Related Guidance, Tools and Templates

Resources and Regulations

DHHS:

- Final Rule for FDAAA 801 (effective January 18, 2017)
- Summary information on FDAAA 801 (U.S. Public Law 110-85) requirements
- General information about the Final Rule for Clinical Trials Registration and Results Information Submission (42 CFR Part 11)
- Checklist for Evaluating Whether a Clinical Study is an Applicable Clinical Trial (PDF) (October 2017)
- FAQs for Applicable Clinical Trials (ACTs)
- FDA's Role: ClinicalTrials.gov Information
- U.S. Public Law 110-85 - FDA Amendments Act of 2007
- ClinicalTrials.gov Protocol Data Element Definitions
- ClinicalTrials.gov Results Data Element Definitions

NIH:

- 2016 NIH Policy on the Dissemination of NIH-funded Clinical Trial Information
- NIH Definition of a Clinical Trial
- NIH Clinical Trial Case Studies (Examples)
- NIMH human subject research subject to NIH Clinical Trial Requirements
- Refining Case Studies and FAQs about the NIH Definition of a Clinical Trial (1/04/2018)
- Clarification regarding basic health research involving fMRI (1/22/2018)
- FAQs for NIH-Funded Clinical Trials and FDAAA
- NIH Office of Science Policy – Clinical Trials
- NOT-OD-16-147 NIH Policy on Funding Opportunity Announcements (FOA) for Clinical Trials (9/16/2016)
- NOT-OD-17-043 NIH Update on Clinical Trial Funding Opportunity Announcement Policy (2/17/2017)

CMS:

- Mandatory Reporting of an 8-Digit Clinical Trial Number on Claims

ICMJE (International Committee of Medical Journal Editors):

- ICMJE FAQs on Clinical Trials Registration

Additional Tools & Guidance

- UCLA Guidance on ClinicalTrial.Gov Registration and Reporting Requirements
- How to Register a Study at UCLA
- Resolving Problem Records
- Outcome Measures Guidance
- Registration and Results Reporting Time Estimates (OMB Burden Statement)

Results Reporting Tools

- Common Errors
- Pre-Submission Checklist
- Results Examples
- How to Submit Results
- Submitting Results Webinar-May 14, 2013
- Sample Results Template (single-arm study)
- Sample Results Template (2-arm study)
- Sample Results Template (3-arm study)
- Checklists, templates, and examples to help gather information needed to report results to ClinicalTrials.gov

If you have questions or need assistance, please contact the CTSI for non-cancer studies and JCCC for cancer studies.

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