Procedure Name: **Closing Completed Trials Procedures**
Effective Date: **March 26, 2010**
Revision: **01**
Initiating Department: **Office of Clinical Trials**
Procedure Number: **OCT-006**
Application: **Closing Completed Trials**

OBJECTIVE:

The objective of this procedure is to ensure that all studies reflect a timely financial closing with reasonable expenses. "Timely financial closing" and "reasonable expenses" will be determined jointly on a case-by-case basis by the Clinical Research Coordinator (CRC) and the Financial Manager, subject to the approval of the Director of Clinical Trials. "Timely financial closing" is normally within 90 days after the IRB closing. "Reasonable expenses" incurred during the closing period are driven by the time the CRC must devote to the closing process.

REFERENCES:

OPHS-IRB Manual, Section 7.5	Project Closure

SCOPE:

This procedure applies to all clinical trial.

PROCEDURE:

The Institutional Review Board (IRB) coordinator will copy the Clinical Trials Financial Manager on all clinical trial final board actions (closing actions).

Upon receipt of the closing action from the IRB, the Financial Manager will:

1. Meet with the CRC to estimate the calendar time required for clinical closing of the trial;

2. Obtain written documentation from the PI if final closing cannot be done within 90 days of the IRB's closing action;

3. Verify the remaining cash balance of the study project;

4. Audit the receipts of the study to ensure all payments due the Office of Clinical Trials (OCT) have been made by the sponsor and correctly processed by the OCT;

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5. Audit the file to ensure that all study expenses have been paid and are reflected in EIS;

6. Prepare a final financial report of the protocol and distribute copies to the Director of Clinical Trials (Director), the PI, the CRC, the Business Manager of the trial's department, and the protocol file folder;

7. Roll the remaining balance from the project account to the department's clinical trial account;

8. Close the study on EIS and on Study Manager; and

9. File the protocol's file in the closed section of protocol files.

REVISION HISTORY

Rev	DCO	Description of Change	Approved by
1	10-106	Replacement of "policy" with "procedure"; addition of references and change history	MVWB

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