As part of Wake Forest University’s commitment to protect human participants involved in research under its purview, we are implementing eIRB, an online submission, review, and approval system currently in use at the Medical School. New to the Reynolda campus, the system will help us to standardize procedures involving our Institutional Review Board (IRB).

Like e-mail and online banking, eIRB will be available to Reynolda campus researchers around the clock. Investigators and other study team members can electronically follow the application approval process for projects under review and review and manage approved projects. The online system uses logic-based SmartForms, which route you through sections of the application that are relevant to your study and help to eliminate redundant processes for both investigators and the IRB.

Researchers on the Reynolda campus will submit social and behavioral science research protocols to the Reynolda IRB and biomedical research protocols to the IRB for Wake Forest University Health Sciences (WFUHS). Many faculty in our Health and Exercise Science department already collaborate with Medical School researchers on studies requiring biomedical expertise and access to WFUHS facilities, personnel, and/or patient populations.

Moving from hard-copy applications to this online system will require some investment of time and effort by investigators and their study teams. The new application for exempt, expedited and full-board review, requests detailed information that will help to ensure compliance with federal regulations and guidelines for research involving human participants. The long-term gains of the more streamlined process are in everyone’s best interest.

In the coming months, the Office of Research and Sponsored Programs (ORSP) will be training faculty in research-active departments and other researchers to use eIRB. Watch for announcements in ORSP newsletters, and check for dates on the IRB website (www.wfu.edu/rsp/irb.html), where you will also find a User’s Guide to eIRB and eIRB FAQs. The eIRB system also provides a HELP feature and a “sandbox”, which is a training environment where investigators and study team members can practice completing an application and using the system.

We expect eIRB to go live on the Reynolda campus in the fall for all new applications and related amendments. The IRB will continue to accept hard copy for active studies approved prior to this implementation date; eventually, all active studies will be converted to eIRB.

I encourage you to stay informed and to plan ahead with your study team members for these significant improvements to the IRB process in support of Wake Forest research excellence.
SUBMISSION TIPS

NIH/grants.gov
As of February, most proposals to the National Institutes of Health (NIH) must be submitted through grants.gov, the portal for finding and applying for federal grants. Below are some guidelines to facilitate the submission process.

1. The Research Plan should be prepared in 1 document, and separated to create the required sections.
   a. Project Summary/Abstract
   b. Research Plan (each in a separate file)
      1. Specific Aims
      2. Background and Significance
      3. Preliminary studies
      4. Progress Report
      5. Research Design and Methods
   c. Project Narrative, stating PUBLIC HEALTH RELEVANCE
   d. References cited
   e. Facilities and other resources
   f. Equipment
   g. Biographical Sketch (4 pages maximum)
   h. Budget justification; ORSP can prepare it or send you a template.

2. DO NOT USE FOOTERS AND HEADERS.

3. Use Arial font, 11 point, to ensure compliance. Times New Roman 11.5 is too small.

4. Use at least .5-inch margins all the way around.

5. Budgets must generally be requested in $25K modules, which should be the same for each year of the proposed project, unless equipment is requested.

6. The budget justification for a modular budget should only include information on personnel and consortium/contractual costs.

7. CONVERT ALL DOCUMENTS TO PDF.

8. After proposal is submitted, review entire proposal in Commons (https://commons.era.nih.gov/commons/).

9. Make sure you are registered in Commons and know your user name.

10. Submit EARLIER THAN DEADLINE to avoid system delays on deadline days.

The bottom line for successful proposal submission? Bring ORSP on-board immediately, as soon as you know you intend to apply, so we can work together to submit the most competitive proposal before the deadline date.

STAFF PARTICIPATION ON GRANTS: NEW ADMINISTRATIVE GUIDANCE

Wake Forest encourages faculty and staff to perform research and other sponsored projects and recognizes the need to pay some research staff above their normal base salary, or overload compensation, for research or other work performed in addition to assigned duties.

