



Procedure Name: Non-Enrolling Trials Procedures
Effective Date: March 26, 2010
Revision: 01
Initiating Department: Office of Clinical Trials
Procedure Number: OCT-005
Application: Non-Enrolling Trials
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OBJECTIVE:

The objective of this procedure is to describe the process to follow in order to close a clinical trial which has not enrolled any subjects within one year of having obtained a fully executed contract.

REFERENCES:

OPHS-IRB Manual, Section 7.5	Project Closure
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BACKGROUND:

The IRB requires study closure after two or more non-enrolling years (mitigating circumstances notwithstanding); however, their policy does not preclude the closure of a study at the one-year mark, as outlined in this procedure.

SCOPE:

This procedure applies to all clinical trial protocols managed by the Office of Clinical Trials (OCT) approved by the Institutional Review Board.

PROCEDURE:

Within 10 days after the end of each quarter, the Financial Manager will furnish the Director of Clinical Trials (Director) a list of protocols which have had no enrollments during the first year of existence. For these protocols the Director will:

1. Notify the Principal Investigator (PI) and the Clinical Research Coordinator (CRC) in writing that the trial will be placed on three months probation, during which time subjects must be enrolled or the trial will be closed administratively;
2. If no subject is enrolled during the probationary period, contact the PI to determine if there are extenuating circumstances to justify keeping a study open (e.g., the study is about a rare condition). If there are none, notify the IRB to close the trial; and

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3. Notify the Financial Manager to close the trial on both the HSC's and OCT's books and to refund any monies due the sponsor under the terms and conditions of the protocol contract.

EXCEPTIONS:

Exceptions to placing a trial on probation include:

1. Administrative reasons, (e.g., sponsor has put the trial on hold); or
2. Adequate written justification for non-enrollment from the PI, with adequacy to be determined by the Director in concurrence with the Vice President, Research.

REVISION HISTORY

Rev	DCO	Description of Change	Approved by
1	10-105	Replacement of "policy" with "procedure"; addition of references and change history	MVWB

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