New Jersey Institute of Technology
Institutional Biosafety Committee (IBC)

This form is for:

- New or amended research proposals involving the use of recombinant materials or Synthetic Nucleic Acid Molecules;
- Modifications to previously approved IBC protocols (see Qualifying Modifications, instructions);
- Full renewal/continuing review of previously approved IBC protocols;

Required (a single pdf. document is recommended for submission)

1. Complete and submit the application to: IBC@njit.edu.
2. Submit the Investigator's NIH-style biosketch to IBC@njit.edu.
3. Provide a scanned or pdf file of the ***signed*** Investigator Assurance Page to IBC@njit.edu.
4. Complete and submit the Laboratory Hazard Assessment for New or Modified Processes or Procedures to IBC@njit.edu.
5. Submit a Standard Operating Procedures/Safety Operating Procedures(SOP) to IBC@njit.edu.

Optional Attachments (submit as necessary)

1. IBC Attachment - 1 for Human Gene Research
2 IBC Attachment – 2 for Plant Research
3. IBC Mentor Agreement

SECTION 1. Investigator Assurance Page

a. I agree to conduct this research in accordance with the compliance policies of the IBC Office, NJIT Institutional Biosafety Committee, including all requisite training of students, staff and other professionals participating in this research.
b. I have consulted Section IV-B-7 of the NIH guidelines http://osp.od.nih.gov/sites/default/files/NIH_Guidelines_0.pdf describing the responsibilities of the Principal Investigator and hereby agree to comply fully with all provisions of the NIH guidelines http://osp.od.nih.gov/sites/default/files/NIH_Guidelines_0.pdf.
c. I understand I am responsible for assuring that my research facilities are in compliance with local, state and federal environmental laws and regulations.
d. I understand that I am responsible for the proper conduct of any research by laboratory personnel that are directly related to this protocol application
e. I understand that all changes in the research protocol (including changes in the source recombinant or synthetic nucleic acids, host-vector systems, dosage ranges, laboratory room changes, etc.) or research participants must be reported to the IBC (IBC@njit.edu) and all other university regulatory offices in connection with this protocol.
f. If funded by an extramural source, I assure that this application accurately reflects all procedures involving Recombinant or Synthetic Nucleic Acids as described in the grant proposal to the funding agency.
g. The information within this application is accurate to the best of my knowledge.
h. I understand that yearly reporting is required for continuing approved research.
i. I understand that all protocols must be resubmitted for committee review after a term of three years.
j. By the submission and acceptance of this signed document at the IBC (IBC@njit.edu) I am in agreement with the statements a-i (above).
k. As Principal Investigator I recognize it is my responsibility to ensure that all personnel involved in this study are appropriately trained, and are provided the equipment necessary to perform at the designate biosafety containment level.

NOTE: NJIT Environmental Health and Safety Department in conjunction with IBC reserves the right to conduct inspections of research facilities at any time.

Principle Investigator's Name typed or printed:_____

Principle Investigator's Signature:_____

Date:_____

A *Signed* copy of *ONLY* this first page must be provided to the IBC (IBC@njit.edu).

SECTION 2. **IBC Research Project Title(s)**	

IBC Office use only:

Date:	**Protocol Number:**	**Revision:**

Application Instructions

Containment determination and issues to consider:

In determining the appropriate containment for a project, it is important to consider factors that may raise concerns regarding the materials or agent(s) used.

Factors used to determine the level of containment include: virulence, pathogenicity, infectious dose, environmental stability/instability, route of spread/infection, communicability/pathogenicity, safety procedures/operations, quantity of agent(s), availability of vaccine or treatment and any gene product effects such as: toxicity, physiological activity, or allergenicity.[1]

> **Note that careful consideration should be given to the type of manipulation planned for some higher risk group agents. Any strain that is known to be more hazardous than the parent (wild-type) strain should be considered for handling at a higher containment level.[2]

Investigators should additionally consider any potential for unintended adverse events and/or potential for misuse of the research. Special consideration should be given to any experimental paradigms that: [3]

- ✓ Would confer resistance to therapeutically useful antibiotics or antiviral agents in humans, veterinary medicine, or agriculture
- ✓ Would enhance the virulence of a pathogen or render a non-pathogen virulent
- ✓ Would increase transmissibility of a pathogen
- ✓ Would alter the host range of a pathogen

Note regarding inserted DNA:

In some instances the investigator may not be able to determine in advance all of the inserted nucleic acid segments (or transgenes) to be used in a particular vector system. In most instances, the addition of new inserts/transgenes will not alter the biosafety level and will not require IBC review, and all that is required is for the investigator to inform the IBC Office of the change. However, there are exceptions that necessitate submission of a modification for review by the committee, including:

- Inserting genes with oncogenic potential into any lentiviral vector
- Manipulating genes from any HHS or USDA Select Agent or Toxin
- Manipulating genes from highly pathogenic avian, 1918 pandemic H1N1, or non-contemporaneous H2N2 influenza strains
- Inserting nucleic acid molecules that have the potential to increase the pathogenicity or virulence of a vector system
- Transferring a drug resistance trait that has the potential to compromise the use of the drug to control disease in humans and/or animals
- Transferring a herbicide or insecticide resistance trait into a crop plant
- Transgenic modification of a food animal

If in doubt, investigators are encouraged to contact the IBC (IBC@njit.edu) for advice on whether modifications are required.

