SOCRA 27TH ANNUAL CONFERENCE
SCHEDULE OF BREAKOUT SESSIONS BY TRACK

Friday, September 28

8:00 - 8:30	Continental Breakfast - Location: Celestin Foyer
8:30 - 12:00	**Opening Plenary - General Session** Location: Celestin Ballroom
10:00 - 10:30	Morning Break - Elite Exhibit Hall (Level 1)

Time/Track	Track 1	Track 2	Track 3	Track 4	Track 5	Track 6	Track 7	Track 8
Location	Celestin H-F	Celestin E	Celestin D	Celestin A-C	Strand 10	Strand 11	Strand 12	Strand 13
12:00 - 1:15	Luncheon - Elite Hall (Exhibit Space)							
1:15 - 2:50	Compliance / Noncompliance	Device Research	Quality Management	Oncology Research	Training Techniques	Therapeutic Areas in Research	Responsible Conduct in Research	Monitoring
2:50 - 3:25	Afternoon Break with Exhibits and Posters - Location: Elite Hall (Exhibit Space)							
3:25 - 5:00	Quality Management	Device Research	Quality Management	Oncology Research	Training Techniques	Therapeutic Areas in Research	Responsible Conduct in Research	Monitoring

Saturday, September 29

Time/Track	Track 1	Track 2	Track 3	Track 4	Track 5	Track 6	Track 7	Track 8
Location	Celestin H-F	Celestin E	Celestin D	Celestin A-C	Strand 10	Strand 11	Strand 12	Strand 13
8:00 - 8:30	Continental Breakfast - Elite Exhibit Hall (Level 1)							
8:30 to 10:05	Poster Session	Device Research	Canadian Regulatory	Finance and Billing	Pediatric Research	International Trials & ICH	Advanced Management	Site Management
10:05 to 10:50	Morning Break with Exhibits and Posters: Elite Exhibit Hall (Level 1)							
10:50 to 12:25	Behavioral Health	Device Research	Canadian Regulatory	Finance and Billing	Pediatric Research	International Trials & ICH	Advanced Management	Site Management
12:25 to 1:40	Luncheon - Location: Elite Exhibit Hall (Level 1)							
	Chapter Orientation Roundtable Session / Lunch - Location: Elite Exhibit Hall (Level 1)							
1:40 to 3:15	Enrollment Retention	GCP Audit Preparedness	Canadian Regulatory	Finance and Billing	Pediatric Research	IRB Issues / Solutions / Methods	Advanced Management	Investigator-Initiated Research
3:15 to 3:45	Afternoon Break with Exhibits and Posters - Location: Elite Exhibit Hall (Level 1)							
3:45 to 5:20	Enrollment Retention	GCP Audit Preparedness	Health Disparities	Risk Management	Integrative Medicine / CAM	Ethics in Research	Adverse Event Reporting	ClinicalTrials.gov

Sunday, September 30

8:00 - 8:30	Continental Breakfast - Location: Celestin Foyer
8:40 - 12:00	**Closing Plenary - General Session -** Location: Celestin Ballroom

SCHEDULE-AT-A-GLANCE

Friday Morning and Afternoon, September 28, 2018

8:00 AM - 8:30 AM Continental Breakfast Location: Celestin Foyer (3rd Floor)

Opening Plenary Session - Location: Celestin Ballroom Moderator: Tammy Neseth, MA, CCRP

8:30 to 9:15 **Welcome and Introduction** Tammy Neseth, MA, CIP, CCRP and Jamie Harper, MHA, CCRP **ID Code 001**

9:15 to 10:00 **Rethinking Research/Rethinking Research Ethics** Jeremy Sugarman, MD, MPH, MA **ID Code 002**

10:00 - 10:30 PM Morning Break Location: Elite Exhibit Hall (Level 1)

10:30 to 11:15 **Precision Medicine versus Precision Health: Transformative Opportunities in the Digital Era** Rhoda Au, PhD, MBA **ID Code: 003**

11:15 to 12:00 **Improving Informed Consent** Jerry Menikoff, MD, JD **ID Code 004**

