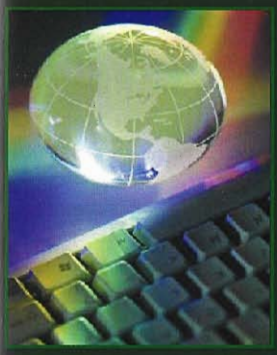
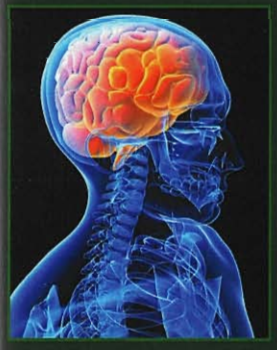
National Drug Abuse Treatment Clinical Trials Network

Web Seminar Series



2009 Course Catalog



- *Courses Targeting Various Experience Levels*
- *CTN – Focused Training*
- *Courses Led by CTN and CCC Experts*

Clinical Coordinating Center

2008 Web Seminar Series

A SUCCESS WORTH CONTINUING!

The Clinical Coordinating Center (CCC) introduced its web seminar series in 2008. Between May and October 2008, the CCC and CTN experts presented and recorded seminars on eight topics to 300 CTN members from 14 Nodes.

CONTRIBUTING CTN MEMBERS

The CCC would like to thank the following CTN members for sharing their knowledge and experience through the 2008 seminars: Maria Campanella with the CCC, Jack Chally with the CCC, Carol Cushing with the CCTN, Debbie Drosdick with the DSC, Anthony Floyd with the PNW Node, Lynn Kunkel with the OR/HI Node, Robert Lindblad with the CCC, Amanda Moore with the CCC, Jennifer Sharpe Potter with the NNE Node, Rajesh Venugopal with the CCC, and Katharina Weist with the OR/HI Node.

DID YOU MISS A 2008 WEB SEMINAR?

All seminar recordings, PowerPoint presentations, and training materials are available on Live Link https://livelink.nida.nih.gov or may be requested on disk via ctntraining@emmes.com. Please feel welcome to use these seminar materials for continued staff training or for customizing to best meet your site's needs. Seminar topics include:

- Timeline Follow Back
- Informed Consent
- Site Management Overview
- IRB and Regulatory Documentation
- Recruitment and Retention
- HIPAA
- Adverse and Serious Adverse Events
- Good Clinical Practice Overview

2009 Web Seminar Series

THE CCC IS PLEASED TO CONTINUE OUR POPULAR WEB SEMINAR SERIES!

Introducing our 2009 web seminar catalog. The CCC and CTN members have once again collaborated to provide interactive training sessions via web seminars. This format provides a cost effective and convenient way to disseminate the vast technical and tacit knowledge available through collaborative discussions with network colleagues from the comfort of your own office.

BENEFITS AND NOTABLE FEATURES

- Gain explicit and tacit knowledge from colleagues within the convenience of your own office
- Compilation of online training resources
- Opportunities for continuing education credits
- Site management mini series
- Topics targeting novice, mid-level and advanced research experience levels
- No travel headaches or expenses, no expense reports and no time away from your research site and family

SEMINAR FORMAT

Join seminars as a team or individually through a web seminar link and an audio connection provided to registrants. Participation requires Microsoft Windows (2000, XP, 2003, or Vista), and Microsoft Internet Explorer 6.0.

SEMINAR TOPIC OR PRESENTER RECOMMENDATION

If you are interested in a particular topic or would like consideration as a future presenter please contact Liz Buttrey at 301-251-1161 ext. 170 or ebuttrey@emmes.com for information.

Series at a Glance

SEMINAR

Fundamentals of Clinical Research in the CTN

March 11
1:00 pm (ET)

SEMINAR DESCRIPTION:

This is a two-hour seminar orienting novice research staff to the CTN and the clinical research environment within the CTN. Participants will receive explanation of the essential principles critical to facilitating CTN research in a clinical treatment program.

LEARNING OUTLINE:

- CTN overview
- Research team overview
- Research protocol overview
- Reasons behind the rules and guidelines
- Working with electronic data capture systems
- Navigating relationships within a CTP and the CTN

WHO SHOULD ATTEND?

