify species of cells)	Human Risk
EXAMPLE: Mouse	*BSL-R*	*Host cell receptor for malaria*	*pBluescript*	*E. coli (K12)*	*pAd-TSX*	*Caco-2 (human intestinal cells)*	*No known risk*
EXAMPLE: Mouse cDNA	*All genes involved in reproduction*	*Reproduction*	*pBluescript*	*E. coli (K12)*	*N/A*	*N/A*	*No known risk*

*** Include all points of use – E. coli, cell lines, yeast, bacteria, plants, animals.**

Section E: VIRAL VECTORS

E1. Are viral vectors used for this research? ☐ Yes ☐ **No (skip to next section)**

E2. If using viral vectors, are any special safety measures to be deployed during the preparation and administration such as surveillance of wildtype particles?
☐ YES ☐ NO
If yes, describe special safety measures:

E3: VIRAL VECTORS

	Vector Systems	Will helper virus be used?	Are infectious virus particles, replication-deficient or wild-type, rescued, propagated or purified in your laboratory?	Indicate number of cells and anticipated culture media volumes per experiment	Will there be surveillance for production of wild type viral particles?
↓ *Check the box next to each system to be used*		*Complete this section only for the vectors being used*			
☐	Adenovirus ☐ Replication Competent ☐ Replication Deficient	☐ YES ☐ NO	☐ YES ☐ NO If No, explain:		☐ YES ☐ NO If YES, explain:
☐	Adeno-associated virus	☐ YES ☐ NO	☐ YES ☐ NO If No, explain:		☐ YES ☐ NO If YES, explain:
☐	Retrovirus – ecotropic (*infects only murine cells*)	☐ YES ☐ NO	☐ YES ☐ NO If No, explain:		☐ YES ☐ NO If YES, explain:
☐	Retrovirus – amphotropic (*can infect human cells*)	☐ YES ☐ NO	☐ YES ☐ NO If No, explain:		☐ YES ☐ NO If YES, explain:
☐	Retrovirus – pseudotyped (*glycoproteins from other enveloped*	☐ YES ☐ NO	☐ YES ☐ NO		☐ YES ☐ NO

E3: VIRAL VECTORS					
Vector Systems		Will helper virus be used?	Are infectious virus particles, replication-deficient or wild-type, rescued, propagated or purified in your laboratory?	Indicate number of cells and anticipated culture media volumes per experiment	Will there be surveillance for production of wild type viral particles?
	viruses/can infect human cells)		If No, explain:		If YES, explain:
☐	Retrovirus – Lentivirus	☐ YES ☐ NO	☐ YES ☐ NO If No, explain:		☐ YES ☐ NO If YES, explain:
☐	Retrovirus - MoMuLV	☐ YES ☐ NO	☐ YES ☐ NO If No, explain:		☐ YES ☐ NO If YES, explain:
☐	Herpes virus	☐ YES ☐ NO	☐ YES ☐ NO If No, explain:		☐ YES ☐ NO If YES, explain:
☐	Epstein Barr Virus	☐ YES ☐ NO	☐ YES ☐ NO If No, explain:		☐ YES ☐ NO If YES, explain:
☐	Pox virus	☐ YES ☐ NO	☐ YES ☐ NO If No, explain:		☐ YES ☐ NO If YES, explain:
☐	Other: Specify	☐ YES ☐ NO	☐ YES ☐ NO If No, explain:		☐ YES ☐ NO If YES, explain:

Section F: ANIMALS

For guidance on animal experiment covered by the NIH Guidelines click on the following hyperlink: Animal Experiments Covered under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules

F1. Will animals be used in this research? ☐ Yes ☐ **No (skip to the next section)**

F2a. Will research involve vertebrate animals: ☐ YES ☐ NO
If "Yes", provide Hampton IACUC protocol number: AN-

F2b. Will research involve animals other than rodents? ☐ YES ☐ NO
If yes, provide a list of animal species to be worked with:

F2c. Will new transgenic mice be generated? ☐ YES ☐ NO

F3. Will animals receive viral vectors? ☐ YES ☐ NO
Answer "YES" if vector is given directly to the animal but "NO" if animals are given cells that were transfected with viral vectors.

F4. Please give a brief description of the animal work, including a description of the anticipated effect the recombinant or synthetic nucleic acid molecules will have on the animal.

F5. If any of the following questions is answered with "YES", complete the Transgenic Rodent breeding Chart

a. Does one of the parental transgenic rodents need to be housed under BL2 or BL3 containment?

