SOPP 9150.1: Notification of National Institutes of Health (NIH) / Office of Biotechnology Activities (OBA) of Changes in a Gene Therapy Protocol

Version #3

Effective Date: October 1, 2002

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1. Purpose

This SOP describes the process that CBER staff should follow to notify OBA that FDA has received changes in study protocols for gene therapy clinical trials submitted as amendments to the Investigational New Drug Application (IND).

2. Background

CBER reviews all human gene therapy protocols as part of the IND process under which clinical trials are conducted. The NIH Guidelines for Research Involving Recombinant DNA Molecules require that human gene therapy protocols subject to the Guidelines and that involve a novel product, disease indication, route of administration or other component be discussed at the quarterly public meetings of the Recombinant DNA Advisory Committee (RAC). In order to coordinate NIH and FDA activities involving gene therapy protocols, FDA agreed to notify NIH of the submission of human gene therapy INDs to CBER. However, it is possible that the protocol could be modified by the sponsor in response to the comments of one group, subsequent to the review of the other. FDA regulations require that sponsors report protocol changes to the IND, and the NIH Guidelines require investigators to report any changes made to address RAC and FDA comments to OBA.

3. Policy

It is CBER's policy to notify OBA of new IND submissions and that FDA has received IND amendments containing changes to gene therapy protocols.

4. Procedures

The Regulatory Health Project Manager the Review Management Staff runs the "Gene Therapy IND Protocol Amendments" report every two weeks. This report queries BIMS for all protocol-new or protocol-revised amendments received for gene therapy INDs for the Office and time period specified. Parameters to be entered are OCTGT for the Office and the data 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

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

CBER's IND acknowledgement letter will state that sponsors subject to the NIH guidelines should report all major protocol changes to OBA. This will include reporting of changes that occur as a result of FDA IND review or changes initiated by the sponsor. CBER will include a similar statement in letters sent regarding requirements for submission of annual reports.

5. Effective Date
October 1, 2002

6. History

Written/Revised	Approved	Approval Date	Version Number	Comment
Leonard Wilson	Robert Yetter, PhD	October 1, 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 9110.1 under OTRR
Glen Jones, PhD	Robert Yetter, PhD	August 17, 2001	2	Changes to reflect the new report format: Eliminates decision date and reviewer names; Changes reporting from weekly to biweekly; changes submission date to IND received date.
			1	Original