

Washington University in St. Louis
Institutional Biological & Chemical Safety Committee

Policy on Severe Adverse Event Reporting for Human Gene Therapy Trials

As outlined in Section IV-B-2-b-(1) of the *NIH Guidelines for Research Involving Recombinant DNA Molecules*, the Institutional Biological & Chemical Safety Committee (IBC) is responsible for ensuring that all Principal Investigators (PIs) meet the requirements outlined in Appendix M of the *NIH Guidelines*. Among those responsibilities are 1) reporting any serious adverse event (SAE) which is both unexpected and associated with the use of the gene transfer product and 2) reporting any data from tests in laboratory animals which suggests a significant risk for human research participants. To assist PIs in meeting these requirements, the IBC is collaborating with the Human Research Protections Office (HRPO) to share SAE information submitted by PIs to HRPO. Under current HRPO reporting guidelines all serious adverse events occurring at WU during the conduct of a study require reporting. In addition, any SAEs occurring on a human gene therapy trial must be reported to the IBC. For any human gene therapy trial, HRPO will provide email notification to the BSO of SAE report submission (whether or not they are associated with treatment). The BSO will have access to the HRPO electronic submission system to obtain the necessary report information. The BSO will then follow up with the PI or study coordinator, provide them with the NIH SAE reporting template, and verify that the PI (or a delegate) has filed the appropriate report with NIH. All reports will be filed with NIH within 30 days as required by the *NIH Guidelines*.