Associate Dean's Message
Diane Holditch-Davis, RN, PhD, FAAN

In this issue of the newsletter, I would like to share a grant-writing tip—that is, the importance of making things easy for your reviewers. No matter where you are submitting, one thing that you can count on is that the reviewers, although good scientists and conscientious, will be over-worked and under-resourced. Reviewers are doing their reviewing on their own time usually on weekends or evenings after their real job and seldom have more than a few weeks to complete detailed reviews on 5-10 grants. Thus, they will not have the time to read every grant multiple times. You do not want your grant to be the one in which something important is overlooked. Therefore, the easier you make it for the reviewers to find what they need to see in your grant, the better chance that you will receive a fair and positive review. Strategies such as putting important ideas at the beginning of paragraphs and bolding key sentences can really help.

To be more specific, the major review criteria at NIH for R-level grants are significance, innovation, approach, investigators, and environment. Approach is seldom a problem to locate because each grant has a separate methods section. The major caveat for helping the reviewers review your approach is to make certain that you don’t bury important methodological details in the middle of paragraphs where reviewers might overlook them.

Significance, or why the study is important, is discussed in the specific aims and background and significance sections of the grant. The biggest mistake that grant applicants make is not clearly addressing significance up front in the specific aims. The investigator needs to clearly answer the “So what?” question by explaining how the study will address a critically important problem and lead to an important outcome—usually the improvement of health or quality of life or the provision of information that is fundamental to developing interventions to improve these outcomes. It is also helpful to mention any NIH or Institute priorities (these can be found on the NIH website) or Healthy People 2010 objective (see http://www.healthypeople.gov/) that the grant will address. If the grant is in response to a specific program announcement or request of proposal, be sure to mention this in the specific aims and if appropriate, cite (or even quote) the aspects of the announcement that the study will address.

Innovation, or what is new or novel about the grant, should also be explicitly discussed in the specific aims. It is usually helpful to the reviewers to include a statement such as, “This study is innovative
because . . .” sometimes, grant writers want to wait until the end of the grant before discussing innovation. This is not a good idea since reviewers are usually making up their minds about the grant’s innovation while reading the first few pages. If you want them to consider the factors that you feel make the study innovative, make sure you tell the reviewers about them before the reviewers’ minds are made up.

The investigator criterion refers to the quality of the research team and evidence that they can work effectively together. Of course, the reviewers can determine this if they read the biosketches carefully but that would require extensive work for them. You can help your reviewers see the quality of your research team by briefly describing their strengths as they relate to the proposed study and their experiences working together in the preliminary studies section.

Finally, grants are scored based on the quality of the environment. The resources and environment section of the grant is usually the part of the grant in which the environment is described. Again, you help the reviewers interpret the R & E section by including a statement (preferably bolded) at the end of each section of the R & E that describes how the proposed study will make use of each aspect of the environment. Also, be sure to edit any standard R & E templates to eliminate any descriptions of aspects of the environment that your study definitely will not be using. Nothing makes reviewers feel like the investigator is wasting their time more than reading about the university’s aging center in the middle of a pediatric grant. In addition, you will probably want to describe your recruitment sites again in the setting sub-section of the methods section.

Altogether, writing your grant so that it makes things easy for your reviewers will add very little to your grant writing time, but it will help insure that your reviewers will be able to give your grant the most accurate review possible. Moreover, it will help your reviewers feel positive about your study, which just might translate into a couple extra points in your final score.