12:00 - 1:15 PM LUNCHEON Location: Elite Exhibit Hall (Level 1)

Track 1 – Compliance / Noncompliance
Location: Celestin F-H
Moderator: Sandhya Patel, BScN

1:15 to 2:00 **ID Code: 109**

The Dangers and Consequences of Fraud and Misconduct in Clinical Research

Nancy Wintering, MSW, LCSW, CCRP

2:05 to 2:50 **ID Code: 111**

Compliance, Auditing and GCP Challenges

Wendy Portier, MSN, RN, CHRC, CHC

Track 2 – Device Research
Location: Celestin E
Moderator: Kathi Durdon, MA, CCRP

1:15 to 2:00 **ID Code: 209**

Total Product Life Cycle

Lindsay Pack, BSE

2:05 to 2:50 **ID Code: 211**

Data & Safety Monitoring Committees: The Important Role They Play

Simmy Thompson-Lucas, MPH, CIP, CCRP

Track 3 – Quality Management
Location: Celestin D
Moderator: Sandhya Patel, BScN

1:15 to 2:00 **ID Code: 309**

Utilizing the Research Ethics Review Process as a Method to Incorporate Quality by Design

Gregory Staios, MSc, CCRP

2:05 to 2:50 **ID Code: 311**

Enhancing Safety and Efficiency Through Implementation of Electronic Tools

David Chan, PharmD, PhD, BCOP, CCRP

Track 4 – Oncology Research
Location: Celestin A-C
Moderator: Susanna Sellmann, BSc, MRT, CCRP

1:15 to 2:00 **ID Code: 409**

Immunotherapy and Nursing Implications on Patient Care

Cynthia Bocaya, RN, CON(C)

2:05 to 2:50 **ID Code: 411**

Research at the VA - Is it Really that Different?

Margaret Chase, BSN

Track 5 – Training Research
Location: Strand 10
Moderator: Anatoly Gorkun, MD, PhD

1:15 to 2:00 **ID Code: 509**

Sink or Swim: Research Training to Keep Your Team Afloat

Melissa McLennon, MPH

2:05 to 2:50 **ID Code: 511**

Communication in Clinical Research: Is There Something to Improve?

Anatoly Gorkun, MD, PhD, Chartered MCIPD

Track 6 – Therapeutic Areas of Research
Location: Strand 11
Moderator: Virginia Doran, MLT, BS, MBA, CCRP

1:15 to 2:00 **ID Code: 609**

Current Trends: The Renaissance of Ophthalmic Research

Jaspreet Grewal, MSc, CCRP

2:05 to 2:50 **ID Code: 611**

A New Foot Soldier in the Opioid Addiction War: Medical Device Implantation and Management for Chronic Long-Term Pain

Melba Isom, ASB, CCRP

Track 7 – Responsible Conduct in Research
Location: Strand 12
Moderator: John Kessler, PharmD, BS

1:15 to 2:00 **ID Code: 709**

Lessons from the National Patient Safety Movement that are Applicable to Clinical Research

John Kessler, PharmD, BS

2:05 to 2:50 **ID Code: 711**

Lessons Learned from Research Misconduct Cases

Donna Kessler, PhD

Track 8 – Monitoring
Location: Strand 13
Moderator: Angela Rock, MBA, CCRP

1:15 to 2:00 **ID Code: 809**

Unique Monitoring Experiences - How to Effectively Manage Challenging Situations

Abby Statler, MPH, MA CCRP

2:05 to 2:50 **ID Code: 811**

Creating Effective Communication Strategies and Relationships with Sites in a Remote Monitoring Environment

Grace Morgan-Holmes, BS, CCRP, CCRA

2:50 - 3:25 PM Afternoon Break with Exhibits and Posters Location: Elite Exhibit Hall (Level 1)

Track 1 – Data Management/ EDC
Location: Celestin F-H
Moderator: Patricia Beers Block, BS, CCRP

