ALBERT EINSTEIN COLLEGE of MEDICINE
ENVIRONMENTAL HEALTH and SAFETY

Document of Registration (DOR)

Registration of Recombinant DNA and Research Involving Infectious Material

Application Status: ☐ New Submission ☐ Renewal

EH&S Use Only

Current DOR:_____

Date Received:_____ Date Expires:_____

Risk Group or Biosafety Level

☐ 1 ☐ 2 ☐ 3

This form must be completed to register biological materials (recombinant or synthetic nucleic acid molecule, human derived materials, non-human primate derived materials, select agents, microorganism and biotoxins with LD50 < 100 micrograms per kilogram of body weight in vertebrates) with the Institutional Biosafety Committee (IBC). This registration document is based on NIH Guidelines https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf

SECTION 1

Please Type or Print (unreadable forms will be returned)		
Principal Investigator:		
Department:		FAX:
Office Address:	Phone:	Email:
Lab room(s) where work will be performed:		Lab phone:

All Principal Investigators must report the acquisition, discovery, disposal or transfer of any poliovirus or poliovirus potentially infectious materials to the biosafety officer. The information will be collected and reported to the Institutional Biosafety Committee and US National Authority for Containment of Poliovirus (NAC) at the Center for Disease Control and Prevention (CDC).

Do you have any poliovirus or poliovirus potentially infectious materials? **Yes** ☐ **No** ☐

Please provide a brief summary of the proposed work (Attach additional sheets if necessary)

List names and position of those who may be involved in working with the agents listed in this registration (Attach additional sheets if necessary)	

This project will require obtaining, receiving, or handling, for research purposes the following:		
Human tissue, including blood or blood products, secretions, body fluids:	Yes ☐ No ☐	
Organ or primary cell line derived directly from human tissue:	Yes ☐ No ☐	
Toxins which are known to affect humans:	Yes ☐ No ☐	If yes, please specify:
Toxins which are known to affect animals:	Yes ☐ No ☐	If yes, please specify:

ALBERT EINSTEIN COLLEGE of MEDICINE
ENVIRONMENTAL HEALTH and SAFETY

List of Infectious Agent(s):	Risk Group (check appropriate)	
	BSL 1 ☐ BSL 2 ☐ BSL 3 ☐	In vitro ☐ In vivo ☐
	BSL 1 ☐ BSL 2 ☐ BSL 3 ☐	In vitro ☐ In vivo ☐
	BSL 1 ☐ BSL 2 ☐ BSL 3 ☐	In vitro ☐ In vivo ☐
	BSL 1 ☐ BSL 2 ☐ BSL 3 ☐	In vitro ☐ In vivo ☐

SECTION 2

☐ **My project does not involve recombinant DNA**

Please check all that apply

IIIA – IBC, RAC, NIH Director Approval needed before starting experiment –

☐ Deliberate transfer of a drug resistance trait to a microorganism that is not known to acquire that trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine or agriculture.

IIIB – NIH/OBA and IBC Approval needed before starting experiment -

☐ Cloning of toxin molecules with LD50 of less than 100 nanograms per kilogram body weight (such as microbial toxins – botulinum toxin, tetanus toxin, diphtheria toxin, S. dysenteriae neurotoxin).

IIIC – IBC, IRB and RAC approval needed before starting experiment -

☐ Deliberate transfer of rDNA or DNA or RNA derived from rDNA into 1 or more human research participants (human gene transfer).

IIID – IBC approval needed before starting experiment -

☐ Experiments using risk group 2, risk group 3, risk group 4, or restricted agents as host-vector systems

☐ DNA from Risk Group 2/3/4 or Restricted Agents is cloned into non-pathogenic prokaryotic or lower eukaryotic host-vector systems

☐ 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

☐ Experiments involving whole animals – the animal's genome has been altered by stable introduction of recombinant DNA into transgenic animals and experiments involving viable recombinant DNA-modified microorganisms tested on whole animals.

☐ Experiments involving > 10L of culture

IIIE – IBC Notification sent at time of experiment initiation -

☐ Experiments involving the formation of rDNA molecules containing no more than 2/3 of genome of any eukaryotic virus

☐ Experiments involving the generation of rodents in which the animal's genome has been altered by stable introduction of recombinant DNA into the germ line (transgenic rodents).

