

Clinical Trials Project Management Series 2: Templates, Tools, and References Companion Guide

CWRU Weatherhead Executive Education [Project Leadership Certificate Program](#)
FDA Guidance Document Search <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>

- o [Investigational New Drug Applications \(INDs\) – Determining Whether Human Research Studies Can Be Conducted Without an IND](#)
- o [Oversight of Clinical Investigations – A Risk-Based Approach to Monitoring](#)
 - [A Risk-Based Approach to Monitoring of Clinical Investigations Questions and Answers](#)

HHS/NIH Resources

- o Health and Human Services (HHS) [Clinical Research Study Investigators Toolbox](#)
 - Data and Safety Monitoring Board: guidelines, templates, and checklists