IACRN
International Association of Clinical Research Nurses

Enhancing clinical research quality and safety through specialized nursing practice.

Newsletter *Issue: October 2013*

What's Inside

CALL FOR AUTHORS

Do you have information that you would like to share with your research nurse colleagues?

We encourage our members to grow professionally, while supporting our mission to enhance clinical research quality and safety through specialized nursing practice.

IACRN welcomes authors to submit on topics that are relevant to clinical research nursing globally.

Please forward submissions to Joy Bailey, RN, PhD(c), MSN, CRRN, BC at joy.bailey@emoryhealthcare.org

President's Corner

by Shaunagh Browning, RN, FNP-BC
President, IACRN

Spring and summer have come and gone. IACRN was however not on vacation. We have been busy behind the scenes developing the organization. Committee structures have been defined, the website look is ever improving, the planning committee for the annual conference has been busy planning an outstanding meeting, the education committee will release its first webinar in November, and the newsletter look has been improved as well as the content expanded. These are just a few examples of the work being done by IACRN. Please be sure to check out the website and Facebook for more information.

This newsletter focuses on providing real examples of the varied roles that Clinical Research Nurses take in institutions and the ways they contribute to the efficacy and safety of clinical trials. Thanks to Joy Bailey, Carmen Blount, and DeBorah Rowser for contributing their stories. In addition Julie Kohn-Godbout has provided a list of education and training resources from NIH. We hope that you will be inspired and gain knowledge for your practice from these newsletters. I would encourage you to contact Joy to share your experiences for the next edition of the newsletter.

Lastly, I want to recognize the members of IACRN for their dedication to the organization. Boston was recognized as the first chapter of IACRN this past spring. Be sure to check out what they are doing, especially if you are in the Boston area. Under the direction of Mary Larkin and Kerry Grennan, the Chapter Governance Committee has developed a Guide for Chapters to guide other areas that might want to start a chapter. Please be sure to contact Mary or Kerry should you want more information about becoming a chapter.

Looking forward to seeing many of you in San Diego for our 5th Annual Conference.

First Chapter - Boston

The International Association of Clinical Research Nurses (IACRN) is pleased to announce the formation of its **first regional chapter, located in Boston, Massachusetts.**

The Boston Chapter of IACRN started its journey towards chapter status 2 years ago. Founding members of the chapter include President Mary Larkin, President Elect Linda Pitler, Vice President Amy Sbrolla, Secretary Kerri Milaszewski and Treasurer Lauren Donahue. Catherine Griffith, current Treasurer for IACRN, was also a founding chapter member.

The inaugural meeting was held June 16, 2011. Meetings are held three times a year at various locations across the city to encourage research nurses from different institutions to attend. Our programs are very diverse. We've discussed: a 20 year follow up to Tuskegee, research subject advocacy, and building a pediatric clinical research program. On March 7, 2012, (in the middle of a blizzard), we welcomed Shaunagh Browning and Liza Behrens, the President and President–Elect of IACRN who had the pleasure of informing our membership of our chapter recognition. President Mary Larkin stated "we are honored to be named as the first IACRN chapter affiliate. We have an active and highly experienced group of research nurses in this area who are eager to advance practice and participate in the chapter to promote IACRN's mission".

The Boston Chapter of IACRN welcomes all clinical research nurses to attend as a guest if not already a member. Members must hold an active membership in the parent IACRN association. Announcements of meetings are via email and are also on our Facebook page. Meeting dates for 2013-2014 are October 3, March 6, and June 6. Incoming President, Linda Pitler is looking forward to welcoming new members and leading this chapter starting January 2014. She states "clinical research nurses are the primary driving force in the success of clinical trials. The role is broad and encompasses many practice settings and specialties. We look forward to learning from one another and contributing to the growth of IACRN internationally". Please join us at an upcoming meeting or send us an email to request additional information.

