Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

National Institutes of Health
Office of Science Policy

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Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. Please complete all fields as fully as possible. The use of this template is not required and other formats for submitting reports may be acceptable.

Completed reports may be sent to OSP via email at NIHGuidelines@od.nih.gov

Please Note:

Human Gene Transfer (HGT) Adverse Events (AEs) should still be reported to the NIH Office of Science Policy (OSP).

A separate template for reporting Human Gene Transfer Adverse Events is available here.

HGT AEs should be emailed to HGTprotocols@mail.nih.gov

Does this incident involve research subject to the *NIH Guidelines*?	☒YES ☐NO If no, this incident does not require reporting to OSP
Institution Name:	University of Wisconsin-Madison
Date of Report:	02/10/20
Reporter name and position:	[redacted] Biological Safety Officer
Telephone number:	[redacted]
Email address:	[redacted]
Reporter mailing address:	[redacted] [redacted] Madison, WI 53715
Date of incident:	12/09/19
Name of Principal Investigator:	[redacted]

Is this an NIH-funded project?	☒YES ☐NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

What was the nature of the incident?	☐Failure to follow approved containment conditions ☐Failure to obtain IBC approval ☐Incomplete inactivation ☐Loss of containment ☐Loss of a transgenic animal ☐Personnel exposure ☐Spill ☒Other (please describe): equipment failure
Did the Institutional Biosafety Committee (IBC) approve this research?	☒YES ☐NO If yes, date of approval: 06/18/18
What was the approved biosafety level of the research?	☐BL1 ☐BL2 ☐BL2+ ☐BL3 ☒BL3+ ☐BL4
What section(s) of the *NIH Guidelines* is the research subject to?	III-D-7

Has a report of this incident been made to other agencies? If so, please indicate	☒CDC ☐USDA ☐FDA ☐EPA ☐OSHA ☒Funding agency/sponsor ☐State or local Public Health ☐Law enforcement ☐Other (please describe):
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)	Ferrets that had been in contact with ferrets infected with VN1203HA(N158D/N224K/Q226L/T318I)/CA04 or a nonrecombinant/wild type control strain

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

Location: BSL3-Ag laboratory

Persons involved: UW-Madison employee

Training received by individual: Lab-specific training according to approved biosafety protocol was done and documented. Institutional UW-Madison Required Biosafety Training was completed.

PPE in use at time of event: scrubs, Tyvek suit with booties, dedicated shoes, two pairs of gloves, Tyvek sleeve covers, shoe covers, and powered air purifying respirator (PAPR)

Event description: A group of researchers were collecting nasal washes from day 1 contact ferrets involved in a transmission experiment. Two experienced researchers handled the ferrets inside a biosafety cabinet (BSC), while a third researcher in training observed. After each collection was completed and ferrets were returned to their HEPA filtered cages, all equipment including the BSC and microisolator transfer boxes were decontaminated according to the lab's IBC-approved biosafety protocol. Then the researchers sprayed all their PPE with disinfectant, removed their Tyvek sleeves and outer gloves, and donned new outer gloves and Tyvek sleeves. While one of the senior researchers was setting up for the next round, the observer noticed that the observer's PAPR hose had disconnected from the blower base. One of the other researchers also saw the hose detach. The hose was immediately reconnected.

Immediate follow-up and medical follow-up: The laboratory followed its established emergency response procedure. One of the experienced researchers radioed out to the Lab Operations Manager and explained what happened. The Lab Operations Manager immediately called the UW-Madison Responsible Official (RO). Following that communication, out of an abundance of caution the observer was directed to follow the laboratory's established quarantine procedure upon exiting the BSL3-Ag laboratory. The RO consulted with medical providers for the program before releasing the researcher from the quarantine protocol. The RO notified the Federal Select Agent Program as well as UW-Madison's Biological Safety Officer (BSO). After discussion the RO and BSO decided that the incident was not reportable to the Office of Science Policy (NIH-OSP) as there was no potential exposure due to the following factors: (1) the animals were handled inside a biosafety cabinet, (2) certification of the BSC was current and the magnehelic gauge indicated appropriate function, (3) the contact ferrets had only been exposed to the infected ferrets for approximately 24 hours and were not shedding virus yet, (4) the ferrets were inside primary containment at the time of hose disconnection, (5) decontamination was performed prior to the hose disconnection, and (6) the air the observer would have breathed during the few seconds the hose was disconnected would have come from inside the PAPR hood, which would have been HEPA-filtered before the hose disconnected. The medical providers agreed with this risk assessment. Following subsequent communications with the Federal Select Agent Program, funding agency, and NIH-OSP, it was recommended that this incident be reported to NIH-OSP.

Has the IBC reviewed this incident?	☒YES ☐NO The IBC was apprised at the monthly meeting on February 5, 2020.
Please describe the root cause of this incident:	Root cause of the disconnection of PAPR hose is not known for certain; the hose connection may not have been completely turned into the lock position and loosened over time

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

The institution followed approved emergency and reporting procedures. This incident and the laboratory's response illustrate the multiple layers of protection in place in this BSL3-Ag laboratory and the excellent training of the laboratory staff.

The laboratory and RO have reviewed the laboratory's training and SOPs. Researchers have been reminded of the importance of checking PAPR connections and this will be emphasized during the annual hands on refresher training.

***Confidential – do not release this information without written authorization of the University of Wisconsin-Madison.**