

**Yale University Open Data Access (YODA) Project  
Public Comment Response to NIH Proposed Changes**

The Yale University Open Data Access (YODA) Project at the Yale-New Haven Hospital Center for Outcomes Research and Evaluation (CORE) supports and applauds the draft NIH Policy on Dissemination of NIH-Funded Clinical Trial Information, expanding public availability of clinical trial summary results. While this is an important step forward in promoting the responsible and comprehensive dissemination of clinical research results, we believe that further steps can, and should, be taken to promote open science and share clinical research data.

The YODA Project strongly supports the proposal to extend reporting of summary results to all clinical trials conducted by all investigators receiving funding from the NIH. However, the YODA Project suggests that this policy would be stronger if the scope of these changes were expanded to include the availability of detailed summary results, such as Clinical Study Reports, as well as de-identified individual patient-level data.

The YODA Project also suggests a more detailed definition be developed to objectively define the term “health related biomedical or behavioral outcomes,” which is used in the proposal to determine whether a study is deemed an “applicable” clinical trial by the NIH. The current definition allows for subjective judgments, which could lead to the exclusion of studies that contain valuable information for public health research, science, and clinical medicine. It is vital to recognize and emphasize that the proposed NIH Policy will apply to all NIH-supported interventional clinical trials, even if they do not fall under the requirements of the NPRM.

Finally, the YODA Project agrees with the NIH that it would be helpful for any and all additional data elements to be required at the time of registration and results submission, and that these elements should align with each other for submission of registration and results. Through rigorous clinical trial policies set forth by the NIH in conjunction with the HHS, we can increase the availability and use of clinical research data to generate new knowledge that will benefit society.