

**Hunter, Renee (NIH/OD) [C]**

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**From:** McKinney, Michelle (NIH/OD) [E]  
**Sent:** Monday, May 11, 2020 3:09 PM  
**To:** glickmam@MSKCC.ORG; NIH guidelines  
**Cc:** cottinge@mskcc.org; GibsonJ2@mskcc.org; Tucker, Jessica (NIH/OD) [E]; Harris, Kathryn (NIH/OD) [C]  
**Subject:** RE: Violation report

Dear Dr. Michael Glickman,

Thank you for your below report to the National Institutes of Health (NIH) Office of Science Policy (OSP). We have reviewed the information you provided, and the actions taken in response to this incident appear appropriate.

No further information about this incident is required at this time. Please contact Dr. Kathryn Harris, Senior Outreach and Education Specialist, by email at [harriskath@od.nih.gov](mailto:harriskath@od.nih.gov) or by telephone at (301) 496-9838 if you have any additional questions.

Regards,

Michelle McKinney

Michelle McKinney, MS, CBSP  
Health Science Policy Analyst  
Division of Biosafety, Biosecurity, and Emerging Biotechnology Policy  
Office of Science Policy  
National Institutes of Health  
Bethesda, MD  
Phone: 301-402-7465  
Mobile: Redacted by agreement  
[michelle.mckinney@nih.gov](mailto:michelle.mckinney@nih.gov)

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**From:** glickmam@MSKCC.ORG <glickmam@MSKCC.ORG>  
**Sent:** Sunday, April 19, 2020 11:46 AM  
**To:** NIH guidelines <NIHguidelines@od.nih.gov>  
**Cc:** cottinge@mskcc.org; GibsonJ2@mskcc.org  
**Subject:** Violation report

Hello,

Please find attached a report of a violation of the NIH recombinant DNA guidelines, and our response to this violation. I am available to answer any questions.

Sincerely,

**Michael S. Glickman MD**

Chairman, MSK IBC

**Memorial Sloan Kettering Cancer Center**

Z1504 MSKCC, New York, NY 10065

Lab Office: 646-888-2368

Assistant: Veronica Shields

Lab: 646-888-2360

Clinical: 212-639-3191

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**Hunter, Renee (NIH/OD) [C]**

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**Sent:** Sunday, April 19, 2020 11:46 AM  
**To:** NIH guidelines  
**Cc:** cottinge@mskcc.org; GibsonJ2@mskcc.org  
**Subject:** Violation report  
**Attachments:** Violation NIH Guidelines-MSK.pdf

Hello,

Please find attached a report of a violation of the NIH recombinant DNA guidelines, and our response to this violation. I am available to answer any questions.

Sincerely,

**Michael S. Glickman MD**

Chairman, MSK IBC

**Memorial Sloan Kettering Cancer Center**

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Memorial Sloan Kettering  
Cancer Center

April 17, 2020

NIH Office of Science Policy  
Biosafety, Biosecurity, and Emerging Biotechnology  
6705 Rockledge Drive, Suite 750  
Bethesda, MD 20892  
301-496-9838  
NIHGuidelines@od.nih.gov

Re: Violation of the NIH Guidelines at Memorial Sloan Kettering Cancer Center (MSK)

In accordance with the NIH guidelines, this report is a follow up of an initial report submitted to the NIH Office of Science Policy via email to NIHGuidelines@od.nih.gov on 4/1/2020.

The MSK Institutional Biosafety Committee (IBC) was notified that an IBC registered investigator was constructing recombinant Modified Vaccinia Ankara (MVA) expressing spike proteins from SARS-COV-2 without IBC approval, a violation of Section III-D-1 of the NIH Guidelines. The objective of the project was to investigate vaccine efficacy using recombinant MVAΔE5R or MVAΔE5R-Flt3L-OX40L to express either the S1 subunit or full length of the SPIKE protein from SARS-CoV-2. Flt3L is a dendritic cell growth factor and OX40L is a T cell co-stimulator. MVA deleted for E5R induces higher levels of type I Interferon compared to its undeleted counterpart.

As the Chairman of the IBC, as soon as I learned of this activity, I directed the PI to halt the unapproved research immediately and initiated an investigation. Our investigation revealed that the recombinant viruses had been generated and the Investigator was awaiting sequence confirmation. It was determined that the viruses must be destroyed immediately. Dr. James Gibson, Interim Vice President, Environmental Health and Safety was tasked to oversee the destruction of the materials. The PI surrendered all the materials from the project and these materials were destroyed by autoclaving them at 121°C for 60 minutes.

The next morning, the Biosafety Officer (BSO) met with the PI and the lab members to review the details of the violation and to audit the laboratory. The BSO also performed a spot check of over 1000 frozen vials in the -80°C freezer. No materials associated with the unapproved activity were found. In addition, the BSO conducted an audit of the PI's animals in the vivarium to determine if animals had been administered with the viruses. No evidence to suggest that any in vivo work had been carried out was discovered. This study was not supported by PHS funds.



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The following steps have been implemented to promote adherence to the NIH Guidelines and to foster best practices:

1. The PI was retrained in the applicability of the NIH Guidelines and the obligations to comply with them.
2. A training session will be scheduled for the PI and the entire lab on biosafety practices and the NIH Guidelines for recombinant work.
3. Unannounced monthly lab inspections for a period of twelve months to ensure compliance with the NIH Guidelines and Institutional policies.

The details of this issue were discussed at the IBC meeting on March 31, 2020. The IBC agreed that the destruction of the materials and retraining/educational efforts were appropriate. Additionally, the IBC also recommended that a review of the group's flow cytometry experiments to determine if any cytometry had been conducted for the unapproved project. This investigation revealed that no sorting had been conducted for the unapproved project.

We believe we have taken the necessary steps to prevent recurrence of this issue. Please do not hesitate to contact me with any questions or if you need further information. I can be reached by telephone at 646-888-2368 or through email at: [glickmam@mskcc.org](mailto:glickmam@mskcc.org).

Sincerely,

Redacted by agreement

Michael Glickman, MD  
IBC Chairperson

Cc: Eric Cottingham, Ph.D., Senior Vice President, Research and Technology Management

Institutional Biosafety Committee (IBC)  
Research and Technology Management  
[RTMIBC@mskcc.org](mailto:RTMIBC@mskcc.org)

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NCI-designated Comprehensive Cancer Center



Memorial Sloan Kettering  
Cancer Center

April 1, 2020

**To:**

Office of Science Policy, NIH  
NIHGuidelines@od.nih.gov

**From:**

Michael Glickman, MD  
IBC Chairman  
Memorial Sloan Kettering Cancer Center

We are writing with an initial report of a violation of the NIH Guidelines under section IV-B-2-b-(7). We are gathering the necessary information for a full report, which will follow.

Regards,

Redacted by agreement

Michael Glickman, MD  
IBC Chairperson

Institutional Biosafety Committee (IBC)  
Research and Technology Management  
RTMIBC@mskcc.org

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