Everyone is welcome! The target audience includes novice research staff responsible for conducting NIDA CTN research trials.

INSTRUCTORS:

Ron Jackson, M.S.W.
Christie Thomas, M.P.H.

REGISTRATION:

Submit registration via e-mail to ctntraining@emmes.com.

Site Management Tools and Practice Workshop Series

April 2 + April 23 + May 7
1:00 pm (ET)

SEMINAR DESCRIPTION:

This is a six-hour workshop delivered in three sessions providing guidance on site management processes and tools developed by seasoned CTN site managers. Seminar participants gain a body of tools and strategies for CTN research site management.

LEARNING OUTLINE:

Session 1

- Project management purpose
- Roles and responsibilities
- Project plan development

Session 2

- Building communication, performance, and teams
- Pre-study implementation checklists and tools

Session 3

- Ensuring good study performance
- Avoiding "Super manager Syndrome" through time management and personal boundaries

WHO SHOULD ATTEND?

Everyone is welcome! The target audience includes experienced research staff responsible for managing NIDA CTN trial conduct.

INSTRUCTORS:

Frankie Kropp, M.S.
Gloria Miele, Ph.D.

REGISTRATION:

Submit registration via e-mail to ctntraining@emmes.com.

Resolutions for Unexpected Site Challenges

June 11
1:00 pm (ET)

SEMINAR DESCRIPTION:

This is a one-hour discussion of probable risks and challenges that may be encountered during a clinical research study. Registrants are encouraged to bring challenging experiences for discussion. Appropriate risk identification processes will be discussed to defuse problems before they arise. Only didactic portions of the seminar will be recorded.

LEARNING OUTLINE:

- Risk identification and challenges in various types of research studies
- Roundtable case study discussion
- Risk assessment and management
- Revealing and planning for vulnerable operations

WHO SHOULD ATTEND?

Everyone is welcome! The target audience includes novice and mid-level research staff responsible for conducting NIDA CTN research trials.

INSTRUCTORS:

Jack Chally, M.S.
Charlotte Royer-Malvestuto, M.Ed., MBE.

REGISTRATION:

Submit registration via e-mail to ctntraining@emmes.com.

Quality Assurance and Site Monitoring Visits

July 14
1:00 pm (ET)

SEMINAR DESCRIPTION:

This is a one-hour seminar providing guidance to CTN clinical research sites on quality assurance monitoring preparation, facilitation, and follow up procedures. Participants will receive an all-encompassing clarification of monitor expectations.

LEARNING OUTLINE:

- Types of CTN site monitoring visits
- Steps a site can take in preparation for a site monitoring visit
- Insight into what takes place during a monitoring visit
- Site responsibilities after a site monitoring visit
- Quality control activities sites can follow between monitoring visits

WHO SHOULD ATTEND?

Everyone is welcome! The target audience includes novice and mid-level research staff responsible for conducting or facilitating research practices for the CTN protocols.

INSTRUCTORS:

Amanda Moore
Scott Provost, M.M., M.S.W.

REGISTRATION:

Submit registration via e-mail to ctntraining@emmes.com.

Recruitment and Retention

August 11
1:00 pm (ET)

SEMINAR DESCRIPTION:

This is a two-hour seminar providing recruitment and retention tools and guidelines. Successful completion of this training course will prepare staff to initiate and maintain successful clinical research, study participant recruitment and retention strategies.

LEARNING OUTLINE:

- Recruitment and retention overview and purpose
- Discussion of proven research recruitment tools
- Developing and maintaining rapport with participants and other clinic staff
- The customer service side of retention

WHO SHOULD ATTEND?

Everyone is welcome! The target audience includes novice and mid-level research and node staff responsible for the recruitment and retention of study participants.

INSTRUCTORS:

Kimberly Pressley, M.A.
Lynn Kunkel, M.S.

REGISTRATION:

Submit registration via e-mail to ctntraining@emmes.com.