3:25 to 4:10 **ID Code: 113**

Trial Master File: Transition from Repository to Study Management Tool

Joanne Malia, BS, MS, MS

4:15 to 5:00 **ID Code: 115**

Electronic Clinical Trial Management Systems: The Basics, Needs, and Outputs

Michael Wieczerzak, BS, MS, CCRP

Track 2 – Device Research
Location: Celestin E
Moderator: Kathi Durdon, MA, CCRP

3:25 to 4:10 **ID Code: 213**

Medical Device Single Audit Program (MDSAP): Basics and Update

Sam Rajkumar, MS, BScN, RN

4:15 to 5:00 **ID Code: 215**

Lessons Learned: Navigating the Medical Device Regulatory Process and the Implications of the Quality System and Design Controls

Donna Headlee, BSN, RN, CCRP

Track 3 – Data Management/ EDC
Location: Celestin D
Moderator: Patricia Beers Block, BS, CCRP

3:25 to 4:10 **ID Code: 313**

Tools and Techniques for Effective Clinical Research Start-Up at an Academic Medical Center

Michael Mapel, CCRP

4:15 to 5:00 **ID Code: 315**

The Internal Research Quality Audit Experience: Lessons Learned So Far

Velma Marzinotto, BScN, RN, CCRP

Track 4 – Oncology Research
Location: Celestin A-C
Moderator: Susanna Sellmann, BSc, MRT, CCRP

3:25 to 4:10 **ID Code: 413**

Current Immunotherapy Treatment in Metastatic Melanoma

Mary Anne Chappell, RN con©

4:15 to 5:00 **ID Code: 415**

CAR T Therapy: Side Effects and Management

Channing Dudley, MSN, RN

Track 5 – Training Research
Location: Strand 10
Moderator: Anatoly Gorkun, MD, PhD

3:25 to 4:10 **ID Code: 513**

Introducing Generation Z: Who They Are and How They Will Impact the Clinical Workplace

Barbara van der Schalie, MS

4:15 to 5:00 **ID Code: 515**

Coaching Beyond the Goal: The Hidden "I" in Team

Avie Banks, MBA, MHA, CCRA

Track 6 – Therapeutic Areas of Research
Location: Strand 11
Moderator: Amy Jo Jenkins, MS, CCRP

3:25 to 4:10 **ID Code: 613**

Using Music Relaxation Techniques for Cardiovascular Health

Connie Cross, BS, CCRP

4:15 to 5:00 **ID Code: 615**

ABCs of Establishing an Ethically-Sound BioBank

Pukar Ratti, MSHCM, MSChE, CIM, CCRP, FACMPE

Track 7 – Responsible Conduct in Research
Location: Strand 12
Moderator: John Kessler, PharmD, BS

3:25 to 4:10 **ID Code: 713**

Research Misconduct in Clinical Trials

Debra Parrish, JD

4:15 to 5:00 **ID Code: 715**

Understanding Research Wrongdoing: Lessons from the PI Program and PSI Lab

James DuBois, DSc, DSc, PhD

Track 8 – Monitoring
Location: Strand 13
Moderator: Angela Rock, MBA, CCRP

3:25 to 4:10 **ID Code: 813**

Our Risk Based Monitoring (RBM) Model for Device Studies - A Team Approach

Sarah Deer, CCRA

Phil Moll, MS

4:15 to 5:00 **ID Code: 815**

Monitoring Plan Development and Key Considerations

Lauren Doherty, CCRP

SCHEDULE-AT-A-GLANCE

Saturday Morning, September 29, 2018

8:00 AM - 8:30 AM Continental Breakfast Location: Elite Exhibit Hall (Level 1)

Track 1 – Poster Session
Location: Celestin H-F
Moderators: Bryce Warren, PhD & Joanne Goldberg, MSc pht, CCRP

8:30 to 10:05 **ID Code: 117/119**

Poster Session Presentations

Joanne Goldberg, MSc, pht, CCRP
Bryce Warren, PhD

Track 2 – Device Research
Location: Celestin E
Moderator: Kathi Durdon, MA, CCRP

8:30 to 9:15 **ID Code: 217**

Navigating the FDA 510(k) Submission Process to Successful Medical Device Clearance

Jennifer Davagian

9:20 to 10:05 **ID Code: 219**

IDE Infrastructure Mapping

Caitlyn Seidl, BS, CCRP

Track 3 – Canadian Regulatory
Location: Celestin D
Moderator: Sandhya Patel, BScN

