Downstate Biotechnology Incubator Application

Business Name: _____

SECTION I: CONTACT INFORMATION

Contact Person		
Dr. ☐ **Mr.** ☐ **Ms.** ☐	**First Name**	**Last Name**
Phone #:	**Mobile Phone #:**	**Email:**

SECTION II: BUSINESS INFORMATION

Current Business Address:

_____
Number and Street

_____
City, State and Zip Code

_____
Phone # *Fax #* *Email*

Principal #1:

Dr. ☐
Mr. ☐
Ms. ☐

_____ _____ _____
First Name *Last Name* *Title*

_____ _____ _____
Ownership (%) *Phone #* *Email*

Principal #2:

Dr. ☐
Mr. ☐
Ms. ☐

_____ _____ _____
First Name *Last Name* *Title*

_____ _____ _____
Ownership (%) *Phone #* *Email*

Principal #3:

Dr. ☐
Mr. ☐
Ms. ☐

_____ _____ _____
First Name *Last Name* *Title*

_____ _____ _____
Ownership (%) *Phone #* *Email*

Please attach separate sheet(s) for any additional Principals.

Effective April 2018
TENAPP0418

Other Person(s) Authorized to Negotiate/Contract on behalf of Business:

Dr. ☐
Mr. ☐
Ms. ☐

First Name	*Last Name*	*Title*
Phone #	*Email*	

Dr. ☐
Mr. ☐
Ms. ☐

First Name	*Last Name*	*Title*
Phone #	*Email*	

Please attach separate sheet(s) for any additional authorized persons.

Describe exactly what the Company will do in the space:

_____

_____

_____

_____

_____

Business Operations began/will begin in (month/year):_____ Incorporated in: State _____ Year _____

Capitalization $_____ FY 20___ Operating Budget: $_____ FY 20___ Sales Revenues: $ _____ FY 20___

Number of Employees: _____ Full Time _____ Part Time _____Research/Science _____ Tech/Other

Describe how the Company will create a symbiotic relationship with SUNY Downstate Medical Center (e.g., internships, hiring graduates, collaborations, teaching, etc.).

_____

_____

_____

SECTION III: START-UP NY

Are you interested in applying for START-UP NY? ☐ Yes ☐ No ☐ Already a member of START-UP NY

If the Company is not incorporated in New York State, has it registered with the New York Secretary of State as a "Foreign Company Doing Business in New York State"? ☐ Yes ☐ No

SECTION IV: REQUIREMENTS

Approximate Space Required: Wet Lab _____ SF Office/Other _____ SF Total _____SF

Required Start Date of Occupancy (approx): Month _____ Year ____ Length of Occupancy (approx): _____ yrs

	Required	Number (if applicable)
Vacuum	☐	
Fume Hoods (1 per lab)	☐	
Biosafety Hoods	☐	
Gas	☐	
Benches	☐	
Animal facility	☐	
Other (specify):		

NO RADIOACTIVITY CAN BE USED IN THE INCUBATOR

SECTION V: COMPANY OPERATIONS

Please provide descriptions for each of the following as they pertain to your space usage and requirements. Attach additional sheets if necessary.

☐ **HUMAN SAMPLES** ☐ **Not Applicable**

Specimen type:

☐ Blood

☐ Body fluid
Type: _____

☐ Cell/Organ/Tissue
(Both primary and commercially procured)
Name: _____

☐ Cell line/culture
Name: _____

Known hazards and infectious agents and required Biosafety level for proper handling (e.g., HIV-1, HBV, HCV):

_____

_____

Describe measures to protect personnel: _____

_____

_____

_____

☐ **INFECTIOUS AGENTS** (attach additional forms for each infectious agent) ☐ **Not Applicable**

Is this agent infectious to animals? ☐ No ☐ Yes

Is this agent infectious to humans? ☐ No ☐ Yes

Does this agent elaborate a toxin? ☐ No ☐ Yes

Is there a vaccine available for use in humans against this agent or its components?
☐ No ☐ Yes _____

Identify any precautionary medical practices that will be implemented, if any _____

Identify all personnel who will work on this project, providing documentation indicating their level of training and experience in working with infectious agents. List all certifications required by FDNY, including C-14 Certificate of Fitness for Non-Production Chemical Laboratories:

If a bacterial agent, provide an antibiogram: (attach additional sheets as needed)

How is the infectious agent propagated in the laboratory?

Specify methods of inactivation/decontamination and disposal of the agent or contaminated materials:

How will the agent stored in your laboratory?