**Congratulations to these PI’s and their Entire Teams**

- Sharron Docherty, PhD, CPNP and Debra Brandon, PhD, CCNS who submitted their R01 application, *Decision-Making for Infants with Complex Life-Threatening Conditions* on 2/28/08
- Ruth Anderson, PhD, RN, FAAN and Cathleen S. Colon-Emerick, MD, MHSc who submitted their R01 application, *Outcomes of Nursing Management Practice in Nursing Homes* on 3/03/08
- Linda K. Goodwin, RN, PhD who submitted her R01 application, *Machine Learning To Build Knowledge for Preterm Birth Disparities* on 03/04/08
- Deirdre K. Thornlow, RN, PhD and Bradi B. Granger, RN, PhD, FAAN who submitted their concept paper, *Advancing the Science of Continuous Quality Improvement*, to the Robert Wood Johnson Foundation
- Ruth Anderson, PhD, RN, FAAN and Cathleen S. Colon-Emerick, MD, MHSc who submitted their Robert Wood Johnson application, *CONNECT for efficient and effective Implementation of QI interventions in Nursing Homes* on 4/09/08
- Debra Brandon, PhD, CCNS and Sharron Docherty, PhD, CPNP who submitted their proposal, *Decision-Making for Infants with Complex Life-Threatening Conditions*, to the Duke Institute on Care at the End of Life on 4/14/09
- Kasey Jordan, RN, BSN and MSN student, who submitted her grant application, *DIG – Gen Y, Differences in Generations – How Generation Y School Nurses Perceive the Workplace*, on 5/01/08

**Study Profile**

The SMART Study

By Linda Folsom

Principal Investigator Sharron Docherty’s first job was on a bone marrow transplant unit. A pediatric oncology nurse since she graduated in 1985, she worked with kids that had cancer, and made an early observation that some kids did better than others with treatment. One group seemed to struggle, have a harder time with side effects, and was very anxious about the tough therapies often required to combat cancer. The other group did much better, and it was interesting to Sharron that the more experienced nurses could predict which group a child would fall into. It seemed to her that they were making their
predictions based upon something about the personality of the child that made them fight the treatment. The results from her dissertation lead her to summarize that, “Some kids fight the treatment, and some kids fight the cancer”.

The kids that fight the treatment have trouble staying on chemotherapy due to a combination of treatment side effects and psychological response to the symptoms. The concept of “symptom distress” has been studied quite a bit in adults, but not in children. So Sharron decided to focus her career on the quality of life of children undergoing treatment for life-threatening conditions. Medical science can discover all the new therapies in the world, but it doesn’t do the kids any good if they can’t tolerate them. As one mother told her, “Sharron, get answers for kids like mine who just can’t stand the treatment”.

About 6 months ago Sharron was approached by Joan Haase from Indiana University, who has been studying adolescent resilience in the face of treatment. Joan wanted to know if Duke would be a site in a large multi-center study looking at an intervention to help adolescents and young adults manage the distress of dealing with a bone marrow transplant. It was called the SMART Study: Stories and Music for Adolescent/Young Adult Resilience during Transplant. Joan and a music therapist colleague of hers, Sheri Robb, wrote this grant to test whether music therapy intervention helps adolescents get through transplant in a better way – whether it improves their psycho-social symptoms. The music therapy would be both a distraction for the adolescents during treatment, and a chance to create something that would tell their story. Since the study was in line with Sharron’s other research, she was glad to participate and bring the study to Duke University School of Nursing.

The SMART Study is a two-group randomized control trial. The therapeutic music video group participants develop a music video over the course of six sessions with the music therapist, while the low dose control group takes part in an audio-book intervention. Board-certified music therapists deliver both interventions. Data collection involves self-report questionnaires that take about 45-60 minutes to complete, collected on a laptop computer with the assistance of the research team. These questionnaires are done pre-transplant, post intervention (at about 3 weeks), and 100 days post transplant. Additional brief data collections are done at sessions 2, 4, and 6 on symptom distress (pain, fatigue, mood, anxiety). The target sample is n=130, so the combined study sites will attempt to recruit 175 participants to assure targeted accrual. The Duke site is slated to obtain about 41 subjects over a two year period of time.

The SMART study has recruited their first subject here, and is anxious for more. One of the challenges that they have at Duke is that there are so many other studies and programs available that also appeal to the adolescents. There is the Best Buddy program, where a Duke freshman visits children undergoing stem cell transplant, and a photography project out of the Documentary Studies department, where the child documents their cancer experience with a camera. Conducting research in clinical setting like a hospital is much different than a lab – all kinds of things happen that are beyond the control of the researcher. However, as Sharron says, “At the School of Nursing we are good at this, finding ways to make things work”.