[1,2] NIH Guidelines **http://osp.od.nih.gov/sites/default/files/NIH_Guidelines_0.pdf**, Section II-A-3, November 2013

[3] National Research Council, Biotechnology Research In An Age of Terrorism, National Academies Press, 2004

Significant (qualifying) Modifications:

Typically minor modifications are handled at the IBC Office level and do not require IBC review. Please contact the IBC (IBC@njit.edu) for help in determining the type of modification. ***Significant (qualifying) modifications require IBC review and will require the investigator to complete the entire form.*** These include such changes as:

- Addition of a new vector system not previously approved by the IBC for use by the investigator
- Addition of new *in vivo* work not previously approved by the IBC (previous approval was for *in vitro* work only)
- Change in Biosafety Level (either upgrade or downgrade)
- Significant change in DNA inserts as noted above (see "Note regarding inserted DNA")
- Change to an investigator not having any current IBC registrations – IBCs must review the investigator's background and experience

IBC Registration:

All research involving recombinant or synthetic nucleic acid molecules materials or procedures must be registered with the IBC Office. Registration includes research in which genetically-modified animals are bred in any NJIT facility (see additional information directly below*).

- Research qualifying for IBC Registration status will be provided a complete term of three years, which is renewable
- The IBC Office distributes *courtesy* renewal notices via email at 120, 60, 30-day, and two weeks prior to expiration of the registration
- Investigators are responsible for updating contact information so that renewal notices are received
- ***Have questions? Contact Norma Rubio at IBC@njit.edu***

*Instructions for completing the IBC application for on-site breeding of Genetically Engineered (GE) animals

Complete Sections 1 – 7 and Section 15. For Section 7, provide a brief statement to indicate that that research application is only for breeding or crossbreeding animals, and list the strains that are expected to be maintained as a colony.

Annual renewal reporting:

To maintain continuing IBC approval, protocol update reports are submitted annually to the IBC. To simplify annual reporting, the researchers complete Sections 1-3 of the application. Additional sections may be required to be completed per changes indicated in the form instructions.

- **Investigators are responsible for their annual renewal reporting to the IBC at IBC@njit.edu.**
- Investigators are responsible for updating contact information with the IBC (IBC@njit.edu)
- ***Have questions? Contact Norma Rubio at IBC@njit.edu.***

3 year (Full Renewals):

To maintain the most relevant data related to research at New Jersey Institute of Technology investigators wishing to continue IBC approval after three years are required to complete the entire IBC application as a "Full Renewal". If the demographic and funding information (Sections 4, 5 and 6) has not changed, then those sections may remain blank, however, beginning at Section 7 and beyond, the remainder of the IBC application is required to be completed as pertaining to the research that falls under the *NIH Guidelines*.

IBC Incident Reports:

Section IV-B-7-a-(3) of the *NIH Guidelines* requires that researchers investigate and report to the Biological Safety Officer (BSO) and the IBC any significant problems, research-related accidents or illnesses, or violations of the *NIH Guidelines*.

- Please refer to the Incident Reporting guidance and information to provide information to the IBC (IBC@njit.edu).

Termination:

Protocols that are not renewed *expire the day following the expiration date and are automatically terminated*. **A termination letter by SRA (Sponsored Research Administration) or IBC is distributed to the investigator and other compliance offices/divisions as appropriate.**

- Expired or Terminated protocols cannot be "re-started" once the close-out letter has been issued.
- A new application must be completed. Send all correspondence to IBC@njit.edu.

Investigators:

The *NIH Guidelines* at http://osp.od.nih.gov/sites/default/files/NIH_Guidelines_0.pdf, state that the Principal Investigator is responsible for ensuring that the laboratory staff are appropriately trained (*Section IV-B-1-h*), is responsible for full compliance of the conduct of the IBC research, and supervision of safety performance of laboratory staff (*Section IV-B-7*). Please note that correspondence from the IBC will be directed to the Principal Investigator as the recognized responsible individual for the research, and not the co-investigators. A co-investigator may be listed as the alternate contact, if so desired.

If the investigator is a post-doctoral fellow, graduate student, or equivalent, a mentor is to be identified in *Section 5* (Alternate Contact) of the application and a Mentor Agreement form must be completed and provided with the application.

Alternate Contacts:

The Alternate Contact is a designated individual to whom IBC correspondence is copied with regards to the named investigator's IBC research protocols. The IBC Office cannot release protocol documents or other information unless the individual is identified as the alternate contact or through written permission from the identified investigator. Do not type in the gray-shaded sections. Do not leave any blanks, unless instructed to do so. Incomplete applications will be returned. Please send the completed form to: IBC@njit.edu.

If you have questions, please contact Norma Rubio at IBC@njit.edu.