Writing Site Specific Standard Operating Procedures (SOPs)

September 15
1:00 pm (ET)

SEMINAR DESCRIPTION:

This is a one-hour seminar providing a process for developing, implementing and revising site specific and protocol specific SOPs to appropriately conduct thorough clinical research trials at CTP sites. Participants will gain tools and guidelines for facilitating process documentation and consistency.

LEARNING OUTLINE:

- SOP value and purpose
- Recommended sections and content guidelines
- Protocol and site specific process breakdown
- Process risk identification and mitigation

WHO SHOULD ATTEND?

Everyone is welcome! The target audience includes mid-level research staff responsible for conducting NIDA CTN research trials.

INSTRUCTORS:

Caroline Baron-Myak
Mary Elise Kaye, R.N., B.S.N.

REGISTRATION:

Submit registration via e-mail to ctntraining@emmes.com.

Ethical Principles in Clinical Research

November 19
1:00 pm (ET)

SEMINAR DESCRIPTION:

This is a two-hour seminar discussing the ethical principles underlying the conduct of research and Good Clinical Practices (GCP) within the CTN. Participants will receive a overview of GCP knowledge and practical examples of research site challenges.

LEARNING OUTLINE:

- Ethical clinical research components
- Origins of research ethics
- Principles governing research
- GCP overview

WHO SHOULD ATTEND?

Everyone is welcome! The target audience includes NIDA CTN research staff seeking a GCP refresher course and novice research staff responsible for conducting NIDA CTN research trials.

INSTRUCTOR:

Ron Jackson, M.S.W.
Charlotte Royer-Malvestuto, M.Ed., MBE

REGISTRATION:

Submit registration via e-mail to ctntraining@emmes.com.

INSTRUCTOR BIOSKETCHES

JACK CHALLY, M.B.A.

Mr. Chally joined the CCC in 2007 as Protocol Specialist for CTN-0027 and 0032 studies. Jack came to the CCC after a 15+ year career in the Navy, including working in hospitals all over the world and most recently the National Naval Medical Center in Bethesda, MD. While in the Navy he earned a B.S. in Management and Human Resources from Park University and an M.B.A. focused in Healthcare Management from Regis University. Jack has expertise in behavioral health, healthcare management, and is a certified cognitive behavioral therapist.

RON JACKSON, M.S.W.

Mr. Jackson is the Executive Director of Evergreen Treatment Services (ETS) in Seattle and Olympia, WA. Ron has been an Investigator on many research projects conducted at ETS over the past decade. Those studies have investigated treatment, motivational enhancement and acupuncture interventions for opiate dependent individuals, cocaine addicts and marijuana dependent individuals. He is currently a Co-Principal Investigator for the NIDA CTN Washington Node and is an Affiliate Professor at the University of Washington's School of Social Work. Ron has been working as a clinician, administrator, educator, researcher, and consultant in the field of addiction treatment since 1972. In April, 2003 he was awarded the Nyswander-Dole Award by the American Association for the Treatment of Opioid Dependence for his contributions to the field.

INSTRUCTOR BIOSKETCHES

MARY ELISE KAYE, R.N., B.S.N.

Mary Elyse Kaye has a bachelor's degree in nursing and psychology from Carlow University and has worked in research and clinical settings involving children, adolescents and adult populations for over 20 years. Mary Elyse worked at Western Psychiatric Clinic for 17 years as a psychiatric nurse and an assistant nurse clinical manager in various child and adolescent units. Since 2002 she has worked in the UPMC Health system as a research nurse, clinical administrator, and a clinical research coordinator in various studies and programs including the NIDA CTN-0028.

FRANKIE KROPP, M.S.

Ms. Kropp is the Director of Training for the NIDA CTN Ohio Valley Node, located in Cincinnati, OH. She has been active in training across the CTN, including serving as the CTN Training Subcommittee Chair in 2005. In addition, Frankie has provided protocol oversight in numerous CTN trials at local and national levels. A Kentucky native (Go Wildcats!), Frankie received her Masters in Clinical Psychology from Eastern Kentucky University in 1981 and provided direct clinical services in a number of settings until entering research in 1997. When not at work, she spends time with her family and serves as Project or The Cornerstone Project, an inner-city ministry in Northern KY.

