SWOG
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March 1, 2018

TO: ALL NATIONAL CLINICAL TRIALS NETWORK (NCTN) MEMBERS

FROM: SWOG Operations Office

RE: Changes to SWOG and CTSU Websites

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MEMORANDUM

The purpose of this memorandum is to inform sites of changes to the documents available on the SWOG and CTSU websites.

Effective immediately, for studies under CIRB purview available on the CTSU website, SWOG will no longer post the Protocol, Model Consent Form, or other materials requiring CIRB approval directly to the protocol abstract pages of the SWOG website. Instead, CIRB will post the CIRB-approved versions of these documents to the CTSU website. The SWOG website will contain links to these documents on the CTSU website. All additional study documents will continue to be available on both the SWOG and CTSU websites, and any training verifications or supplemental webpages will continue to be available on the SWOG website.

Additionally, please note the following:

- For studies available on the CTSU menu, the "Most Recent Updates" links on the protocol abstract pages of the SWOG website will no longer contain the entire protocol and consent when the protocol/consent are revised. Instead, the MRU link will include only the summary of change for the revision. This change is being made to comply with the requirement that protocols and consents only be posted to the CIRB tab of the CTSU website.
- For all currently active SWOG studies, the SWOG protocol abstract pages will now contain a link called "Notifications." This link will contain all of the Status Notices, revision/amendment summaries of change, and general cover memoranda for each study.

Additional details regarding documents available on the CTSU website and where each document is located are provided on the attached CTSU Educational Document.

If you have difficulty finding documents on the SWOG website, please contact the SWOG Operations Office at protocols@swog.org. If you have difficulty finding documents on the CTSU website, please contact the CTSU Helpdesk at CTSUContact@westat.com or the CIRB Helpdesk at adultcirb@emmes.com .

This memorandum serves to notify the NCI and SWOG Statistics and Data Management Center.

cc: PROTOCOL & INFORMATION OFFICE

Uniform Document Posting for CIRB-Reviewed Studies - Understanding Document Types

Introduction

The CTSU in conjunction with NCI has implemented a new requirement to display a single version of CIRB-approved protocol documents. Starting in December 2017, the lead protocol organization (LPO) and participating organizations must link to the CIRB-approved protocol documents housed on the CTSU members' website.

In November 2017, the CTSU released a new protocol page design, located in the Protocols tab > Documents subtab, to accommodate the uniform document posting for the CIRB-reviewed studies. "CIRB Documents" is the primary section of the Document subtab and contains all the CIRB-reviewed and approved documents for a study. "Supplemental Documents" and other sections contain protocol documents that are not CIRB-reviewed but released by the LPO for a study. If a study is open cross-network, LPOs have the option of posting supplemental documents solely on the CTSU website, but may post to both the CTSU and LPO websites.

Types of documents located in the CIRB Documents section

- ⇒ Protocol document
- ⇒ Amendments (change memos for protocol/consent)
- ⇒ Informed Consents (and translations)
- ⇒ Participant-facing documents and forms either given to or read to the patients (e.g. quality of life questionnaires, surveys, etc.)
- ⇒ Recruitment and educational material for patients
- ⇒ Action Letters
- ⇒ CIRB Application(s)
- ⇒ CIRB Outcome Letter(s)
- ⇒ Amendment Review Meeting Minutes (as applicable)
- ⇒ Continuing Review Meeting Minutes (as applicable)
- ⇒ Expedited Review Worksheet (as applicable)
- ⇒ CIRB Recruitment Material Application
- ⇒ Recruitment Material Review Meeting Minutes (as applicable)
- ⇒ CIRB Minutes (as applicable)
- ⇒ Status change documents and memoranda that may affect participants
- ⇒ (Note: Routine status changes, such as initial and amendment activations and routine status changes, will not be acknowledged nor posted by the CIRB.)

Types of documents located in Supplemental Documents and other sections

Supplemental Documents	Education & Promotion	Case Report Forms	Site Registration	Patient Enrollment	Adverse Event Reporting	Pharmacy
– General LPO Memoranda – Data and Safety Monitoring Board Reports – Study Summaries – Other LPO communication	– Schema – Study Calendar – Other study materials* (e.g., slide sets, study summaries, protocol cards, etc.)	– CRFs (not given or read to patient) – Link to Medidata Rave login	– HIPPA Forms – Request for Clinical Brochure* – Training documents for site registration*	– Link to OPEN – Registration Worksheet/ Eligibility Checklist	– Link to CTEP Adverse Event Reporting System (AERS) – Link to CTEP-AERS Training Guide	– Link to PMB for online ordering* – Links to investigational agent forms – Drug Request Forms

*All document type are not available for all protocols.

Version Date: 2/19/2018