Regulatory Oversight Table

Reporting Requirements	FDAAA Final Rule – ACT[1]	NIH Transparency Policy[2]	ICMJE Policy	Revised Common Rule	NCI Clinical Trial Access Policy
Scope	Registration & Result Reporting	Registration & Result Reporting	Registration	Supported by a Common Rule department or agency[4]	Registration & Results Reported NCI Covered Trials[5]
Phase	Not phase 1 or device early feasibility	All	All	All	All
Intervention Type	Drug, Biologic, & Devices regulated by the FDA	Meets the definition of a clinical trial (NIH)	Meets the definition of a clinical trial (WHO)[3]	Meets the definition of a clinical trial (NIH)	All types of interventional clinical trials[6]
Funding Source	Any	NIH (full and partial)	Any	Supported by a Common Rule department or agency	NCI
ICF Upload	Not required	Required	Not required	Required	Not required
Protocol Upload	Required	Required	Not required	Not required	Not required
Data Sharing Statement	Not required	Not required	Required	Not required	Not required

[1] Controlled clinical investigations (other than phase 1 investigations) of any U.S. Food and Drug Administration (FDA)-regulated drug or biological product for any disease or condition. Certain studies of FDA-regulated medical devices, excluding small clinical trials to determine feasibility and certain clinical trials to test prototype devices, but including FDA-required pediatric post-market surveillances of a device product https://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf

[2] Policy applies to all NIH-funded awardees and investigators conducting clinical trials, funded in whole or in part by NIH, regardless of study phase, type of intervention, or whether they are subject to the FDAAA registration and results submission requirements set forth in Section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)). https://www.federalregister.gov/documents/2015/02/13/2015-02994/announcement-of-a-draft-nih-policy-on-dissemination-of-nih-funded-clinical-trial-information

[3] A clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioral treatments, process-of-care changes, preventive care, etc.

[4] Departments that have signed onto the Common Rule: Dept. of Agriculture, Dept. of Energy, NASA, Dept. of Commerce, National Institute of Standards and Technology, Consumer Product Safety Commission, Agency for International Development, HUD, Dept. of Justice, National Institute of Justice, DOD, DOE, VA, EPA HHS, NSF, DOT SSA.
https://about.citiprogram.org/wp-content/uploads/2018/07/Handout-1-Common-Rule-Agencies-and-Departments.pdf

[5] All initiated or commenced NCI-Supported Interventional Clinical Trials whether extramural or intramural. Extramural trials include research grants, cooperative agreements, and contracts to conduct Interventional Clinical Trials in all phases and disciplines (e.g., treatment, prevention, supportive care, diagnosis). "Covered Trials" excludes Observational Studies and any NCI-Supported Interventional Clinical Trial in which no subjects are enrolled but includes any NCI-Supported Interventional Clinical Trial in which at least one subject is enrolled even if the trial is not completed.
https://grants.nih.gov/grants/guide/notice-files/NOT-CA-15-011.html

[6] Studies involving human beings (subjects) in which the investigator assigns study subjects (randomly or not randomly) to receive a specific intervention based on the applicable protocol. Such subjects may receive diagnostic, therapeutic, behavioral, and/or another type of intervention. These interventions may, but need not, be investigational or involve an investigational agent (e.g., clinical trials involving surgery, radiation, or screening tests). The subjects are then followed and biomedical and/or health outcomes are assessed. "Interventional Clinical Trials" encompasses all types of trials in all phases including pilot trials; phase zero trials, and normal (or healthy) volunteer trials.