NIH OFFICE OF SCIENCE POLICY REPORTING REQUIREMENTS FOR CLINICAL RESEARCH

The following table summarizes the NIH Office of Science Policy reporting requirements for Principal Investigators. Copies of NIH submissions, including cover letters, are sent to the University of Washington (UW) IBC Coordinator at ehsbio@uw.edu or Box 357165.

NIH Reporting Requirement	When	What to Submit
Initiation of clinical investigation	No later than 20 working days after enrollment of first research participant	See Appendix M-I-C-1
Additional clinical trial sites	Prior to enrollment of research participants at the new clinical trial site	See Appendix M-I-C-2
Annual reports	Within 60 days after the one-year anniversary of the date on which the investigational new drug (IND) application went into effect, and after each subsequent anniversary until the trial is completed	See Appendix M-I-C-3
Safety Reporting*	**When**	**See Appendix M-I-C-4**
Serious adverse event: fatal or life-threatening, unexpected, and associated with use of gene transfer product.	Must be reported as soon as possible, but not later than 7 calendar days after sponsor's initial receipt of the information	See Appendix M-I-C-4-a
Serious adverse event: unexpected and associated with the use of the gene transfer product, but not fatal or life-threatening	Must be reported as soon as possible, but not later than 15 calendar days after the sponsor's initial receipt of the information	See Appendix M-I-C-4-a
If, after further evaluation, an adverse event initially considered not to be associated with the use of the gene transfer product is subsequently determined to be associated	Must be reported within 15 days of the determination	See Appendix M-I-C-4-a

Safety Reporting*	When	See Appendix M-I-C-4
If relevant additional clinical and laboratory data becomes available following an initial serious adverse event report	Must be reported within 15 calendar days of the sponsor's receipt of the information	See Appendix M-I-C-4-a
If a serious adverse event occurs after the end of a clinical trial and is determined to be associated with the use of the gene transfer product	Must be reported within 15 calendar days of the determination	See Appendix M-I-C-4-a
Any finding from tests in laboratory animals that suggests a significant risk for human research participants including reports of mutagenicity, teratogenicity, or carcinogenicity	Must be reported as soon as possible, but not later than 15 calendar days after the sponsor's initial receipt of the information	See Appendix M-I-C-4-a

* Adverse events can be reported using the NIH/FDA Genetic Modification Clinical Research Information System (GeMCRIS).

Questions?

Contact the IBC Coordinator for assistance at ehsbio@uw.edu or 206.221.7770.