ClinicalTrials.gov Registration and Reporting Requirements Summary Table

	FDAAA 801	NIH	ICMJE
Definition and Scope of "Clinical Trial"	Interventional studies (with one or more arms) of FDA-regulated drugs, biological products, or devices • Applicable Clinical Trial (ACT) is the term used to designate the scope of trials that may be subject to the registration and reporting requirements in FDAAA • See for FDAAA Definition (page 4) (115 KB) and Decision Tools here (945 KB) and here	A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes • See for NIH Definition and Decision Tool	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 • See for ICMJE Definition
Studies Requiring Registration	Applicable Clinical Trials (ACT) (945 KB) regulated by the US FDA • Drugs & Biologics: controlled clinical investigations of products subject to FDA regulation • Devices: 1. controlled trials with health outcomes of devices subject to FDA regulation 1. pediatric post market surveillance of a device as required by FDA	Clinical trials that are partially or fully funded by the NIH, regardless of whether the trial involves an FDA regulated product	Applies to clinical trials where the intention is to publish in an ICMJE member journal • See here for journals stating that they follow the ICMJE policy
Studies Not Requiring Registration	• Phase 1 drug and small feasibility device trials • Behavioral interventional trials (unless funded by NIH) • Observational studies • Registries • Retrospective chart reviews	• Observational studies • Registries • Retrospective chart reviews	• Observational studies • Registries • Retrospective chart reviews
Registration Requirement	No later than 21 days after enrollment of the first participant – see here	No later than 21 days after enrollment of the first participant - see here	At or before the first patient is enrolled in the study – see here
Results Reporting Requirement	No later than 12 months from the study completion date – see here	No later than 12 months after the study's primary completion date – see here	Results reporting is not required
Penalties	• Criminal proceedings and civil penalties (over $14,000/day until noncompliance is resolved) • Loss of HHS funding	Loss of current or future NIH funding	Refusal to publish in ICMJE journals