SECTION 3. Project Submission — Indicate Yes/No in check boxes	Yes	No
a. Is this an existing (approved) IBC application? • **If *NO* (e.g. this is a New application) skip to the next section (Section 4)**	☐	☐
b. Provide the protocol number for the existing/renewing IBC approved project:		
c. Have there been any changes in the *investigator contact information* since the last IBC review interval? • **If *YES*, Section 4 must be updated to reflect the new information**	☐	☐
d. Have there been any changes in the *alternate contact information* since the last IBC review interval? • **If *YES*, Section 5 must be updated to reflect the new information**	☐	☐
e. Have there been any changes to the *funding* of this research since the last IBC review interval? • **If *YES*, Section 6 must also be updated to reflect the new information**	☐	☐
f. Have there been any changes in the *location of the research facilities* since the last IBC review interval? Did the lab relocate to another building or room? • **If *YES*, Section 18 must be updated to reflect the new information**	☐	☐
g. Have there been any changes or additions to the recombinant or synthetic nucleic acid molecules or vectors since the last IBC review interval? • **If *YES*, Section 7 must be updated to reflect the new information included with the previously described materials and procedures** • **Highlight the updated information in the section**	☐	☐
h. Have there been any changes or modifications to any linked IACUC protocols since the last IBC review interval? • **If *YES*, Sections 15 and 16 must be updated, as applicable**	☐	☐
i. Are there any changes in the title(s) for this continuing IBC protocol? • **If *YES*, Section 2 must be updated to reflect the new title information**	☐	☐
j. Have there been any reported injuries/exposures of laboratory personnel since the last IBC review interval? • **If *NO*, skip to question L, below**	☐	☐
k. Indicate in the boxes to the right, the office or department to which the incident was reported. *Check all that apply.* • **Please note that the IBC may require additional information for the incident reported**	☐ Public Safety ☐ Department Head ☐ Direct Supervisor ☐ Institutional Animal Care & Use Committee ☐ Environmental Health &Safety ☐ Institutional Biological Committee ☐ Institutional Review Board ☐ Workers' Compensation ☐ Incident not reported NJIT Facilities	
l. Is this application being submitted as a Full (3 year) Renewal or a modification for substantial changes to the research previously described? • **If *NO*, and all required Sections as noted above have been updated, the renewal report has been completed – submit to IBC@njit.edu.** • **If *YES*, skip to Section 7 (unless contact changes), and complete the remaining sections of the application that are applicable to the research project that you are renewing.**	☐	☐

SECTION 4. Principal Investigator – *The person responsible for the recombinant research*	
Principal Investigator name	
Professional title/Job Title	
Degree	
Department/School	
Office; room and building	
Telephone contact	
Office street address	
Mailing zip code	
Email address	

SECTION 5. Alternate Contacts – *The named alternate contacts listed below will only receive the IBC approval and final renewal reminder (2 weeks prior to expiration)*	
Alternate contact name	
Professional title/Job Title	
Degree	
Telephone contact	
Email address	
Administrative/Dept. Admin. name	
Email for Departmental Administrator	

SECTION 6. Funding information	Reference the *NIH Guidelines*: Sections: I-C-1-a, I-C-1-b		
	Indicate Yes/No in check boxes:	**Yes**	**No**
a. Is this project NIH/PHS funded?		☐	☐
b. List *ALL* funding sources that are supporting this protocol: • **List funding for this project; include all funding sources** • **Provide the start and end dates of grants** • **Include internal (departmental) funding (e.g. "start up")** **Note: For internal funding insert "not applicable" for grant info.**	**Funding sources**	**Grant #s and active dates of the grant**	
c. Is any funding administered through NJIT?		☐	☐
d. If *NO* to the question directly above, name the institution responsible for administering the grant			

SECTION 7. Project summary

Describe the experimental procedures involving recombinant or synthetic nucleic acid materials. Use non-technical terminology to enable IBC community representatives to understand your project.

Helpful Hints: Email the IBC (IBC@njit.edu) if you need assistance or have questions about the application:

- ✓ **Do *not* copy from a grant application!**
- ✓ **Limit the description to the materials relevant to IBC review (recombinant or synthetic nucleic acid molecules) of the project**
- ✓ **Address any potential biosafety issues and how they will be minimized**
- ✓ **Use non-scientific language so that the IBC community members may understand the research project**

NOTE: The IBC Office reserves the right to return any proposals that do not meet the above conditions or require extensive clarification or corrections prior to committee review

Enter Project Summary on this page below the line.

Note: *For Breeding/Cross-breeding applications:* Complete Sections 1 – 7 ***and* Section 15.

For Section 7, provide a brief statement to indicate that that research application is only for breeding or crossbreeding genetically engineered animals, and list the strains that are expected to be maintained as a colony. If you have questions regarding your research or completing this application please contact the IBC Office.

A. Provide a 2-3 sentence abstract of the project that *specifically relates to the work* with the recombinant or synthetic nucleic acid molecules

B. Describe the procedures and techniques to be used with the nucleic acid molecules in the project
For example, if the research involves a recombinant virus, bacteria, or other organism:

- **Describe the vectors and the transgenes being used**
- **Describe how the vectors are used in the research project**

C. Summarize the use of all viruses, including lentiviral vectors

D. If an Institute Animal Use and Care Committee protocol will be associated with this Institute BioSafety Committee protocol, be sure to summarize how the work with recombinant or synthetic nucleic acid molecules relates to the animal work

E. If using multiple biosafety levels, describe the procedures to be performed at each level
For example, work with infectious HIV-1 at BSL-2+; work with 3rd generation (4-plasmids) HIV-1 lentiviral vectors at BSL-2; vaccine study with a single HIV-1 gene at BSL-1

