



Instructions

This form is used to report recombinant DNA and synthetic recombinant DNA activities covered under the **NIH Guidelines** and to report activities that may pose a hazard to researchers working with biological agents, biological toxins and /or Genetically Modified microorganisms to the Biological Safety Officer and to the Icahn School of Medicine Institutional Biosafety Committee (ISMMS-IBC).

Check off the appropriate items in each category and give the full name of the vector(s), gene insertion(s) and /or agent(s) including strain designations 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.

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.

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 Recombinant DNA vectors, 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 complete **NIH Guidelines** are available at:

https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html



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 in this project in the table below)

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

Section 2. Recombinant DNA Protocols



PROJECT INFORMATION:

The NIH Guidelines For Research Involving Recombinant DNA Molecules
(NIH Guidelines) is at: https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html)

Please consult this document in order to complete the following section accurately.

Submissions to The Office of Biotechnology Activities Major Action request
https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html#_Toc446948317

Appendix M Submission (Human Gene Transfer)
https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html#_Toc446948489

Approval Letter(s) received from The Office of Biotechnology
https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html#_Toc446948491

Attach Lay Summary

(Specific Aims etc, any description of the r-DNA Molecule or synthetic molecule activities to be used).



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 *NIH Guidelines* for Recombinant DNA Research for each experiment. Mark all appropriate items that pertain to your project . Copies of the *NIH*

Guidelines are available on the Web at:



https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html

The ISMMS IBC will review and finalize the Biosafety Level and Appropriate Section III designation

Please check all the appropriate boxes. For further information, see:

https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html#_Toc446948306

and

https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html#_Toc446948323

- 1. Biosafety Level: BSL-1 BSL-2 BSL-3 Other :
- 2. Risk Group: RG-1 RG-2 RG-3 Other :
- 3. Type of Protocol: *in vitro* System Only Animal Protocol Transgenic Animal
 Large Scale Human Gene Transfer Protocol⁺ Gene Therapy⁺

⁺ Product Brochures, OBA approval letters and Appendix M, *NIH Guidelines* **MUST** accompany the Risk Assessment submission. http://osp.od.nih.gov/sites/default/files/NIH_Review_Process_HGT.pdf

4. Type of Experiment : Refer to: <http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines> for definitions and conditions for each type of experiment.

- ___ III - A Experiments that Require Institutional Biosafety Committee Approval, RAC Review, and NIH Director Approval *Before Initiation*
- ___ III - B Experiments That Require NIH/OBA and Institutional Biosafety Committee approval *Before Initiation*
- ___ III - C Experiments that Require Institutional Biosafety Committee and Institutional Review Board Approvals and RAC Review *Before Research Participant Enrollment*
- ___ III - D Experiments that Require Institutional Biosafety Committee Approval *Before Initiation*
- ___ III - E Experiments that Require Institutional Biosafety Committee *Notice Simultaneous with Initiation*
- ___ III - F Exempt Experiments (Register the BioSafety Officer only)

5. Characterization of Host-Vector Systems, Gene Insertions and Gene Expression Products (Complete the table below; expand as necessary).



Vector Name	Virus / plasmid / BAC Backbone	c DNA Inserts	Size and Source of the Inserts ⁺¹	Expression Products	Location of Preparation

EXAMPLE BELOW* For further information, see: http://oba.od.nih.gov/oba/rac/guidelines_02/APPENDIX_E.htm

****Sample Responses** ⁺¹ Use the format expressed in the Entrez Gene citations found at:

Vector Name	Virus / plasmid / BAC Backbone	c DNA Inserts	Size and Source of the Inserts ⁺¹	Expression Products	Location of Preparation
Ad-LacZ**	Ad5	LacZ	3.1Kb, Bacteria	Beta-galactosidase	ISMMS

www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=gene This example box can be deleted

6. Anticipated Outcomes of Gene Insertion and Expression (Check all appropriate boxes)**

- a. The inserted gene will code for a(n):**
- Known toxin Uncharacterized toxin
 Known oncogene None of these

Comments 6.a

- b. The inserted gene will alter:**
- Host range Known cell tropism
 None of these Not known

Comments 6.b.

- c. The inserted gene significantly modulate the replication capacity the virus:**
- Yes No NA

Comments 6.c.

- d. The inserted gene will be capable of altering the (host) cell cycle:** Yes No NA

Comments 6.d.

- e. If you are using a viral vector, what fraction of the wild type virus sequence is present in the vector (ratio of the insert to the total wild-type genome contained in DNA)?**

- $x < 1/2$ $1/2 < x < 2/3$ $x > 2/3$ Not applicable

**** IT IS ACKNOWLEDGED BY THE COMMITTEE THAT NOT ALL ANTICIPATED OUTCOMES CAN BE KNOWN OR PREDICTED ACCURATELY – PLEASE COMPLETE THIS SECTION BASED ON YOUR KNOWLEDGE AND EXPERIENCE.**

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 the laboratories indicated on this form have attended, within the year: (training is on the PEAK system at: PEAK.mountsinai.org)

- Chemical Hygiene Plan Session
- Bloodborne Pathogens / Biosafety Sessions
- EPA Training

2. Copies of the following MSSM manuals are available, and have been read by all employees:

- Biosafety
- Hazardous Waste Management
- Bloodborne Pathogens / ECP
- Chemical Hygiene Plan
- Hazardous Materials Handling and Storage

The Biosafety Program web site is

<http://www.mssm.edu/biosafety>

The Environmental Health and Safety web site is

http://www.mssm.edu/health_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 by: _____
Principal Investigator

E. Additional Information

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