Contact information: bostoniacrn@gmail.com or contact Mary Larkin, Chapter President at mlarkin1@partners.org

Caring for the Sleep Study Participant: An Emerging Role for the Research Nurse?

by DeBorah B. Rowser, RN, MSN
Clinical Research Nurse, Atlanta Clinical and Translational Science Institute (ACTSI)

Introduction

Over the last 30 years, a keen interest within the medical community has surfaced in sleep analysis and its relationship to various disease processes. Historically, analysis is linked to those suffering primarily from sleep apnea and neurobehavioral diagnoses, and is traditionally managed by respiratory therapy professionals, sleep technicians and physicians (many times neurologists or psychiatrist) and/or PhD prepared professionals.

Polyysomnography

Polysomnography is a type of sleep study that involves objective diagnostic testing during sleep wherein several physiological variables are recorded, measured and later scored for interpretation. Sensor leads are placed to record leg movements, eye and jaw movements, respiratory airflow through the mouth and nose, respiratory effort, EKG (heart rate and rhythm), oxygen saturation and carbon dioxide levels, and brain electrical activity. Once appropriate leads are placed, a 7-8 hour recording submits adequate information for interpretation purposes. Interpretation is based on scoring principles developed by the American Academy of Sleep Medicine. Each sleep study is scored epoch by epoch for the stages of sleep and any viewed abnormalities documented. Sleep apnea is a type of sleep disorder and when diagnosed it is recommended the patient utilizes a C pap machine as the treatment of choice. Additionally, individuals with neurobehavioral conditions are being studied by researchers for innovative diagnosis and treatment.

The nurse's role in sleep study research at Emory

More recently, researchers are linking sleep interpretations to diagnoses such as hypertension and stress related health issues as documented by the National Heart Lung Blood Institute. Consequently, polysomnography could present as a new practice domain for the nurse professional in the sleep science research world. Over the past 24 months, two clinical research nurses (CRNs) with ACTSI were prepared to provide technological support in studies involving polysomnography. They were trained by a respiratory therapist over five months in proper lead placement, monitoring, recording and troubleshooting. The training was done to provide staffing for a physician initiated study. Nurses are ideal for this role because of their ability to assess, evaluate, monitor and manage potential unusual occurrences during the testing period.

Challenges encountered

The nurses encountered a number of challenges while conducting these studies. Some of the challenges included lack of pre-study education of the patient. Initially, the research coordinators (non-nursing personnel) did not fully understand how to prepare the participants for the procedure, so the nurses were instrumental in their education. Providing necessary guidelines to coordinators for patients in terms of conducive sleepwear and facial/hair care that might impact lead hook-up was a teachable moment during the initial study phases. In addition, the clinical research nurse's detailed scrutiny and proper education of the patient during the screening and intervention stages were critical to patient commitment and completion. For example, it was important to provide patient education during all visits, but especially during visit two, the first night of the procedure. Participants who generally encountered difficulty sleeping would often came prepared to watch television and use their computer and cell phone before falling asleep and during the night. Such activities led me to wonder how well the population as a whole manages to rest during sleep given our propensity to technological tinkering. If one experiences no REM (Rapid Eye Movements), one is probably not experiencing refreshing rest, necessary for physical recovery. This could easily be a precursor to physiological stress with the manifestation of patho-physiological results.

During patient preparation for the night, precise lead placement, which is necessary for study fidelity, was often problematic. Situations such as fingernail and hair enhancements had to be handled on an individual basis as they had the potential to impact recordings, scoring and subsequent interpretations. Nurses had to employ a great deal of tact and sensitivity in dealing with many situations that presented.

It cannot be overemphasized that sleep studies require a high level of autonomous decision making and technical skills. Nurses need to be able to assess individual needs and overcome patient obstacles. Not adequately understanding the impact that these obstacles may have on the quality of the data can impact both the study integrity and the clinical care of the patient. In addition, assessing equipment to ensure it is in good repair and functionally operative before the start of the study is crucial. In our center, nurses had minimal technology support at night while conducting the studies. Trouble shooting complex technological issues while continuing to provide quality care would have been problematic had we not been given adequate training and experience.

