TITLE:	**IBC24- Reporting of Research-Related Adverse Event**
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.
DEFINITIONS:	***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 Compliance.

In accordance with institutional requirements, the Principal Investigator provides a signed assurance that he/she will comply with IBC requirements for reporting adverse events and for non-compliance to *NIH Guidelines*. The assurance is signed with the final submission of the approved version of the IBC protocol.

Reporting Procedures

Specific internal reporting procedures vary according to the type of problem encountered and are generally categorized into: a) an adverse events involving a biohazardous agent, b) an adverse event involving a human gene transfer trial, or c) non-compliance with the *NIH Guidelines*.

See **Appendix 1,** "Adverse Event and Non-Compliance to *NIH Guidelines* Report Form", for the notification process.

a) Adverse Event Involving a Biohazard

Note: *For individuals with known or potential exposure to a RG-2 or RG-3 agent, immediately contact the medical call center by using the OUCH pager (*9-888-OUCH [6824]) or by direct dial to 9-OUCH. The individual will be given advice as to the next steps based on approved protocols. A surveillance program and post-exposure follow up plan will be instituted. At the time of reporting, the UNMC Confidential Reporting of Occurrence form will be completed. This report is submitted to the office of UNMC Risk Management for review. A risk management employee will screen all reports of occurrence and immediately contact the Biosafety Office or the UNMC Office of Regulatory Affairs on all occurrences that involve or potentially involve a biohazardous agent.*

A written report is filed **by the Principal Investigator** within 7 days of occurrence with the UNMC-ORA at ibcora@unmc.edu using the Biosafety Program's, "Adverse Event and Non-Compliance to *NIH Guidelines* Report Form" available on the IBC website.

The Associate Vice Chancellor for Academic Affairs, Regulatory Compliance (UNMC-ORA), in consultation with the Biosafety Officer and the IBC Chair will review the report and determine whether a report must be sent to the NIH Office of Biotechnology Activities, NIH, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985. Reports that are filed with the NIH-OBA must be filed within 30 days after the occurrence. All exposures will be documented with the UNMC IBC as well.

b) Adverse Event Involving Gene Transfer

A written report is filed **by the Primary Investigator** within 48 hours of occurrence with the UNMC-ORA at ibcora@unmc.edu using the Biosafety Program's, "Adverse Event and Non-Compliance to *NIH*

	Guidelines Report Form" available on the IBC website. A report must also be filed using the IRB Research Infrastructure Support and Compliance (RISC) site as an internal adverse event. Supporting documentation should include either a completed NIH Gene Transfer Adverse Report Template or a completed FDA MedWatch form. Report fatal events by telephone or e-mail to the UNMC-IRB and to the UNMC Office of Regulatory Affairs immediately. Report all other adverse events within 48 hours of occurrence. The IBC Chair or the Biosafety Officer in consultation with an individual with expertise in the area of gene transfer research will review the report and forward it to the full IBC with recommendations. The UNMC IBC and the Associate Vice Chancellor for Academic Affairs, Regulatory Compliance will determine whether a report must be sent to the NIH Office of Biotechnology Activities, NIH, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 regardless of whether or not the sponsor will report the event. Adverse events which occur in gene transfer studies that must be reported to NIH-OBA are defined as events that are serious, unexpected and related or possibly associated with the use of the gene transfer product. Events which UNMC determines must be reported to NIH-OBA will be reported within: 1) 7 days of notification of sponsor for fatal or life-threatening events; 2) 15 days of notification of sponsor for all others. When the sponsor has accepted responsibility for reporting an adverse event to OBA, the IBC requires verification from the sponsor that the report has been filed. ***c) Non-compliance with the* NIH Guidelines** A written report is filed by the Primary Investigator within 7 days of occurrence with the UNMC-ORA at ibcora@unmc.edu using the Biosafety Program's, "Adverse Event and Non-Compliance to *NIH Guidelines* Reporting Form" available on the IBC website. The Biosafety Officer or the IBC Chair along with the Associate Vice Chancellor for Academic Affair, Regulatory Compliance will review the report to determine whether a report must be sent to the Office of Biotechnology Activities, NIH, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 within 30 days after the occurrence.
	Records will be kept on file in the UNMC Office of Regulatory

	Affairs/IBC.
OTHER INFORMATION:	The *NIH Guidelines* specifically require the reporting of significant problems, violations of the *Guidelines*, or any significant research-related accident or illness by the Institution (Section IV-B-1-j), the IBC (Section IV-B-2-b-[7]), or the Principal Investigator (Section IV-B-7-e-[2]). Safety reporting requirements for human gene transfer experiments are found in Appendix M-1-C-4. The UNMC Infection Control Specialist will monitor the UNMC OSHA log report to screen for individuals that may have had a biohazardous exposure while performing research activities. These reports will be forwarded to the Biosafety Officer or IBC Chair for follow up. The OSHA log reports will also be recorded in the UNMC Safety Leadership Team monthly minutes.
REFERENCES:	*NIH Guidelines for Recombinant DNA and Gene Transfer*, November 2013
STATUS:	Updated: July 7, 2015