Sharron is also grateful to have the Office of Research Affairs services available to her, and for her research team – Donna Ryan, Julie Thompson, Angel Barnes and Justin Levens.

Sharron Docherty is an Assistant Professor at the Duke University School of Nursing. She is the Director, Pediatric Acute/Chronic Care Advanced Practice Specialty, and a Pediatric Nurse Practitioner in the Children’s Health Center. Sharron obtained her BScN from the University of Windsor, Windsor, Ontario; her MScN from the University of Western Ontario, Canada; and her PhD from the University of North Carolina at Chapel Hill, Chapel Hill, NC where she is also adjunct faculty.

¿Lapse in IRB Approval? Submitted by Denise Snyder and Leslie Fife

What to do when IRB Approval of a study has lapsed: This is a big deal!

- **The research must stop**, unless the IRB finds that it is in the best interest of individual subjects to continue participating in research interventions or interactions, and
- **No Funds** may be drawn down from the payment system and no obligations may be made against funds for the period of the lapse. **This includes salaries**
- **Renewal or closure reports must be filed** as quickly as possible followed by a deviation report.

The IRB holds the principal investigator responsible for ensuring that all information required for continuing review is delivered prior to the expiration date of the IRB. The due dates of these materials are
not the expiration dates. The due date is the first working day of the month prior to the expiration month. In short, this means that if your study renews on September 18, 2008, by August 1, 2008 your renewal should be filed with the e-IRB. Yes, that far in advance and Yes, all IRB’s will now being renewed and filed electronically. Investigators and study teams must plan ahead to meet required continuing review dates. To assist investigators, the IRB Office sends out a notice to renew or file study closure prior to IRB expiration. However, investigators and study teams must not rely on this correspondence as a sole reminder mechanism. Regardless of whether or not a notice from the IRB is received, the investigator is responsible for renewal or submitting a final report (study closure). You must ensure sufficient time prior to the expiration date of the IRB approval in order for it to be reviewed and approved.

Something you may not have been aware of, exempt studies expire 3 years from the time of approval and the same rules apply, you must choose to renew or close the study by submitting a final report.

DUSON’s ORA office is working to develop an internal tracking system to assist in helping you avoid lapses in your IRB. Many of you have already received an e-mail notification on the need to renew or close your protocol as stated above. In addition, we are tracking the process of your approvals and amendments. Please contact us with your questions concerning this process. denise.snyder@duke.edu or leslie.fife@duke.edu.

Please note: All IRB’s, paper and electronic, will now be renewed in the e-IRB system. Amendments and reports for current paper protocols will remain as paper submissions until time to renew.

NEW – Required registration of studies in ClinicalTrials.gov
Submitted by Denise Snyder and Jennifer Dungan
On September 27, 2007 Congress enacted US Public Law 110-85 (aka HR 3580 or FDA Amendments Act of 2007). This act mandates the expansion of ClinicalTrials.gov – expanding the required submission elements and establishes penalties for not listing a trial. Investigators and sponsors must ensure that applicable drug, biologic and device trials are registered within 21 days of enrollment of the first subject and preferable before first subject enrollment.

Do I have to register my study?
YES – IF YOU DO RESEARCH THAT:
• Uses a drug, biologic, or device as the intervention or control/comparison
• Prospectively assigns human subjects to intervention and at least one concurrent control or comparison groups
• Studies the safety, efficacy or cause-and-effect relationship between an intervention and a health outcome.
OR
• You plan to publish the data [registration is required by ICMJE (International Committee of Medical Journal Editors)]

NO – IF YOU DO RESEARCH THAT:
• Uses FDA approved, marketed products used in the course of medical practice
• Is a Phase I clinical investigation of drugs or biologics
• Is a small clinical trial (please consider registering your trial if you are planning to publish or request NIH finding in the future)

