Template for Reporting Incidents Involving Recombinant DNA to the NIH Office of Biotechnology Activities (OBA)

The *NIH Guidelines for Research Involving Recombinant DNA 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 OBA within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents in BSL-2 laboratories resulting in an overt exposure must be immediately reported to NIH OBA. Spills or accidents occurring in high containment (BSL-3 or BSL-4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH OBA.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines.* Use of this template is not required and other formats may be acceptable.

A separate template for reporting Human Gene Transfer Adverse Events is available at: http://www4.od nih.gov/oba/rac/adverse_event_template.doc

Please note that submitting this completed template to the NIH OBA does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.

Completed reports may be sent via U.S. mail, courier service, e-mail, or facsimile to:

Attention: Incident Reports
NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892-7985
(For all non-USPS deliveries use Zip Code 20817)
Telephone 301-496-9838
FAX 301-496-9839
E-mail: oba@od nih.gov

NIH OBA Incident Reporting Template	
Does this incident involve research subject to the *NIH Guidelines?*	X Yes If no, this incident does not have to be reported to OBA
Institution name:	University of Wisconsin - Madison
Date of report:	11/19/13
Reporter name and position:	Jim Turk – Biological Safety Officer
Reporter telephone:	(608)263-9013
Reporter email:	jturk@fpm.wisc.edu
Date of Incident:	11/16/13
Name of principal investigator:	[redacted]

Is this an NIH funded project?	X Yes □ No
If yes, please provide	NIH Grant or contract number Rebecca Moritz will be forwarding the grant number for this specific project. NIH funding institute or center NIH program officer contact information (name, email etc.)
What was the **nature** of incident?	Needle Stick
Did the institutional Biosafety Committee (IBC) approve this research?	X Yes If yes, on what date? 04/04/2012
If yes, please provide:	Approval date: 04/04/2012 Approved biosafety level for the research: ABSL-3 Additional approval requirements:
What section(s) of the *NIH Guidelines* is the research subject to?	Section III-D-3-b, Section III-D-4-b, Section III-D-7
Has a report of this incident been made to other federal or local agencies? If so, please indicate by checking the appropriate box.	X CDC X USDA □ FDA □ EPA □ OSHA □ Research Funding Agency/Sponsor: (name) □ State/Local Public Health □ Federal/State/ Local Law Enforcement X Other – please describe: City/County Public Health

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.**

A description of:

- The recombinant agent or material involved.
- The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space).
- Who was involved in the incident/violation, including others present at the incident location? **Note - please do not identify individuals by name. Provide only position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker).**
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event.
- The training received by the individual(s) involved and the date(s) the training was conducted.
- The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation.
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation.
- The personal protective equipment in use at the time of the incident/violation.
- The occupational health requirements for laboratory personnel involved in the research.
- Any medical advice/treatment/surveillance provided or recommended after the incident
- Any injury or illness associated with the incident.

- Medical surveillance results (if not available at the time of initial report please indicate when results will be available).
- Equipment failures.

DESCRIPTION OF INDICENT: (use additional space as necessary)

Needle Stick - November 16, 2013

~18:20-18:30 – The researcher was working in the ABSL3+ laboratory and accidentally punctured skin with an 18 gauge needle with a reassortant virus on it, containing the HA from [redacted] (H5N1) with the [redacted] mutation in the receptor binding site, and the rest of the genes from A/California/04/2009 (H1N1). The approximate concentration of the tissue culture supernatant on the syringe needle was ~10^8 pfu/ml.

18:34 – A co-worker called the on-call iPhone, the lab manager answered, this co-worker relayed that the researcher called out on the radio that help was needed because the researcher had stuck themself with a needle in the ABSL-3+ laboratory. The co-worker was in the BSL-3Ag suite.

18:36 – The lab manager called the researcher in. The researcher had sprayed the puncture site with disinfectant and had been running the site under water at the sink for 5 minutes. The lab manager instructed the researcher to squeeze a few more drops of blood out of the finger and continue running the site under water for another 10 minutes, and then call back for the next set of instructions.

18:43 – The lab manager asked the co-worker to listen for the radio in case the researcher had any difficulty.

