# SOPP 9150.2: Notification of National Institutes of Health (NIH) / Office of Biotechnology Activities (OBA) of FDA's Receipt of Adverse Event Reports to Gene Therapy INDs

**Version #3**
**Date: October 1, 2002**

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## 1. Purpose

This SOP describes the process that Office of Cellular, Tissue and Gene Therapies (OCTGT) staff should follow to notify OBA of FDA's receipt of reports of adverse events to gene therapy Investigational New Drug Applications (INDs).

## 2. Background

Sponsors of INDs are required to notify the FDA, in an IND safety report of any serious and unexpected adverse event associated with the use of the investigational product (21 CFR 312.32(c)). The NIH Guidelines for Research Involving Recombinant DNA Molecules require certain sponsors of gene therapy clinical trials to report adverse events to OBA. The sponsors subject to the NIH Guidelines are those receiving NIH funds or conducted at or sponsored by institutions receiving NIH funding.

The Review Management Staff processes incoming IND amendments and categorizes them according to content. Amendments containing IND safety reports are categorized and labeled under the heading of Clinical Information, either as adverse event-initial written report-death, adverse event-initial written report -15-day, adverse event-follow-up report-autopsy, adverse event-follow-up report-autopsy, or clinical report-safety update. This information is entered into the Biologics Information Management System (BIMS) and is accessible for compilation into reports.

## 3. Policy

CBER will report to OBA the fact that it received initial IND safety reports of serious and unexpected adverse events as defined in 21 CFR 312.32 as well as the receipt of any other adverse events that are similarly reported. This reporting will be carried out in order to allow OBA to monitor investigator compliance with the adverse event reporting requirements in the *NIH Guidelines for Research Involving Recombinant DNA Molecules*.

## 4. Procedures

The Regulatory Health Project Manager the Review Management Staff will run the "Gene Therapy IND Adverse Event Amendments" report every two weeks. This report queries BIMS for all adverse event-initial written report-death or adverse event-initial written report-15-day amendments received for gene therapy INDs for the Office and

time period specified. Parameters to be entered are OCTGT for the Office and the date range for the two week period since the last report. . The following information will be included in the report:

a. IND number
b. IND receipt date
c. Sponsor
d. Title
e. Proposed use (from original IND submission)
f. IND status
g. Amendment number
h. Amendment receipt date
i. Amendment type

The report will be sent by facsimile by the Review Management Staff to the designated contact person at OBA on the day it is generated.

**5. History**

| Comment/ Revision | Approved By | Approval Date | Version Number | Comment |
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| Leonard Wilson | Robert Yetter, Ph.D | 10/01/2002 | 3 | This version updates the change in responsibility for these procedures from the Office of Therapeutics to the Office of Cellular, Tissue, and Gene Therapies. Version 2 of this SOPP was SOPP 9110.2 under OTRR. |
| Glen Jones, Ph.D. | Robert Yetter, Ph.D. | 8/17/2001 | 2 | Changes to reflect the new report format:<br>• Eliminates decision date and reviewer names;<br>• Changes reporting from weekly to biweekly;<br>• Changes submission date to IND received date. |
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