

# **NIH Clinical Trial Initiatives: How it Impacts NLM Data Science and Biomedical Informatics Research and NIH Peer Review**

Alan VanBiervliet, PhD and Zoe Huang, MD  
National Library of Medicine, National Institutes of Health  
AMIA November 4-8, 2017

## **New NIH Guidelines for Human Subjects Research and Clinical Trial Requirements for Grants and Contracts**

NIH is launching a series of initiatives that are rolling out in 2017-2018 to enhance the accountability and transparency of clinical research. These initiatives target key points along the whole clinical trial lifecycle from concept to results reporting. The following are links to useful information about these changes.

### **Clinical Trial Requirements for Grants and Contracts**

<https://grants.nih.gov/policy/clinical-trials.htm>

### **Video Overview of new NIH policies on human subjects research**

[https://grants.nih.gov/policy/clinical-trials/tutorial/story\\_html5.html?lms=1](https://grants.nih.gov/policy/clinical-trials/tutorial/story_html5.html?lms=1)

### **Clinical Trial Requirements for Grants and Contracts**

<https://grants.nih.gov/policy/clinical-trials.htm>

### **Why Changes to Clinical Trial Policies?**

<https://grants.nih.gov/policy/clinical-trials/why-changes.htm>

### **Determine if your research meets the NIH definition of a clinical trial**

<https://grants.nih.gov/ct-decision/index.htm>

### **NIH Definition of Clinical Trial Case Studies**

<https://grants.nih.gov/policy/clinical-trials/case-studies.htm>

Expect the case studies and related guidance to evolve over the upcoming year.

### **New Human Subjects and Clinical Trial Information Form**

<https://grants.nih.gov/policy/clinical-trials/new-human-subject-clinical-trial-info-form.htm>

### **Clinical Trial-Specific Funding Opportunities**

<https://grants.nih.gov/policy/clinical-trials/specific-funding-opportunities.htm>

### **Clinical Trial-Specific Review Criteria**

<https://grants.nih.gov/policy/clinical-trials/review-criteria.htm>

### **Updated Appendix Policy**

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-098.html>

### **Clinical Trials Protocol Template**

<https://grants.nih.gov/policy/clinical-trials/protocol-template.htm>

### **Single IRB Policy for Multi-site Research**

<https://grants.nih.gov/policy/clinical-trials/single-irb-policy-multi-site-research.htm>

### **Certificates of Confidentiality**

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html>

### **Requirements for Registering & Reporting NIH-funded Clinical Trials in ClinicalTrials.gov**

<https://grants.nih.gov/policy/clinical-trials/reporting/index.htm>

### **Good Clinical Practice Training**

<https://grants.nih.gov/policy/clinical-trials/good-clinical-training.htm>

### **Steps to Compliance for NIH Awardees**

<https://grants.nih.gov/policy/clinical-trials/reporting/steps.htm>

### **Frequently Asked Questions**

[https://grants.nih.gov/grants/policy/faq\\_clinical\\_trial\\_definition.htm](https://grants.nih.gov/grants/policy/faq_clinical_trial_definition.htm)