



## Instructions

This form is used 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 report recombinant DNA and synthetic recombinant DNA activities covered under the **NIH Guidelines** to the Icahn School of Medicine Institutional Biosafety Committee (ISMMS).

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](http://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:

[http://osp.od.nih.gov/sites/default/files/NIH\\_Guidelines.html](http://osp.od.nih.gov/sites/default/files/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:

[http://osp.od.nih.gov/office-biotechnology-activities/oba/rac/guidelines\\_02/NIH\\_Guidelines\\_Apr\\_02.htm](http://osp.od.nih.gov/office-biotechnology-activities/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm)

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

**Submissions to The Office of Biotechnology Activities Major Action request**

[http://osp.od.nih.gov/sites/default/files/NIH\\_Guidelines.html#\\_Toc351276229](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_Toc351276229)

**Appendix M Submission (Human Gene Transfer)**

[http://osp.od.nih.gov/sites/default/files/NIH\\_Guidelines.html#\\_Toc351276401](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_Toc351276401)

[http://osp.od.nih.gov/sites/default/files/NIH\\_Guidelines.html#\\_Appendix\\_M-I-A\\_Requirements](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_Appendix_M-I-A_Requirements)

**Approval Letter(s) received from The Office of Biotechnology**

[http://osp.od.nih.gov/sites/default/files/NIH\\_Guidelines.html#\\_Toc351276401](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_Toc351276401)

[http://osp.od.nih.gov/sites/default/files/NIH\\_Guidelines.html#\\_Appendix\\_M-I-A\\_Requirements](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_Appendix_M-I-A_Requirements)

#### **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:

[http://osp.od.nih.gov/office-biotechnology-activities/oba/rac/guidelines\\_02/NIH\\_Guidelines\\_Apr\\_02.htm](http://osp.od.nih.gov/office-biotechnology-activities/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm)

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:**

[http://osp.od.nih.gov/office-biotechnology-activities/oba/rac/guidelines\\_02/NIH\\_Guidelines\\_Apr\\_02.htm](http://osp.od.nih.gov/office-biotechnology-activities/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm) ,

[http://osp.od.nih.gov/sites/default/files/NIH\\_Guidelines.html#\\_Toc351276228](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_Toc351276228) and

[http://www.mssm.edu/static\\_files/Test2/06081716/www.mssm.edu/biosafety/pdfs/biological\\_safety\\_levels.pdf](http://www.mssm.edu/static_files/Test2/06081716/www.mssm.edu/biosafety/pdfs/biological_safety_levels.pdf)

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<sup>+</sup>  Gene Therapy<sup>+</sup>

<sup>+</sup> 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](http://osp.od.nih.gov/sites/default/files/NIH_Review_Process_HGT.pdf)

**4. 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

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



**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 <sup>+1</sup>	Expression Products	Location of Preparation

**EXAMPLE BELOW\*** For further information, see: [http://oba.od.nih.gov/oba/rac/guidelines\\_02/APPENDIX\\_E.htm](http://oba.od.nih.gov/oba/rac/guidelines_02/APPENDIX_E.htm)

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

**\*\*Sample Responses <sup>+1</sup>** Use the format expressed in the Entrez Gene citations found at: [www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=gene](http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=gene)

**6. Projected Outcomes of Gene Insertion and Expression (Check if “Yes” only)**

- a. Will the inserted gene code for a(n):
- Known toxin                       Uncharacterized toxin
- Known oncogene                       None of these
- b. Will the inserted gene alter:
- Host range                       Known cell tropism
- None of these
- c. Will the inserted gene have the replication capacity of a virus?                       Yes     No     NA
- d. Will the inserted gene be capable of altering the (host) cell cycle ?                       Yes     No     NA
- 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

**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)

- 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](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

**APPROVALS:**

\_\_\_\_\_  
**VIVIANA SIMON, MD, PH.D.**  
IBC CHAIR

\_\_\_\_\_  
DATE

\_\_\_\_\_  
**PHILIP G. HAUCK, MS, MSHS, CBSP, SM(NRCM)**  
BIOSAFETY OFFICER

\_\_\_\_\_  
DATE

**ISMMS IBC MEETING APPROVAL**

\_\_\_\_\_  
DATE