

Summary of Modifications to 2008 Interim Guidelines

Overall

Margins and spacing have been increased for better document readability.

The term 'transdisciplinary' is now used consistently in place of 'multi' and 'inter' - disciplinary.

The guidelines for application and review of consortia, previously consolidated as separate sections, have been inserted into the relevant individual components.

Table of Contents

A more detailed Table of Contents is included.

Clarifications (previously posted on our website and distributed to reviewers)

Categories of Staff Investigator (i.e., Research v Clinical) and their relevant criteria have been better defined (pages 20 and 51).

Specifics relevant to the application and review for Clinical and Protocol Data Management Shared Resource, the Protocol Review and Monitoring System, Data and Safety Monitoring, and Protocol Specific Research Support have been added to the Guidelines (pages 32-36 and 53-54)

Text on minority accrual has been modified to reflect consideration of all interventional trials in decisions relevant to approval (pages 40 and 54).

Application instructions and review criteria for the 2nd stage non-scientific review of comprehensiveness have been clarified (pages 40 and 55-56).

Other Changes

Standard language (paralleling that found in new National Cooperative Group and SPORE guidelines) regarding consideration/reward for participation/leadership in all types of clinical trials (including cooperative group trials, etc.) has been incorporated (pages 8 and 52).

New application dates have been inserted (page 13).

Shared resource reporting criteria have been modified to request the top 75% of users, rather than 90% (page 30-31).

Templates provided for clinical study reporting have been modified to eliminate sections not useful for review and provide greater clarity. More explicit instructions have been added for their completion (pages 32-33 and 35).

Peer Review

Overall Quality of the Programs and Duration of Award have been re-inserted as review criteria (pages 52 and 55).