

## DMID INFORMATION SHEET – CROMS DOCUMENT REDACTION SERVICES

### Description

Document redaction is a support service provided by the CROMS Medical Writing Contractor and available upon request to DMID Staff for all DMID sponsored studies for which DMID is also 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 approximately 15 business days from time of request and documents are submitted via the [DMID-CROMS website](#).

### 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

Documents to be redacted should be compiled. Ensure all documents for submission are in MS WORD format, unlocked and fully editable. Concerns or questions regarding regulatory requirements for posting or content 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 website](#) and upload the editable, unlocked document(s) in WORD format with the request.

Include the DMID point of contact for questions about information that may or may not be redacted.

Specify data to be redacted. For example:

- Intervention/Product Name, trade secret and/or confidential commercial information
- Proprietary information or manufacturer details
- Specific design or formulation information
- Personally identifiable information, such as personal address or phone numbers, name(s) of participants

Medical Writing may also assist with identifying redactable information, if requested to do so.

### Questions

Contact the DMID Office of Clinical Research Affairs (OCRA) at [OCRAOps@mail.nih.gov](mailto:OCRAOps@mail.nih.gov).

#### Information Disclaimer

The information provided in this information sheet is only intended to be general summary information. It is not intended to take the place of either the written law, regulations or DMID policies and standards.