SECTION 8. Determination of use: Indicate all that apply; Check ***All*** applicable boxes *****Note to Mac users: for checkboxes - highlight the box and then press the spacebar***			***NIH Guidelines*** **references**
A. ☐	**Using recombinant or Synthetic Nucleic Acid molecules for detection purposes (e.g. GFP, YFP, radioactive nucleotides, etc.)**		III-F
B. ☐	**Creating or using genomic libraries**		III-E; III-F
C. ☐	**Cloning and vector construction in bacteria and yeasts**		III-E; III-F
D. ☐	**Expression of recombinant or synthetic nucleic acid products in cultured cells**		III-E; III-F
E. ☐	**The use of human cells/cell lines or tissues (e.g. human blood, 293 cell lines, CSF)**		BBP standard
F. ☐	**Use of animal cells/cell lines or tissues (e.g. tissue culture research)**		III-E; Appendix C
G. ☐	**Use of *human* stem cells or iPS cells (embryonic or adult)** • **If YES provide hSCRO registration/protocol number**		**Email the IBC(IBC@njit.edu)**
H. ☐	**Using or cloning genes from, or into a risk group 2 or 3 agent (e.g. HSV, SIV)**		III-D-1; III-D-2
I. ☐	**Administration of recombinant or synthetic nucleic acid molecules into animals (e.g. transformed cells, vectors)**		III-D-4
J. ☐	**Experiments involving whole plants in research - requires completion of IBC Form Attachment 2 with application**		III-D-5; Appendix P
K. ☐	**Propagating culture volumes exceeding 10 liters at one time**		III-D-6
L. ☐	**The use or manipulation of infectious viruses or replication-defective viruses or viral vector(s) with helper viruses**		III-D-3
M. ☐	**Experiments involving influenza viruses under Section III-D-7 of the NIH Guidelines; risk group 3 strains (*must be fully described in Section 7*)**		III-D-7
N. ☐	**Using or cloning of genes from, or into a risk group 4 or a Select Agent**		III-D-1-d
O. ☐	**Administration of recombinant or synthetic nucleic acid molecules into humans – (Human Gene Transfer Clinical Trial) requires completion of IBC Attachment 1 with application, plus additional documents**		III-C-1
P. ☐	**Using or cloning of toxin molecule genes (e.g. deliberate formation)**		III-B-1; Appendix F
Q* ☐	**Transfer of a drug resistance trait into a risk group 2 or 3 agent**		III-A-1-a; III-B-2
R* ☐	**Transfer of a drug resistance trait into a risk group 4 or a Select Agent** see also 42CFR73, 7CFR331, 9CFR121 for more information regarding Select Agents Regulations		III-A-1-a; III-B-2
S. ☐	**Research involves animals that require non-standard housing for laboratory animals; Large Animal Containment or special family housing allowances (e.g. mini-pig, goat, family-housed transgenic NHP, etc.)**		Appendix Q

NOTE for boxes ***Q* & ***R*** :

Per the *NIH Guidelines*: Section III-A-1-a. The deliberate transfer of a ***drug resistance trait*** to a microorganism, that is not known to acquire the trait naturally, when such a manipulation could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture, is considered to be a ***Major Action*** and requires federal Recombinant Advisory Committee (RAC) review. If either box Q or R, are checked, please provide the drug resistance information in the Project Summary (Section 7).

SECTION 9. Biosafety Level Containment and Risk Group Information

Note: more than one option may apply to your project; check all boxes that apply to this research application

Please reference the *NIH Guidelines*: Sections: II-A-1, IV-B-7-c, Appendix B and Appendix G

1. Indicate your assessment of the risk groups (or class) of ALL material(s) used in the research project

☐	Risk Group 1	Agents are *Not* associated with disease in healthy adult humans
☐	Risk Group 2	Agents are associated with human disease that is rarely serious for which preventive or therapeutic interventions *ARE OFTEN* available
☐	Risk Group 3	Agents are associated with serious or lethal human disease for which preventive or therapeutic interventions *MAY* be available
☐	Risk Group 4	Agents are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are NOT USUALLY available

2. Indicate *ALL* biosafety level(s) at which work is performed

Note: more than one biosafety level may apply to your project; check all boxes that apply

☐	BSL-1/ABSL-1	**Low risk agents (generally risk group 1) of minimal potential hazard to laboratory personnel and the environment** • Work is done on open bench tops; physical containment devices are usually not required • Standard microbiological practices are observed (washing hands and disinfecting exposed surfaces upon completion of work; all liquid and solid wastes potentially contaminated with recombinant or synthetic nucleic acids are decontaminated before disposal) • Biohazard signs should be posted
☐	BSL-2/ABSL-2	**Moderate risk agents (generally risk group 2) of moderate potential hazard to laboratory personnel and the environment** All the above BSL-1 containment and practices *plus the following*: • Access to laboratory is restricted when experimental work is in progress • Personnel have specific training in handling of pathogenic agents • Extreme precautions taken with use and disposal of contaminated sharps • Biological safety cabinets (BSC) or other physical containment devices are used for procedures with a high potential to create aerosols or when high concentrations or large volumes of microorganisms are used • Wastes are chemically inactivated or autoclaved before disposal from laboratory • Biohazard signs must be posted • Personal protective equipment (PPE) and entrance requirements must be met • Spills and accidents that result in exposures to organisms containing recombinant or synthetic nucleic acid molecules are immediately reported to the IBC using the Incident Reporting Form*