8:30 to 9:15 **ID Code: 317**

Negotiating a Reasonable Allocation of Risk in Clinical Trial Agreements (and why the new mCTA falls short)

Marlon Rajakaruna, BA, MBA, LLB, CRCP

9:20 to 10:05 **ID Code: 319**

Negotiation of Clinical Trial Agreements with Canadian Sites

Anat Feldman, PhD, CCRP

Track 4 – Finance & Billing
Location: Celestin A-C
Moderator: Jennifer Goldfarb, MSN, RN,CCRP

8:30 to 9:15 **ID Code: 417**

Effective Management of Clinical Trial Finances

Sandra Sarafin, BA, CCRP

9:20 to 10:05 **ID Code: 419**

Financial Management of a Clinical Trial at an Academic Institution: Lessons Learned

Veronica Kain, MBA

Track 5 – Pediatric Research
Location: Strand 10
Moderator: Susan Devine, CCRP

8:30 to 9:15 **ID Code: 517**

Initiating a Pediatric Research Program

Janelle Allen, BS, MS, CCRP

9:20 to 10:05 **ID Code: 519**

Enrollment in Pediatric Research: What Works and What Does not Work

Muhammad Waseem, MD, MS, CCRP, CIP, CHSE-A

Track 6 – International Trials & ICH
Location: Strand 11
Moderator: Anatoly Gorkun, MD, PhD

8:30 to 9:15 **ID Code: 617**

Now It's Time for a Change - What You Should Know About the EU Regulation for Clinical Trials

Gerhard Fortwengel, PhD, MPH, MSc

9:20 to 10:05 **ID Code: 619**

Challenges in Managing Clinical Trials in Asia

Xinmei Shi, MSc, CCRP, CCRA

Track 7 – Advanced Management
Location: Strand 12
Moderator: Lisa Benson, BS, CRCP, CCRP

8:30 to 9:15 **ID Code: 717**

Optimizing Investigational Pharmacy Operations in Support of Clinical Trials

Douglas Parr, PharmD

9:20 to 10:05 **ID Code: 719**

Investigator Responsibilities - Explaining FDA's Guidance Document

Harvey Arbit, PharmD, PharmD, MBA, CCRP, RAC

Track 8 – Site Management
Location: Strand 13
Moderator: Susan Corl, MSW, MPH, CIP, CCRP

8:30 to 9:15 **ID Code: 817**

Become a Preferred Site: Quality and Documentation Tips for Compliance for the CRC

Janet Ellen Holwell, BA, CCRC, CCRA, TIACR, FACRP

9:20 to 10:05 **ID Code: 819**

5 Key Strategic Decisions for Research Sites

Andrew Snyder, MBA, PMP, CRCP

10:05 - 10:50 AM Morning Break with Exhibits and Posters Location: Elite Exhibit Hall (Level 1)

SCHEDULE-AT-A-GLANCE Saturday Morning, SEPTEMBER 29, 2018

(CONTINUED)

10:05 - 10:50 AM Morning Break with Exhibits and Posters Location: Elite Exhibit Hall (Level 1)

Track 1 – Behavioral Research
Location: Celestin H-F
Moderator: Nancy Wintering, MSW, LCSW, CCRP

10:50 to 11:35 **ID Code: 121**
Conducting Behavioral Health Research
Andrew Gepty, BA

11:40 to 12:25 **ID Code: 123**
Implementing Quality Assurance in Behavioral Health Research
Jessica Rowe, MA, MS, CCRP

Track 2 – Device Research
Location: Celestin E
Moderator: Kathi Durdon, MA, CCRP

10:50 to 11:35 **ID Code: 221**
Mobile Medical Devices in Research
Jonathan Young, PhD, MS, CIP, CCRP

11:40 to 12:25 **ID Code: 223**
Balancing the (Clinical Trial) Budget
Tammy Floore, BSN, MBA, CCRP, RN, CPC-A

Track 3 – Canadian Regulatory
Location: Celestin D
Moderator: Joanne Goldberg, MSc pht, CCRP

