incident report to nih oba

Does this incident involve research subject to the NIH Guidelines? [ ]  Yes [ ]  No

 If ‘NO’, this incident does not have to be reported to OBA.

Institution name: Click here to enter text.

Date of report: Click here to enter a date.

Reporter name and position: Click here to enter text.

Reporter Telephone #:

Reporter email: Click here to enter text.

Reporter mailing address: Click here to enter text., Click here to enter text., Click here to enter text.,

Date of Incident: Click here to enter a date.

Principal Investigator: Click here to enter text., Click here to enter text.

Is this an NIH funded project? [ ]  Yes [ ]  No

 If ‘YES’ please provide:

 NIH Grant Contract #:

 NIH Funding Institute or Center: Click here to enter text.

 NIH Program Office Contact Information (name, email, etc.): Click here to enter text.

What was the nature of the incident?

[ ]  Personnel exposure

[ ]  Spill

[ ]  Loss of containment

[ ]  Loss of transgenic animal

[ ]  Failure to obtain IBC approval

[ ]  Failure to follow approved containment conditions

[ ]  Other; please describe: Click here to enter text.

A protocol involving the use of recombinant Influenza A strain and E. coli DH5 alpha, was granted approval but was not reviewed and approved by the DU IBC full committee as required by the NIH Guidelines. This institutional error is in violation of the NIH Guidelines which requires that a convened committee review and approval be conducted for rDNA and synthetic nucleic acid molecules.

When did the Institutional Biosafety Committee (IBC) approve this research? Click here to enter a date.

 If yes, please provide:

 Approval date: Click here to enter a date.

 Approved biosafety level(s) for the research: Click here to enter text.

 Additional approval requirements: Click here to enter text.

What section(s) of the NIH Guidelines is the research subject to?

Click here to enter text.

Has a report of this incident been made to other federal or local agencies? If so please indicate by checking the appropriate box.

[ ]  CDC

[ ]  USDA

[ ]  FDA

[ ]  EPA

[ ]  OSHA

[ ]  State/Local Public Health

[ ]  Federal/State/Local Law Enforcement

[ ]  Research Funding Agency/Sponsor: Click here to enter text.

Description of recombinant or synthetic agent or material involved (please indicate strain, attenuation etc. as relevant.)

Click here to enter text.

Description of Incident:

Click here to enter text.

Has the IBC reviewed the incident?: [ ]  Yes [ ]  No

 If yes, please provide a copy the minutes of the IBC meeting in which the incident was reviewed.

Has a root cause for this incident been identified? [ ]  Yes [ ]  No

 If yes, please describe: Click here to enter text.

Describe measures taken by the institution to mitigate any problems identified:

Click here to enter text.