

## HUMAN GENE TRANSFER POST-APPROVAL REPORTING REQUIREMENTS SUMMARY SHEET

This table summarizes which events or information should be reported to the UCLA IBC and/or NIH Office of Science Policy (NIH OSP) and the reporting window. Refer to the [OHRPP website](#) for information on post-approval reporting to the IRB. If a post-approval report warrants a change to the research (i.e., change in study status, informed consent form), submit an amendment in [SafetyNet](#) along with the report.

What to Report	When to Report	How to Report
<b>SERIOUS ADVERSE EVENT (SAE)</b>		
<b>INTERNAL (on-site) SAE</b> that PI determines to be: 1) Fatal or life-threatening, 2) Unexpected, <b>and</b> 3) Associated or possibly associated with the use of the HGT product <sup>c</sup>	Within <b>7 calendar days</b> after sponsor's initial receipt of information (i.e., at the same time the event must be reported to the FDA) <sup>a, b, d</sup>	Use <a href="#">NIH OSP</a> form, <a href="#">FDA MedWatch</a> forms, or other means, provided that all elements outlined in <a href="#">NIH Guidelines Appendix M-I-C-4-a</a> are included. Clearly label as a "Safety Report".
<b>INTERNAL (on-site) SAE</b> that PI determines to be: 1) Not fatal or life-threatening, 2) Unexpected, <b>and</b> 3) Associated or possibly associated with the use of the HGT product <sup>c</sup>	Within <b>15 calendar days</b> after sponsor's initial receipt of information (i.e., at the same time the event must be reported to the FDA) <sup>a, b, d</sup>	Report to: <ul style="list-style-type: none"> <li>• NIH OSP<sup>e</sup></li> <li>• UCLA IBC via email at <a href="mailto:ibc@research.ucla.edu">ibc@research.ucla.edu</a></li> </ul>
<b>EXTERNAL (off-site) SAE</b>	UCLA Reporting Not Required	
<b>LABORATORY ANIMAL FINDINGS</b>		
Any finding from tests in laboratory animals that suggests a significant risk for human research participants including reports of mutagenicity, teratogenicity, or carcinogenicity.	Within <b>15 calendar days</b> after sponsor's initial receipt of information (i.e., at the same time the event must be reported to the FDA) <sup>b</sup>	Reports must be submitted in a narrative format and clearly labeled as a "Safety Report".  Submit to: <ul style="list-style-type: none"> <li>• NIH OSP<sup>e</sup></li> <li>• UCLA IBC by creating and amendment in <a href="#">SafetyNet</a></li> </ul>
<b>ANNUAL REPORTS</b>		
<ul style="list-style-type: none"> <li>• Report must include all information set forth in <a href="#">NIH Guidelines Appendix M-I-C-3</a></li> <li>• When multiple studies are conducted under single IND, the PI (or delegate) may choose to submit a single annual report covering all studies, provided that each study is identified by its OSP protocol number</li> </ul>	1) Within <b>60 days</b> after the one-year anniversary of the date on which the IND application went into effect, <b>and</b> 2) After each subsequent anniversary until the trial is completed	Submit to: <ul style="list-style-type: none"> <li>• NIH OSP<sup>e</sup></li> <li>• UCLA IBC by creating and amendment in <a href="#">SafetyNet</a> (attach report to Human Gene Transfer page of BUA)</li> </ul>
<b>INCIDENTS (BIOSAFETY-RELATED)</b>		
Biosafety-related incidents including spills, staff exposures, etc. Refer to <a href="#">EH&amp;S Website</a> for additional information	Within <b>8 hours</b> of Incident	Call EH&S Hotline (x59797, 310-825-9797)

<sup>a</sup> If SAE occurs after the end of a clinical trial and is determined to be associated with the use of the gene transfer product, that event shall be reported to the NIH OSP and UCLA IBC within 15 calendar days of the determination.

<sup>b</sup> Changes to this schedule are permitted only where, under the FDA IND regulations, changes in this reporting schedule have been approved by the FDA and are reflected in the protocol

<sup>c</sup> 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, then the event must be reported to the NIH OSP and UCLA IBC within 15 days of the determination.

<sup>d</sup> Any follow-up information relevant to a serious adverse event must be reported within 15 calendar days of the sponsor's receipt of the information.

<sup>e</sup> Use one of the following methods to report to NIH Office of Science Policy (NIH OSP):

- email to [HGTprotocols@mail.nih.gov](mailto:HGTprotocols@mail.nih.gov);
- fax to 301-496-9839; or
- mail to the Office of Science Policy, National Institutes of Health, MSC 7985, 6705 Rockledge Dr, Suite 750, Bethesda, MD 20892-7985)