ClinicalTrials.gov: Essentials for Academic Medical Centers – Resources

- Frequently Asked Questions
- Applicable Clinical Trials
    - FDA's Role
    - 42 CFR Part 11
    - ACT Checklist
- PRS User's Guide
- PRS Guided Tutorials
- ClinicalTrials.gov Support and Training Materials
- Transitioning to Modernized PRS
    - NLM Technical Bulletin – Phasing Out the Classic PRS: Timeline, Features and User Support
    - Modernization Transition Top Questions
    - ClinicalTrials.gov PRS E-Bulletin: ClinicalTrials.gov PRS News and Updates
- ClinicalTrials.gov Updates and PRS
    - ClinicalTrials.gov News and Updates
    - ClinicalTrials.gov Release Notes
    - PRS What's New
    - PRS Release Notes
- Resources for determining whether a product is a device:
    - How to Determine if Your Product is a Medical Device | FDA
    - Digital Health Policy Navigator | FDA
- Questions and Answers on Informed Consent Elements 21 CFR 50.25(c)
- Certification of Compliance to Accompany Drug, Biological Product, and Device Applications/Submissions
    - Guidance
    - FDA Form 3674

Questions?

- For PRS related questions: register@clinicaltrials.gov
- For General ClinicalTrials.gov inquiries: gcpquestions@fda.hhs.gov