Icahn School of Medicine at Mount Sinai	***INSTITUTIONAL BIOSAFETY COMMITTEE NON-RECOMBINANT DNA RISK ASSESSMENT***

Instructions

When is this form used? This form is used to report activities that may pose a hazard to researchers working with biological agents, IND's, biological toxins, or biologically - active constructs that are ***not recombinant-DNA–derived,*** to the Biological Safety Officer and to the Icahn School of Medicine Institutional Biosafety Committee (ISMMS).

This form covers all research that is conducted in *in vitro* models or in human gene-therapy trials regulated by the ISMMS IRB as well as the ISMMS IBC.

Check off the appropriate items in each category and give the full name of the subject agent used in the therapeutic protocol where required. If you have questions contact the Biological Safety Officer in the Institutional Biosafety Program at Ext. 45169. Additional information can also be obtained at www.mssm.edu/biosafety .

If your project involves hazardous agents that are used *IN-VIVO IN EXPERIMENTAL ANIMALS*, the BIOSAFETY RISK ASSESSMENT section of the VERTEBRATE ANIMAL STUDY FORM is the correct form for reporting IND's, transgenic animals and early stage gene-therapy experiments to the IACUC and the IBC. Consultation with by the MSSM Biosafety Officer is required prior to submission of protocols to the ISMMS Grants and Contracts Office, IBC and the IACUC.

A copy of the IACUC ***Vertebrate Animal Study Form*** can be found at: http://ideate.mssm.edu The CDC –NIH publication Biosafety in Microbiological and Biomedical Laboratories is recommended for evaluating a biologically active molecule (such as a polypeptide construct or shRNA). It is available at: http://www.cdc.gov/biosafety/publications/bmbl5/bmbl.pdf

SECTION 1. GENERAL INFORMATION FOR ALL SUBMISSION TYPES

PROJECT TITLE:

APPLICATION NO: **GCO #00-0000** **IACUC LA# 00-00000**

STATUS: ☐ **New Proposal** ☐ **Renewal** ☐ **Funding Pending** ☐ **Funded**

Date when this protocol will begin: _____

Department : **e-mail:**

Phone : **MSMC Mail Box No.:**

Laboratory Building: ☐**Icahn** ☐**Annenberg** ☐**Atran-Berg** ☐**CMA** ☐**HESS-CSM**

☐**Other Location:**_____

Floor Number:_____ **Room Numbers:**_____

Total Number of Personnel in Laboratory group:_____

Principal Investigators and Co-Investigators

(Enter all participants on this project in the table below – expand as necessary)

INVESTIGATORS	LIFE NUMBER	DEPARTMENT	DEPARTMENT CHAIR	LAB
CO-INVESTIGATORS	LIFE NUMBER	DEPARTMENT	SUPERVISOR	LAB

Section 2. Non-Recombinant DNA Protocol**

PROJECT INFORMATION:

Agent Description and Use

(any physical / chemical description of the therapeutic agent, IND, or synthetic molecule and how it will be used. The Committee is interested in the activity of the agent within the subject, not the overall goals of the protocol).

** "-mab" or autologous treatments, etc. :If your protocol **involves recombinant DNA** in any manner, use the standard IBCRA form found at www.mssm.edu/biosafety

Section 3. Assessment of Biological Containment

The Principal Investigator makes the initial assessment of physical and biological containment levels required under the current edition of the *Biosafety in Microbiological and Biomedical Laboratories, 5th Edition or most recent edition.* Mark all appropriate items that pertain to your project. Copies of the *BMBL* are available at www.cdc.gov/biosafety. Where Human subjects are involved, OSHA 29 CFR 1910.1300 BloodBorne Pathogen Standard requires **BSL-2 equivalent** protection to be incorporated into the standard operating procedures.

The ISMMS IBC will review and finalize the Biosafety Level.

Please check all the appropriate boxes. For further information and guidance , see:
http://www.cdc.gov/biosafety/publications/bmbl5/bmbl.pdf **and**
https://icahn.mssm.edu/files/ISMMS/Assets/Research/IBP/manual.pdf

1. Biosafety Level: ☐ **BSL-1** ☐ **BSL-2 (BBP)** ☐ **BSL-3** ☐ **Other :**

2. Toxin ☐ **Select toxin#** ☐ **Non-Select toxin**

3. Type of Protocol: ☐ ***in vitro* System Only** ☐ **Large Scale** ☐ **Human Trial**

☐ **Human Treatment Protocol**+

4. ☐ **monoclonal antibody (-mab)** ☐ **small molecule** ☐ **modified autologous cells**

☐ **ex vivo / in vitro protocol** ☐ **Other:**_____

+ Product Brochures, other descriptions of the trial and the agent *must be forwarded to the IBC.*

 # Federal Select Agent Program regulated toxin (See: https://www.selectagents.gov/)

SECTION 4. SAFETY AND HEALTH ASSURANCES
Complete this section for all submissions

A. Training

The Icahn School of Medicine at Mount Sinai complies with all requirements to train its employees in accordance with US EPA laws, OSHA Standards, FDNY laws, and the NIH Guidelines that regulate laboratory activities with respect to employee health and safety, and environmental health and safety. The Principle Investigator has attested that:

1. All Faculty and staff in my laboratory and indicated on this form have completed within the year the following required training (training can be accessed on PEAK):
    a. Basic Laboratory Safety (New Hire)
    b. Hazard Communication
    c. Personal Protective Equipment
    d. Laboratory Hazardous Waste Management
    e. Principles of Biosafety

2. Copies of the following MSSM manuals are available, and have been read by all employees:
    a. Biosafety Manual - http://icahn.mssm.edu/research/institutional-biosafety/policies
    b. Bloodborne Pathogens / ECP - http://policies.mountsinai.org/web/environmental-health-and-safety/policies/-/policy-management/view
    c. Chemical Hygiene Plan / Laboratory Safety Manual - http://intranet1.mountsinai.org/compliance/envhs/labSafetyManual.asp

All Laboratory personnel have been:

1. Appropriately informed of the potential hazards associated with the project by reviewing the Standard Operating Procedure (SOP) with the PI or LSO, and
2. Trained in specific measures necessary to preserve health and safety when using or being exposed to the particular hazardous agent(s) employed in this project.

I certify that the statements herein are true, complete, and accurate to the best of my knowledge. I acknowledge that compliance with required laboratory training could be independently assessed in SECTOR by an authorized representative from Environmental Health and Safety.

B. Occupational Health and Safety

All MSSM employees are required to submit an annual report to the Employee Health Service. If work is related to animal protocols where contact is more than three hours per week, an Occupational Health and Safety Questionnaire must be completed and forwarded to the Biosafety Officer annually.

All protocol participants have animal contact > 3hours per week ____
(Must complete Occupational Health and Safety Form at:
http://sinaicentral.mssm.edu/ **go to "Sinai Central Log-in"**

All protocol participants *do not* have animal contact ____
http://intranet1.mountsinai.org/ go to "Employee Services"

C. Standard Operating Procedures (SOPs)

Do you have SOP's available for all hazards listed in this report?

____ Yes. Please attach any /all SOP Documents associated with this project as an appendix.

____ No. I need assistance in developing SOPs.

D. Affirmation

All Faculty and staff associated with this project have been trained in the specific safety / health precautions associated with the biohazards and / or chemical hazards inherent in this project.

Signed : _____
Principal Investigator

E. Additional Information

Use this space or attach a separate sheet with any required additional information