Course Faculty:

Elizabeth (Liz) Ness has been involved in oncology clinical trials for the past 22 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 NCI CTEP. For the past 12 years, Liz has worked as a Nurse Consultant at the Center for Cancer Research, part of the NCI's intramural research program, coordinating and providing orientation and continuing education for research teams.

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, November 14, 2015
TIME: Registration 8:00 am - 8:30 am
Course 8:30 am - 4:30 pm

LOCATION:
Holy Cross Hospital
Room Edu 4 (1st floor)
1500 Forest Glen Road
Silver Spring, MD 20910
Parking: $7

Metro stop: Red Line- Forest Glen
(0.5 mile/12 minute walk to Holy Cross)

FACULTY:
Elizabeth Ness, RN, MS

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 has been submitted to the Oncology Nursing Society for approval to award contact hours. ONS is accredited as an approver of continuing nursing education 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

8:00 – 8:30 am **Registration**

8:30 – 8:45 am **Welcome and Overview**

8:45 – 9:45 am **Clinical Trial Design and Protocol Development**

9:45 – 10:00 am BREAK

10:00 –11:00am **Roles and Responsibilities of the Research Team**

11:00am–12:15pm **Adverse Events and Unanticipated Problems**

12:15 pm – 1:15 pm **Lunch** *(on your own)*

1:15 – 2:15 pm **IND Clinical Trials: Role of the Sponsor and the FDA**

2:15 – 2:30 pm BREAK

2:30 – 3:30 pm **Documentation and Document Management**

3:30 – 4:25 pm **Data and Safety Monitoring**

4:25 – 4:30 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'
- If you have a group of **5** or more participants, you may register and pay by check by contacting Liz Fagan at lizfagan815@gmail.com or 202-431-1611.

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 31, 2015

Course Fee:
$95.00 for non-Holy Cross employees
$80.00 for Holy Cross 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 31, 2015.** Partial refunds are not provided. Contact Nonniekaye Shelburne at 240-276-6897 prior to October 31st to cancel.