Protocol Support Committee
Introduction to Clinical Trials: Principles of Clinical Trial Management

Date: **Thursday, January 9, 2020**
Start and End Time: **7:30 am – 4:10 pm**
Facilitators: **Sharon Stockman BA, CCRP and Cindy Licavoli RN, BSN, MA**
Room: **TBA**

Learning Objectives
Following this activity, participants will be better able to:

1. Discuss NRG Oncology membership requirements
2. Describe the events leading up to the development of IRB's
3. Describe the roles and responsibilities of the IRB relative to the performance of clinical research involving human subjects
4. Describe the roles and responsibilities of clinical research sites in following IRB regulatory and ethical requirements
5. Describe the processes to be followed by clinical research sites in adhering to IRB requirements
6. Describe the standard drug accountability procedures for NCTN trials
7. List resources for additional information regarding investigational drug
8. Describe the basic methodology of RECIST 1.1 and other response criteria used in NRG Oncology trials
9. Discuss RECIST 1.1 criteria as well as other response criteria used and identify methods of source documentation
10. Describe how to record the RECIST information to facilitate data submission
11. Identify proper forms of source documentation
12. Describe useful tools and methods to ensure timely and accurate data management in the clinical trial setting
13. Describe procedures for completion and submission of case report forms
14. Identify methods for screening patients for clinical trials
15. Identify the informed consent process according to federal regulations and local practices
16. Explain the clinical trial enrollment process
17. Navigate in the RAVE system
18. Utilize basic commands to key data into the RAVE system
19. Describe the key components of serious adverse event assessment including term selection, grading and attribution
20. Discuss the importance of QOL components to our trials
21. Discuss NRG Oncology Mentorship Program
22. Discuss protocol requirements for administration of chemotherapy, immunotherapy, radiation therapy and surgery
23. Discuss the nature of and preparation for NCI-mandated Quality Assurance Audits
24. Discuss the basics of pathology and translational research specimen requirements and submissions

AGENDA

Time	**Topic**	**Speakers**
7:30am- 7:40 am	Welcome	Sharon Stockman, BA, CCRP & Cindy Licavoli RN, MA
7:40 am-7:55 am	NRG Oncology Overview	Kati Stoermer, MSBA
7:55 am-8:15 am	NRG Membership	Mimi Passarello, MBA
8:15am-8:45 am	IRB's: Who, What, Where, When and How	Lynne Lippmann, BA, CCRP
8:45 am-9:15 am	Serious Adverse Event Reporting	Sara McCartney, MS, RN
9:15 am-9:35 am	Investigational Drug Management	Nancy Knudsen, RN, BSN

9:35am-9:50 am	Break	
9:50 am- 10:15 am	Medidata Rave	Joseph Mroziak
10:15 am-10:45 am	Quality Assurance Audits	Tamara McLaughlin, MHA, MPH
10:45 am-11:10 am	Pathology/Biospecimen Collections	Lisa Beaverson, BA, CCRP Sandy DeVries, MA
11:10 am-11:40 am	RECIST	Mark Shahin, MD
11:40 am – 11:50 am	Mentorship Program	Nancy Fusco, RN, BSN
11:50 am- 12:00 pm	QOL	Sharon Stockman, BA, CCRP
12:00 am – 12:05 pm	Morning Closing Remarks	Sharon Stockman, BA, CCRP
12:05 pm – 1:15 pm	Lunch (on your own)	
1:15 pm – 4:10 pm	Afternoon Breakout Sessions- All sessions run concurrently (40 minutes/session)	

Topic	**Speaker**
Patient Screening and Enrollment Room:	*Lead Facilitator*- Cindy Licavoli, RN, BSN, MA Joni Shortt, RN, BSN, CCRC Tiffany Elsea, BA, CCRP
Treatment Modalities in Clinical Trial Management Room:	*Lead Facilitator*- Joyce Neading, RHIT, CTR Chrisann Winslow, RN, MSN Karen Holeva, BS
Data Management Room:	*Lead Facilitator*- Lynne Lippmann, BA, CCRP Sue Eaton, CCRP Whitney Jacobson, RN, BSN, CCRP
Adverse Event Reporting Room:	*Lead Facilitator*- Mary Smrekar, RN, MSN, CNP Donna White, RN, BSN, OCN Alison Ivey, RN, BSN, OCN, CCRP
4:10pm – 4:30pm	Evaluation

QUESTIONS/DISCUSSION
EVALUATION

Protocol Support Committee Workshop
Education & Training Working Group (CLOSED)

Date:	**Thursday, January 9, 2020**
Start and End Time:	**4:30pm – 6:30pm**
Chair:	**Susan Nolte, PhD, CRNP**
Co-Chairs:	**Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC**
Working Group Facilitators	**Karen Holeva, BS, Melinda Weiblen, BS , Chrisann Winslow RN, MSN**
Room:	

