

Collaboration of Academic and Non-academic Research Sites

Multi-Site Study Projects

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ITHS Research Coordinator Core
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Main Coordinating Center: initial responsibilities

- Funding
- Recruitment of non-academic sites
- Research training
- Protocol development
- IRB
- Manual of Procedures / Case report forms and study supplies

Main Coordinating Center: study launch responsibilities

- Contracts, Significant Financial Interest Disclosure, and Individual investigator Agreements (IIA) for non-academic sites
- Calibrating coordinators for site training
- Study initiation visits



Main Coordinating Center: study launch responsibilities

- Research training for sites
 - Responsible conduct of research certification
 - HIPAA
 - Protocol (Manual of Procedures)

STUDY STAFF LOG			TRAINING REQUIREMENTS (DATE & DENTIST INITIALS)			
STAFF MEMBER NAME	JOB TITLE	ROLE IN STUDY PRIMARY CONTACT, DATA ENTRY	RCR TRAINED	HIPAA TRAINED	STUDY MANUAL REVIEWED	DENTIST INITIALS

Main Coordinating Center: study launch responsibilities

- Research training for sites
 - Patient selection
 - Patient recruitment
 - Consent/assent process
 - HIPAA



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Main Coordinating Center: study launch responsibilities

- Protocol specific training
- Monitoring sites visits
- Monitoring data collection
and study progress



Main Coordinating Center: study closure responsibilities

- Reporting to funding agency
- IRB study closure
- Records retention
- Data cleaning and analysis
- Manuscript preparation

