In September, a group of 10 CON faculty members headed to Corolla, NC to engage in a long weekend of writing and project development. Kathy Newnam was gracious enough to host the four day event in her beautiful beach home. Although the drive was long, everyone who participated was able to accomplish their goals and enjoy a gorgeous scenery. A special thanks to Joel Anderson, who lead the writing sessions, Tami Wyatt for providing breakfast and transportation to and from the Outer Banks, and Diane Carr for organizing the event. If you are interested in future writing retreats, or would like to host a writing retreat, please contact the ORS.

The ORS is seeking your feedback! At the beginning of 2017 we sat down with faculty to discuss the needs of CON researchers. Now that some time has passed we want to know how we are doing. If you are interested please visit the qualtrics survey https://utk.co1.qualtrics.com/jfe/form/SV_5lI0or3g3Vm8nPL. All feedback is welcomed and appreciated!

They’re Back! GRAs Available. If you are interested in working with a GRA to complete research related tasks, please complete the GRA request form on the resources site at https://nursing.utk.edu/research/resources/.
Dr. Lisa C. Lindley, PhD, RN is conducting pioneering research in end-of-life care for children with intellectual disability. Dr. Lindley is an Associate Professor at the University of Tennessee, Knoxville, College of Nursing and a health services and policy researcher. Her work examines approaches to delivering care for seriously ill children aimed at improving quality of care at end of life.

Recently, Dr. Lindley was the principal investigator (PI) on three studies that generated the first empirical findings about end-of-life care for children with intellectual disability. The initial study examined the influence of intellectual disability status on hospice utilization. With interdisciplinary colleagues from special education and medicine, Dr. Lindley explored the relationship between intellectual disability and hospice enrollment and length of stay. The study findings revealed that intellectual disability was negatively related to hospice enrollment and length of stay. This study was the first to demonstrate that children with intellectual disability were under served by hospice at end of life.

In a second study, Dr. Lindley examined whether residential care (i.e., state-regulated, long-term care facilities) moderated the relationship between learning disability and hospice utilization. This research tested whether residential care intensified the relationship between intellectual disability and hospice utilization (i.e., hospice enrollment, hospice length of stay). Dr. Lindley found that residential care promoted hospice enrollment among children with intellectual disability, while have no effect on hospice length of stay. The findings of this study were the first to highlight the important role of residential care in facilitating access to hospice care for children with intellectual disability.

The third study examined the effectiveness of a care coordination intervention (usual source of care plus targeted case management vs. usual source of care only) to improve end-of-life outcomes for children with intellectual disability. Dr. Lindley collaborated with a health economist to conduct this study. The study reported that “usual source of care plus targeted case management” relative to “usual source of care only” had no effect on hospice enrollment; however, it significantly reduced the probability of emergency room utilization and hospital readmissions. This study provided critical evidence for the first time about a care coordination intervention aimed at improving end-of-life care for children with intellectual disability.

Children with intellectual disability at end of life and their families benefit from this research. To place a child in residential care, seek health care from a usual source of care, or engage a targeted case manager is the choice of the family and child. This decision is complicated and more difficult when the child is terminally ill, along with an intellectual disability. Families often have no information on how these choices influences the health and health care of their child. The information from the studies conducted by Dr. Lindley will provide much-needed data for children and families to assist their decision-making, and ultimately improve the quality of end-of-life care for these children. Dr. Lindley’s research also influences the care delivered by hospice and palliative care clinicians. These articles are increasing awareness among nurses, physicians, and other clinicians of children with intellectual disability and encouraging them to think about their practice of end-of-life care for this special population.

RESEARCH DAY RECAP

Research Day, 2017 proved to be another huge success. One hundred-ten Students, faculty, and community partners came together to discuss their research projects and interests. Prior to the event, DNP and PhD students met with our guest speaker, Dr. Jeff Adams to engage in collaborative discussions about how PhDs and DNPs can work together in their research. Thirty five research posters were on display during the poster session, and an over-whelming buzz of discussion could be heard. The evening ended with a group icebreaker and a wonderful presentation by Dr. Jeff Adams. Many thanks to those who attended and shared their research interests with the group. See you in 2018!

Funding is still available!!

The ORS still has funds available for any service or tools you may need as it pertains to your research and scholarly projects. Services can be anything from editorial, transcription, statistician, printing, etc.

To date, only $600 has been used and we have plenty of funds left in the pot to assist you! Funds must be used by June 30th and although there is still time, we want to help you get your research projects underway!

To apply for funding consideration please fill out the Resource Request form located at nursing.utk.edu/research/resources/. Look under the forms and documents tab and then select the Resource Request Form under Accounts Payable. Please keep in mind the Research Advisory Committee will make all decisions about money distribution.

