C›I›R›B
FOR THE NATIONAL CANCER INSTITUTE

MEMORANDUM

To: CIRB Stakeholders

From: Laura Covington, MS, CIP
Director of Local Operations; NCI CIRB Operations Office

Date: January 21, 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.

Throughout the SOPs, updated references to the regulations under the 2018 requirements are included. The pre-2018 Requirements and 2018 Requirements are cited when the content or reference has changed.

Section 1.0 Introduction

1. Section 1.4 – added to address the 2018 Common Rule requirements.

Section 2.0 Foundational Principles

1. Section 2.1 – updated to reflect the 2018 Requirements.
2. Section 2.3 – definitions updated to reflect the 2018 Requirements.

Section 3.0 Division of Responsibilities

1. Section 3.3.2 – updated to reflect the CIRB policy change that HIPAA language is no longer permitted to be included as boilerplate language and inserted into the consent form.

Section 5 Meeting Administration

1. Section 5.15.1.9 – added to address additional requirements for documenting in minutes when conducting continuing review of research that would not otherwise require continuing review.

Section 7 CIRB Decision-Making

1. Section 7.2.2 – added the 2018 Requirements defining the categories for exempt research.

2. Section 7.4.2.13 – included the additional requirements for the consent form based on the 2018 Requirements.
3. Section 7.4.3 – added the additional elements to be provided to subjects.
4. Section 7.4.6.3 – added the 2018 Requirements for the waiver of signing the written consent form.
5. Section 7.4.7.3 – added the 2018 Requirements that the CIRB may approve research that includes obtaining information or biospecimens for screening, recruiting, and determining eligibility of prospective participants without informed consent.
6. Section 7.5 – updated the definition of vulnerable subjects.
7. Section 7.6.4.1.4 – removed Approve with recommendation as actions that may be taken by the CIRB.

Section 8.0 CIRB-Decision Making: Specific Considerations Based on Review Type

1. Section 8.6.3.1 – included that the CIRB will continue to conduct continuing review for all research under its purview.

Section 11.0 Retention of Records

1. Section 11.1.1 – added the additional records that must be maintained by the CIRB.