

Regulatory Organization

Multi-Site Research Projects

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Regulatory Requirements

- Federal Wide Assurance—FWA
- IRB Submission
- IRB Approval
- Locally Approved Consents
- Human Subjects Training

OHRP Regulatory

- Confirm site Federal-wide Assurance is current—OHRP has an online database
- Develop an online regulatory documents database that accepts site submissions and approvals and will also alert site and coordinating center about upcoming expirations or expired documents.

FDA Requirements

- Support sites with FDA requirements: 1572-Statement of Investigator
- Prepare and manage IND/IDE reports and other requirements

Human Subjects Protections

- Track human subject's protection training for appropriate study staff
- Create and distribute consent/notification document templates
- Ensure that IRB-approved consent forms at clinical sites have required elements and are factually correct

Human Subjects Protections

- Track consent forms annual approval and review consent documents for signatures and use of IRB date stamp (or other verification)
- Develop a reporting process for adverse events and unanticipated problems that are specific and in compliance with all local IRB requirements, FDA if appropriate and
- Report all events to the Data and Safety Monitoring Board

Organizing without a database

- Collect documents by email, save on network drive, and print out a hard copy
- Track documents on an Excel spreadsheet by site
- Send weekly status reports to sites for expirations within 8 weeks

Site spreadsheet

Dallas	IRB	FWA	Expiration	MOA	Initial IRB Approval	FDA Amend 1 Approval	Approval to Start Study
Hospitals							
Baylor							
Baylor Medical Center at Carrollton	Baylor Res Instit	00001234	12/3/2018		1/2/2014	2/3/2014	3/5/2014
Baylor Medical Center at Garland	Baylor Res Instit	00001234	12/3/2018		1/2/2014	2/3/2014	3/5/2014
Baylor Medical Center at Irving	Baylor Res Instit	00001234	12/3/2018		1/2/2014	2/3/2014	3/5/2014
Baylor University Medical Center	Baylor Res Instit	00001234	12/3/2018		1/2/2014	2/3/2014	3/5/2014
Baylor Regional Medical Center at Plano	Baylor Res Instit	00001234	12/3/2018		1/2/2014	2/3/2014	3/5/2014

Weekly status report

SITE	HOSPITAL or AGENCY	FWA	ROC PRIMED EXPIR. DATE	REMINDER SENT	RESPONSE
SEATTLE KC	Harborview				

Electronic Filing

- Organize electronic file by:
 - Study
 - Spreadsheet for each site
 - Track each spreadsheet weekly for expirations and errors
 - Send weekly status report to sites

Electronic file folder

- Site
- IRB
- Title file by date/study/IRB/type of document