Course Faculty:

Leslie Greenberg is the Clinical Trials Program Manager at the Mid-Atlantic Permanente Research Institute (MAPRI) and serves as a primary point of contact for Principal Investigators (PIs) or sponsors wishing to conduct clinical trials in the Mid-Atlantic States region. She gathers information and assists PIs with completion of required documentation, engaging and notifying the Medical and Administrative Directors of proposed studies in the region, and facilitating communication between the PI, MAPRI staff at the medical centers, sponsors/CROs and Institutional Review Board.

Elizabeth (Liz) Ness has been involved in oncology clinical trials for the past 23 years. Her experience includes: 6 years as a Phase I research nurse at Lombardi Cancer Center, 3 years working as a contractor for the NCI which included 2 years with National Cancer Institute Cancer Therapy Evaluation Program (NCI CTEP). For the past 14 years, Liz has worked at the Center for Cancer Research, part of the NCI's intramural research program, coordinating and providing orientation and continuing education for research teams and quality management activities.

ONS
Where Oncology Nurses Connect

The National Capital Chapter of the Oncology Nursing Society is pleased to sponsor:

Clinical Trials: From Study Design to Monitoring

DATE: Saturday, October 28, 2017
TIME: Check-in/Breakfast: 8:30 am – 9:00 am
Course: 9:00 am – 5:00 pm

LOCATION:
Washington Cancer Institute located in MedStar Washington Hospital Center
Siegel Auditorium
110 Irving St NW
Washington, DC 20010
Washington Hospital Center map, click here.

FACULTY:
Leslie Greenberg, MSN, MBA, RN, OCN®
Elizabeth Ness, MS, RN

Target Audience:
Oncology clinical research teams, specifically research nurse coordinators, non-nurse study coordinators, and data managers who are new to their role or would like a refresher.

Course Objectives

Upon completion of the course, the participant will be able to:

1. Describe basic study designs used in clinical trials.
2. Describe activities associated with protocol development.
3. Differentiate the roles and responsibilities of the research team.
4. Define adverse event associated terminology.
5. Describe adverse event reporting criteria for regulatory oversight authorities.
6. Describe the roles and responsibilities of the sponsor and FDA in drug and biologic development.
7. Describe quality patient documentation throughout study participation.
8. Describe the contents of a regulatory file.
9. Describe various types of data and safety monitoring plans.
10. Describe how to prepare for a monitoring visit.

Continuing Nursing Education Credit:

This activity was approved by the Oncology Nursing Society, an accredited approver by the American Nurses Credentialing Center's COA.

For more information regarding contact hours, please call Liz Ness at 301-451-2179.

Attendees who are not registered nurses, will receive a certificate of attendance. CNE will only be provided to registered nurses.

PROGRAM SCHEDULE

8:30 – 9:00 am **Registration**

9:00 –9:15 am **Welcome and Overview**

9:15 – 10:15 am **Clinical Trial Design and Protocol Development**

10:15 – 10:30 am BREAK

10:30 –11:30am **Roles and Responsibilities of the Research Team**

11:30am–12:45pm **Adverse Events and Unanticipated Problems**

12:45 pm – 1:45 pm **Lunch** *(on your own)*

1:45 – 2:45 pm **IND Clinical Trials: Role of the Sponsor and the FDA**

2:45 – 3:00 pm BREAK

3:00 – 4:00 pm **Documentation and Document Management**

4:00 – 4:55 pm **Data and Safety Monitoring**

4:55 – 5:00 pm **Wrap-up and Final Questions**

Registration Information:

- Register and Pay Online via PayPal at http://nationalcapital.vc.ons.org/ and select 'RSVP for meetings/courses'

For registration questions, contact: Nonniekaye Shelburne at nshelburne@nih.gov or 240-276-6897

** All course proceeds benefit the National Capital Chapter of ONS**

Registration Deadline: October 20, 2017

Course Fee:

$95.00 for non-Washington Hospital Center employees
$80.00 for Washington Hospital Center employees

The course fee includes: continental breakfast, handouts and Continuing Nursing Education Credits or attendance certificate.

No on-site registrations accepted

Cancellation/Refund Policy:

No refunds will be provided after **October 13, 2017.** Partial refunds are not provided. Contact Nonniekaye Shelburne at 240-276-6897 prior to October 13th to cancel.