☐ **ANIMAL WORK** ☐ **Not Applicable**

Will you be working with animals? ☐ Yes ☐ No

If yes, where will this be done? _____

☐ **RECOMBINANT DNA** ☐ **Not Applicable**

Are recombinant DNA procedures used in your laboratory limited to PCR amplification of DNA fragments (i.e., no subsequent cloning of amplified DNA)?

☐ Yes (Only check this if your recombinant DNA studies are exempt from restrictions described in the *NIH Guidelines for Research Involving Recombinant DNA Molecules*).

☐ No (Please provide the following information using a separate table for each gene):

Biological source of DNA or gene (2):			
Name and function of the gene:			
Selectable marker			
Host:			
Cell/animal recipient:			
Assessment of levels of physical and biological containment (consult current *NIH Guidelines for Research Involving Recombinant DNA Molecules* at http://www.nih.gov/od/orda/toc.html)	☐ Risk group 1 ☐ Risk group 2 ☐ Risk group 3	☐ BSL - 1 ☐ BSL - 2 ☐ BSL - 3	☐ Animal BSL-1 ☐ Animal BSL-2 ☐ Animal BSL-3

☐ **TOXIC/HAZARDOUS SUBSTANCES** ☐ **Not Applicable**

Name of the toxic/hazardous substance (include carcinogenic, mutagenic, teratogenic substances):
Attach a Material Safety Data Sheet (MSDS) for each substance.
Each Company must maintain on-site an up-to-date file of MSDS documents for each reagent in their lab.

_____

_____

_____

_____

_____

Is this substance to be given to animals? ☐ No ☐ Yes

Amount of the substance to be kept in the laboratory:

Storage location: Use location:

Inventory control procedure:

Method of deactivation:

Risk of human exposure and containment procedure?
(describe measure to protect personnel)

_____

_____

_____

_____

☐ FLOW CYTOMETRIC HAZARD ASSESSMENT ☐ Not Applicable

1. Cells to be used:
   - ☐ Fresh or frozen animal cell
   - ☐ Fresh or frozen human cells
   - ☐ Cell lines

2. If a cell line to be used, indicate name(s)/designation(s):

3. If the cells are from human donors, were the donors screened for bloodborne pathogens?

   ☐ Yes; proceed to # 4 ☐ No; proceed to # 6

4. Any pathogens the sample may contain?

   ☐ None ☐ HIV ☐ HCV ☐ HBV ☐ Other

5. Has the infectious agent been inactivated?

   ☐ No ☐ Unknown ☐ Yes; describe method

6. Do the cells contain infectious agents such as viruses, bacteria, fungi, protozoa?

   ☐ No ☐ Yes; give name(s):

7. Were the cells genetically engineered?

☐ No
☐ Yes

Was a virus used?

☐ Adenovirus ☐ Retrovirus
☐ Lentivirus ☐ Herpes virus

☐ **CHEMICAL USAGE** (detail types, quantities, and method of storage) ☐ **Not Applicable**

The Company is responsible for the safe storage and handling of all chemicals, including appropriate disposal.

☐ **WASTE GENERATION** ☐ **Not Applicable**

[**Regulated Waste** means liquid or semi-liquid blood or other potentially infectious materials, chemical waste or hazardous substances; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials.]

Does your work generate waste that would be considered "regulated waste"? ☐ Yes ☐ No
If "Yes", detail types, quantities and disposal plan

- Will the waste be autoclaved before leaving the facility? ☐ Yes ☐ No
- Will the waste be "red bagged" before leaving the facility? ☐ Yes ☐ No
- Will you have sharps disposal containers appropriately placed in your laboratory? ☐ Yes ☐ No

The Company is responsible for the proper storage, handling and disposal of all regulated waste.

☐ **IS THERE SPECIALIZED EQUIPMENT YOU WILL BE USING THAT WE SHOULD BE AWARE OF?** ☐ **Not Applicable**

_____

_____

_____

Are you or do you plan on being CLIA (CLEP)? ☐ Yes ☐ No

Do you have a Safety Plan? ☐ Yes ☐ No ☐ Under Development
(All companies occupying laboratory space are required to have a Safety Plan.)

Company's Safety Officer is responsible for implementing company's safety plan and monitoring ongoing compliance. Please note the Company is responsible for all applicable safety guidelines, approvals and training.

Safety Officer Name: Phone #: Email:

This application has been completed by:

_____ _____ _____
Name Signature Date

Please submit this completed application along with your Business Plan, which includes R&D Plan, audited financial statements, resumes of principals, and supporting documentation to:

David Norton, Executive Director, Downstate Biotechnology Incubator 450 Clarkson Ave., MSC 129, Brooklyn, NY 11203-2098; Phone: 718-270-4632, Email: david.norton@downstate.edu