Who is responsible for registering the study?
• Investigator-initiated – the lead PI responsible for conducting and coordinating the overall trial
• Sponsor-initiated – sponsor
• Trials sponsored by the federal government (e.g. NIH) – grantee
• Trials associated with IND or IDE applications with FDA – IND/IDE holder
• If investigator or sponsor who should register is unwilling or unable – participating investigator

How do I register a study at Duke?
Contact Rebeka Branagan (rebeka.branagan@duke.edu or 668.2579) to establish a user account that can be used with the ClinicalTrials.gov Protocol Registration

For more information: Contact Rebeka Branagan or Welsey Byerly (welsey.byerly@duke.edu)
Historically it has been difficult to analyze open ended response questions. The researcher had to read each response and try to interpret what the respondent said. The more text, the more subjects – the more difficult the task.

In recent years SAS has released a tool for text mining such data. Just as “data mining” discerns trends in quantitative data, “text mining” discerns trends in qualitative data.

The tool provides a rich suite of text processing and analysis tools that can uncover underlying themes or concepts across large documents collections. Text documents can be clustered automatically into groups, classified into predetermined groups, and used in conjunction with structured data to build predictive models.

Dimension reduction is performed using singular value decomposition and text clustering algorithms group documents into common themes and topics based on their content. An analysis of vocabulary usage – frequency and parts of speech – is provided.

SAS Text Miner can read text stored in a variety of document formats such as PDF, ASCII, HTML, Microsoft Word, and WordPerfect. The software can handle multiple foreign languages including English, Danish, Dutch, Finnish, French, German, Italian, Japanese, Portuguese, Spanish, and Swedish.

The SAS text mining software was recently added to the Duke OIT site license. Additional applications include evaluating paper abstracts for planning conference tracks or analyzing the many hits from a search engine to better classify the Web sites found before additional investigation.

To the right is a screen capture of output produced by SAS’s text mining procedure reporting word usage and document clustering.

Research Question

What can make a normally competent professional suddenly change all habits and start carrying basket of cupcakes and a little yappy dog? We need an investigator to study the Granny Syndrome…..

Our own research administrator Robbin Thomas recently experienced this dramatic change. While traveling with her family Sunday, April 27, 2008, she received a phone call that changed her life, she was informed that her grandson, Nathaniel Thomas Weber, 6 lb, 5 oz., has joined her family. Now Robbin is resigned to carrying a cane, baking cupcakes, taking afternoon naps and being called Grandma. Please let Robbin know you support her as she adjusts to this new transition in life. Congratulations Granny!
Welcome Janet Levy, PhD

We hope you have had the opportunity to meet Dr. Janet Levy who has recently joined the DUSON family. Dr. Levy appointment allocates a portion of her effort to the School’s Faculty/Staff Statistical Consultation Team that is coordinated through the ORA. Please Join the ORA in welcoming Dr. Janet Levy.

http://dusonnet.nursing.duke.edu/janet-levy-faculty-spotlight/

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.

Staff Spotlight – Justin Levens

By: Linda Folsom

Justin Levens came to Durham in January 2007 to spend time with his girlfriend Laura. She had moved to Duke to attend the Divinity School. Justin had a degree in Broadcast Journalism from the University of Arkansas, but took a job as a Duke Temp to get started here. The TRAC Center was hiring interviewers for the PROMIS Study, a large NIH study examining and developing Quality of Life measurement tools, and was lucky enough to catch Justin fresh out of college and at the beginning of his career.

Justin began by doing phone consents, interviews and subject follow-up, but the TRAC staff soon learned that he had many talents and learned quickly. Within a short period of time he was doing Cognitive Interviews for the PROMIS study – a very detailed and sensitive type of face-to-face interviewing. He also showed a knack for Access database work, so the PROMIS study sent him to a three day Access Boot Camp, and he quickly took over a lot of the database development and maintenance work for the Research Management Team (RMT). Other talents are web development and management, all kinds of data entry, and skill with SurveyMonkey and Viewsflash. Besides the PROMIS study, he is working on Ellie McConnell’s GNIE grant, helping develop their on-line base learning project. And he is an assistant on Sharron Docherty’s SMART project, also profiled in this newsletter.

