

m

MEMORANDUM

To:	CIRB Stakeholders
From:	Amanda P. Sly, BA, CIP Director of Central Operations; NCI CIRB Operations Office
Date:	August 2, 2019
Subject:	Revisions to CIRB SOPs

An updated version of the CIRB SOPs is now available on the CIRB website.

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.

Section 3.0 CIRB Responsibilities

- 1. Section 3.1.1.6 – Removed this section, as the CIRB reviews Unanticipated Problems and Serious or Continuing Noncompliance but not individually Adverse Event Reports.
- 2. Section 3.1.7 – Updated to clarify that documents will be provided directly to coordinating groups if a secure website is not available.

Section 4.0 CIRB Membership

- 1. Throughout the terminology 'patient advocate' was changed to 'non-scientist'.
- 2. 4.1.2.7 – Added the requirement for an ethics professional to serve as a member of the CIRB.
- 3. 4.3.3 – Added the requirement for reappointment letters to be issued to CIRB members upon reappointment. Lengthened CIRB term lengths from two to three years.
- 4. 4.3.6, 4.3.6.1 and 4.3.6.2 – Updated to clarify when a CIRB member may be removed from the CIRB before the end of their term.
- 5. 4.4.4 – Added text confirming new CIRB members cannot serve on the CIRB until all training requirements have been completed.
- 4.4.11 Added text requiring a training session during CIRB meetings once per 6. month