Where overload compensation is requested, the assignment must be either beyond the duties of the written job description; outside the department unit; or performed outside normal working hours. In addition, vacation leave must not be used, so that the university is not paying the employee twice; hiring a temporary employee is infeasible; the assignment clearly serves Wake Forest’s interests; and total overload compensation in a fiscal year does not exceed 20% of annual salary.

To view the policy and detailed procedures, please see www.wfu.edu/rsp/pdf/Staff.pdf.
ORSP started the year with a luncheon to acquaint new faculty with its services and their colleagues who have won external support. Associate Provost for Research and Professor of Chemistry Mark Welker had 2 proactive words: get mentored! Whether research in your discipline requires publication or grant support, seek advice from your department and other experts. Ask them to critique everything you write and to explain how best to field it.

Herman Eure, Associate Dean of the College and Professor of Biology, agreed. Partner with senior faculty. Serve on review panels; meet sponsors and master their criteria. Knowing who to see is vital to getting things done.

That includes the crew at ORSP. Director Lori Messer sets research administration policies and procedures and provides the institutional signature that authorizes the university’s commitment to your project. She negotiates contracts and subcontracts and handles preaward activities (proposal/budget development and interpretation of sponsor guidelines) for the Health and Exercise Science department.

Assistant Director Stephen Williams handles preaward activities for all departments except Biology and Health and Exercise Science. Gloria Stickney serves Biology and internal award submissions and sets up and reconciles accounts.

Henny Wakefield is Institutional Review Board (IRB) Coordinator, facilitating the process that protects human participants in research. Julie Edelson edits proposals and disseminates funding information.

Three professors modeled mentoring. Joseph Soares, Associate Professor of Sociology, spoke, first, as an IRB member. For research involving human participants, investigators must check the IRB website and complete the CITI tutorial. Securing certification isn’t difficult—if you fail, you can immediately repeat the test—but the course is a sobering reminder of the reasons for compliance. The IRB wants to enable safe research, which includes projects where students conduct surveys; you may not need IRB approval if the results will not be published, but err on the side of caution. The IRB cannot eliminate all risk, but it will assure that risks are proportional to the study’s value and participants understand them. Turnaround is quick—one week or one month, if complications arise.

Next, as an award-winning author, Dr. Soares addressed publication. Always have two pieces in the works, one submitted. Determine the top publishers where your manuscript is a good fit. Once you find the fit, acceptance is fast, but book-in-hand can take 2 years, which is tense if your department requires it for tenure. You must mount a sustained campaign. The next book will be easier.

Errin Fulp, Associate Professor of Computer Science, won Wake Forest’s first Department of Energy Early Career Award and support from the Z. Smith Reynolds Foundation. His research has produced publications, presentations, 2 pending patents, and a company, GreatWall Systems, in Winston-Salem, which continues to receive DOE funding.

Dr. Fulp advised volunteering for review panels and spending summers at national laboratories or other venues where you will meet mentors. Their recommendations are vital to winning awards, and they will eventually be your reviewers.

Contact POs by phone or in person to assess interest in a project. He first approached agency representatives at conferences, asking, “Would you like to see a white paper or sales document?” Dr. Welker noted that ORSP will pay for faculty to visit funding agencies. Meeting you assures POs that you’re not difficult, since convening the 15 most argumentative scholars in a field doesn’t nurture review.

If you get the green light, tailor your pitch specifically to the agency’s guidelines. Even if you’re rejected, contact the PO to ask, “Should I revise or look elsewhere?”

Projects are evaluated on technical merit, your accomplishments, and your institution’s accomplishments. Agencies will work with you on the budget. Dr. Eure said that sponsors also want to see independence from your dissertation advisor. Preliminary data are a huge plus, and WFU awards can help you to acquire them. Devote at least one day a week to your research. Have colleagues read your proposals; ORSP’s Edelson cuts to the quick.

