As everyone who does research knows, dealing with administrative requirements is the hardest and least satisfying aspect of doing research. In this column, I would like to discuss research cost compliance, one of those administrative aspects. Although all Duke researchers must take research cost compliance training in order to receive funding, few of them think about it again until they want to do something that turns out to be not allowed. But why are there all of these restrictions anyway?

The origins of research cost compliance regulations are in the agreements that Duke has with the federal government. Your budget is to pay for the direct costs of conducting your study. The budget is expected to pay for the designated percent of your total work time (not just a 40-hour work week). It does not pay for you to do your regular job. Thus, you can never be funded 100% because you need to allow time for you to write additional grants, participate in committee work, mentor students, and teach. Being unable to devote the promised percentage to your grant is considered a conflict of commitment.

Likewise, the resources you buy on your budget are supposed to directly support your study. Therefore, buying capital equipment in the last 6 months of your grant is generally not allowed because it is assumed that the equipment is not really needed for the conduct of your study. If you are in the happy situation of having extra money at the end of your grant, contact Phyllis Harris in ORA to learn about acceptable ways to “spend out” your grant. In addition, some items, like food, are virtually never allowable on a federal grant.

The other source of research compliance is the agreement that Duke has with the federal government over indirect costs. Duke receives an additional 56% of the direct costs for each NIH grant to pay for the building, heat, lights, routine office costs (staff and supplies), local telephone service, and postage associated with you and your study. This is why, for example, you are expected to use your regular secretary when working on manuscripts from your study. Your secretary’s time on your project has already been paid for by the indirect costs. The key here is that indirect costs pay for usual costs of these facilities and services. Budgeting for the extra costs due to specific research activities—such as the
postage costs of a mailed survey, the costs of copying your instruments, or postage and phone costs to communicate between multiple research sites—is acceptable. In fact, it would be unfair to expect DUSON to pay for these types of expenses. These costs do need to be justified to make certain they truly are not the usual costs, but the ORA staff will be happy to help you with this.

On the other hand, if your grant will not receive the full indirect costs or is not a federal grant, it is not covered by the indirect cost agreement. In that case, you need to include the cost of office supplies, postage, phones, etc., even if usual, in your budget since DUSON is not receiving funding for them. You can discuss this in more detail with Jane Halpin as you work on the budget for your grant submission.

Altogether, research cost compliance, although annoying at times, insures that your grant is managed according to the standards that the funding agency expects. This is a protection for you since it guarantees that you are spending you funding legitimately and are not in risk of inadvertently being guilty of misappropriating funds. One of the jobs of the ORA staff is to help you navigate the important and oft confusing world of research cost compliance.

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**Congratulations to these PIs and their entire teams, Nice Job!**