18:46 – The lab manager called the ARO, relayed the situation, asks her to call the Infectious Disease doctors.

18:54- The ARO called the UW Hospital Operator and asked to page the ID Fellow on-call.

18:54 – The lab manager called the researcher and gave the researcher the following instructions: put on new gloves, clean up the work area and then shower out normally. Do not hurry. Go upstairs, sit in the conference room and do not leave the building.

18:57 – The lab manager called a senior scientist in the lab to call the researcher's family and instruct them to start packing belongings to go to a hotel.

19:19- ID Fellow called the ARO back and they discussed the situation. The Fellow paged the attending to get the prescription sent in.

19:28- The ID attending physician called the ARO and got the required information for the Tamiflu prescription.

19:29 – The lab manager called Dr. [redacted] to report what happened.

19:40 – The lab manager arrived at the [redacted] spoke with the researcher, and arranged for a hotel

room for the researcher's family.

20:10 – The lab manager called Walgreens to make sure the Tamiflu prescription was ready for pickup and that Walgreens had the researcher's contact information and insurance information.

20:15- The ID attending physician follows up with the ARO and asked for the lab manager's contact information.

20:18 – The ID Attending Physician called the lab manager to check that there are issues with obtaining the Tamiflu prescription.

20:20 – Another co-worker went to pick up the prescription.

20:22- The ARO notified CDC DSAT via the Form 3 email address.

20:26- The ARO called the Director of University Health Services to explain the situation. The Director sent an email to UW housing to see if we could get the a show apartment for the family starting on Sunday.

20:31- The ARO called the City of Madison/Dane Public Health on-call pager.

20:32- The ARO called the Chief Medical Officer and State Epidemiologist for Wisconsin Department of Health. He confirmed the quarantine would be 7 days and the individual should be taking a treatment dose of 75mg twice a day for 10 days.

20:34- The ARO talked to the City/Dane County Health on-call individuals and explains the situation.

20:35pm – The research took the first Tamiflu dosage, (~2 hours after the injury). The Tamiflu prescription was written for 75mg, once daily. (The lab manager voiced concern to the ARO about the prescription being the prophylaxis dosage and not the treatment dosage. The ARO had already spoken with the doctors about this, the Chief Medical Officer for Wisconsin Dept. of Public Health wanted the researcher on the treatment dosage (75mg twice a day for 10 days). The researcher was instructed to take one pill every 12 hours.

21:00 – The researcher's family was pickup and driven to the hotel.

21:30 – The researcher was driven home by the lab manager and was wearing a glove on the hand with the puncture wound and an N-95 mask with no exhalation valve.

21:00-22:00 – The lab manager spoke to two of the lab scientists about beginning the nasal and throat swab sample testing the next morning.

21:55 – Researcher took a reference body temperature: [redacted] F (axillary).

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8:00 – The researcher too the second Tamiflu dosage and body temperature was [redacted] F (axillary).

9:00 – The lab manager obtained the first throat and nasal swab samples.

10:00 – Scientists began sample testing.

12:00 – The rapid Directigen test results are [redacted]

16:00 – The researcher's family was moved to a show apartment available on campus.

18:00 – The lab manager obtained nasal swab and throat gargle samples. The test results are [redacted]

19:00 – The researcher's body temperature was [redacted] F (axillary).

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7:15 – The researcher's temperature was [redacted] F

9:00 – The researcher's body temperature was [redacted] F (axillary). The UW-Madison Occuptional Health nurse visited the researcher, drew blood, measured blood pressure and pulse ([redacted] The lab manager obtained nasal swab and throat gargle samples. These test results were [redacted]

11:00 – The researcher's body temperature is [redacted] F (by mouth).

13:00 – The researcher's temperature is [redacted] F (by mouth).

Daily updates are sent out by the ARO.

Has the IBC reviewed this incident?	X No If yes, provide minutes
Has the root cause for this incident been identified?	X Yes If yes, please describe: Employee failed to follow proper procedure, despite training.

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)

Employee will be retrained and SOPs will be rewritten to reflect a more direct and specific sharps policy.