Jefferson Holdridge, Associate Professor of English and Director of the Wake Forest University Press, won National Endowment of the Arts support for publication of The Wake Forest Series of Irish Poetry, volume 2. His advice? “Only connect.” Go to conferences, exchange ideas, keep abreast of the field. Books can address major figures, but for journals, write on novel themes and less canonical authors and be sure you know the journal well. Every publication makes the next easier.

As your best ideas often emerge during the process, not before it, they may be too complex for a grant proposal, which must be readily accessible. Ask colleagues - even junior colleagues - to read your work; you’re never more educated than just after you’ve achieved your PhD. Apply early and often, but if you’re late, don’t NOT apply. Dr. Eure quipped, “Keep submitting – maybe they’ll get so sick of you, they’ll give you the money.”
President Bush has finally signed into law a joint congressional resolution finalizing FY 2007 funds for federal agencies. While most programs remain at FY 2006 levels, money saved by eliminating earmarks this year has been reallocated to certain research and education activities.

**Agriculture Department**—$10M increase for the national competitive research initiative

**Department of Energy, Office of Science**—$200M increase to support research, including new energy technologies, such as improved conversion of cellulose biomass to biofuels

**National Institute of Standards and Technology**

**Innovation Programs**—$50M in new funding for physical science research and lab support for nanotechnology and neutron research

**National Institutes of Health**—$619.5M to support an added 500 research project grants, 1,500 first-time investigators, and increased high-risk/high-impact research

**National Science Foundation**

**Science**: $335M increase for basic science research

- **$7.1M for Research on Learning:** the core Research and Evaluation in Education in Science and Engineering (REESE) program supports wide-ranging research on behavioral, cognitive, social, and technological aspects

- **$13.4M for Undergraduate Education**, including:
  - **$30M** for a round of new **Math and Science Partnership** grants, concentrating on the transitions from middle to high school, and high school to college; new teacher institute projects would focus on developing school-based teacher leaders with deep content expertise
  - **$3.5M for the Course, Curriculum, and Laboratory Improvement** program, to create learning materials and teaching strategies, develop faculty expertise, implement educational innovations, assess learning and innovations, and conduct research on STEM teaching and learning

- **$8.9M for Graduate Education**

*The NSF will soon launch a new Division of Research on Learning in Formal and Informal Settings. It merges the Elementary, Secondary, and Informal Education and the Research, Evaluation, and Communications divisions to stress the connections between formal and informal education and to enable more systematic, integrated research—both basic and applied—and evaluation.

**CENTRAL ELECTRONIC GRANTEE DATABASE**

Congress has been working toward a public database to track federal grants, contracts, subawards, loans, and even earmarks. Sens. Tom Coburn and Barack Obama said their bill would “lift the veil of secrecy” surrounding federal funding. Dedicated grantseekers can already find award data on the web, but it is scattered, often incomplete, and dated. “I am hopeful that a searchable database . . . will help reduce the ever-increasing number of earmarks in appropriations bills,” said Sen. John McCain, co-sponsor of a bill to create a tracking system.

Earmarks generally bypass any competitive grant process but are not a sure thing. The term applies to funds reserved for such purposes as research and demonstration projects, hospitals, and laboratory and university grants in specified congressional districts or states or for specific organizations or institutions.

Pork-barrel legislation refers to federal appropriations, bills, or policies awarding benefits to please a legislator’s district rather than on an objective assessment of need or merit.

**What does an agency do when a member of Congress succeeds in directing funds to a pet project or organization?**

At the Bureau of Justice Assistance, for example, each earmark is assigned to a state policy advisor, who contacts the designated recipient organization. As locating them can be difficult, BJA invites recipients to make direct contact to expedite the process. Grant application and approval are the same for earmarks as for all other grants. The recipient must submit an application that conforms to BJA requirements, adequately explains the proposed program, and includes a detailed budget. Funds are not awarded until the agency approves the application, and the award documents are in hand, a process that can take months. Grants that result from earmarks must still comply with the statutory, programmatic, and financial requirements governing the grant program under which they are funded.

