

DRAFT LANGUAGE FOR CRDW COVID RESEARCHERS

In connection with research relating to Covid 19, you have requested information from the Clinical Research Data Warehouse (CRDW). The CRDW includes information about the treatment Covid 19 patients received at the University of Chicago Medical Center (“UCMC”). In some cases, this information may include treatments administered as part of a clinical trial. In general, data generated under or concerning an ongoing clinical trial is confidential and may not be published or disclosed, including to researchers at other institutions. A comprehensive list of agents that have been investigated in COVID-19 clinical trials is maintained by the Office of Clinical Research (OCR)

When publishing results that relate to Covid 19, researchers should take extra care not to disclose confidential information about ongoing clinical trials or present data or results in a way that permits others to draw conclusions or approximations about particular trials. For example, researchers should not summarize or present the outcomes for subjects that received a particular investigational agent as part of a summary of data analysis (e.g., “100 patients received investigational agent A, 50 of them improved”). Instead, researchers should either omit such information entirely or present such information in a less granular manner that does not enable subgroup analysis for clinical trial participants (e.g., “200 subjects received treatment with one or more of the following four agents: W, X, Y, and Z, 100 of them improved.”)

We understand that it may not always be clear whether a summary or presentation that includes information derived from clinical trial subjects presents a risk of disclosing confidential information. If you are unsure, we encourage you to contact Center for Research Informatics (CRI) or the Office of Clinical Research (OCR) who can provide assistance.