

Site Evaluation Assistance
Person Responsible: Office Assistant – Study Tracking

Study Coordinator/PI will contact the CRA Division with site evaluation date, if they want assistance. Call 85589 or 81484
§ Arrange time to meet

- CRA staff attends site evaluation
- Provide base regulatory and information packet to CRO/sponsor
 - Answer questions regarding contract and HSC submissions and turnaround

A summary of the CRA portion of the site evaluation is documented and placed in a potential file (manila).

- Follow up for study status
- Is it going to be conducted at KUMC (why or why not, document reason in file and in DB)
 - Potential file review every 4 –6 weeks

If accepted by sponsor and PI decides to conduct the study becomes a “New Privately Funded CT Submission”

During New Submission Receiving review, the potential file is pulled and merged with “New Submission” Documents.

- If not conducted at KUMC or accepted as a site:
- Complete DB entry (CRA Access DB)
 - File in “Dead files” which are shredded yearly. Shredding is document in DB.