***IBC Incident Reporting: Investigators are required to report accidental exposures, spills, or loss of containment**

SECTION 9. Biosafety Level Containment Information (Continued)		
NOTE: For Research proposed at BSL-2+ and above, an inspection of laboratory facilities and a completed Biosafety Operations Manual are REQUIRED for IBC approval; contact the NJIT Environmental Health and Safety (EHS) for additional information 973-596-3059		
☐	**BSL-2+** (may also be known as BSL-2 Enhanced)	**Moderate-High risk agents (generally risk groups 2 or 3), BSL-2 containment with specific BSL-3 practices** All the above BSL-2 containment and practices *plus the following*: • Laboratory access is restricted at all times • Personnel have specific training in handling of agents; *Section 19 must be completed* • All manipulations of infectious and/or, recombinant or synthetic nucleic acid containing materials must be performed in biological safety cabinets (BSC) • Additional containment devices must be used to minimize creation of aerosols (e.g., centrifuge safety cups) • Written safety policies provided by the investigator defining laboratory procedures including appropriate PPE, waste disposal, disinfection and medical surveillance (Biosafety Operations Manual) • Spills and accidents that result in exposures to organisms containing recombinant or synthetic nucleic acid molecules are *immediately* reported to the Biosafety Officer (BSO) and the IBC using the Incident Reporting Form*
☐	**BSL-3**	**Indigenous or Exotic agents which may cause serious or potentially lethal disease, via respiratory exposure (inhalation); High risk agents (generally risk group 3), BSL-3 containment facilities, and practices** All BSL-2 containment and practices *plus the following*: • Specific facility design parameters must be followed, including requirements for location, ventilation, room integrity and security • Facility must be commissioned according to NJIT safety office protocols • Laboratory access is restricted at all times • Personnel have specific training in work practices at BSL-3 as well as handling of agents; *Section 19 must be completed* • All manipulations of infectious and/or, recombinant or synthetic nucleic acid containing materials must be performed in biological safety cabinets (BSC) • Respiratory protection required • Facility, and laboratory procedure-specific written safety policies provided by the investigator defining laboratory procedures, waste disposal, disinfection and medical surveillance (Biosafety Operations Manual) • Specific medical surveillance and/or vaccination requirements may apply • Limitation of work to specific facilities (RBL) or additional agent-specific practices (NIH BL3-Enhanced) may be required for work involving certain agents (e.g. Select Agents and Toxins; Risk Group 3 Influenza Viruses)
☐	**RBL**	RBL and NIH BL3-Enhanced practices if required

***IBC Incident Reporting: Investigators are required to report accidental exposures, spills, or loss of containment**

SECTION 10. Biosafety Risk Information ***NOTE: Protocols using BSL-2 or higher must be registered with NJIT Environmental Health and Safety Department***			
1. Provide the date of your most recent laboratory inspection; if unknown, contact EHS at 412-624-9505			
2. Describe whether the agent(s) used in the course of this research may be infectious to humans (i.e. replication-competent vector vs. single-round of infection; potential for integration of vector into host chromosomes; use of human cells or cell lines that may harbor unknown infectious agents)			
3. Describe any procedures that may increase risk for accidental exposure to personnel via percutaneous or mucous membrane exposure routes or environmental release (e.g. use of needles, centrifugation, *in vivo* studies)			
	Indicate Yes/No in check boxes:	**Yes**	**No**
4. Does the research involve any potential for airborne transmission of agent(s)?		☐	☐
5. Please describe procedures, including any personal protective equipment, work practices, and/or engineering controls (such as a Biological Safety Cabinet) that will be used to mitigate potential risks identified in questions 3 and 4 above			
6. Describe the methods used for proper decontamination (e.g. specific disinfectant or physical decontamination method used) and disposal of the following (if applicable): **For more information see NJIT Environmental Health and Safety Review and Approval Checklist For Laboratories.**			
a) solid waste(s)			
b) liquid waste(s)			
c) animal carcass(es)			

To register with Environmental Health and Safety telephone: 973-596-3059

SECTION 11. Investigator Experience and Training Requirements		
Indicate Yes/No in check boxes:	**Yes**	**No**
1. Does the investigator have prior experience with organisms (viruses, bacteria, fungal agents, etc.), vectors, or recombinant materials described in this application? • **If *YES*, provide the number of years of laboratory and safety experience working with these materials** • **If *NO*, describe training and/or experience with relevance to biosafety in microbiological and biomedical laboratories**	☐	☐
2. Please list all current training, including on-line modules, live sessions, etc., relevant to the proposed work that will support IBC approval of research with the recombinant materials described. Specifically identify the training such as: Chemical Hygiene, BBP, General laboratory safety, required IACUC training, etc.		
***NOTE: For all research applications at BSL-2+ or above, Section 19 is required to be completed.* All personnel listed in Section 19 of the application must be current with applicable Health and Safety training in order to obtain IBC Approval for research performed at BSL 2+ and higher**		

For additional information on decontamination, contact Environmental Health and Safety telephone: 973-596-3059

SECTION 12. Vectors, Hosts, and Recombinant or Synthetic Nucleic Acid Molecules Used ***Do not leave blanks*** If the question is not applicable to your research, indicate: ***NONE*** or ***N/A*** (not applicable)			
If desired, insert vector map(s) at the end of the application in Section 20 (Additional Materials).			
1. List the organisms (bacteria, viruses or fungi, etc.) used in the research. • **Provide the specific strains of organisms to be used** • **Describe how these organisms will be used in the research** • **If no such organisms are used, state *NONE***			
2. List any known oncogenes or toxins that will be expressed and identify the expression system(s) used for expression			
	Indicate Yes/No in check boxes:	**Yes**	**No**
3. Does the research include any oligonucleotides used to manipulate gene function (e.g. siRNA, shRNA, etc.) • **If *NO*, skip down to question 6**		☐	☐
4. What genes will be expressed or targeted for altered expression (knockdown)?			
5. What type of vector is used with the oligonucleotides?			
6. Is there any potential for increased virulence by manipulation of any of the nucleic acid molecules or genes listed above with respect to the vector or organism? • **If *NO*, skip to question 8**		☐	☐
7. Explain the details regarding the potential for increased virulence and provide the steps taken to mitigate the risks involved with the increased virulence			
8. List all cell lines or eukaryotic cells *including commercially available* human cell lines (e.g. CHO, COS, or HEK 293 cells) to be used in the research • **State the species of origin of each of the cell lines used** • **If no cells are used, state *NONE* in the first column**	Cell line	Species of Origin	
9. List other *non-vertebrate* organisms (e.g. amoebas, nematodes, drosophila); *not under IACUC purview* • **If no such organisms are used in this research, state *NONE* and go to the next section**			
10. If transporting or shipping genetically modified arthropods or insects, provide the authorized transport permit number and agency source(s) Reference 7 CFR 340 • **If it does not apply, state *N/A* and go to the next section**			