The future for nurses in sleep study research

The clinical research nurse brings a diverse skill set to the conduct of sleep studies. The basic skill set of precise data collection differentiates the CRN from general nursing experiences. While detailed documentation is first and second nature, the learning need is to develop the skill set to score and interpret the studies. If they are trained to undertake this role, new and exciting experiences are guaranteed for clinical research nurses in sleep research and patient care. Future careers in sleep studies is an arena wherein clinical research nurse expertise is needed and warranted because, in addition to patient advocacy, precision and troubleshooting is what we do instinctively. Collaborative efforts with polysomnography healthcare teams is certainly on the horizon and we should seize the moment!

References:

What Are Sleep Studies? National Heart Lung and Blood Institute. US Department of Health & Human Services. http://www.nhlbi.nih.gov/health/health-topics/slpst/

Sleep Studies. National Sleep Foundation. http://www.sleepfoundation.org/article/sleeptopics/sleep studies.

The Role of the Clinical Research Nurse: Ethical Considerations

by Joy Bailey, RN, PhD(c), MSN, CRRN, BC
Director of Clinical Research Nursing Emory Healthcare, Atlanta, GA

The clinical research-nursing specialty holds unique opportunities for nurses who want to be right where medical innovations are translated to use in humans. In the past few years authors and researchers have more clearly defined, the role of the clinical research nurse. According to Castro et al (2011) clinical research nurses are "specially trained nurses responsible for safeguarding research subjects and maintaining the integrity of the research study in settings ranging from ambulatory to inpatient with healthy to acutely ill subjects." More definitively, Bevans et al (2011) published a taxonomy of roles within the domain of clinical research nursing, which helped to clarify and identify the role as a valid specialty. Nurses serve in a variety of roles in human subjects research; however, the clinical research nurse's role comes with certain ethical responsibilities. The Belmont rule emphasizes certain imperatives in the application of its core principles. In this regard, in addition to maintaining the integrity of the research protocol, the clinical research nurse has a distinct responsibility to assure the protection of human participants in the research process.

ANA code of ethics for nurses in clinical research

It might be useful to review the nurse's role in clinical research as defined in the American Nurses Association's (ANA) code of ethics. The ANA guide to the code of ethics outlines the nurse's fiduciary responsibilities to volunteers in human subjects research (ANA, 2010). According to the ANA's Interpretive Statement 3.3, "because of the complexity of options that occur when research is combined with care…(the provision) focuses the primary role of the nurse in all research activity on insuring that subjects are aware of the potential risks and are protected to the greatest extent possible from those risks" (p.29). In addition, the provision states that nurse researchers also are obligated to reduce risks to participants in their own research. In essence, in their role as a member of the research team the nurse is especially duty bound to protect the rights and welfare of the study participant. Nurses must maintain a delicate balance between the needs of the study subject and those of the principal investigator or study sponsor. In the following paragraphs we present perspectives on the role of the clinical research nurse as patient advocate, study team member and nurse clinician.

The ANA code of ethics and the nurse's role in the clinical setting

The informed consent document in clinical research is perhaps the most important one for the human research participant. In the clinical setting, the informed consent should contain, in precise detail, the procedures that will be undertaken, the risks and benefits of participating as well as the voluntary nature of the research process. Although the principal investigator or a member of the study team will have explained the nature of the procedure and obtained informed consent, before starting any procedure the research nurse at the bedside or in the outpatient setting still needs to ensure that participants fully understand what they have agreed to do. The ANA emphasizes the informed consent process as an ongoing one in which the nurse ascertains that participants "understand the ongoing dynamic of the research process" ANA, (2010, p. 29). The role as advocate for the research participant is an explicit one. The nurse must constantly observe and evaluate the participant's understanding of the research process as it evolves. For example, nurses should intervene as advocates, should they observe a study team member hurriedly obtaining consent from an uncertain participant at the time he presents for a procedure. The conduct of the study team member also may fit into interpretive statement 3.5 that requires the nurse to act on questionable practice. In this scenario the nurse is duty bound to ask the participant if he understands what he has been told, and if he does not, refer him back to the study team member for further explanation before the nurse starts the procedure. The nurse also might remind the study

team member that, in order to ensure that a participant fully understands, the informed consent process should not be hurried.

