**NPRM**

The Yale University Open Data Access (YODA) Project at the Yale Center for Outcomes Research and Evaluation (CORE) fully supports and applauds the proposed changes and extension to the FDA Amendments Act (FDAAA) of 2007. While this is a big step forward in promoting the responsible sharing of clinical research data, we believe that this is also an opportunity to take even further steps to promote open science. In support of the transparency of clinical trials, we believe that the scope of these changes should be expanded to also include the availability of individual patient-level data, in addition to summary results. We feel the availability of summary results and patient-level data should also apply to phase 1 trials of drugs and biological products and small feasibility studies of devices. Through rigorous clinical trial policies set forth by the FDA, we can increase the use of clinical research data to generate new knowledge that will benefit society.

The NPRM does not propose to require the responsible party to submit a written summary of the clinical trial and its results or to submit the full clinical trial protocol. It seeks public comment on the advantages and disadvantages of including technical and non-technical summaries in ClinicalTrials.gov and of requiring submission the full clinical trial protocol document or other information on the protocol that would assist in interpreting results information. It also seeks comment on additional information that could assist in understanding the available adverse event information.

**NIH**

The Yale University Open Data Access (YODA) Project at the Yale Center for Outcomes Research and Evaluation (CORE) fully supports and applauds the proposed NIH Policy to complement the NPRM for the FDA Amendments Act (FDAAA) 2007. While this is a big step forward in promoting the responsible sharing of clinical research data, we believe that this is also an opportunity to take even further steps to promote open science. We strongly support the proposal to extend reporting of summary results to all clinical trials conducted by investigators funded partially or fully by the NIH. In support of the transparency of clinical trials, we also believe that the scope of these changes should be expanded to include the availability of individual patient-level data, in addition to summary results. Furthermore, we urge for a more detailed definition to objectively define the term “health related biomedical outcomes,” which is used in the proposal to determine whether a study is deemed a clinical trial by the NIH. The current definition allows for subjective judgments and the existence of studies that would not be required to register. 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 NRPM. We agree that it is important to post certain descriptive information to be submitted with results information that is the same as a subset of information contained in the registration data elements. Through rigorous clinical trial policies set forth by the NIH in conjunction with the FDA, we can increase the use of clinical research data to generate new knowledge that will benefit society.