

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:

Date of report:

Reporter name and position:

Reporter Telephone #:

Reporter email:

Reporter mailing address:

Date of Incident:

Principal Investigator:

Is this an NIH funded project? Yes No

If 'YES' please provide:

NIH Grant Contract #:

NIH Funding Institute or Center:

NIH Program Office Contact Information (name, email, etc.):

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:

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.

Institutional Biosafety Committee (IBC)

When did the Institutional Biosafety Committee (IBC) approve this research?

If yes, please provide:

Approval date:

Approved biosafety level(s) for the research:

Additional approval requirements:

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

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:

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

Description of Incident:

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:

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