

**Department of Medicine
Clinical Research Coordinators Orientation Training**

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
DOM Reception, 2-4292, for session registration
Beth Davis, 2-3176, bdavis@medicine.ucsf.edu for content and advice

CRC Trainings with Beth Davis for CY 2009

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|-------------------------|--------------------|--------------|---------|
| Tuesday | January 27, 2009 | 9:00-11:30AM | C517 |
| Wednesday | January 28, 2009 | 9:00-11:30AM | N729 |
| | | | |
| Tuesday | February 24, 2009 | 9:00-11:30AM | C517 |
| Wednesday | February 25, 2009 | 9:00-11:30AM | HSE 402 |
| | | | |
| Tuesday | March 24, 2009 | 9:00-11:30AM | C517 |
| Wednesday | March 25, 2009 | 9:00-11:30AM | S168 |
| | | | |
| Tuesday | April 28, 2009 | 9:00-11:30AM | HSE 402 |
| Wednesday | April 29, 2009 | 9:00-11:30AM | HSE 402 |
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| Tuesday | May 26, 2009 | 9:00-11:30AM | HSE 402 |
| Wednesday | May 27, 2009 | 9:00-11:30AM | HSE 402 |
| | | | |
| Tuesday | June 23, 2009 | 9:00-11:30AM | HSE 402 |
| Wednesday | June 24, 2009 | 9:00-11:30AM | HSE 402 |
| | | | |
| Tuesday | July 28, 2009 | 9:00-11:30AM | HSE 402 |
| Wednesday | July 29, 2009 | 9:00-11:30AM | HSE 402 |
| | | | |
| Tuesday | August 25, 2009 | 9:00-11:30AM | HSE 402 |
| Wednesday | August 26, 2009 | 9:00-11:30AM | HSE 402 |
| | | | |
| Tuesday | September 22, 2009 | 9:00-11:30AM | HSE 402 |
| Wednesday | September 23, 2009 | 9:00-11:30AM | HSE 402 |
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| Tuesday | October 27, 2009 | 9:00-11:30AM | HSE 402 |
| Wednesday | October 28, 2009 | 9:00-11:30AM | HSE 402 |
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| Tuesday | November 24, 2009 | 9:00-11:30AM | HSE 402 |
| Wednesday | November 25, 2009 | 9:00-11:30AM | HSE 402 |
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| NO TRAINING IN DECEMBER | | | |