Comments of the Association of Academic Health Sciences Libraries (AAHSL), Medical Library Association (MLA), and Cancer Libraries Section of MLA

In Response to the NIH Notice of Proposed Rulemaking for Clinical Trials Registration and Results Submission under FDAAA

As health sciences librarians who fulfill requests for information from clinicians, scientists, and patients, we applaud NIH for proposing to expand the ClinicalTrials.gov requirements to all NIH clinical trials. As studies have shown, many "outcomes" of research studies are never reported in the literature for various reasons. This results in important data and scientific information being inaccessible that might inform future research discoveries, the design of new protocols, or decisions made by patients and health care providers. The research community and public should know when a study is closed due to adverse events, difficulties in research design making accrual difficult, or simply feasibility problems. Negative results also go unpublished which can lead others to try and repeat similar protocols. Knowledge of failed studies may also lead to scientists to try different approaches to the same or similar intervention. Ultimately, expanding the requirements will create an incredible and vastly important database of clinical data and knowledge for clinicians, scientists, and patients who need access to cutting-edge information.