10:50 to 11:35 **ID Code: 321**
The Tri-Council Policy Statement: Understanding Canada's "Common Rule" for Human Research
Martin Letendre, LLB, LLM

11:40 to 12:25 **ID Code: 323**
Health Canada's Clinical Trial Compliance Program
Alicja Kasina, MSc, BPharm

Track 4 – Finance & Billing
Location: Celestin A-C
Moderator: Jennifer Goldfarb, MSN, RN,CCRP

10:50 to 11:35 **ID Code: 421**
Leveraging CTMS and EHR to Build a Compliant Research Billing Program
Mary Veazie, MBA, CPA, CHC, CHRC

11:40 to 12:25 **ID Code: 423**
Successfully Allocating, Managing, and Paying for Study Coordinator Time on Industry-Sponsored Clinical Trials (bold italicize and)
Jennifer Goldfarb, MSN, RN, CCRP

Track 5 – Pediatric Research
Location: Strand 10
Moderator: Susan Devine, CCRP

10:50 to 11:35 **ID Code: 521**
The Importance of Affirmative Assent in Pediatric Clinical Trials
Mary Cataletto, MD, MD, MMM

11:40 to 12:25 **ID Code: 523**
Building Networks to Support Pediatric Research
Emily Owens Pickle, BS, CCRP

Track 6 – International Trials & ICH
Location: Strand 11
Moderator: Anatoly Gorkun, MD, PhD

10:50 to 11:35 **ID Code: 621**
The History of Clinical Research in Jamaica West Indies and Nutraceutical Development Including Cannabinoid Therapy
Francine Campbell-Hakim, BSc

11:40 to 12:25 **ID Code: 623**
Self-Medication - A Too Little Regarded Aspect in Medical Research?
Dnyanesh Limaye, PhD, MPharm

Track 7 – Advanced Management
Location: Strand 12
Moderator: Lisa Benson, BS, CRCP, CCRP

10:50 to 11:35 **ID Code: 721**
Single and Central IRB Review - Helpful Hints for Coordinators
Rebecca Abel, MA, CIP

11:40 to 12:25 **ID Code: 723**
Human-Centered Design in Clinical Trial Operations: Setting Your Team Up for Success
Heather Baldwin, MPH, CPCM

Track 8 – Project Management
Location: Strand 13
Moderator: Janelle Allen, MS, BS, CCRP

10:50 to 11:35 **ID Code: 821**
Project Management: Introduction to Tools and Templates
Melissa Harris, BS, MPA, CCRP

11:40 to 12:25 **ID Code: 823**
Committee Project Management
Stacey Houser, BA, CCRP

12:25 - 1:40 PM LUNCHEON Location: Elite Exhibit Hall (Level 1)

SCHEDULE-AT-A-GLANCE

Saturday Afternoon, September 29, 2018

12:25 - 1:40 PM LUNCHEON Location: Elite Exhibit Hall (Level 1)

Chapter Orientation Luncheon Location: Imperial 5

12:40 to 1:05 **Chapter Orientation - North America -** Amy Jo Jenkins, MS, CCRC, CCRP **ID Code #224**

1:05 to 1:30 **Chapter Orientation - International -** Joanne Goldberg, MSc, BSc, pht, CCRP **ID Code #224**

Track 1 – Enrollment/Informed Consent
Location: Celestin F-H
Moderator: Michelle Culp, BSN, MPH, RN, CCRP

1:40 to 2:25 **ID Code: 125**

Community Based Recruitment

Mary Jessica St. Romain, BS

2:30 to 3:15 **ID Code: 127**

Creating a Community that Supports Recruitment for Alzheimer's Disease Research

Cyndy Cordell, BS, MBA

Track 2–GCP Audit Preparedness
Location: Celestin E
Moderator: Milton Marshall, PhD, DABT, RQAF, CCRP

1:40 to 2:25 **ID Code: 225**

So You Think You Know GCP....

