ClinicalTrials.gov Registration and Results Reporting

Studies meeting any of the clinical trials definitions below must be registered on ClinicalTrials.gov. FDA Applicable Clinical Trials and new NIH trials also require results reporting.

Organization	Clinical Trials Definition	ClinicalTrials.gov Obligation		Penalties
ICMJE	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	**Registration** prior to first enrollment		**Publication** Manuscripts that are not prospectively registered will not be published by ICMJE journals
NIH	a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes	**Registration** within 21 days of first enrollment, but ICMJE & VCU require prospective registration (initiated on/after Jan 18th 2017)	**Results Reporting** no later than 12 months after primary completion date (initiated on/after Jan 18th 2017)	**Funding** Loss of grant funding; Future grant funding may be affected
FDA	Applicable Clinical Trial Drugs & biologics: controlled clinical investigations, other than phase 1, of products subject to FDA regulation Devices: 1) controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies 2) pediatric postmarket surveillance as required by FDA	**Registration** within 21 days of first enrollment, but ICMJE & VCU require prospective registration	**Results Reporting** no later than 12 months after primary completion date	**Fines** Civil monetary penalties up to $11,383 per day until noncompliance is resolved

To register or report results, log into the Protocol Registrations and Results System (PRS): https://register.clinicaltrials.gov

PRS Organization: VirginiaCU

For questions and PRS account assistance, contact:

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