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Example Cover Letter: RESPONSE to STIPULATIONS

February 13, 2009

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

Re: IRB # 2009-2-9999, Expedited Continuing Review
Title: An Introspective Approach to Research Coordinator Training: How not to lose my mind!

To Whom It May Concern:

Please find attached to this letter, materials in response to the stipulations for approval of the continuing review for IRB # 2009-2-9999, "An Introspective Approach to Research Coordinator Training: How not to lose my mind!"

Below is a listing of each stipulation and our responses:

Form CR-C

1. Page 1: The progress report indicates that the grant was reviewed and renewed by the NIH in the past year. However, "no" is checked for "has a new grant application or competing renewal been submitted since the last continuing review". Please reconcile. Is the current grant on file, the most recent version?

Form CR-C was filled out incorrectly. There has been a new grant application submitted in the past year. Form CR-C has been revised to reflect this and a copy of the full grant is included with this submission.

2. Page 2: In the progress report, you indicate that 352 subjects and 55 controls have been enrolled in the study. However, the enrollment table is only indicating 352 persons. The 55 controls should be included in the total enrollment number. Please revise the enrollment table to include the controls.

The enrollment table on page 2 has been revised appropriately.

3. Page 5: The team listing indicates Mickey Mouse as a research assistant. Please clarify when the IRB was notified of this addition as he is not currently listed as team member in the IRB database.

The team listing was incorrect. Mickey Mouse is a research assistant on a similar study but is not a team member on this study. The team listing in Form CR-C has been revised.

4. Page 6: Please complete the tracking of disclosures section.

Page 6 has been revised to show that no PHI has been disclosed outside of the institution.

Protocol:

1. Please include a title page for the protocol which includes the Study title, IRB #, PI name, and version date so that the IRB can track versions of the protocol.

A title page has been created and is now part of the protocol. The version date for the protocol is 2/13/2009. This version date will be updated as necessary with any future changes.

2. Please provide information regarding the enrollment procedures (i.e., when/where are subjects approached, who introduces the study to them, etc).

Information regarding the enrollment procedures has been added in Section 3.01 (page 14), Section 6.3 (page 18) and Section 6.5 (page 19). Please refer to the tracked changes version attached to see the additions. A clean version (dated 2/13/2009) which includes these changes has also been provided.

Consent:

1. Please review the attached edited consent form and accept the proposed changes.

The revised consent has been reviewed and the changes are acceptable. The new version date is now 2/13/2009.

We hope the responses above adequately address each of the IRB's concerns.

The following documents are included with this review:

- Form CR-C- (revised dated 2/13/2009)
- Study Protocol- edited with tracked changes (previously undated)
- Study Protocol- clean version (dated 2/13/2009)
- Consent Form- edited with tracked changes (dated 1/28/2009)
- Consent Form- clean version (dated 2/13/2009)
- Updated NIH grant (dated 12/11/2008) # 5 R01 HL123451-01A2

The expiration date for this study is April 1, 2009.

Please contact myself (x45141) or my study coordinator, Stewart Gilligan Griffin (x-55555), if you have any questions or require any further information.

Sincerely,

Mary Smith, MD
Principal Investigator