Learning Objectives: Following this activity, participants will be better able to:

1. Discuss alternative methods of education
2. Provide the PSC with potential topics and speakers for the 2020 Summer Meeting & 2021 Winter Meeting
3. Have a structured working group agenda

WORKSHOP AGENDA

1. Welcome
2. Announcements
3. Discuss progress of working group
    a. Conference Call Frequency
    b. Create Sub Groups
4. Discuss plans for Summer 2020 meeting
5. Suggestions for Winter 2021 meeting

QUESTIONS/DISCUSSION
EVALUATION

Protocol Support Committee Workshop
Mentorship Working Group (CLOSED)

Date:	**Thursday, January 9, 2020**
Start and End Time:	**4:30pm – 6:30pm**
Chair:	**Susan Nolte, PhD, CRNP**
Co-Chairs:	**Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC**
Working Group Facilitators	**Nancy Fusco RN, BSN, Sue Eaton CCRP**
Room:	

Learning Objectives: Following this activity, participants will be better able to:

1. Identify potential new topics for the Introductory Materials
2. Discuss the development of mentor program tools
3. Review the effectiveness of the mentor program

Workshop Agenda:
**First hour: meeting with mentors

1. Roll call of Mentorship Working Group members and mentors
2. Update from Quality Control Working Group Liaison:
3. Announcements:
4. Mentor updates: Reports from mentors

**Second hour: Working Group members only for business meeting

5. Approval of minutes from most recent conference calls
6. Review committee member number of participants
7. Review the need for a Call for Mentors
8. Mentor Conference Call Reports: Sue and Mary
9. Review ongoing projects for the working group:
    a. Introductory Materials For NRG Oncology Research Clinical Trials Coordinators:
        i. Annual review: Review of sections assigne
        ii. Discuss new topics to include: Topic list
        iii. FAQ section: Review the PSC mailbox topics and update questions
    b. Mentor working group documents:

i. Review due in July of 2021

c. Mentor Program:
   i. Development of Mentorship Program tools: New tools as needed
   ii. Lead/Second Lead mentor report
   iii. New updates regarding the program: Monitoring of effectiveness
   iv. Mentor/Mentee evaluations

10. Meeting Plan: Monthly conference calls and Working meetings at NRG Oncology Semi-Annual Business Meeting

QUESTIONS/DISCUSSION
EVALUATIONS

Protocol Support Committee Workshop
Protocol Review Working Group (CLOSED)

Date:	**Thursday, January 9, 2020**
Start and End Time:	**4:30pm-6:30pm**
Chair:	**Susan Nolte, PhD, CRNP**
Co-Chairs:	**Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC**
Working Group Facilitators	**Terry Thomas MS, CCRC, Nancy Knudsen RN, BSN**
Room:	

Learning Objectives

Following this activity, participants will be better able to:

1. Review current process of circulating protocols for review
2. Discuss the tracking form for the protocol working group reviewer responses
3. Discuss current method for updates and corrections of existing protocols
4. Discuss additional ways the working group can assist the protocol development teams.
5. Discuss the role the protocol review committee identifying issues and concerns for the other working groups like education and mentor to review/discuss
6. Discuss current procedures and approval with CTSU, protocol development and CIRB

WORKSHOP AGENDA

Call to order
Intro new members
Circulate Roster for approval and Protocol review Sheet
Intro Guests

Agenda Items

1. Review current Protocol review process.

2. Update from the Protocol Development team.
   a. Protocol template
   b. Protocol team discussion
   c. Development of standard protocol guidelines across NRG protocols
3. CIRB update
4. CTSU update
5. NRG regulatory
6. Update from Quality Control representative
7. Other business

QUESTIONS/DISCUSSION
EVALUATION

Protocol Support Committee Workshop
Quality Control Working Group (CLOSED)

Date:	**Thursday, January 9, 2020**
Start and End Time:	**5:30pm – 7:00pm**
Chair:	**Susan Nolte, PhD, CRNP**
Co-Chairs:	**Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC**
Working Group Facilitator	**Joyce Neading CTR(retired)**
Room:	

Learning Objectives
Following this activity, participants will be better able to:

1. Describe the role of the Quality Control Working Group's relationship with the other PSC Working Groups.
2. Define the relationship between the Quality Control Working Group and the Quality Assurance/Audit Team.

