

## CHECKLIST FOR ADDENDUM SUBMISSIONS

- 1 -

This checklist is to assist you in submitting a complete addendum application to the IRB. Please note that *an incomplete submission may delay the processing of your application.*

**Please submit two complete sets (original and one copy) of the following materials**

### **REQUIRED:**

- \_\_\_\_\_ HS-1 form, page 1, signed by the principal investigator
  
- \_\_\_\_\_ Explanatory cover letter, signed by the principal investigator The cover letter should:
  - \_\_\_\_\_ Provide a summary of the modifications made to items
  - \_\_\_\_\_ Describe the reason(s) for the modifications
  - \_\_\_\_\_ Update the IRB with regards to how many subjects are currently participating (if any) and whether the changes affect those subjects
  
- \_\_\_\_\_ **If your application is more than 50 pages, please provide a signed and completed Copy Center Request form.**
  
- \_\_\_\_\_ This checklist with indication of the submitted materials

### **AS APPLICABLE:**

**Please provide bold typeface or underline changes on one copy for the reviewers and provide two clean copies to be used as the official version of each revised document.<sup>1</sup>**

- \_\_\_\_\_ modified Protocol Summary (Form HS-1, Section IV)\*
  - \* ***When to submit a revised Protocol Summary:*** For proposed amendments which result in new recruitment or study procedures, including a change in inclusion/exclusion criteria, please submit a REVISED copy of the Protocol Summary (HS-1, IV)<sup>2</sup>, which reflects the proposed modifications in all applicable sections. Amendments such as change in research personnel, or revisions to previously approved recruitment materials or consent forms do NOT require a revised Protocol Summary.
  
- \_\_\_\_\_ new/modified recruitment materials
- \_\_\_\_\_ new/modified informed consent forms, assent forms, or information sheets
- \_\_\_\_\_ addendum to consent form for current subjects (if necessary)
- \_\_\_\_\_ new/modified instruments (incl. surveys, questionnaires, etc.)
- \_\_\_\_\_ new/modified investigator's brochure, sponsor's protocol, package insert, etc.
- \_\_\_\_\_ new/modified Form HS-1, Section II and Section VIII if reporting any new financial interests or any changes to financial interests (especially important if adding new investigators)

<sup>1</sup> For more information, see *Guidance – How to Track Changes While You Edit*, at end of this checklist.

<sup>2</sup> OHRP's "Guidance Relevant to Review of Protocol Changes" advises "... that each revision to a research protocol be incorporated into the written protocol. This practice ensures that there is only one complete protocol with the revision dates noted on each revised page and the first page of the protocol itself. This procedure is consistent with the procedure used for revised and approved informed consent documents which then supersede the previous one."  
[Guidance on Written IRB Procedures. Office for Human Research Protections (OHRP), Department of Health and Human Services. July 11, 2002. < <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/irbgd702.htm>>.]

*Please see page 2 for additional requirements for items listed in “As Applicable” section.*

**Please submit two complete sets (original and one copy) of the following materials**

**AS APPLICABLE - ADDITIONAL REQUIREMENTS:**

*\* If the addendum requires a Revised Protocol Summary, please note the following:*

- \_\_\_\_\_ **Please bold/underline added text or proposed changes AND please show all deleted text using strikethrough markings. (e.g., ~~strikethrough~~)<sup>3</sup>**
- \_\_\_\_\_ For clarity, we suggest that you provide information under separate sub-headings (e.g., for each subject population and/or phase of the research)
- \_\_\_\_\_ The Protocol Summary should include a description of ALL research procedures - including those which have been completed, those which are currently proposed, and those which are planned for the future. This enables the Committee to assess the proposed revision in the context of the research which has been previously approved.

*\*\*For each revised clinical protocol or investigational drug brochure, please include:*

- \_\_\_\_\_ A copy of the new protocol/brochure
- \_\_\_\_\_ A summary of the revisions made to the new protocol/brochure
- \_\_\_\_\_ A description of the reason(s) for the revisions to the protocol/brochure

*If the addendum includes submission of additional funding source, please:*

- \_\_\_\_\_ Submit a revised HS-1 form, Section II
- \_\_\_\_\_ Include a copy of the grant application for the new funding source
- \_\_\_\_\_ Submit a cover letter explaining whether the new funding will result in change(s) to the previously-approved protocol (list the IRB# as the reference number). If yes, also submit:
  - \_\_\_\_\_ Cover letter describing the changes
  - \_\_\_\_\_ REVISED Protocol Summary (HS-1, IV) which includes a description of the changes in all applicable sections
- \_\_\_\_\_ Find out whether study personnel have any financial interests related to the new funding source. If yes, please submit:
  - \_\_\_\_\_ modified Form HS-1, Section II, Question 3 (if necessary)
  - \_\_\_\_\_ Form HS-1, Section VIII completed by each individual with a financial interest related to the new funding source

*If addendum includes a request to change the principal investigator (PI)*

- \_\_\_\_\_ The cover letter must be signed by both the “new” PI and the “old” PI
- \_\_\_\_\_ The cover letter must state whether or not the “new” PI has a financial interest in the study (based on the definition in Form HS-1, Section II, Question 3). If yes, please submit:
  - \_\_\_\_\_ modified Form HS-1, Section II, Question 3 (if necessary)
  - \_\_\_\_\_ Form HS-1, Section VIII completed by the “new” PI

<sup>3</sup> For more information, see *Guidance – How to Track Changes While You Edit*, at end of this checklist

**GUIDANCE - HOW TO TRACK CHANGES WHILE YOU EDIT**

Open the document you want to revise.

On the **Reviewing** toolbar, click **Track Changes**.

When change tracking is turned on, Microsoft Word uses **revision marks**, the equivalent of "redlining" or "blacklining" in the legal profession, to indicate tracked changes.

**revision mark**

A mark that shows where a deletion, insertion, or other editing change has been made in a document. Microsoft Word can track changes in one of two ways: by marking the revisions as you make them, or by marking the revisions later when it compares the two versions of the document.

To specify whether Word should show tracked changes and how you want inserted, deleted, and changed text to appear, click the **Track Changes** tab in the **Options** dialog box (**Tools** menu).

Tracked changes can appear as follows:

Marco, please send this out for review now.

After viewing tracked changes, you can accept or reject each change.

You can also choose to show or hide tracked changes on the screen or in the printed document by using the **Highlight Changes** dialog box (**Tools** menu, **Track Changes** submenu, **Highlight Changes** command).