

Resources related to NIH Clinical Trial Changes for 2017 - 2018

NIH Policy Information and Training Resources

Summary of New Clinical Trial Requirements for Grants and Contracts:

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

Training Resources on new NIH Clinical Trial Policies:

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

Clinical Trials Frequently Asked Questions:

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

NIH Definition of Clinical Trial Case Studies:

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

New Human Subjects and Clinical Trial Information Form:

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

NIH Notices

Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-Funded Clinical Trials:

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-148.html>

Update on Clinical Trial Funding Opportunity Announcement Policy:

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-043.html>

Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research:

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html>

Revision: Notice of Extension of Effective Date for Final NIH Policy on the Use of Single Institution Review Board for Multi-Site Research:

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-076.html>

NIH and FDA Release Protocol Template for Phase 2 and 3 IND/IDE Clinical Trials:

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-064.html>

NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information:

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-149.html>

New NIH "FORMS-E" Grant Application Forms and Instructions Coming for Due Dates On or After January 25, 2018:

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-062.html>

Other guidance sources

Building Better Clinical Trials through Stewardship and Transparency:

<https://nexus.od.nih.gov/all/2016/09/16/clinical-trials-stewardship-and-transparency/>

Continuing to Clarify the NIH Definition of a Clinical Trial:

<https://nexus.od.nih.gov/all/2017/09/08/continuing-to-clarify-the-nih-definition-of-a-clinical-trial/>

Towards a New Era of Trust and Transparency in Clinical Trials, Hudson et al, JAMA 2016:

<http://jamanetwork.com/journals/jama/fullarticle/2553888?guestAccessKey=554e0981-9434-45f2-b122-d0e673cd1182>

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