- Marva M Price, RN, DrPH, FNP, FAAN who submitted her DOD entitled: *Metabolic Determinants of Prostate Health*.
- Robin Knobel, PhD, RNC, NNP who answered Sigma Theta Tau’s call and submitted a proposal entitled: *Body Temperature and Vasomotor Tone During the First 5 days of life in Preterm Infants Weighing Less than 800 Grams at Birth*.
- Linda L. Davis, PhD, RN, ANP, DP-DAP, FAAN and Ann Henshaw Gardiner Professor of Nursing who submitted a competing renewal of her current R01: *Project ASSIST for Chronic Illness Caregivers*.
- Diane Holditch-Davis, PhD, RN, FAAN, and Marcus C. Hobbs Distinguished Professor of Nursing and our Associate Dean of Research who was asked by UNC-Chapel Hill to collaborate via subcontract agreement on their proposal entitled *Reducing Depressive Symptoms in Low-Income LEP Latina Mother*.
- Bradi B. Granger, RN, PhD, FAAN who submitted a NIH R15 application entitled: *Feasibility and Efficacy of a Novel Approach for Long Term Medication Adherence*.
- Susan M Schneider, PhD, RN, AOCN who submitted her NIH R15 before the June 25th deadline. The proposal is entitled: *Tailored Intervention Protocol for Oral Chemotherapy Adherence*.
- Marva M Price, RN, DrPH, FNP, FAAN who submitted her 2nd DOD entitled: *Centered Upon Research and Education (CURE) – Prostate Cancer Mentorship*.
- Julie Thompson, PhD and Post doc, who submitted her R03 grant, *Mother-Sibling Interaction to the National Institutes of Health*.
- Deirdre Thornlow’s project entitled: *Mentoring Grant in Gerontology* has been awarded by the University of Iowa. This award is for one year with the emphases on the mentorship.
- Jada Brooks, who was awarded an NIH, NINR, National Research Service award, to conduct a longitudinal study using mixed methods to describe the interactive behaviors of American Indian mothers and their prematurely born infants from the Lumbee tribe in southeastern North Carolina.
- Dorothy Powell and DUSON’s Office of Global and Community Health Initiatives (OGCHI), has submitted a proposal entitled: *Continuing Education Institute on the Management of Cardiovascular Disease among the Elderly in the Caribbean* to the Pfizer Medical Education Group. The proposal award will support the OGCHI Caribbean Conference.
- Rosa Solorzano, Dorothy Powell and the OGCHI team are to be congratulated for their Southern Regional AHEC award. These funds will allow DUSON’s ABSN students to plan, develop and deliver a health care curriculum to children and their families to address health concerns that have been grossly under-addressed in the school environment.

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**Call for Datasets:**

If you have funded or unfunded datasets that need to be analyzed by the statistical team, the ORA encourages you to use the services of the Statistical Consultation Team today! The services of Janet Levy, Dick Landerman, Rick Sloane and John Boling are available to the DUSON Faculty. Please contact Robbin Thomas, 684-3101 to schedule the use of this service.
Study Feature
Daughters And MothErS against breast cancer
"DAMES"

In 2008, the American Cancer Society projects that 182,460 women will be newly diagnosed with breast cancer. Breast cancer is the most common cancer in females and is the second leading cause of death from cancer. Despite this, when breast cancer is detected early and women undergo treatment, the 5-year survival rate for localized breast cancer has increased from 80% in the 1950s to 98% today.

Many internal and external factors contribute to a woman’s likelihood of developing breast cancer. Valeda Stull, a clinical trials coordinator for the Duke University School of Nursing (DUSON), understands the benefits of helping women target controllable risk factors by making lifestyle changes that either may reduce the risk of recurrence among women with breast cancer or the risk of developing breast cancer among daughters whose mothers have breast cancer. While developing cancer can be due to a host of factors (environmental, genetic, etc), one modifiable factor is lifestyle.

Excessive body weight (body mass index $\geq 25$kg/m$^2$) is a strong independent predictor of post-menopausal breast cancer risk. Also, at the time of a breast cancer diagnosis, an elevated BMI has been shown to be a negative prognostic factor. Finally, more recent research points to weight gain post-diagnosis as being associated with poorer survival. These factors led a team of investigators at Duke to propose a feasibility study testing a distance-based one-year lifestyle intervention that aims to promote weight loss among overweight mothers with breast cancer and their overweight adult daughters called DAMES (Daughters And MothErS against breast cancer). DAMES is funded by the National Institutes of Health and is the brainchild of Principal Investigator, Wendy Demark-Wahnefried, PhD, adjunct faculty at DUSON and professor of Behavioral Sciences at UT MD Anderson Cancer Center and currently lead at DUSON by Denise Snyder.

Over the course of the year-long study, mothers and daughters will participate in one of 3 study arms to lose weight by developing healthier eating and exercise habits. Mother-daughter pairs receive the necessary tools for the program over a 50-week schedule by mail, and are encouraged to exercise and lose weight. DAMES is currently in the field at both Duke and MDA – enrolling, delivering the intervention and collecting data. The full sample size will accrue 67 mother-daughter pairs (134 total subjects). Currently, 23 mother-daughter pairs have been identified between both sites.

All mothers in the study must be at least 50 and overweight, with a history of breast cancer within the past five years. Daughters must be at least 21 and overweight. None of the participants can be participating in another weight loss program while involved with the DAMES study.

