DMID INFORMATION SHEET – CROMS DOCUMENT REDACTION SERVICES

Description

Document redaction is a support service provided by the DMID-CROMS Medical Writing contractor and available upon request in support of DMID-sponsored studies for which DMID is the designated *Responsible Party*, in accordance with *DMID ORA REG SOP-002: Process for Consideration of IND/IDE Sponsorship of DMID-Funded Clinical Trials*.

Timeline for services

Turnaround time for completion is 15 business days.

Regulatory basis

In accordance with 42 CFR 11.48(a)(5), all Applicable Clinical Trials with a Primary Completion Date on or after January 18, 2017 require a full version of the Protocol and Statistical Analysis Plan (SAP), including all amendments approved by a human subjects protection review board, be submitted to ClinicalTrials.gov for posting as part of the clinical trial results information.

Information that may be redacted:

Names, addresses, and other personally identifiable information, as well as any trade secret and/or confidential commercial information (as those terms are defined in the Freedom of Information Act (5 U.S.C. 552) and the Trade Secrets Act (18 U.S.C. 1905)) contained in the Protocol or SAP, unless such information is otherwise required to be submitted under this part, is allowed by law to be redacted.

Pre-service requirements

Ensure all documents to be redacted are in MS WORD format, unlocked and fully editable. Concerns or questions regarding regulatory requirements for posting or specific text to be redacted should be resolved before submission of documents to CROMS Medical Writing.

Procedure

Complete a Request for Medical Writing Services on the DMID-CROMS WebLibrary website and upload the editable, unlocked document(s) in WORD format with the request for services. Specify the data to be redacted at the time of request.

Include the DMID point of contact for questions about information that may or may not be redacted. A draft of the document(s) will be sent to the requestor for review and approval. Following receipt of approval, the final redaction will be completed.

Questions

Contact Elisa Sindall, DMID OCRA Medical Writing Coordinator, or email the DMID Office of Clinical Research Affairs, OCRA Help.