



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 .

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



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)

Table with 5 columns: INVESTIGATORS, LIFE NUMBER, DEPARTMENT, DEPARTMENT CHAIR, LAB. Includes rows for CO-INVESTIGATORS with columns for 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

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

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#_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#_Appendix_M-I-A_Requirements

Attach Lay Summary

(Please summarize the proposed research in sufficient detail for the committee to make an informed decision on this protocol. Please include Specific Aims of the funded project, if relevant, and 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

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/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

- 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

- 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.



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

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
Ad-LacZ**	Ad5	LacZ	3.1Kb, Bacteria	Beta-galactosidase	ISMMS

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: 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 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 by: _____
Principal Investigator

E. Additional Information

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