

Clinical Research Associates Committee

REGULATORY SESSION I

Southwest Oncology Group 2010
Thursday April 15, 2010 (Afternoon Session)
Hyatt Regency – San Francisco, Ca

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| 1:00 – 1:10 | Statistical Center/Data Operations Update
Jacqueline Benedetti, PhD
Statistical Center
Southwest Oncology Group |
| 1:10 – 1:40 | Review Process for Protocols and Consents
Elaine Armstrong, MS
QA
SWOG Operations Office |
| 1:40 - 2:40 | Challenges Faced by IRBs
Steve Bartlett, R.Ph., MSPH
U of Colorado |
| 2:40 – 3:00 | Break |
| 3:00 – 3:30 | “Conflict of Interest: No Conflict, No Interest”.
Vernon K. Sondak, M.D.
H. Lee Moffitt CC
Tampa, FL |
| 3:30 – 4:00 | The Whys and Wherefores of HIPAA
Michael F. Kruley
Regional Manager
HHS Office for Civil Rights
Region IX
San Francisco, CA |

Through this program, CRA's/Nurses will become familiar with the review process for protocols and consents, will hear information about the IRB process from the IRB's point of view and will understand the need and rationale for completion and submission of the Conflict of Interest Form. The Society of Clinical Research Associates (SoCRA - www.SoCRA.org) accepts documentation of candidate participation in continuing education programs for re-certification if the program is applicable to clinical research regulations, operations or management, or to the candidate's clinical research therapeutic area. Pre-Registration is **not** required for this program but is recommended.

REGULATORY SESSION II

Southwest Oncology Group 2010
Friday , April 16, 2010
Hyatt Regency – San Francisco, Ca

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| 8:00 – 8:05 | Opening Remarks
Susan Majeski, CCRP
Chair, CRA Committee |
| 8:05 – 8:20 | Federal Guidelines for Audits
Elaine Armstrong, MS
QA
SWOG Operations Office |
| 8:20 – 9:20 | OHRP Overview: Assurances, Compliance and More
Office for Human Research Protections (OHRP)
Elyse Summers, J.D.
Director
Division of Education and Development
Office for Human Research Protections |
| 9:20 – 9:30 | Break |
| 9:30 – 10:00 | OHRP Overview: Assurances, Compliance and More (Part II)
Elyse Summers, J.D.
Director
Division of Education and Development
Office for Human Research Protections |
| 10:00 – 10:30 | The Central IRB – Interaction with your local IRB
Jeanne M. Adler RN, MPH
Project Officer/COTR-CIRB Initiative
CTEP
Bethesda, MD |
| 10:30 – 11:00 | The Informed Consent Zone
An Educational Video for Clinical Research Institutions |

Through this program, CRA's/nurses will become more familiar with the guidelines for audits, will understand OHRP compliance issues and assurances and will have a better understanding of how the CIRB benefits those institutions who use it as their IRB. The Society of Clinical Research Associates (SoCRA - www.SoCRA.org) accepts documentation of candidate participation in continuing education programs for re-certification if the program is applicable to clinical research regulations, operations or management, or to the candidate's clinical research therapeutic area. Pre-Registration is **not** required for this program but is recommended.