Paul Below, MS, CCRA

2:30 to 3:15 **ID Code: 227**

Delegation of Authority: The Importance of Qualifications and Training of Investigator Site Staff

Terrence Purnell, MS, CCRP, RQAP-GCP

Track 3 – Canadian Regulations
Location: Celestin D
Moderator: Jennifer Li, BSc, CCRP

1:40 to 2:25 **ID Code: 325**

Participant Recruitment Strategies in the Canadian Clinical Trials Environment.

Lisa Johnston, BScN, RN, CCRP

2:30 to 3:15 **ID Code: 327**

Inspection of a Clinical Investigator: Conducting Clinical Trials in Canada

Mike Rashti, BS

Track 4 – Finance & Billing
Location: Celestin A-C
Moderator: Jennifer Goldfarb, MSN, RN,CCRP

1:40 to 2:25 **ID Code: 425**

Increase Revenue By Billing Compliantly

Kelly Willenberg, DBA, RN, CHRC, CHC, CCRP

2:30 to 3:15 **ID Code: 427**

Charging Patients for Costs Associated with Clinical Trials and Expanded Access Uses: Understanding FDA Limitations and Requirements

Katlin Backfield, JD

Track 5 – Pediatric Research
Location: Strand 10
Moderator: Susan Devine, CCRP

1:40 to 2:25 **ID Code: 525**

Strategies for AE and SAE Tracking in Pediatric Clinical Trials

Amanda Galster, MPH, CCRP

2:30 to 3:15 **ID Code: 527**

Managing Complex Pediatric Trials

Christy Rowley, BA, MSc

Lorraine Hodsdon, BSc, MSc, RN

Track 6 – IRB Issues, Solutions, Methods
Location: Strand 11
Moderator: Wendy Lloyd, BA, LPN, CCRP

1:40 to 2:25 **ID Code: 625**

Establishing a High Quality Human Research Protection Program (HRPP)

Michelle Feige, MSW, LCSW-C
Elyse Summers, JD

2:30 to 3:15 **ID Code: 627**

Centralized IRB Review of Multi-Site Clinical Research. Do you have Single/ Central IRB questions? Ask the panel

Wendy Lloyd, BA, CCRP, LPN

Track 7 – Advanced Management
Location: Strand 12
Moderator: Lisa Benson, BS, CRCP, CCRP

1:40 to 2:25 **ID Code: 725**

Fraud, Waste, and Abuse in Clinical Research and the False Claims Act

Shauna Itri, JD, MA, BS

2:30 to 3:15 **ID Code: 727**

Improved Site Management Through the Lens of Training and Education

Kathleen O'Malley, BSN, RN, CCRP, CCE

Track 8 – Investigator-Initiated Research
Location: Strand 13
Moderator: Nancy Wintering, MSW, LCSW, CCRP

1:40 to 2:25 **ID Code: 825**

So Your Investigator Wants to Run a Multi-Site Investigator-Initiated Research Study?

Christine Jerome, BS, CCRP

2:30 to 3:15 **ID Code: 827**

How to Prepare for an FDA Audit

Astrid Eder, PhD, CCRP, CIP

3:15 - 3:45 PM Afternoon Break with Exhibits and Posters Location: Elite Exhibit Hall (Level 1)

Saturday Afternoon, SEPTEMBER 29, 2018
(CONTINUED)

3:15 - 3:45 PM Afternoon Break with Exhibits and Posters Location: Elite Exhibit Hall (Level 1)

Track 1 – Enrollment/Informed Consent
Location: Celestin F-H
Moderator: Tina Willbee, BS, CCRP

3:45 to 4:30 **ID Code: 129**

Automated Documentation of the Informed Consent Process

Joan Whitted, BS, CCRC, HCCA

4:35 to 5:20 **ID Code: 131**

Transitioning to eConsenting--Implementing New Technology to Increase Efficiency within a Research Study

Elizabeth Solinger, MS, CCRP

Track 2–GCP Audit Preparedness
Location: Celestin E
Moderator: Milton Marshall, PhD, DABT, RQAF, CCRP

3:45 to 4:30 **ID Code: 229**

The FDA is Coming - How to Prepare Clinical Sites

Gloria Miller, BS, RAC-US, CQA-ASQ

4:35 to 5:20 **ID Code: 231**

What to Do When the FDA Just Shows Up

Jasmine Neumann, BS, CCRP

Track 3 – Health Disparities
Location: Celestin D
Moderator: Nancy Wintering, MSW, LCSW, CCRP