IIIF – Exempt -

☐ Purchase or transfer of transgenic animals.

Exempt -

☐ Experiment not listed above

ALBERT EINSTEIN COLLEGE of MEDICINE
ENVIRONMENTAL HEALTH and SAFETY

Biosafety Cabinet (BSC)		
Work performed at BSL 2 or above requires the use of a Biosafety Cabinet. The Biosafety Cabinet requires annual certification.		
Will this work be performed in a BSC?	Yes ☐ No ☐	**Location:**
Has the BSC been certified?	Yes ☐ No ☐	**Expiration date:**

SECTION 3

DNA INSERT (S):		
Specify source and nature of the DNA sequence(s) to be inserted (genus, species, gene name, abbreviation and function of the gene):		
Will the inserted gene(s) be expressed?	Yes ☐ No ☐	
If yes, what is the biological activity of the gene product or sequence inserted? (Specifically, any toxicity, increase virulence, oncogenic potential or ability to alter cell cycle).		

VECTOR (S):		
Describe the virus, phage and/or plasmid used for constructing recombinants:		
Identify host cell(s) or packaging cell line in which recombinant vector will be amplified:		
Is the vector replication competent?	Yes ☐ No ☐	
Are any viral component(s)/sequence(s) present? If yes, specify the nature of the viral component (s):	Yes ☐ No ☐	
Does the insert contain >2/3 of viral genome?	Yes ☐ No ☐	
Is helper virus used?	Yes ☐ No ☐	If yes, specify:

ALBERT EINSTEIN COLLEGE of MEDICINE
ENVIRONMENTAL HEALTH and SAFETY

HOST (S):		
Indicate cell line (s) and species: (If E. coli, please provide strain)		
Are viral sequences present in the host that could recombine with the vector and lead to replication competent constructs?	Yes ☐ No ☐	If yes, specify:
Does the project involve the use of transgenic animals?	Yes ☐ No ☐	
Will animal(s) be exposed to rDNA or infectious agents?	Yes ☐ No ☐	If yes, specify:
Can the infected animal(s) release this microorganism into the environment (excreted into bedding etc)?	Yes ☐ No ☐	
Will transgenic animals be purchased or transferred as part of this research?	Yes ☐ No ☐	
Has the Institutional Animal Care and Use Committee been notified?	Yes ☐ No ☐	

SECTION 4

Please answer each question:		
* Will this research render a vaccine ineffective?	Yes ☐ No ☐	
* Will this research involve the deliberate transfer of a drug resistance trait to microorganisms, other than antibiotic resistance genes used for cloning bacteria?	Yes ☐ No ☐	
* Will this research enhance the virulence of a pathogen or render a non-pathogen virulent?	Yes ☐ No ☐	
* Will this research involve the cloning of toxin molecules with LD50 < 100 ng/kg of body weight.	Yes ☐ No ☐	
Will this research enable the weaponization or a biological agent or toxin?	Yes ☐ No ☐	
Will this research produce any other hazards not listed above?	Yes ☐ No ☐	If yes, specify:

See section 2 and check appropriate box(es)

By signing below, I certify that I have provided accurate information regarding my research project and that I have read the following statements and agree that I and all listed participants will abide by those statements and all Einstein policies and procedures governing the use of recombinant or synthetic nucleic acid molecule, infectious agents and other biological materials, as outlined in this application. I will:

- Ensure all personnel on the project know where to seek medical attention and know how to report all incidents involved in this project.
- Accept responsibility for maintaining a safe working environment, for training all personnel and informing them of the hazards associated with this protocol before any work begins on this project and at least annually thereafter.
- Submit in writing a request for approval from the Institutional Biosafety Committee (IBC) of any significant modifications to the study, facilities, or procedures.

Signature of Principal Investigator: _____ Date: _____

Return Original Document of Registration (DOR), to: Delia Vieira-Cruz, Biosafety Officer - Forchheimer 800
delia.vieira-cruz@einsteinmed.edu