☐ YES ☐ NO

b. Does one of the parental transgenic rodents contain genetic modifications, which incorporate more than one-half of the genome of an exogenous eukaryotic virus from a single family of viruses?
☐ YES ☐ NO

c. Does one of the parental transgenic rodents contain genetic modifications, which incorporate a transgene that is under the control of a gammaretroviral long terminal repeat (LTR)?
☐ YES ☐ NO

d. Is the transgenic rodent that results from this breeding expected to contain more than one-half of an exogenous viral genome from a single family of viruses?

☐ YES ☐ NO

F6. Transgenic Rodent Breeding Chart

Add more rows if needed

	Rodent Line 1	Genes Affected	Rodent Line 2	Genes Affected	Generated Rodent Line	Genes Affected	Anticipated Effect on Animal
Example	*TgXFP*	*FP (filter protein) – over expressed*	*TgXGLPR*	*GLPR (glycoprotein receptor) – over expressed*	*TgXFPGLPR*	*FP & GLPR – overexpressed*	*Kidney disease*
1							
2							
3							
4							
5							
6							

Section G: PLANTS

G1. Will plants be used in this research? ☐ Yes ☐ **No (skip to the next section)**

G2. Please give a brief description of the plant work, including a description of the anticipated effect the recombinant or synthetic nucleic acid molecules will have on the plant and a list of plant species to be worked with.

G3. Please describe the safety features (physical/practical) that are used to prevent release of plant material.

G4. Transgenic plants (or their components) will be:

a.	Generated?	☐ YES	☐ NO
b.	Propagated	☐ YES	☐ NO
c.	Fed to animals?	☐ YES	☐ NO
d.	Fed to humans?	☐ YES	☐ NO
e.	Together with microorganism or insects containing recombinant or synthetic nucleic acid molecules	☐ YES	☐ NO
f.	Purchased or transferred from another lab?	☐ YES	☐ NO
g.	Bred to other wildtype strains or other transgenic lines?	☐ YES	☐ NO If yes, complete the transgenic plant breeding chart.

G5. Transgenic Plant Breeding Chart

Add more rows if needed

	Plant Line 1	**Genes Affected**	**Plant Line 2**	**Genes Affected**	**Generated Plant Line**	**Genes Affected**	**Anticipated Effect on plant**
Example	*TgXFP*	*FP (filter protein) – over expressed*	*TgXGLPR*	*GLPR (glycoprotein receptor) – over expressed*	*TgXFPGLPR*	*FP & GLPR – overexpressed*	*Kidney disease*
1							
2							

G5. Transgenic Plant Breeding Chart *Add more rows if needed*							
	Plant Line 1	**Genes Affected**	**Plant Line 2**	**Genes Affected**	**Generated Plant Line**	**Genes Affected**	**Anticipated Effect on plant**
3							
4							
5							
6							

Section H: HUMAN GENE Transfer

H1. Will human subjects be used in this research? ☐ Yes ☐ **No (skip to the next section)**
If "Yes", complete an IRB protocol in BRAIN and provide the Hampton IRB protocol number: H-

H2. Please state concisely the overall objectives and rationale to the proposed human study.

H3. Is the protocol designed to:

a. prevent all manifestations of the disease?	☐ YES	☐ NO
b. halt progression after symptoms that have begun to appear?	☐ YES	☐ NO
c. reverse all disease manifestations?	☐ YES	☐ NO

H4. What is the structure of the cloned DNA that will be used? Describe the gene, bacterial plasmid or phage vector and delivery system.

H5. Provide any results that demonstrate the safety, efficacy and feasibility of the proposed procedures that were obtained with animal and/or cell culture models.

H6. Will cells be removed from human subjects and treated ex-vivo? ☐ YES ☐ NO

H7. Is there significant possibility that the added recombinant or synthetic nucleic acid molecules will spread from the human subject to other persons or the environment? ☐ YES ☐ NO

PLEASE SUBMIT APPENDIX M, CONSENT FORM AND ALL RAC CORRESPONDENCE WITH THIS APPLICATION.

