SWOG CANCER RESEARCH NETWORK

July 01, 2024

TO: ALL NATIONAL CLINICAL TRIALS NETWORK MEMBERS; CTSU

FROM: SWOG Quality Assurance Department

RE: Regulatory Audit Guidance and Patient Chart Review Documents

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MEMORANDUM

The purpose of this memorandum is to inform sites that the Regulatory Audit Guidance and Patient Chart Review documents have been updated. The following is a summary of changes:

Regulatory Audit Guidance document

1. IRB Review – CIRB
   Revised submission of reportable internal SAEs to reportable unanticipated problems or serious/continuing non-compliance

2. Delegation of Task Log
   Removed S1418 and added S2302

3. Minor administrative edits

Patient Chart Review document

1. Clarifications for toxicity assessment
   Revised attributions to include unrelated, unlike, and definite and removed likely

2. Clarifications for data quality
   Revised Site Authority Log statement to include clarification that Site Authority Log is to be used for studies that are not covered by CTSU Delegation of Tasks Log

Minor administrative edits

1. Throughout the documents, formatting, typographical errors, pagination, and cross-references have been corrected as needed.

cc: PROTOCOL & INFORMATION OFFICE