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**Example Cover Letter: AMENDMENT**

February 31, 2010

IRB Office  
3535 Market St, Suite 1200  
Philadelphia, PA 19104

Re: IRB # 10-006999, Minor Amendment

Title: An Introspective Approach to Research Coordinator Training: How not to lose my mind!

To Whom It May Concern:

The materials for a minor amendment of IRB # 10-006999 “An Introspective Approach to Research Coordinator Training: How not to lose my mind!” have been attached in the eIRB application.

## Amendment Overview

Provide an overview of the proposed changes to the protocol, consent documents, recruitment materials, study scales, tests, etc. Include a list of the documents being attached in eIRB.

Include a rationale for the amendment, the effect of the changes on the likelihood for harm and prospects for benefit (if any) to subjects and any impact on risk – benefit assessment. If the amendment is due to newly identified risks or impact on prospect for benefit, discuss the plans, if any, for informing current and former subjects.

Version Control: Be sure that every document that is being modified is dated and preferably, has a version number to identify it as “new”. The new versions should be submitted in two versions, one with highlighted changes and one that is clean.

Example:

The minor amendment includes revisions to the protocol, consent form and eIRB SmartForm. Specific changes include:

* The removal of a study visit. Formerly there were 5 study visits but we have found that 4 visits are sufficient to complete the data collection.
* A decrease in the amount of reimbursement being provided. Each subject will now be reimbursed $40 instead of $50 to reflect the removal of a study visit.
* An increase in number of subjects to be enrolled. We would like to increase our enrollment by 20 subjects to increase precision, as outlined in the revised statistics section of the protocol.
* A change to a study procedure. Blood pressure will no longer be completed as a study procedure at the study visits. All subjects in this population receive blood pressure measurements at standard care visits. Therefore, instead of performing a duplicate measurement, this information will be extracted from subjects’ charts.

We feel that the proposed changes meet the criteria for a minor amendment and do not affect the risk or benefits of participating in the study.

The following documents are attached in Section 12.01 of the Modified Study SmartForm:

* Study Protocol- clean version (Version 2.0 dated 2/31/2010)
* Study Protocol- edited version (changes tracked)
* Consent Form- clean version (dated 2/31/2010)
* Consent Form- edited version (changes tracked)

If you have any questions or require any further information, please contact me at extension 45141 or my study coordinator, Stewart Gilligan Griffin at extension 65555.

Sincerely,

Mary Smith, MD

# List of Changes

This section defines the IRB’s preferred format for listing the changes in a protocol amendment. The use of this format permits that IRB to rapidly identify the proposed modifications, the justification for the modifications and to link those changes to the amended documents.

Multi-center studies that provide the CHOP investigator with an alternative format will be accepted, provided that all of the information outlined below is included.

## Protocol Changes

### 1) Change #1

Specify the proposed change and list the Section of the protocol where the change is being made.

Justification

Provide the scientific, technical, editorial or other rationale for this change.

Old Text

“Include the previous wording exactly as listed in the protocol.” (if applicable)

New Text

“Include the new wording as included in the new version of the protocol.”

### 2) Change #2

Specify the proposed change and list the Section of the protocol where the change is being made.

Justification

Provide the scientific, technical, editorial or other rationale for this change.

Old Text

“Include the previous wording exactly as listed in the protocol.” (if applicable)

New Text

“Include the new wording as included in the new version of the protocol.”

Etc.

## Consent Document Changes

### 1) Change #1

Specify the proposed change and list the Section of the consent form where the change is being made.

Justification

Provide the scientific, technical, editorial or other rationale for this change. May refer to justifications in protocol above.

Old Text

“Include the previous wording exactly as listed in the approved consent document.” (if applicable)

New Text

“Include the new wording as included in the new consent document.”

Etc.

## Recruitment Materials

### 1) Change #1

Specify the proposed change and list where the change is being made.

Justification

Provide the scientific, technical, editorial or other rationale for this change. May refer to justifications in protocol above.

Old Text

“Include the previous wording exactly as listed in the approved materials.” (if applicable)

New Text

“Include the new wording as included in the new materials.”

## Study Instruments, Questionnaires, Scales, Tests, etc.

### 1) Change #1

Specify the proposed change in and list where the change is being made.

Justification

Provide the scientific, technical, editorial or other rationale for this change. May refer to justifications in protocol above.

## Attach all Amended Documents

(can delete this requirement for Click)