INSTRUCTOR BIOSKETCHES

LYNN KUNKEL, M.S.

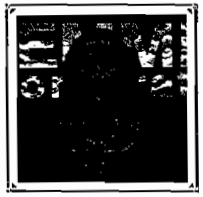
Ms. Kunkel has been with the Oregon/Hawaii Node of the NIDA CTN since its inception in 1999. In 2003 she became its Node Coordinator and Regulatory Specialist. The Node has implemented over 11 protocols, six of which Lynn served as the Node Protocol Coordinator. Ms. Kunkel oversees the protocol management for all protocols and serves as the training director for the Node. Lynn received her M.S. from Portland State University in Applied Psychology, with an emphasis on applied research in 1995. In September of 2007, she became a certified Clinical Research Professional.

GLORIA MIELE, Ph.D.

Gloria M Miele, Ph.D. is a Clinical Psychologist who, for many years, has been providing a broad range of trainings related to substance use disorders, with an emphasis in assessment and psychosocial treatments for women with trauma, co-morbid mental disorders, and HIV. She fully developed her love of training through the CTN, where she has served as Training Director for the Long Island Node and has been active in various CTN training activities since 2001. She is an Instructor of Clinical Psychology (in Psychiatry) at Columbia University College of Physicians & Surgeons and a Regional Trainer for the American Psychological Association's HIV Office for Psychology Education (HOPE). Gloria resides in Southern California, where she also works as a consultant, trainer and personal coach, with special interests in strengths-based approaches to personal and professional development and organizational change.

INSTRUCTOR BIOSKETCHES

AMANDA MOORE



Ms. Moore is a CCC Project Manager. She has also served as the Protocol Specialist and Protocol Monitor for CTN-0029, 0031, and 0031A. Amanda has been integral in designing manuals, training, and processes assuring appropriate protocol implementation and regulatory compliance. Prior to joining the CCC, she was a Research Assistant on CTN-0017 through Wayne State University. Amanda earned her B.S. in Psychology from Western Michigan University and is currently pursuing a Master's degree in clinical research administration from George Washington University.

CAROLINE BARON-MYAK

Caroline Baron-Myak has a bachelor's degree in nursing from Penn State University and has worked in research and clinical settings involving children, adolescents, and adult populations for over 15 years. She has worked in the UPMC Health system since 1993 as a research nurse, clinical administrator, and a clinical research manager in various studies and programs including the NIDA CTN.

INSTRUCTOR BIOSKETCHES

KIMBERLY PRESSLEY, M.A.

Mrs. Pressley has worked with the NIDA CTN Southern Consortium Node since 2001. Kimberly has worked in various roles on the CTN-0011, 0018, 0019, and 0028. Currently, she is the Research Coordinator for the CTN-0032 protocol at the Morris Village inpatient substance abuse treatment center in South Carolina. She earned her BA in psychology from the University of South Carolina and her MA in counseling from Webster University.

SCOTT PROVOST, M.M., M.S.W.

Mr. Provost is a Clinical Project Manager and Director of Quality Assurance and Regulatory Affairs for the Northern New England Node based at McLean Hospital's Alcohol and Drug Abuse Treatment Program. Scott has been affiliated with the Node since 2003 and been involved in several CTN protocols in site management and quality assurance capacities. Currently, Scott is the Co-Project Manager for CTN-0030. Scott received a Master's degree in social work from the University of Pennsylvania and a Master of Management degree with a concentration in health and human services from the Heller School for Social Policy and Management at Brandeis University.

INSTRUCTOR BIOSKETCHES

CHARLOTTE ROYER-MALVESTUTO, M.Ed., MBE.

