ClinicalTrials.gov Registration Requirements

	NIH Policy	***HHS Final Rule***	***ICMJE Policy***
Policy Summary	The National Institutes of Health (NIH) policy applies to ***all* NIH-defined clinical trials** funded, wholly or in part, by NIH regardless of whether they are subject to the Final Rule.	The US Department of Health and Human Services (HHS) regulation describes requirements for registering and submitting summary results information for **Applicable Clinical Trials** of drug, biological, and device products plus pediatric post-market surveillance studies of devices required by the Food and Drug Administration (FDA) under the FD&C Act to ClinicalTrials.gov.	All clinical trials which wish to publish in an International Committee of Medical Journal Editors (ICMJE) journal, **or journals following its recommendations**, must register prior to enrolling the first subject.
Effective Date	January 18, 2017	January 18, 2017	Currently in effect
Compliance Date	April 18, 2017	April 18, 2017	N/A
Definition of Clinical Trial	A research study in which one or more human subjects are prospectively assigned[1] to one or more interventions[2] (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes[3]. Examples include: delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; diagnostic strategies; drugs/small molecules/compounds; biologics; devices; and, procedures (e.g., surgical techniques).	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.	Any research project that prospectively assigns people or a group of people to an intervention, with or without concurrent comparison or control groups, to study the cause-and-effect relationship between a health-related intervention *and* a health outcome.

[1] The term "prospectively assigned" refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.

[2] An "intervention" is defined as a manipulation of the subject of subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures; (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.

[3] A "health-related biomedical or behavioral outcome" is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical or behavioral status or quality of life." Examples include: positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and/or information retention); positive or negative changes to disease processes; positive or negative changes to health-related behaviors' and, positive or negative changes to quality of live.)

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Scope/ Applicability	All clinical trials funded wholly or partially by NIH. ***Includes*** trials that do not involve any FDA regulated product ***such as trials involving only behavioral interventions***. Includes phase 1 clinical trials Applies to NIH-funded clinical trials where ***applications or proposals are received by NIH on or after*** the policy's effective date. Applies to NIH-conducted clinical trials initiated on or after the policy's effective date.	Does not apply to phase 1 trials or small feasibility device studies. Applies to public and private sector sponsors and other entities who meet the definition of a responsible party.	Health-related interventions are those used to modify a biomedical or health-related outcome; examples include drugs, surgical procedures, devices, ***behavioral treatments, educational programs, dietary interventions, quality improvement interventions, and process-of-care changes.*** Health outcomes are any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events.
Timeframe for Registration	Not later than 21 days after enrollment of the first participant.	Not later than 21 days after enrollment of the first participant.	Prior to enrollment of first participant.
Data Elements Required for Registration	Elements defined in the final rule. Consists of descriptive information, recruitment information, location and contact information, and administrative data.	Elements defined in the final rule. Consists of descriptive information, recruitment information, location and contact information, and administrative data.	Elements defined in the final rule. Consists of descriptive information, recruitment information, location and contact information, and administrative data.
Timeframe for Results	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.	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.	Not mandated in policy, but must meet the requirements of FDAAA 801.
Data Elements Required for Results	Elements defined in the HHS final rule.	Includes participant flow, demographic and baseline characteristics, outcomes and statistical analyses, adverse events, the protocol and statistical analysis plan, and administrative information.	Elements defined in the HHS final rule.

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Penalties of Noncompliance	• May lead to suspension, termination or recovery of grant or contract funding • Consideration of noncompliance in future funding decisions • Identifying clinical trial record as non-compliant in ClinicalTrials.gov	• Identifying clinical trial record as non-compliant in ClinicalTrials.gov • 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)	Inability to publish in ICMJE or any journal that follows ICMJE recommendations.

*****Table elements taken from NIH and The University of Iowa

If you are uncertain whether or not your study meets the definition of a clinical trial, you should err on the side of registration. However, please note that if you register a research study with ClinicalTrials.gov, you will be responsible for completing the entry and updating the information throughout the course of the trial.

NIH and ICMJE affiliates (as well as many other journals) have even more stringent criteria for submitting to ClinicalTrials.gov. **It is highly recommended that each PI be aware of each of these rules, or to practice following the most stringent of these to assure compliance.**

For Further Information:

NIH

Does your human subjects research study meet the NIH definition of a clinical trial?
Requirements for Registering & Reporting NIH-funded Clinical Trials in ClinicalTrials.gov
NIH FAQ for NIH Grantees
NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information, September 21, 2016
NIH Definition of Clinical Trial, revised version issued October 23, 2014
Training Resources – NIH Clinical Trial Policies
Case Studies for NIH Definition of Clinical Trial

HHS/ClinicalTrials.Gov

ClinicalTrial.gov
How to Apply for an Account, ClinicalTrials.gov
How to Register Your Study, ClinicalTrials.gov
HHS Final Rule, September 21, 2016
FDAAA 801 Requirements