

DEFINITION OF CRC

A Clinical Research Coordinator (CRC) facilitates the daily management and operations of trials that study the therapeutic effectiveness of FDA approved pharmaceuticals and devices on human subjects, and those pharmaceuticals being evaluated under an investigational new drug (IND) approval. Responsibilities usually include but are not limited to the completion and tracking of institutional review board (IRB) approval, recruitment and enrollment of subjects, consenting patients for participation, data collection and maintenance, reporting of regulatory documents, recognizing and reporting adverse and significant adverse events, and reporting of clinical data for financial reimbursement.

COMPLIANCE RISKS

- Adverse and significant adverse events
- Federal anti-kickback statute
- Medicare Clinical Research Policy

POLICY

Effective February 1, 2008, all new CRCs and those that have been in their positions 6 months or less in Medicine are required to attend the Department's new CRC orientation training. It is a five-hour training provided over two days by Beth Davis, Clinical Research Manager of the BMT Clinical Research Unit. Trainings will be provided once per month. CRCs can pick any monthly session to attend to fulfill the requirement. (Calendar attached.) The course will cover:

- Types of Clinical Trials
- Phases of Clinical Trials
- Regulatory Agencies / Authority
- Financial Aspects of Clinical Trial
- Opening A Clinical Trial
- Conducting the Trial
- Adverse Events

This is a free but mandated course for any staff person, regardless of job title who has CRC responsibilities for clinical trials in the Department of Medicine.

RESOURCES

Suzanne Sutton, 2-4896, ssutton@medicine.ucsf.edu for questions about policy and course

Michele Carter, 2-4292, mcarter@medicine.ucsf.edu for session registration

Beth Davis, 2-3176, bdavis@medicine.ucsf.edu for content and advice

Monthly Department of Medicine CRC meeting every fourth Tuesday of the month at 2-3 pm.

CRC Trainings with Beth Davis (Schedule)

Tuesday	February 26	9:00-11:30AM	PAR	HSE 402
Wednesday	February 27	9:00-11:30AM	PAR	HSE 402
Tuesday	March 25	9:00-11:30AM	PAR	HSE 402
Wednesday	March 26	9:00-11:30AM	PAR	HSE 402
Tuesday	April 22	9:00-11:30AM	PAR	HSE 402
Wednesday	April 23	9:00-11:30AM	PAR	HSE 402
Tuesday	May 27	9:00-11:30AM	PAR	HSE 402
Wednesday	May 28	9:00-11:30AM	PAR	HSE 402
Tuesday	June 24	9:00-11:30AM	PAR	HSE 402
Wednesday	June 25	9:00-11:30AM	PAR	HSE 402
Tuesday	July 22	9:00-11:30AM	PAR	HSE 402
Wednesday	July 23	9:00-11:30AM	PAR	M1296
Tuesday	August 26	9:00-11:30AM	PAR	HSE 402
Wednesday	August 27	9:00-11:30AM	PAR	M1296
Tuesday	September 23	9:00-11:30AM	PAR	HSE 402
Wednesday	September 24	9:00-11:30AM	PAR	M1296
Tuesday	October 21	9:00-11:30AM	PAR	HSE 402
Wednesday	October 22	9:00-11:30AM	PAR	M1296
Tuesday	November 25	9:00-11:30AM	PAR	HSE 402
Wednesday	November 26	9:00-11:30AM	PAR	M1296
NO TRAINING IN DECEMBER				