CLINICAL RESEARCH

LET'S GET STARTED!

HOW TO BEGIN CONDUCTING CLINICAL STUDIES AT YOUR SITE

6 KEY AREAS*

1. RESEARCH TEAM & STAFFING	2. STUDY SITE INFRASTRUCTURE & BUDGETING	3. STUDY MANAGEMENT	4. DATA COLLECTION & MANAGEMENT	5. QUALITY OVERSIGHT	6. ETHICS & SAFETY
					

AREAS	ELEMENTS	USEFUL RESOURCES
1 RESEARCH TEAM & STAFFING	• Workforce & Hiring • Experience • Training & Mentorship	• Clinical Research Team (NIH) • Investigator Training (NIH) ; Clinical Investigators Training (CITI) • Clinical Research Nurse (NIH) • Research Coordinator Training (ISCORE-RC) ; Clinical Research Coordinator Training (CITI) • Good Clinical Practice (CITI) ; GCP / CGMP (NIH) • FDA Product Regulation (FDA)
2 STUDY SITE INFRASTRUCTURE & BUDGETING	• Study budgeting • Sites & facilities • Operational infrastructure • Equipment & maintenance • Information storage • Record keeping • Physical & digital security • Technology capabilities • Managing conflicts of interest	• Study Budgeting (NIH) ; Webinar ; Template (NIH) • Clinical Research Infrastructure (AHRQ/HHS) • Electronic Source Data Guidance (FDA) • Electronic Systems, Electronic Records, and Electronic Signatures Webinar (FDA)
3 STUDY MANAGEMENT	• Standard operating procedures • Oversight • Study initiation, conduct, and close-out • Study recruitment & retention • Material handling • Documentation	• Standard Operating Procedures (ISCORE-RC) • Sample SOPs (NIH) • Study Participant Selection Slides (NIH) ; Webinar Pt 1 ; Web Pt 2 ; Web Pt 3 (NIH) • Inclusion in Clinical Research Slides Pt 1 ; Pt 2 ; Pt 3 ; Pt 4 (NIH)

AREAS	ELEMENTS	USEFUL RESOURCES
4 **DATA COLLECTION & MANAGEMENT**	• Data handling & sharing • Software & systems controls • Data quality • Data transparency • Randomization masking/blinding & management	• Data Management Overview Slides (NIH) ; Webinar Pt 1 ; Web Pt 2 ; Web Pt 3 ; Web Pt 4 (NIH) • Data Quality (NIH) • Electronic Source Data Guidance (FDA) • Digital Health Tech for Remote Data Acquisition Guidance (FDA) • RWD/RWE Data Guidance (FDA) • Indigenous Data Governance Webinar (Collab for IDG)
5 **QUALITY OVERSIGHT**	• Quality requirements • Preventive & corrective actions • Reporting	• Quality Management Slides (NIH); Webinar Pt 1 ; Webinar Pt 2 ; Webinar Pt 3 (NIH) • Oversight of Clinical Trials Guidance (FDA) • Risk-Based Approach to Monitoring Clinical Trials (FDA) • Clinical Trial Data Monitoring Guidance (FDA) • Bioresearch Monitoring Inspections Guidance (FDA)
6 **ETHICS & SAFETY**	• Institutional Review Board (IRB) & Central IRB • Study participant welfare • Informed consent/assent • Safety reporting • Confidentiality & transparency • Participant engagement • Risk/benefit communication • Cultural competency & relevance • Community engagement	• IRB Guidance (FDA) • Informed Consent Guidance (FDA) • Safety Reporting Slides (NIH) ; Webinar Pt 1 ; Web Pt 2 ; Web Pt 3 ; Web Pt 4 (NIH) • IND Safety Reporting Guidances (FDA); Webinar (FDA) • Cultural Competency (JABSOM/UHawaii) • Community Engagement Slides (NIH) ; Webinar Pt 1 ; Web Pt 2 ; Web Pt 3 (NIH) • Other Topics: Legal Issues in Clinical Research (NIH)

REFERENCES:

*A framework for assessing clinical trial site readiness. Buse et al., 2023