But research nurses also need to understand their role in situations where they must balance the participant's rights with maintaining the integrity of the study process. Consider the following example of a real experience as narrated by a research nurse. One afternoon while she is admitting a participant for a procedure the nurse recalls that some weeks before she had collected specimens from the participant for a study in which one of the inclusion criteria is HIV positive status. She is aware that one of the exclusion criteria of the study for which he has now presented is positive HIV status. She tactfully informs the participant that, having enrolled for the other study, he might not be eligible for the one today and encourages him to disclose the matter to the research coordinator. He is reluctant to do so because he wants the monetary incentive at recruitment and does not want to lose the opportunity. What should the nurse do? What are her responsibilities to the patient and what are her responsibilities to the investigative team? It is conceivable that this participant may not fully understand the nature of the study for which he is volunteering. In this scenario, the nurse needs to balance her responsibility as the participant's confidante with her duty to disclose to the PI. How would you handle this ethical dilemma?

Rethinking the clinical research nurse's role

In today's clinical research environment, it is perhaps time to re-examine and consider clinical research nursing in the context of diminishing federal funding in the US and a climate that may lead many investigators to retain non-nurse coordinators to manage their studies. Why is this important? It is important because the nurse may need to be more vigilant in meeting her obligation to ensure the safety and protect the rights of research subjects, not because non-nurse study team members are less capable, but because they may be less knowledgeable about medical issues likely to impact the research process. For example, as manager of the study operations or lead clinical research coordinator, the nurse may need to guide and coach the non-nurse coordinator so that they grasp and understand the nuances of explaining the medical component of the informed consent or explain to them why the nature of a disease or condition might lead a prospective participant to react in a negative manner when approached. Also, because of her experience, a nurse also may be more effective in recruiting for certain studies. When the study coordinator is not a nurse, the research nurse in the hospital setting, will need to work more closely and collaboratively with the principal investigator to ensure that protocol orders are written with clarity in order to prevent deviations. At the IRB level, the clinical research nurse who serves on the committee can play an important role in identifying feasibility or safety concerns that an analyst may have overlooked.

In summary, as nurses we should be cognizant of our unique role in the support and conduct of clinical research. We cannot and must not abdicate our responsibility to make paramount, protecting the rights and safety of the participant in investigational studies. The rules and regulations of human subjects research charge all persons engaged in investigational studies with ensuring the safe and ethical conduct of research. The code of ethics for nurses goes even further. As nurses, we must make our primary responsibility ensuring that subjects are aware of and protected from the potential risks attendant to study participation. As we conduct or facilitate human subjects research this should be foremost in our thoughts.

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Clinical Research Nurses and the Institutional Review Board

by Carmen M. Blount, RN, MSN
Atlanta Clinical and Translational Science Institute

Have you ever been asked to serve on your Institutional Review Board (IRB)? Nurses are often asked to serve on IRBs so that the research protocol approval process can have a multidisciplinary team approach in order to promote the welfare and safety of human subjects. Working with people in diverse settings has customarily required nurses to gain new knowledge and apply that knowledge to accomplish myriad tasks. Also, nurses have always served as advocates for their patients to ensure their health, safety, rights, and welfare. Implementation of research protocol orders has always been a major responsibility of the Clinical Research Nurse, ensuring accurate data collection for analyses. However, in clinical research, now we are being asked to play a proactive role in approving research protocols in the institutions where we work.