Due to new University policies, all services must be processed as an invoice and you can no longer be reimbursed via petty cash for services rendered. As always, please feel free to contact the ORS with any questions or concerns. We are happy to help!
Changes Ahead for NIH Funded Human Subjects Research

The National Institutes of Health (NIH) are rolling out several policy changes related to NIH-funded research involving human subjects. These changes began with the implementation of NIH’s revised definition of clinical trial that went into effect earlier this year and includes research on both biomedical and behavioral health outcomes. Other policy changes, including the required use of an updated application forms package (FORMS-E), start with application due dates on and after January 25, 2018. NIH Deputy Director for Extramural Research Michael Lauer further clarified these upcoming changes on August 11th in both an e-mail to the research community and in a blog post on the NIH website. Additional readings and resources on this topic including an article by the Association for Psychological Science about these changes and their impact on behavioral research and a video tour of the new NIH form can be found at https://irb.utk.edu/september-2017-hrpp-newsletter/.

Writing Readable Informed Consent Forms

2nd Person
Write in the second person (you, not third person (the participant)).

Plain Language
Use common, everyday words familiar to the non-academic/non-scientific reader. Check the reading level, recruitment materials and study instructions are recommended to be written at or below an 8th grade reading level.

Have a Conversation
Use a conversational tone. Write short, simple and direct sentences. Keep paragraphs short and limited to one idea.

Don’t Abbrev.
Avoid abbreviations and acronyms if using an abbreviation, spell out when it is first used. Avoid using e.g. or etc. use instead. “For example,” “so forth.”

Group Text
Use headings and subheadings to group text together.

Font
Use at least 12-point font and consider a larger font based on your audience. If appropriate, use page numbers. Avoid large blocks of printed text and embrace “white space.”

Be consistent
Be consistent with use of all terminology, such as procedures, activities and abbreviations. Make sure that what you state in the consent form is consistent with what you state in the application.

Be clear
Check the text to see if each idea is clear and logically sequential. Avoid repetition.

Informed Consent Forms submitted with new applications are rarely approved without required changes. This is most often because, in addition to including the required elements of consent, ICFs must also communicate those elements in a language understandable to the research participant or their legally authorized representative.
IRB Tips and Tricks

Responsibilities of the Principal Investigator

The Principal Investigator (PI) named on the IRB application assumes overall responsibility for the conduct of the research, and as such, assumes responsibilities in addition to those listed above. While the PI may delegate responsibilities to other investigators and research personnel, the PI remains ultimately responsible for all aspects of the research.

General Responsibilities - Principal Investigators

- Ensures they have sufficient time to properly conduct and/or supervise proposed research and study personnel, and that adequate resources (qualified personnel, facilities, medical/psychosocial services, etc.) are available to safely carry out the approved research.
- Reports to the IRB any changes in availability that impacts the conduct of, or supervision of, ongoing research such as going on sabbatical, taking extended leave or leaving UT. The PI is responsible for either amending the study appointing another PI or closing the research as appropriate.
- Registers the research on ClinicalTrials.gov, if applicable.

Record keeping Responsibilities - Principal Investigators

- Maintains records of all IRB-approved documents and correspondence which must include, at a minimum, the IRB application, screening, recruitment and consent documents, data collection materials and instruments, documentation of participant eligibility and participation and a copy of all signed consent documents (unless waived by the IRB).
- Retains all study records for a minimum of three years after closure of the study with the IRB. For studies involving PHI, a minimum of six years is required. If there are sponsor requirements (for funded studies) retains the records for the longest applicable retention period.
- Makes all research records accessible for review by authorized representatives of the IRB and/or the department or agency supporting or conducting the research to ensure proposer performance of the study and compliance with federal regulations and institutional policies.
- Maintains confidentiality of stored records in accordance with the IRB-approved application.
- Retains records for studies involving FDA regulated test articles (devices, drugs, biologics) in accordance with applicable FDA regulations.

NIH Definition of a clinical trial:

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Is it still unclear if your study is considered a “clinical trial”? Consider these questions:

1. Does the study involve human participants?
2. Are the participants prospectively assigned to an intervention?
3. Is the study designed to evaluate the effect of the intervention on the participants?
4. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?

If you answered YES to ALL 4 questions, then you are conducting a clinical trial according to NIH. This means you must ensure you are submitting a proposal to a call that will fund clinical trials and you must register your study and report findings with clinicaltrials.gov. For more information, please visit clinicaltrials.gov

ATTENTION ALL PIs!

All PIs who have funded projects must complete training from the Office of Research and Engagement prior to receiving funding. Once you have been notified of an award, please contact Nancy Taylor who will make the training accessible to you via canvas.
Welcome to Workspace!

Have you recently written a paper, but you’re not sure to which journal you should submit it? Or maybe you want to find relevant articles to cite in your paper? Or are you an editor, and do you need to find reviewers for a particular paper? Jane can help! Just enter the title and/or abstract of the paper in the box, and click on ‘Find journals’, ‘Find authors’ or ‘Find Articles’. Jane will then compare your document to millions of documents in PubMed to find the best matching journals, authors or articles. Visit jane.biosemantics.org for more information!

Starting January 1st, 2018 most federal proposals will need to use Workspace as the platform for grant submissions. All PIs must have a grants.gov login tied to UTK in order to see and review submission packages through Workspace. The Assist platform is recommended for NIH Proposals. For assistance or more information please contact the ORS.