Section I: NIH Classification of Proposed Research Involving Recombinant or Synthetic Nucleic Acid Molecules

NIH GUIDELINE CLASSIFICATION *For more information please consult the NIH Guidelines*		
Check all applicable boxes (one or more if applicable) next to the most relevant classification(s) that describe your project(s).		
☐	**III-A**	• Deliberate transfer of drug resistance to microorganisms (*does not include selection resistance conferred by vector*)
☐	**III-B**	• Cloning of toxin molecules with LD_{50} < 100 ng/kg
☐	**III-C**	• Deliberate transfer of recombinant or synthetic nucleic acid molecules into humans
☐	**III-D**	• Risk Group 2 or 3 Agents as host-vector systems or DNA from risk group 2 or 3 agents • Infectious DNA or RNA viruses • Defective DNA or RNA viruses in the presence of helper virus • Recombinant or synthetic nucleic acid molecules related experiments involving whole animals (i.e. gene therapy), excluding the generation of transgenic rodents. • Generation of transgenic animals (non-rodent species, rodents requiring ABSL2 or 3) • Experiments involving whole plants • Experiments involving more than 10 liters of culture • Experiments involving influenza viruses
☐	**III-E**	• Formation of recombinant or synthetic nucleic acid molecules containing no more than 2/3rds of the genome of any eukaryotic virus • Experiments involving whole plants • Generation of transgenic rodents (ABSL1 only), includes generation via breeding
☐	**III-F**	• Those synthetic nucleic acids that: − Can neither replicate nor generate nucleic acids that can replicate in any living cell, and − Are not designed to integrate into DNA, and − Do not produce a toxin that is lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight • Not in organisms, cells, or viruses • Consist entirely of recombinant or synthetic nucleic acids from a: − Single source that exists contemporaneously in nature − Prokaryotic host and is propagated in that host − Eukaryotic host and is propagated in that host − Species that exchanges DNA by physiological processes • Those genomic DNA molecules that have acquired a transposable element provided the transposable element does not contain any recombinant and/or synthetic DNA • No significant risk to health of the environment (Appendix CI/CII) as determined by the NIH Director: − Recombinant or synthetic nucleic acid molecules containing < ½ of any eukaryotic viral genome that are propagated and maintained in cells

NIH GUIDELINE CLASSIFICATION *For more information please consult the NIH Guidelines*		
Check all applicable boxes (one or more if applicable) next to the most relevant classification(s) that describe your project(s).		
		– *E. coli* K-12, *Saccharomyce cerevisiae* or *uvarum*, *Kluyveromyces lactis*, any asporogenic *Bacillus subtilis* or *lichenformis* host vector systems and extrachromosomal elements of gram positive organisms propagated and maintained as described in Appendix C-V unless used in (i) experiments described in Section III-A which require IBC approval, RAC review, and NIH Director approval before initiation, (ii) experiments described in Section III-B which require NIH/OBA and IBC approval before initiation, (iii) experiments involving DNA from Risk Groups 3, 4, or restricted organisms (see Appendix B and Sections V-G and V-L) or cells known to be infected with these agents may be conducted under containment conditions specified in Section III-D-2 with prior IBC review and approval, (iv) large-scale experiments (e.g., more than 10 liters of culture), and (v) experiments involving the deliberate cloning of genes coding for the biosynthesis of molecules toxic for vertebrates (see Appendix F) – Purchase or transfer of transgenic rodents for experiments that require BL1 containment – Propagation of transgenic rodents for experiments that require BL1 containment (only within the same wildtype background line)

Certification by Principal Investigator

(1) I certify that I will not initiate or modify recombinant or synthetic nucleic acid molecule research which requires Institutional Biosafety Committee (IBC) approval prior to initiation until that research or the proposed modification thereof has been approved by the IBC and has met all other requirements of the *NIH Guidelines.*

(2) I certify that I will report any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses to the IBC.

(3) I certify that I will adhere to IBC approved emergency plans for handling accidental spills and personnel contamination, and comply with shipping requirements for recombinant or synthetic nucleic acid molecules.

(4) I understand that Hampton University and its representatives on the IBC have the authority to suspend any part of my research, should I not be in compliance at any time with the *NIH Guidelines*, or Hampton institutional policies and procedure regarding research involving recombinant or synthetic nucleic acid molecules.

(5) I am familiar with the Hampton Laboratory Safety Guidelines on Infectious Agents and the Chemical Hygiene Plan. I will abide by the policies and procedures setforth in these documents and in all additional policies and procedures that relate to research at Hampton. I will ensure that all laboratory personnel engaged in this project will be informed of potential hazards and adequately trained in procedures involving recombinant or synthetic nucleic acid molecules and hazardous agents.

_____ _____

Principal Investigator Date