The role of the IRB

The IRB was established in America by the National Research Act of 1974. The National Commission for Protection of Human Subjects of Biomedical and Behavioral Research also was promulgated by the Research Act of 1974. Because of past historical events involving the violation of human rights, the Act dictated that human rights and welfare needed to be protected. The National Commission issued the document the Belmont Report which provided for the ethical treatment of humans involved in research. Included in the Belmont Report were guidelines for the establishment of the IRB and how it must function. Policies and procedures that govern its activities were written and continue to be augmented as necessary in the code of federal regulations (21 CFR 56). The IRB's authority involves reviewing investigational research protocols that involve human subjects.

According to Amdur and Bankert (2011) the "IRB is a committee whose primary responsibility is to protect the rights and welfare of research subjects and to function as a kind of ethics committee focusing on what is right or wrong and on what is desirable or undesirable" (p.5). The IRB usually has its own staff and committees to help it accomplish its goals. The committee should consist of individuals from diverse professions and disciplines e.g., medicine, law, social sciences, psychology, nursing, religion, and laypersons. At Emory University where I volunteer, there are at least six IRB committees serving those who conduct biomedical and behavioral sciences research.

My role as nurse on the IRB

For the past eight years I have worked as a research nurse in the National Institute of Health (NIH) Clinical and Translational Scientific Awards (CTSA) funded Research Center at Emory University hospital centers. My main job function has been implementing orders for IRB approved research protocols. About two years ago I was invited to serve as an IRB member. I investigated the matter completed the application process and agreed to join the IRB so that I could participate in two stages in the life cycle of a research protocol approval process by the IRB and the actual implementation of the research protocol.

When a research protocol is submitted for IRB review and approval, the IRB staff determine status according to preset guidelines, i.e. whether the protocol should be exempt, expedited or for full committee review. Exempt status is given to projects that do not need full committee review in that they would not require

initial regulatory or continuing review (Amdur & Bankert, 2011). Expedited reviews go through the same process as a full committee review; however, the study can be reviewed by a committee chairperson or an experienced reviewer, and must be reviewed annually thereafter.

The full committee review involves an open discussion of the research protocol and a vote is cast for approval status. This is where the nurse as IRB member is needed. As an IRB member I am required to critically evaluate a research protocol for its safety, risk/benefits ratio, recruitment and informed consent processes. I evaluate the protocol and offer my opinion to the committee on whether the protocol should be approved or whether the committee should ask the PI to make changes prior to approval. The IRB is ever cognizant that the investigator is waiting on the IRB for clearance to initiate the project. Because reviewing research protocols may be very time consuming, it may not be possible to go through each protocol in detail during an IRB meeting; therefore board members have to complete their evaluation of the assigned research protocol in a timely manner for submission to the IRB prior to the IRB meeting.

Reviewing the informed consent gives me another opportunity to safeguard human's rights. The information presented in the research consent should be congruent with the information written in the research protocol. Because health literacy is an important principle to consider, the research consent is examined to make sure it is written on an eighth grade level and easy to understand. Because of my clinical experience as a research nurse, I understand that the role of the participant, the purpose/aim of the study, the procedures to be performed, risks/benefits and emergency contact information, etc. should be clearly defined in the research consent and I check to see that this has been done. This helps to facilitate the IRBs approval of the informed consent document.

As a primary reviewer, I must be prepared to deliver a summary of my findings in a one to two minute succinct and clear presentation. As a secondary reviewer I am expected to disclose any disagreements or agreements with the primary reviewer and any additional comments. It is important for me to disclose any conflict of interest and, for example, recuse myself from voting on protocols such as those submitted by my program director.

Performing in the role of an IRB reviewer has required me to utilize many skills such as critical thinking, organizational, computer and, evaluative skills and to develop and hone my speaking and prioritizing abilities. It has been rewarding in that I have a better understanding of how the system works and the role that I am able to play in that system. Serving also has increased my learning in the area of physiology and patho physiology and the treatment of disease processes.