Subjects receive a free Apple iPod at the completion of the study, in addition to the diet and exercise materials provided throughout the study.

Valeda’s hope for the study is that the subject pairs will lose a significant amount of weight, and in the long term have fewer instances of cancer. The goal is for subjects to develop healthier lifestyles, which can contribute to staying cancer free in later life.

Helpful Tips - Stats

An important question in the development and design of clinical trials is not only whether a particular intervention works, but how it works. As pointed out by MacKinnon (2002), this question has been investigated by authors in a number of fields and under different names. In psychology, methodologists refer to “mediators” of treatment effects. In sociology these effects are referred to as “indirect” and in epidemiology they are referred to as either “intermediate endpoints” or “surrogate” effects. Recently, there has been emerging work on how to quantify such effects, as shown in the references below. Particularly interesting is the article by D.P. MacKinnon et al. discussing how to capture intermediate effects in the context of logistic regression. This might serve as the basis of a special lecture in Nursing 604.


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**Staff Spotlight – Valeda Stull**

*By: Patrick Lane and Linda Folsom*

A double-major in linguistics and film may not seem the most likely precursor for a career in scientific research at Duke University. However, for Valeda Stull, her varied background ended up being more relevant to her work than one might expect.

Valeda spent her early years in the Riverdale section of the Bronx, where she enjoyed reading, playing music, and finding access to nature wherever and whenever she could. After high school she attended Antioch College, a small private liberal arts school in Ohio. Upon graduating from Antioch she had not quite decided what path to take for graduate school, so she took a job as a research assistant at Duke, hoping that this exposure to the nuts and bolts of research methodology would help her determine whether a career in social sciences research would be of interest.

Three years later, this love of research has moved her from a research assistant to her current position as a Clinical Trials Coordinator I for the Duke School of Nursing. As a CTC, Valeda organizes and plans out the logistics of research studies, which typically involves extensive interaction with both faculty investigators as well as study participants. Valeda is currently working on several grants: DAMES, an intervention study to help mother-survivors of breast cancer and their overweight daughters lose weight; a study linking flaxseeds with the treatment of Polycystic Ovarian Syndrome; and the CaPS study, a subset of the PROMIS program. Her inclination to be a “meticulous problem solver” has benefited Valeda in her career, as research requires attention to detail and management of large amounts of subject data and other information. She enjoys treating her work as a series of specific problems to which she must find solutions.

Other interests include learning languages, biking, gardening, and playing chess. In fact, after graduating from Antioch, Valeda found work as an ESL (English as a Second Language) teacher in Manhattan for immigrants whose lives were directly affected by the September 11th attacks. This position was part of the grant-funded 9/11 Program to encourage immigrants to learn English and find suitable work. Simultaneous to teaching ESL, she worked with Chess In The Schools, teaching public school children the game. Interestingly, researchers have linked playing chess to development of rational thinking and problem-solving skills among young children, and chess is becoming a part of many public education curricula throughout the United States.

Valeda plans to attend graduate school in 2009 for Cultural Studies, although she has not decided on the particular program. Nevertheless, she is excited about pursuing Cultural Studies, which she described as a merging of both her disciplines—linguistics and film. Wherever that takes her, Valeda said that her exposure to research at Duke will be invaluable for future research in her academic program, and it will certainly have a lasting positive effect.

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**We Published!**

*Check out these recent publications from Nursing School Researchers*


The Spring 2008 desk-to-desk message from Dr. Zerhouni, may be read at:
There is also a print-ready pdf of the newsletter at:

Be sure to check the NIH website for updates, funding opportunities, changes in policy and grant deadlines. Important information such as below may be of interest to you.

Empty pockets never hold anyone back. Only empty heads and empty hearts can do that.
Norman Vincent Peale
CTN Best Practices Web Site Offers Free Online Training

In October 2004, the NIH began funding the Clinical Trials Networks Best Practices (CTNBP) project under its Roadmap initiative Reengineering the Clinical Research Enterprise. CTNBP, steered by the Duke Clinical Research Institute, created a Study Coordinator Advisory Committee (SCAC) to identify programs and tools that could improve clinical-site recruitment, retention, and performance.