Workshop Agenda

1. Review and approval of minutes from July 18, 2019 meeting
2. Introductions/Welcome
3. Quality Assurance /Audit Team Liaison report/discussion
4. Working Group Liaisons report
    a. Protocol Review Working Group – Donna White
    b. Education and Training Working Group – Robin Burgess
    c. Mentorship Working Group - TBA
5. Review progress on new projects
6. New Business

QUESTIONS/DISCUSSION
EVALUATION

Protocol Support Committee Workshop
Clinical Trial Nurse Subcommittee and Clinical Research Associate Subcommittee (JOINT MEETING- First hour open, second hour closed)

Date:	**Friday, January 10, 2020**
Start and End Time:	**7:00am – 9:00am**
PSC Chair:	**Susan Nolte, PhD, CRNP**
PSC Co-Chairs:	**Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC**
CTN Chair:	**Cindy Licavoli RN, BSN, MA,**
CTN Co Chairs:	**Nancy Fusco RN, BSN, HeeSun Kim-Suh RN**
CRA Chair:	**Sharon Stockman BA, CCRP**
CRA Co-Chairs:	**Karen Holeva ,BS, Joyce Neading, CTR (retired)**
Room:	

Learning Objectives:
Following this activity, participants will be better able to:

1. Identify, describe and discuss aspects of RAVE Set-Up and how Committee Members can assist with review process
2. Identify, describe and discuss aspects of roles and responsibilities for the PSC Working Groups

3. Identify, describe and discuss the purpose and expectations of individual appointments to committees/working groups
4. Identify and discuss educational needs of both new and experienced CRAs/Nurses
5. Discuss the current activities of NRG Committees by CTN/CRA representatives

Agenda:

1. RAVE Overview and Discussion with Headquarters Representative(s)
2. Working Group Reports
   a. Protocol Review
   b. Education and Training
   c. Quality Control
   d. Mentorship
3. Discuss roles and responsibilities for appointments to NRG Oncology committees
4. Review Meeting Programs (Introduction to Clinical Trials)
5. Discuss meeting schedules and educational needs
6. Newsletter articles
7. Future meeting planning
8. Other business

QUESTIONS/DISCUSSION
EVALUATION

Protocol Support Committee Workshop
Clinical Trial Nurse/Clinical Research Associate Workshop-Educational Session

Date:	**Friday, January 10, 2020**
Start and End Time:	**2:00pm - 6:00pm**
Chair:	**Susan Nolte, PhD, CRNP**
Co-Chairs:	**Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC**
Program Facilitators:	**Karen Holeva, BS, , Melinda Weiblen, BS, Chrisann Winslow RN, MSN**
Room:	

Learning Objectives
Following this activity, participants will be better able to:

1. Describe tools on the CTSU website
2. Discuss the purpose of Institutional performance reports
3. To understand the role of patient reported outcomes (PROs) in cancer clinical trials
4. To understand the options for PRO assessment and analysis
5. To explore new frontiers in PRO assessment and opportunities for NRG Oncology to lead the way
6. Discuss the intersection of patient autonomy and the health care provider's moral duty to render evidence-based care in the cancer research population
7. To recognize the caregiver's role in leading nuanced compassionate discussions of how to best meet patients' goals according to patients' values (i.e what matter most to them)
8. To discuss the rationale for the request of non-medically indicated treatment & requests for violations of protocol care
9. To address the duo role of researcher/provider in clinical trials: an analysis of potential pressure for patient to receive "protocol driven" treatment
10. To identify moral distress in self or others which can contribute to (or result from) patient/family requests or "protocol specific" requirements
11. To identify breast cancer risk factors
12. To explain breast cancer pathology

13. To describe breast cancer diagnosis in relationship to treatment
14. To construct risk factors, pathology diagnosis and treatment in relationship to clinical trials

AGENDA

Time	**Topic**	**Speakers**
2:00-2:10	Introduction/Welcome	Karen Holeva BS
2:10-2:20	Welcome	Katie Stoermer, MSBA Executive Director, NRG Oncology
2:20-3:00	Updates and information from CTSU	Amanda Fournier
3:00-3:25	Update on NRG Oncology QA Audits, monitoring and Institution Performance reports	Mimi Passarello, MBA
3:25-3:35	break	
3:35 -4:20	Patient reported outcomes: Why we do it and how we do it	David Cella, PhD
4:20-5:05	Ethics related to care of the Oncology research Patient: moving concern to courage	Karen Iseminger PhD, ANP-BC, FNP
5:05-5:50	Basics of Breast Cancer	Brenda Lee Steele BSN, RN, OCN, CCRC
5:50-6:00	Questions and evaluation	

QUESTIONS/DISCUSSION
EVALUATION

Protocol Support Committee Workshop (Closed)

Date: **Saturday, January 11, 2020**
Start and End Time: **7:00 – 9:30 am**
Chair: **Susan Nolte, PhD, CRNP**
Co-Chairs: **Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC**
Room:

AGENDA

1. Meeting summary
2. Leadership Transition update
3. Report from CTN and CRA Subcommittees- Sharon Stockman & Cindy Licavoli (includes reports from Working Groups)
4. PSC mailbox
5. NRG Oncology Newsletter PSC column
6. NRG Oncology Committee reports
7. PSC representation on NRG Oncology committees
8. New Business
   a. Future meeting times

QUESTIONS/DISCUSSION
EVALUATION