

TO: Centre Representatives
Principal Investigators
Contact Clinical Research Associates
Ethics Representatives

From: NCIC Clinical Trials Group

RE: Changes in CRF and EDC Folder Signature Requirements

DATE: 2010 April 16

POLICY

The NCIC CTG has recently reviewed applicable regulations and guidelines (including ICH-GCP) related to delegation of duties and data submission for clinical trials conducted by the Group. As a result, the NCIC CTG case report form (CRF)/electronic data capture (EDC) folder signature/completion policy has been amended.

As of the date of this memorandum, NCIC CTG-led trials conducted in Canada and Internationally will no longer require signatures on case report forms or data queries, however the individual completing the forms/folders must be indicated. Case report forms (paper) or electronic data submissions (folders) and data queries may be completed by any participant named on a trial specific participants list or participants list change form.

The study PI is ultimately responsible for the accuracy and completeness of the data reported as documented via the signed study acknowledgement/disclosure page, Participating Centre Agreements, or other sources as required by trial. Updated study acknowledgement/disclosures will in future include language that addresses this requirement.

Participants list and Participants List Change forms for new studies will be amended to remove CRF signatures as a delegated duty; CRF completion as a delegated duty will remain. As long as CRF completion has been delegated, an updated Participant List is not required.

Please note that at this time, paper case report form signature blocks will not be updated for trials in progress. This memorandum will serve as documentation of permissible delegation with respect to CRF completion.

For non-NCIC CTG-led trials that are conducted in Canada (Intergroup/CTSU trials/International Intergroup), the processes, formats and requirements for reporting data are determined by the lead group.

IMPLEMENTATION

1. Study PI will sign an updated trial specific acknowledgement/disclosure page, on request if applicable.
2. Sites should ensure that local standard operating procedures on delegation of duties/CRF completion, as well as the NCIC CTG delegation of duties guidance, are followed.

QUESTIONS

If you have any questions regarding this policy change, please contact Anna Sadura at [(613) 533-6430.