It is important that people receive appropriate and adequate health care services when they participate in research studies. Nurses often serve as advocates for patients to ensure their safety and welfare. As gatekeepers in the research environment, nurses also can contribute to ensuring that individuals are provided accurate information to help them make informed decisions. It should be emphasized however, that clinical research nurses also serve as advocates for principal investigators to make sure that the research protocol is carried out consistently and accurately so that the data that is collected provides answers to the questions being asked. Our IRB team members count on us to do our part so that the business of the committee is completed in a timely manner. Given the regulatory charge of IRBs, do you not think that nurses make ideal committee members? Please consider serving!

Reference:

Amdur, R. & Bankert, E., (Eds.)). (2011). Institutional Review Board Member Handbook. (3rd. ed.) Boston, MA: Jones and Bartlett.

Education and Training Resources from NIH

by Julie Kohn-Godbout, MSN, RN, PMHCNS-BC & Elizabeth Ness RN, MS

The NIH Intramural Research Program (IRP) has several clinical research education and training opportunities many of which are available to the extramural community. We would like to share these with you along with other resources we have found useful:

NIH Resources:

- Humans Subject Protection Training
  As a public service, the NIH Office of Extramural Research offers a free tutorial on Protecting Human Research Participants that institutions may elect to use to fulfill requirement for education in the protection of human subjects. A Spanish language version is also available: Protección de los participantes humanos de la investigación.
- NIAID GCP training (for NIAID grantees)
- NIH IRP Clinical Trial Orientation
  Set of 13 modules intended for members of research teams including the Research Nurse Coordinator. Some content is specific to the NIH so some of the links (e.g., Policies) will not be accessible to others.
- NCI Center for Cancer Research On-line Learning Modules
  Set of 12 modules intended for members of research teams including the Research Nurse Coordinator with a bit more focus on oncology clinical trials. Some content is specific to the NIH and the NCI CCR so some of the links (e.g., Policies) will not be accessible to others.
- Principles of Clinical Pharmacology
  This on-site course consists of a weekly lecture series covering the fundamentals of clinical pharmacology as a translational scientific discipline focused on rational drug development and utilization in therapeutics. The course is offered yearly at the NIH Clinical Center and runs from September through April, one evening a week (Thursday). Past sessions are archived and available at: http://clinicalcenter.nih.gov/training/training/principles/schedule.html.
- Introduction to the Principles and Practice of Clinical Research
  This on-site course focuses on how to effectively conduct clinical research. It is offered yearly at the NIH Clinical Center. This activity will be of interest to physicians and other health professionals training for a career in clinical research. The course is videocast at other locations. If you are outside the NIH commuting area and would like to check availability at one of the participating locations, please contact us at 301-496-9425 or od_ippcr@mail.cc.nih.gov. For archived sessions visit http://ippcr.nihtraining.com/ .
- Ethical and Regulatory Aspects of Clinical Research
  On-site course offered annually to anyone interested or involved in clinical research involving human subjects. 2012 slides available.

Non-NIH Resources:

- 2 fee-based CEU web courses previously highlighted in the newsletter are geared to two nursing audiences: Research Nurse Coordinator and Direct Care Giver
  - *Clinical Trials Awareness on a Global Level*
  - *Shedding Light on Clinical Research: An Introduction to Clinical Trials Nursing*
- FDA's Clinical Investigator Training Course
  Fee-based course offered annually for Clinical Investigators. The November 2012 course videos are

available at: http://www.fda.gov/Training/ClinicalInvestigatorTrainingCourse/ucm331320.htm

- Office of Human Research Protection (OHRP) YouTube videos
  Videos represent OHRP's current thinking on these topics and should be viewed as recommendations unless specific regulatory requirements are cited. These videos and others are also listed on the OHRP YouTube Playlist.

Quick Links:

Conference

Agenda: http://iacrn.org/Agenda2013

Hotel / Travel: http://iacrn.org/Hotel_Travel

Lights! Camera! Action!: http://iacrn.org/LightsCameraAction

Value of a CRN: http://iacrn.org/CRN_Value

Past Newsletters: http://iacrn.org/Newsletters

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