3:45 to 4:30 **ID Code: 329**

Trust and Willingness to Participate in Research - Implications for Enrollment of Hard to Reach Populations

Leah Dawson, PhD, CCRP, CHES

4:35 to 5:20 **ID Code: 331**

Health Disparities: Why Inclusion and Health Equity Matter in Clinical Research

Nancy Wintering, MSW, LCSW, CCRP

Track 4 –Risk Management
Location: Celestin A-C
Moderator: Patricia Beers Block, BS, CCRP

3:45 to 4:30 **ID Code: 429**

The Latest Industry Pulse on Risk Based Monitoring

Abby Abraham, MPharm, PGDHHM

4:35 to 5:20 **ID Code: 431**

Chaos to Structure

Sandhya Patel, BScN, BSc

Track 5 – Integrative Medicine / CAM
Location: Strand 10
Moderator: Amy Jo Jenkins, MS, CCRP

3:45 to 4:30 **ID Code: 529**

Complementary and Alternative Therapies: Using Reporting Standards for Nonpharmacologic Trials to Explore Research Design Issues

Terry Selfe, PhD, DC, PhD, CCRP

4:35 to 5:20 **ID Code: 531**

Ayurvedic Approach to Chronic Diseases

Peeyush Bhargava, MD, ABIHM

Track 6 – Ethics in Research
Location: Strand 11
Moderator: Laura Holtz, MS, CCRP

3:45 to 4:30 **ID Code: 629**

Ethical Considerations in the Genetic Testing of Human Research Subjects

Wrenda Teeple, PharmD

4:35 to 5:20 **ID Code: 631**

Human Experimentation in the United States: Before, During and After the Beecher Article - Are We Learning From Our Mistakes?

Quincy Byrdsong, EdD, CIP, CCRP

Track 7 – Adverse Events Reporting
Location: Strand 12
Moderator: Jennifer Li, BSc, CCRP

3:45 to 4:30 **ID Code: 729**

Operationalizing the Serious Adverse Event Process

Tracy Popp, MBA, CRCP, CCRP

4:35 to 5:20 **ID Code: 731**

Adverse Event Reporting Using the CTCAE Criteria

Nicole Luimes, HBSc, CCRP

Track 8 – ClinicalTrials.gov
Location: Strand 13
Moderator: Janelle Allen, MS, BS, CCRP

3:45 to 4:30 **ID Code: 829**

ClinicalTrials.gov Registration and Results Reporting for Investigator-Initiated Trials

Kate Anderton, MPH, CCRP

4:35 to 5:20 **ID Code: 831**

ClinicalTrials.gov: How to Meet Clinical Trial Disclosure Requirements

Rebecca Williams, PharmD MPH

SCHEDULE-AT-A-GLANCE

Sunday, SEPTEMBER 30, 2018

Location: Celestin Ballroom
Moderator: Jamie Harper, MPH, CCRP

8:00 AM - 8:30 AM Continental Breakfast - Celestin Ballroom

8:40 to 9:25 **ID Code: 901**

Lessons Learned: A Review of Common GCP Deficiencies and Examination of Warning Letters Issued to Clinical Investigator Sites

Barbara Wright, BGS

9:25 to 10:10 **ID Code: 903**

Implementing the Changes to the Common Rule

Cynthia Gates, JD, ADN, CCRP, CIP

10:10 -10:30 AM Morning Break - Celestin Ballroom

10:30 to 11:00 **ID Code: 904**

Learning Compliance From Living It - What I Discovered When My Husband Died

Kelly Willenberg, DBA, RN, CHRC, CHC, CCRP

11: 00 to 11:30 **ID Code: 905**

Clinical Trial Recruiting - A Partnership

Jzaneen Lalani, JD

11:30 to 12:00 **ID Code: 906**

eConsent and eSource - The Revolution is Here: Now What?

Irfan Khan, MD, MD, FACC, FHRS

CONFERENCE NOTES: