

MEMORANDUM

To: CIRB Stakeholders
From: John D. Horigan, MA, CIP
Director of Central Operations; NCI CIRB Operations Office
Date: October 18, 2017
Subject: Revisions to CIRB SOPs

An updated version of the CIRB SOPs has been posted at <https://www.ncicirb.org/about-cirb/sops>.

If you have any questions regarding the changes to the SOPs, contact the CIRB Helpdesk: ncicirbcontact@emmes.com or 1-888-657-3711.

An overview of the changes to the SOPs is detailed below.

General Changes

1. Editorial and Administrative updates have been made throughout.
2. The mission statement and logo for the CIRB has been updated in the cover pages.

Section 2 Foundational Principles

1. Section 2.3.8.3 was added to clarify that the CIRB's review does not cover activities of the coordinating center.

Section 4 CIRB Membership

1. Section 4.1.1 was revised to allow Patient Advocate members of the CIRBs to serve as alternates for Patient Advocates serving on other CIRBs (related changes have been made throughout the SOPs).
2. Section 4.11 has been updated to clarify the Conflict of Interest policy for CIRB members.

Section 5 Meeting Administration

1. Section 5.9.1.4 was added to clarify the establishment of the expiration date (period of approval) at the time of initial review.
2. Section 5.9.6.7 was revised to indicate that the period of approval begins when the CIRB approves a study (rather than when the CIRB approves pending modification; related changes have been made throughout the SOPs).
3. Section 5.9.9.5 was added to address CIRB review and approval of validated translations.
4. 5.9.9.5 – addresses CIRB review of validated instruments/translations
5. 5.12.3 – added to address quorum and alternates (see also 4.1.1)

Section 7 CIRB Decision-Making

1. Section 7.8 “Inclusion of Individuals who do not Speak English” has been added. This section addresses translation of consent forms, use of short form consent forms, and instruments directed to study participants.

Section 8 CIRB Decision-Making: Specific Considerations Based on Review Type

1. Section 8.2.3 was revised to allow expedited review of Study Chair responses when the Study Chair declines to make a change requested by the CIRB when the expedited reviewer determines that there is sufficient justification for declining to make the requested change.