TITLE:	**Reporting of Research-Related Adverse Event [SOP#UNMC-IBC 24]**
OVERVIEW:	Principal investigators using biohazardous agents are required to report any violation of the *NIH Guidelines* or any research-related accident/illness to the UNMC Office of Regulatory Affairs. This policy addresses the reporting process.
APPLIES TO:	All principal investigators conducting experiments with an approved IBC protocol.
DEFINITION(S):	***An adverse event involving a biohazardous agent is:*** any event (i.e., laboratory accident) that involves contamination of personnel and/or the environment with a biohazardous agent that has the potential to cause illness or may cause significant concern to the general public. ***An adverse event involving gene transfer is:*** any event involving risk to the subject or others, that is both unexpected and associated with the use of the gene transfer product (i.e. there is reasonable possibility that the event may have been caused by the use of the product); or 2) any finding from tests in laboratory animals that suggests a risk for human research participants including reports of mutagenicity, teratogenicity, or carcinogenicity. ***Non-compliance to* NIH Guidelines *is:*** failure of the primary investigator during the conduct of the research to: (1) supervise the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed; (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 biohazardous materials; (4) ensure the integrity of the physical containment [e.g., biosafety cabinets] and the biological containment [e.g., purity and genotypic and phenotypic characteristics]; and 5) any violation of the *NIH Guidelines* that results in personal injury.
PROCEDURES:	The *NIH Guidelines* contain requirements for reporting of significant problems, violations of the Guidelines, or any significant research-related accidents and illnesses. At UNMC/UNO, the Principal Investigator will report to the UNMC Office of Regulatory Affairs [UNMC-ORA]) who will subsequently forward the report to the Biosafety Officer or the IBC Chair for review. Significant incidents determined to require reporting to the NIH Office of Biotechnology Activities [NIH-OBA] will be transmitted on behalf of the Institution by the Associate Vice Chancellor for Academic Affairs, Regulatory