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 (ISMMS) Institutional Biosafety Committee (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, then contact the Biological Safety Officer in the Institutional Biosafety Program (212-241-5169). Additional information can also be obtained at https://icahn.mssm.edu/research/institutional-biosafety.

This form covers all research that is conducted in *in vitro* models or in human gene therapy trials regulated by the ISMMS Institutional Review Board (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 Institutional Animal Care and Use Committee (IACUC) 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.

IACUC ***Vertebrate Animal Study Forms*** can be submitted 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 # **GCO #** **IACUC #**

Protocol Status:
☐ New Proposal ☐ Renewal ☐ Funding Pending ☐ Funded

Date when this protocol will begin:

Department		**Office Phone #**	
E-mail		**Mailbox #**	

Laboratory Building:
☐ Icahn ☐ Annenberg ☐ Atran-Berg ☐ CMA ☐ Hess-CSM
☐ Other:

Floor Number(s): **Total Number Research Personnel:**

Room Number(s):

Principal Investigators, Co-Investigators, and Personnel

Investigator(s)	Life #	Department	Department Chair	PI Laboratory

Personnel	Life #	Department	Department Chair	PI Laboratory

Attach additional sheets if necessary.

SECTION 2. RECOMBINANT DNA PROTOCOLS

PROJECT INFORMATION:

The *NIH Guidelines for Research Involving Recombinant DNA Molecules* (NIH Guidelines) is available 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.

Are there any special provisions concerning this protocol?

☐ Major Action request of The Office of Biotechnology Activities
https://osp.od.nih.gov/biotechnology/faqs-about-major-actions-under-section-iii-a-of-the-nih-guidelines-for-research-involving-recombinant-or-synthetic-nucleic-acid/

☐ Human Gene Transfer
Novel and Exceptional Technology and Research Advisory Committee (NExTRAC) Submission
https://osp.od.nih.gov/biotechnology/novel-exceptional-technology-research-advisory-committee/

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

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 recombinant 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:

- https://osp.od.nih.gov/biotechnology/novel-exceptional-technology-research-advisory-committee/
- https://osp.od.nih.gov/biotechnology/nih-guidelines/
- https://www.cdc.gov/cpr/infographics/biosafety.htm

Biosafety Level:	☐ **BSL-1**	☐ **BSL-2**	☐ **BSL-3**	☐ **BSL-4**
Risk Group:	☐ **RG-1**	☐ **RG-2**	☐ **RG-3**	☐ **RG-4**

Type of Protocol (check all that apply)

☐ ***in vitro* system only**	☐ **Large scale**
☐ **Animal protocol**	☐ **Human gene transfer protocol***
☐ **Transgenic animals**	☐ **Gene therapy***

***Product Brochures and NExTRAC approval MUST accompany the Risk Assessment submission.**
https://osp.od.nih.gov/biotechnology/novel-exceptional-technology-research-advisory-committee/

Type of Experiment

☐	**III-A**	Experiments that Require NIH Director Approval and Institutional Biosafety Committee Approval Before Initiation
☐	**III-B**	Experiments That Require NIH OSP and Institutional Biosafety Committee Approval Before Initiation
☐	**III-C**	Experiments Involving Human Gene Transfer that Require Institutional Biosafety Committee Approval Prior to Initiation
☐	**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

For definitions and conditions for each type of experiment, refer to:
https://osp.od.nih.gov/biotechnology/nih-guidelines/

Characterization of Host-Vector Systems, Gene Insertions and Gene Expression Products

For further information, refer to Appendix E. Certified Host-Vector Systems, of the NIH Guidelines: https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html

Attach additional sheets if necessary.

Vector Name	Virus/Plasmid/BAC backbone	DNA Inserts	Size and source of inserts*	Expression products	Location of preparation

*Use the format expressed in the Entrez Gene citations found at: **www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=gene**

EXAMPLE

Vector Name	Virus / plasmid / BAC Backbone	c DNA Inserts	Size and Source of the Inserts*	Expression Products	Location of Preparation
polycistronic Klf4	Sendai Virus	N/A	N/A	Oct3/4–Sox2, cMyc, and Klf4	Purchased from Thermo Fisher Sci

Projected Outcomes of Gene Insertion and Expression

Will the inserted gene code for a(n)?	☐ Known toxin	☐ Uncharacterized toxin	☐ Known oncogene	☐ None of these
Will the inserted gene alter?	☐ Host range	☐ Known cell tropism	☐ None of these	
Will the inserted gene have the replication capacity of a virus?	☐ Yes	☐ No	☐ Not Applicable	
Will the inserted gene be capable of altering the (host) cell cycle?	☐ Yes	☐ No	☐ Not Applicable	
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 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:
- https://sinaicentral.mssm.edu/
- Employee Self Service → Occupational Health Survey

☐ All protocol participants DO NOT have animal contact

- http://intranet1.mountsinai.org/ or Visit Employee Health Services

C. Standard Operating Procedures (SOPs)

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

- ◯ Yes — Please attach any /all SOPs associated with this project as an appendix.
- ◯ No — I need assistance in developing SOPs

D. Additional Information

Use this space to provide comments, or to indicate if additional pages/documents are associated with the protocol.

E. 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.

Principal Investigator

Date prepared:

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