The SCAC consists of 10 research coordinators representing 9 clinical sites. Identifying the need for a central, low-cost means of offering programs and tools for research coordinators, the SCAC proposed a Web site, https://www.ctnbestpractices.org/, and began identifying tools and templates to post. The Web site went public in January 2006 and, in May 2008, it received 14,520 visits, a new record.

The most popular content is online training for clinical-site personnel who do not have the time or budget to travel for training. Training topics include a clinical research overview, building a successful research site, Good Clinical Practice, human research subject protection, essential regulatory documents, and therapeutic-area training. Trainees complete programs at their own paces, and many courses offer free CEUs.

Start Here for Grant Support

Why you should avoid last minute submission?? . . . .

And you thought you were busy!!!

Recently the ORA office had reason to submit 2 grants electronically in the same day. The process took staff members a little more than 2 hours. In that period of time there were more than 206 application submitted via grants.gov!! This copy of a blog posting reflects the problems we like to avoid....

“Definitely a server issue, at least yesterday. I spent 7 hours trying to submit, 50 minutes on hold for grants.gov to be told there is a server issue and to call my agency. The agency was aware that grants.gov was having a problem but did not indicate how they where going to handle it. I can only hope that they will contact me regarding their decision. I am keeping my fingers crossed that it doesn't go something like: you know that we are not responsible for technical difficulties and you could have submitted earlier.”

To avoid this feeling, here are some steps to get started on the preparation of your next grant submission

1. Schedule a scientific consult with Diane Holditch – Davis by contacting Leslie Fife at 684-5376
2. Submit an Intent to Submit form to ORA at least 16 weeks prior to the target deadline if possible. The form is linked here, on the SON website and DUSONnet, both web pages have a link Research Resources
3. Contact Jane Halpin for help with funding searches and drafting a budget
4. Also available for consult and process assistance is Robbin Thomas. Robbin can help with assigning editing and statistical resources.
ORA Schedule of Events

Introduction to SAS training. This training session is a precursor for all other SAS training. John Boling will be conducting this training – in the old faculty lounge of the Clipp Building. Classes only meet on Thursdays and will run from July 17 – August 21. You must be a faculty member or staff member. Space is limited so be sure to make reservations with Leslie Fife.

Research Conference Series will return on September 10, 2008. Janet Levy, PhD will be presenting on her findings from the NIH Clinical Trials Conference. Please join us in Room 1017 of the Clipp Building at Noon. You are welcome to bring your lunch and light refreshments will be served.

Attention: There will be an opportunity to apply for the Small Grant Funding from DUSON ORA again on September 1, 2008. Deadline for submitting an application is October 15, 2008. Funds are awarded to faculty, of any rank, for use in four areas (listed in order of priority):

1) Pilot work or other research essential to qualify for external large-scale funding
2) Short-term bridge funding for established studies submitting for competing continuation or other forms of additional funding
3) New investigators launching their research through pilot work.
4) Other small-scale research studies or research needs.

Please look to our webpage on the school of nursing website for more details.

Highlights from Conferences

An exploratory visit was made to Tanzania and Kenya between May 1 and May 11, to establish relationships and to determine opportunities for collaboration between DUSON and the Kilimanjaro Christian Medical Center (KCMC) and College (affiliation of Tumaini University) in Moshi; the City of Hope in Ntagacha Tanzania; and the University of Nairobi, Kenya. Specifically, the focus was on research interest, capacity building, and student experiences.

KCMC Student Center in Moshi, Tanzania

National Nursing Association of Kenya
To the left we have Susan Schneider, PhD and Duke SON Oncology MSN student Rita Steinbauer with poster at the annual Oncology Nursing Congress in Philadelphia this past May.

Are you presenting at a conference, gathering information for a research, or just making a special presentation? If so and you would like to see your work highlighted in the next News You Can Use please contact Leslie Fife.