Justin has always been interested in people and helping others – maybe that interest is what makes him a good interviewer. In college he was camp counselor that went around urban St Louis doing painting projects with kids 12-18 years old. He found it very rewarding, and says he enjoys driving by some of these places now, and remembering his time with the kids. He also built wheelchair ramps for homes where the family needed them.

Other interests include music – he played lead guitar for a high school rock band called “Fourth Seed” and even recorded an album. Nowadays he sometimes shows up to practice with Brian Burton and his band, “Intimate Soul”. Seems like we are developing musical theme over here in the Clipp building.

In January 2008 Justin and Laura got married, and in March Laura accepted an Evangelism Fellowship for a Doctorate of Theology at Duke Divinity School, so it looks like Justin will be in the Durham area for a few more years. The Research Management Team is very glad to have him – in fact, they just promoted him to Senior Data Technician. Whether or not he remains in research is uncertain, but he really enjoys what he is doing here, and is thinking about taking SAS training and getting more involved in statistical analysis. He also might foster his creative side, and take advantage of the Duke program for a Documentary Certificate.

“I’m still at that stage that I’m thinking about what I want to do. It’s really nice right now – I’m very happy where I’m at. The work is interesting and I’m learning new things about research. I enjoy reading articles and journals. I can ride my bike to work. I know that having the Duke School of Nursing on my resume carries a lot of clout. And it’s important to me that what we’re learning might help people in the future”.

Click Here and check out this new journal Article by Marva Price, RN, DrPH and FNP Student Maureen Butts

Click here to read the latest journal contribution by Denise Snyder, MS, RD, LDN our Lead Study Coordinator-SON SBR and Clinical Trials Manager
You say your deadline for your federal grant proposal is in 3 days, you aren’t finished writing the narrative and you haven’t started working on your budget yet? Do you plan on sleeping in the next 3 days?

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.

Schedule of Events

<table>
<thead>
<tr>
<th>Event</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jenifer Dungan to present for the Research Conference series: Blood-Based Gene Expression Signatures Distinguish Exercise Training Regimens, This event will be May 14, in SON class room 1009. Please come give Jennifer your support. Refreshments will be served.</td>
<td></td>
</tr>
<tr>
<td>Linda L Davis will have her Mock Review for her R01 Competing Renewal, Project Assist. Event to be held May 14, 2008 from 1- 3 in room 1032.</td>
<td></td>
</tr>
<tr>
<td>Introduction to SAS training. These are training sessions that are precursor for all other SAS training. John Boling will be offer 2 sessions of this class. First session will run from May 15 – June 26 in the old faculty lounge of the Clipp Building. Second Session will run from July 10 – August 21. You must be a faculty member or Staff member. Space is limited so be sure to make reservations with Leslie Fife.</td>
<td></td>
</tr>
<tr>
<td>John Boling will be presenting his talk on Text Mining on June 11, 2008 in room 3088 at Noon. Please bring your lunch and join him for this presentation on statistics that you may not have though about gleaming before.</td>
<td></td>
</tr>
<tr>
<td>Dr. Janet Levy, will be presenting her NIH talk “Methodological Issues in Clinical Trials of Interventions with both Pharmacological and Behavioral Components” Faculty, Students and Staff are welcome to bring their lunch and join her in room 3088 on June 25 from Noon till one.</td>
<td></td>
</tr>
</tbody>
</table>

Be sure to check the NIH website and your e-mail for funding opportunities and grant deadlines.
Debbie Brandon, Jada Brooks, Sharron Docherty and Diane Holditch-Davis visited Vancouver on March 27th -29th to learn about the latest research on infants. They also learned a lot about Vancouver’s weather. In the 3 days they visited it was sunny, and also rained every day, hailed 2 of the days and snowed 2 days. This gives new meaning to the phrase “If you don’t like the weather, stick around it will change.”

Jada Brooks’ Poster

The Duke team and the Mountie

Debbie Brandon’s Poster