Tool Summary Sheet

Tool:	Protocol Amendment Summary of Changes Template
Purpose:	To support the documentation of changes from one IRB approved version of a protocol to the next
Audience/User:	The protocol amendment author will use the tool to create the summary of changes.
Best Practice Recommendations:	

- Administrative details of template
  - Review this template and customize to the specific needs and requirements of the study. Sample text may be updated as needed.
  - In the template, the instructions and explanatory text are indicated by {blue italics}. Instructional text will also be enclosed in braces to signify this text for screen-readers used by the visually impaired.
  - Text enclosed with <> is a placeholder for a specific detail (e.g., <protocol title>); replace as appropriate.
  - Remove <> and instructional text before finalizing the document.

- Pre-amendment
  - It is useful to maintain an ongoing list of potential protocol changes: both administrative changes as well as substantive changes that are being considered for inclusion in a protocol amendment. Some maintain a working version of a protocol amendment where the POTENTIAL changes have been tracked in a version of the protocol that is maintained separately from the active version.
  - To reduce paperwork and confusion, when possible it is helpful to batch protocol changes together into one amendment.
  - The list of potential changes should be vetted through the protocol team, prior to inclusion in the draft protocol amendment that is submitted to the IRB.

- Preparing and reviewing the protocol amendment summary document
  - Consider IRB-specific guidelines/preferences when

preparing the protocol amendment summary document.

- o The structure of the protocol amendment summary document may depend on the contents of the amendment. In some cases, it may be most appropriate to list the changes 1 by 1 as they appear in the protocol. In other cases, an ordering by conceptual change [e.g., 1) DSMB requested changes; 2) administrative changes] may be best.

- o When possible, protocol section numbers should be referenced. It is also helpful to reference page numbers.

- o Include a rationale for each set of protocol changes. Document as "Administrative change" when appropriate.

- o The protocol amendment summary document should be carefully reviewed and confirmed against the actual protocol amendment immediately before submission. Remember that page numbers change as things are updated in the protocol. It is therefore important to do a quality control check of the section and page numbers.

- It is best to submit a pdf of the protocol if you are referencing page numbers. This is because page numbers for pdfs are constant across all computer software and systems, whereas the pagination in MS Word documents is system/printer dependent.

- The protocol amendment summary document will be submitted to the IRB and will be stored in the study files and accessed by the study team.

- It is preferable to maintain both a track-changes and a clean version of the protocol version that is submitted to the IRB.

Tool Revision History:

Version		
Number	Date	Summary of Revisions Made:
1.0	30March2011	Approved version

Detailed Summary of Protocol Changes

Protocol Number:

Protocol Title:

	Version Number	Version Date
Current Approved Protocol	<Version # of most recently approved protocol>	<Date of most recently approved protocol>
Amended Protocol	<Version # of amended protocol being submitted to the IRB>	<Date of amended protocol being submitted to the IRB>

Section and page numbers are references to the {indicate track-changes version, if that is what you are using} amended protocol.

1. <Section Number, Section Title, Page Number(s)>

Old Text:

New Text: {Include new text, preferably with track-changes on to reveal the differences from the previous version of the document}

Rationale for Change:

2. <Section Number, Section Title, Page Number(s)>

Old Text:

New Text: {Include new text, preferably with track-changes on to reveal the differences from the previous version of the document}

Rationale for Change:

3. Administrative changes: Minor changes involving grammar, wordsmithing, punctuation, and other editorial changes have been made throughout the document. All are clearly identified in the track-changes version of the amendment.