Summary Table of HHS/NIH Initiatives and ICMJE Guidelines to Enhance Availability of Clinical Trial Information

Element	Final Rule	NIH Policy	ICMJE
Effective Date	January 18, 2017. Compliance date is 90 days from the effective date.	January 18, 2017	Not Applicable
Scope/Applicability	• Applicable clinical trials of FDA-regulated drug, biological, and device products and pediatric post-market surveillance studies of devices required by the FDA under the FD&C Act. • Does not apply to phase 1 trials or small feasibility device studies. • Applicable clinical trials are (1) clinical trials of drug and biological products that are controlled, clinical investigations, other than phase 1 investigations, of a product subject to FDA regulation; and (2) prospective clinical studies of health outcomes comparing an intervention with a device product against a control in humans (other than small feasibility studies) or any pediatric post-market surveillance studies required by FDA under the FD&C Act. • Applies to public and private sector sponsors and other entities who meet the definition of a responsible party.	• All clinical trials funded wholly or partially by NIH. • Includes phase 1 clinical trials and trials that do not involve any FDA regulated product such as trials involving only behavioral interventions. • Applies to NIH applications for funding submitted on or after the policy's effective date that request support for the conduct of a clinical trial that is initiated on or after the policy's effective date. • Applies to NIH-conducted (intramural) clinical trials initiated on or after the policy's effective date.	Interventional studies (any intervention type or phase)
Responsible Party	Person or entity who initiates the trial (Sponsor), conducts the trial (Principal Investigator), or does both (Sponsor-Investigator for IND/IDE trials).	All NIH-funded awardees and investigators conducting clinical trials funded in whole or in part by the NIH.	Same as Final Rule
Timeframe for registration on ClinicalTrials.gov	Not later than 21 days after enrollment of the first participant.	Same	Prior to enrollment of first participant
Registration data elements to be submitted to ClinicalTrials.gov	Elements defined in the final rule. Consists of descriptive information, recruitment information, location and contact information, and administrative data.	Same	Similar; the WHO Trial Registration Data Set (TRDS) https://prsinfo.clinicaltrials.gov/trainTrainer/WHO-ICMJE-ClinTrialsgov-Cross-Ref.pdf
Timeframe for results information submission to ClinicalTrials.gov	Not later than 12 months after primary completion date; possible delay of up to an additional 2 years for trials of unapproved products or of products for which initial FDA marketing approval or clearance is being sought, or approval or clearance of a new use is being sought.	Same	Not Applicable (Encouraged, but policy restricted to registration)
Results information data elements to be submitted to ClinicalTrials.gov	Elements defined in the final rule. Includes participant flow, demographic and baseline characteristics, outcomes and statistical analyses, adverse events, the protocol and statistical analysis plan, and administrative information.	Same	Not Applicable (Encouraged, but policy restricted to registration)
Potential Consequences of Noncompliance	• For federally funded trials, grant funding can be withheld if required reporting cannot be verified. • Civil monetary penalties of up to $10,000/day (amount to be adjusted going forward). • Identifying clinical trial record as non-compliant in ClinicalTrials.gov.	• May lead to suspension or termination of grant or contract funding. • Can be considered in future funding decisions. • Identifying clinical trial record as non-compliant in ClinicalTrials.gov.	May not be eligible for journal publication

Website: https://www.nih.gov/news-events/summary-table-hhs-nih-initiatives-enhance-availability-clinical-trial-information