University of Nebraska Medical Center
Biosafety Policies and Procedures

IBC24-Form1. Adverse event and non-compliance to *NIH Guidelines* report form.

File this report within 7 days of the event with the UNMC Office of Regulatory Affairs. This form is used to report research-related adverse events only. Events involving the clinical laboratory are recorded using an "Incident Report" form.

Type of Report
(check appropriate box)

☐**Adverse event involving biohazardous agent**
(Event that involves contamination of personnel and/ or the environment with a biohazardous agent that has the potential to cause illness or that may cause significant concern to the general public.)

☐**Non-compliance to *NIH Guidelines***
(Failure of the PI to [1] supervise the safety performance of the laboratory staff, [2] investigate and report any significant problems pertaining to the operation and implementation of containment practices and procedures, [3] correct work errors and conditions that may result in the release of a biohazardous material, [4] ensure the integrity of the physical and biological containment, and [5] report any violation of the *NIH Guidelines* that results in personal injury.)

☐**Adverse event involving gene transfer experiments**
(Any event involving risk to the subject or others, that is both unexpected and associated with the use of the gene transfer product or any finding from tests in laboratory animals that suggests a risk for human research participants including reports of mutagenicity, teratogenicity, or carcinogenicity.)

Date of exposure _____ Individual reporting incident _____
Location _____ Primary Investigator (if applicable)_____
Biohazardous agent _____ Individual exposed (if applicable) _____
IBC # (if applicable) _____

Nature of the event _____
_____
_____
_____
_____

Action taken _____
_____
_____
_____

(Adverse event involving gene transfer experiments must also be filed using the IRB Research Infrastructure Support and Compliance web site.)

Office Use Only
Receipt date _____

_____
Signature, Title, Date

Follow-up response _____
_____
_____