Ms. Royer-Malvestuto is a healthcare professional with extensive experience in clinical research and healthcare administration, including: adjunct professor/medical bioethics; implementation and oversight of multi-site clinical trials; bioethics reviews of research protocols; and human subjects auditing/training activities, for national and international studies. Group facilitation experience includes multi-site training on the administration of standardized assessment tools and good research practices. Charlotte has provided training and consultation in the United States, Austria, Russia, and the Baltic States. She has a Master's degree in Medical Bio-Ethics from the University of Pennsylvania and a Master's of Education from Temple University, where she majored in psychology and education.

CHRISTIE THOMAS, M.P.H.

Ms. Thomas has 12 years of clinical research experience conducting behavioral and medication trials for substance abusing populations. Christie is a Project Director at Friends Research Institute / UCLA Integrated Substance Abuse Programs and is part of the NIDA CTN Pacific Node based in Los Angeles, California. Currently she is the National Coordinator for the CTN-0027. She is responsible for coordinating national study activities to assure appropriate protocol implementation and regulatory compliance. She also serves as Node Protocol Manager for the Pacific Node CTN-0031. Christie holds a Masters degree in Public Health and a Bachelor of Arts degree in Psychology from the University of California.

TRAINING RESOURCES

CONTINUING EDUCATION (CEU) RESOURCES

- The Society of Clinical Research Associates (SoCRA) accepts participation documentation for recertification if the program is applicable to clinical research regulations, operations or management, or to the candidate's clinical research therapeutic area. The CTN web seminar series courses qualify as appropriate sources of continuing education credits. Please use the following conversion formula. 1 hour = 1 CME or 0.1 CEU or 60 minutes.
- Professional education resources designed for healthcare professionals including access to sites offering ACCME-accredited through CME Gateway http://www.cmecorner.com.
- Online resources to substance-abuse education for medical students and health professionals http://www.addictioncme.com.

BIOLOGICAL MEASURES AND SPECIMEN HANDLING

This recorded training session covers good practices and universal precautions for collecting, handling, and shipping biological specimens. The training session is available on Live Link https://livelink.nida.nih.gov. Certificates of completion are granted for quiz scores at 80% or above. Requests for quizzes may be directed to ctntraining@emmes.com.

DEMOGRAPHICS

This recorded training session covers measures used to gather candidate information for CTN protocols. Designations used by the US census are clarified. The training session is available on Live Link https://livelink.nida.nih.gov. Certificates of completion are granted for quiz scores at 80% or above. Requests for quizzes may be directed to ctntraining@emmes.com.

2008 WEB SEMINAR RECORDINGS

Each web seminar recording is accessible on Live Link https://livelink.nida.nih.gov. Requests for a session on CD may be directed to ctntraining@emmes.com.

TRAINING RESOURCES

PROTECTING HUMAN RESEARCH PARTICIPANTS

This two-hour, web-based course is designed for conducting research and presents information on the rights and welfare of human research participants. It satisfies the NIH human subjects training requirement for obtaining Federal Funds. A certificate is available upon completion http://phrp.nihtraining.com.

OHRP HUMAN SUBJECT ASSURANCE TRAINING

Institutions engaged in federally conducted or supported human subjects research must commit itself in writing to the protection of those subjects. This written commitment is called an Assurance of Compliance. For human subject research conducted or supported by the Department of Health and Human Services (HHS), the Office for Human Research Protections (OHRP) must approve an institution's Assurance before the funds can be awarded and human subject research can begin. The Federal Wide Assurance (FWA) is the most common type of assurance approved by OHRP http://ohrp-ed.od.nih.gov.

CTN BEST PRACTICES

Provides education and training program access for researchers and healthcare staff. Programs include Building a Successful Site, CITI Online Training, Introduction to Clinical Research, Clinical Research Writing, Essential Regulatory Documents, Evidence-Based Medicine, and Human Research Subject Protection. Many programs offer CE credits in exchange for a course evaluation https://www.ctnbestpractices.org.

GOOD CLINICAL PRACTICE TRAINING

This online course covers the requirements of Good Clinical Practice in clinical trials research. This training prepares staff responsible for conducting informed consent processes, assessing the safety of participants, or having primary responsibility for the site's study conduct. All members of the CTN are welcome to complete this training http://www.nihtraining.com/ctn.