SECTION 13. Biosafety Information; Use of Viruses/Viral Vectors

If the question is not applicable to your research, state: ***NONE*** or ***N/A*** (not applicable)

1. List viruses and/or viral vectors used in this research project.

- **If more than one virus or viral vector is used, please number or organize the responses accordingly across the three boxes (examples follow below):**

A. Specify the Virus Family and/or Subfamily – please be specific for strains	**B. Identify the species of origin or preferred host for *each* virus or vector used**	**C. Identify whether the virus is a recombinant and/or wild type strain for each one listed**
Example: 1) Herpesvirus: HHV-8 2) Oncogenic Retrovirus: RSV, HTLV-1 3) Adenovirus: Ad-14 4) Bacteriophage	Example: 1) human 2) avian, human 3) human 4) bacterial	Example: 1) wild type 2) recombinant 3) recombinant 4) recombinant, etc.

	Yes	**No**
Indicate Yes/No in check boxes:		
2. Does the project involve the use of Lentiviruses or Lentiviral vectors? • **If *YES*, Section 14 must also be completed**	☐	☐

3. List inserted Nucleic Acids used in this proposal including both: the species (*column A*) from which the insert is derived *and* the gene product (*column B*) that is to be expressed • **If no inserts are used, state *NONE* under the first column**	**(A) Species**	**(B) Gene Product**

4. Is there any potential for increased virulence with insertion of the Nucleic Acid molecules listed above into the vector or organism? • **If *NO*, skip to question 6**	☐	☐
5. Describe the potential of this research for increased virulence and what steps will be taken to mitigate the risks of transmission: • **Note: virulence may be increased by changing existing sequences without introduction of new sequences (i.e. mutations in viral genes "mutants")**		
6. Is the virus or viral vector able to *enter or infect human cells* including cell lines, such as 293 cells? Please consider risks to laboratory workers from Section 10.	☐	☐
7. Is the virus/viral vector replication-defective (replication incompetent)? • **Note: if lentivirus are being used in this research, Section 14 also must be completed**	☐	☐
8. Is the biosafety level of any replication-defective virus described in this application different from the generally accepted BSL for work with the wild type virus? • **Lentiviral** • **Adeno Associated Virus (AAV)** •	☐	☐
9. Is any portion of this work to be considered for a downgrade in biosafety containment level from the currently accepted standards at NJIT? • **If *YES*: provide downgrade information either within the Project Summary (Section 7) or amend additional materials to Section 20 to support consideration to downgrade the biosafety containment level for the work** • **Note that downgrade requests are based on safety considerations** • **Downgrade requests are not guaranteed approval**	☐	☐

SECTION 14. Use or manipulation of Lentivirus or Lentiviral Vectors ***NOTE: If your work does <u>not</u> use lentiviruses or lentiviral vectors, skip to 15***			
***NOTE*: It is not required that vectors generated with 4-plasmid lentivirus systems (3rd generation vectors) be tested for replication-competent virus. However, 3-plasmid vector lentivirus systems (2nd generation vectors) must be shown to be free of replicating virus for approval at BSL-2 (for example, you must provide data or the results of a RCV assay). Please contact IBC for guidance.**			
1. List the specific lentiviral strain and species of origin (e.g. HIV-human; FIV-feline; SIV-simian). For more information refer to the NJIT IBC for Lentiviral Guidance			
	Indicate Yes/No in check boxes:	**Yes**	**No**
2. Is the lentivirus/lentiviral vector generated/produced in your laboratory?		☐	☐
3. Provide the name(s) of the source of the lentivirus or lentiviral vector(s) • **The company name or investigator name(s) and/or institution(s)**			
4. Is the lentiviral vector produced from a multi-component system? (e.g., separate plasmids for packaging, envelope and gene transfer)		☐	☐
5. Has the replication-defective vector been tested for replication-competent virus (RCV)? • **Please describe the safety features of each different lentivirus or lentiviral vector system that is used in this research in the text box below:**		☐	☐
6. Please state the expected volume of vector to be produced or received for each lentivirus or lentiviral vector			
7. Please list the transgenes used (the genes inserted) in each lentivirus or lentiviral vector • **If no transgenes are used or inserted, state *NONE* in the text box**			
8. Will lentiviruses be used to generate stable cell lines? • **If *NO* (no cell lines are generated using: lentivirus, lentiviral particles, lentiviral vector, and/or plasmids containing genes from lentivirus) continue to the next section**		☐	☐
9. Provide the number of passages of the transduced cell lines prior to experimental use (e.g., administration into in vivo models)			

SECTION 15. Animal Use Information, Part I

Reference *NIH Guidelines* II-A-1, Appendix B, III-E-3

NOTE: If you are obtaining cells or tissues from live vertebrate animals under an IACUC protocol specific to this research, or you plan on administering recombinant or synthetic nucleic acid molecules/materials to animals, (*including cells from other genetically modified animals, or transformed cells*) you must complete this section

Indicate Yes/No in check boxes:	**Yes**	**No**
1. Does the work involve live (living) vertebrate animals? • **If *NO* skip to Section 17**	☐	☐
2. Is there an Institutional Animal Care and Use Committee (IACUC) application submitted or approved for this research involving recombinant or synthetic nucleic acid molecules? • **If *YES* provide the IACUC protocol number(s) to be linked to this IBC project** • **NOTE: If you are *not* the named Principal on the linked animal protocol application, provide the name of the investigator on the IACUC protocol in addition to the IACUC protocol number** ***ATTENTION*: *Research described in an IACUC protocol involving materials under IBC oversight must correspond to an approved IBC protocol***	☐	☐
Need more information? Contact the IBC (IBC@njit.edu)		
3. Will tissues, cells, or organs from animals be used in *in vitro* experiments? For example, do you plan to harvest tissues for culture or biometric-analysis? • **If *YES*, please review *Section 7* (Project Summary) to ensure the details are provided**	☐	☐
4. Will transgenic, knockouts, gene-targeted, or other genetically engineered animals be used? • **If *NO* go to question 7 below**	☐	☐
5. Does the project involve rodents (parental or offspring) that contain more than 50% of the genome of an exogenous eukaryotic virus from a single virus family?	☐	☐
6. Does the project involve rodents where a transgene is under the control of a gammaretroviral long-terminal repeat (LTR) and where the LTR is functional?	☐	☐
7. Will recombinant or synthetic nucleic acids be *administered to live or intact animals*? Injection of viral vectors, *transfected cells*, plasmids, or the *transplantation of genetically modified cells*, tissues or organs into animal research subjects that fall under IACUC oversight • **If *YES*, continue to the next Section, 16 (administration to living animals)** • **If *NO:* breeding only protocols are complete, or continue to Section 17 if other reagents are used in this research that require IBC oversight**	☐	☐

SECTION 16. Animal Subjects Involvement; Part II Reference *NIH Guidelines* II-A-1, Appendix B, III-E-3 Complete this section for administration of recombinant or synthetic nucleic acid molecules into live animal subjects			
1. What are the target cells/tissues/organs for the recombinant/synthetic genetic material?			
2. List ALL recombinant/synthetic nucleic acid molecules or materials to be administered to animals: ➢ **include both transformed or infected cells and any vectors (viral or non-viral)** ➢ **For cells, identify the vector(s) used to modify the cells prior to administration** ➢ ***If in doubt, investigators are encouraged to contact the IBC (IBC@njit.edu)***			
	Indicate Yes/No in check boxes:	**Yes**	**No**
3. Do you anticipate that work with the live animal subjects will be conducted at a different BSL than the *in vitro* or wet bench portions of the study? • **If *NO* go to question 5**		☐	☐
4. Explain the requirement for different containment requirements for the work with the animals. If this requirement is related to a downgrade request, please ensure that appropriate support of the position is detailed within the application			
5. Provide the animal species (and strain if applicable) receiving the experimental agents; be sure to list each species to be used			
6. Describe the route of administration for each experimental agent used *in vivo* and per species as applicable			
7. Provide the concentration and volume for each recombinant or synthetic nucleic acid molecule to be administered and per species			
NOTE TO ANIMAL USERS: For animal research involving the administration of experimental agents/materials at BSL-2 or higher, the NJIT Institute Animal Care & Use Committee must be notified.			

SECTION 17. Human Subjects Involvement

Reference *NIH Guidelines* III-B, III-C

The term "*primary cells*" indicates that the cell cultures are *directly* derived from human tissues, cells or samples

Please visit the http://www.njit.edu/policies/pdf/human_subject_research.pdf for additional information regarding human subjects research and human subjects protection

Indicate Yes/No in check boxes:	**Yes**	**No**
1. Does work involve human subjects, unfixed human tissues or blood, or **primary* human cell cultures that are *obtained directly from human participants*? • **Cell lines available commercially (e.g. from a cell bank such as *ATCC*) do not qualify as *primary cells, as they are generally immortalized)** • **If *NO* skip to the next Section (Section 18)**	☐	☐
2. Has an Institutional Review Board (IRB) application been submitted through OSIRIS? • **IRB Exemption information : http://www.njit.edu/policies/pdf/human_subject_research.pdf** • **If *NO* skip to question 4**	☐	☐
3. Provide the IRB protocol (preferred) or the IRB submission date		
4. Will human tissues or primary cells* be used *in vitro*? • **If *NO* skip to question 6**	☐	☐
5. Describe the use of the tissues or cells in your research if not described in the Project Summary, Section 7		
6. Is this a gene transfer proposal (deliberate transfer of Recombinant or Synthetic Nucleic Acid Molecules or DNA or RNA derived from Recombinant or Synthetic Nucleic Acid Molecules into human subjects)? See information box below.** • **If *YES*, Attachment 1 and other supporting documents must be submitted for review of a new human gene transfer proposal** • **Please contact the IBC Office for additional information regarding clinical trial review of human gene transfer proposals**	☐	☐

****What is Human Gene Transfer?**

Human Gene Transfer is defined in *Section III-C-1 of the NIH Guidelines* as the deliberate transfer into human research participants of either:

1) Recombinant nucleic acid molecules or DNA or RNA derived from recombinant nucleic acid molecules
2) Synthetic nucleic acid molecules or DNA or RNA derived from synthetic nucleic acid molecules that meet any ONE of the following criteria:
   - A. Contain more than 100 nucleotides
   - B. Possess biological properties that enable integration into the genome (for example, cis elements involved in integration)
   - C. Have the potential to replicate in a cell
   - D. Can be translated or transcribed

SECTION 18. Research Facilities Information; Part I

Facilities: Locations where the recombinant or synthetic nucleic acid molecule research will be conducted

Indicate Yes/No in check boxes:	**Yes**	**No**
1. Is this "research" for a "Core Facility" with the goal or mission of production and distribution of materials to other research laboratories?	☐	☐
2. Are recombinant or synthetic nucleic acid molecules or materials manufactured by or obtained from an outside/external source (e.g. commercial vendor)? • **If *NO* skip to question 4**	☐	☐
3. Identify the materials obtained, and the sources responsible for providing the materials		
4. Are recombinant or synthetic nucleic acid molecules or materials produced by or obtained from another collaborating researcher or "Core" facility? • **If *NO* skip to question 6**	☐	☐
5. Identify the materials obtained from NJIT laboratory facilities and provide the IBC registration number for each laboratory		

6. Provide facilities information for *all* locations, including the facility used for work with animals or tissue culture, as applicable to your described project.

- **Provide the procedures performed in each location, for example, cell transfections, propagation of plasmids, administration of viral vector into animals, animal housing, etc**
- **Provide the EHS approved biosafety level of the location- *not the procedural biosafety level***
- **If a specific site is not currently EHS approved, please provide an explanation as to why the site does not have approval (e.g. a clinical site may be approved under the UPMC Dept of Infection Control)**
- **If more than 4 locations, please list the additional facilities under Section 20**

Location #1	Room number and building	
	Describe procedures for this location	
	Provide approved biosafety level	
Location #2	Room number and building	
	Describe procedures for this location	
	Provide approved biosafety level	
Location #3	Room number and building	
	Describe procedures for this location	
	Provide approved biosafety level	
Location #4	Room number and building	
	Describe procedures for this location	
	Provide approved biosafety level	

SECTION 19. Personnel and Training Information

This information is ONLY required for applications with a designated containment of BSL-2+ or higher at this time

- List only the personnel working with the materials described in this application in the laboratory
- Please list each individual on a separate line, be sure to include all pertinent information
- Listed personnel must be current on all applicable Health and Safety training prior to IBC granting approval
- To expedite IBC approval of your research, please verify current training certificates.
- Any questions regarding EH&S training programs and certification should be directed to EH&S at **412-624-9505**

Name	E-mail address	University Identifier *

*** What is the University Identifier?**

The unique identification number employee ID number and is specific to individuals.

Important information regarding Facilities Inspections and Biosafety Operations Manuals

For laboratories intending to operate at BSL-2+ (BSL-2 enhanced) or higher, the IBC will NOT provide approval for the research until the following conditions are verified:

- A Biosafety Operations Manual must be reviewed and approved by the University Biosafety Officer (BSO), Biohazards Committee, and other authorized officials as required for the designated biosafety level
- Lab facilities must be inspected by the Department of Environmental Health and Safety.

For questions, or to schedule an inspection appointment, contact the EHS Office via phone at (**973-596-3059)**

Section 20: Additional Materials

Insert any additional materials below if desired. For example, restriction map(s), host-vector diagrams, data or informational reference materials in support of a lower BSL, detailed preparatory information that does not fit into the provided space, etc. These materials will be reviewed by the IBC members and become part of the record for this research.

IBC Protocol:

Attention Reviewers:

1) Please refer to the IBC Conflict of Interest Policy, and if you have cause to recuse yourself from the review of a proposal, please inform the IBC Office staff immediately, so that the application under review is not unnecessarily delayed.

2) When preparing comments/concerns for the investigator to address, reference the section(s) and question number from the application.
   -Word comments carefully; ***the IBC Office Staff will send comments verbatim to the investigator*** for response.
   - Use explanations and examples to assist the investigator in understanding the concerns. It is appropriate to cite the *NIH Guidelines* or IBC Policies in support of concern(s)
   - **Try to avoid personal pronouns (e.g. I, you)**

3) Keep in mind that all materials reviewed by committee members may be determined to be confidential, and as such, must be appropriately safeguarded.

4) Have concerns, questions about review? Contact the IBC Office (IBC@njit.edu)

IBC reviewer evaluation, summary or concerns:	
Reviewer recommendation: (Mark an "X" in the blue-shaded box)	
	Approval; no revisions required. Current application is approvable
	Approval pending; minor revisions required A revised application is required for approval
	Additional information required; substantial revisions are needed or important information is missing from the application
	Defer to convened meeting; biosafety issues are identified which required full committee discussion

IBC reviewer evaluation, summary or concerns:	
Reviewer recommendation: (Mark an "X" in the blue-shaded box)	
	Approval; no revisions required. Current application is approvable.
	Approval pending; minor revisions required A revised application is required for approval
	Additional information required; substantial revisions are needed or important information is missing from the application
	Defer to convened meeting; biosafety issues are identified which required full committee discussion