The Education Department first tries to locate the recipient organization, which, again, can be difficult. The ED program officer usually sends a letter and an application package, explaining how to apply. Although application procedures are simpler and without competition, applicants must still explain what they intend to do with federal funds and to provide a budget. If the application is adequate, the award may be made, but the planned activities must also be consistent with the earmark language in the appropriations law and the law authorizing the program.

In addition, earmarked projects may not violate the law; for example, federal funds cannot be used to teach religion; for a project that expressly excludes anyone because of race, religion, gender, or disability; or if the intended recipient is in financial trouble that makes funding risky.
IRB Adds Meeting
To accommodate researchers planning to conduct summer studies overseas, the IRB has added a 14 May 2007 meeting before it adjourns for the academic year. Investigators whose study requires full review must secure final IRB approval at this meeting. The submission deadline is 5 P.M., Monday, 30 April 2007.

What’s New for 2007-2008?
• CITI certification is required for all researchers and key personnel, whether the submitted protocol receives exempt, expedited, or full-board review.
  • Group 1 (social/humanistic/behavioral research) is for graduate students, faculty, and staff. Certification is good for 5 years.
  • Group 2 (social/humanistic/behavioral research) is for graduate education students. Certification is good for 5 years.
  • Group 3 (biomedical research) is for collaboration with the Medical School. Certification is good for 2 years.
Those conducting international or internet research must take the international or internet research modules.
• All active studies presented on paper before the projected fall 2007 eIRB rollout will be processed in hardcopy.
• Beginning July 2007, departmental IRB reference binders will no longer be updated. Researchers are directed to the IRB website (www.wfu.edu/rsp/irb) for current information and forms.

IRB Previews eIRB
Cheryl Byers, WFUHS IRB director, and Scott Mann, WFUHS analyst/programmer, introduced IRB members to eIRB, a work-in-progress that will be implemented on a staggered schedule in the fall. By that time, intercampus connectivity will ensure that researchers on both campuses have easy access. The electronic IRB system, used successfully at WFUHS for a year, sees 140 users daily, has a user base of over 1,000, and 790 active studies, including 100 applications currently under review. These numbers will continue to increase when eIRB is implemented on the Reynolda campus.

“T’m excited and look forward to using it all next year,” commented Bob Evans, Professor of Education. “eIRB looks like it will bring big improvements to our IRB process, both in clearer and more efficient communication and greater consistency of review....”

Tony Marsh, Associate Professor of Health and Exercise Science, has been using eIRB through a Medical School account. “eIRB means no paper! Its automated emails remind you to do things and keep you informed of the status of the application. Like TurboTax, which allows users to customize their tax return, eIRB will walk investigators through the process, only presenting the forms that are applicable to the PI’s study.”

eIRB Changes Application Process
Investigators will prepare their applications, including narrative, informed consent/assent, and debriefing script, as before (see www.wfu.edu/rsp/irb/forms.html), uploading them where appropriate in the eIRB application. The narrative provides the rationale and background, methodology and the operational details of the study. eIRB will lead researchers through the relevant sections of the application to ensure study compliance with federal regulations and Reynolda campus IRB policies and procedures.
• With eIRB, the study team will identify the type of research (exempt, expedited, full-board) being submitted for review.
• All study team members must agree to participate (electronic signature) before the PI can submit the application.
• Only the PI can submit the eIRB application. The PI or study coordinator may submit an amendment and continuing review. All study team members will be able to edit the application.
• Deadlines to respond to full board concerns must be met within 60 days of the date issued to avoid administrative closure of the protocol. Investigators and study team members have 30 days to respond to concerns for expedited and exempt applications to avoid administrative closure.
• All correspondence between the IRB and the study team will go through eIRB.
• The PI must add a watermark to approved consent documents for “stamping” before printing them for use in the consent process.
• eIRB provides transparency for study team members who can track the progress of their application via eIRB at any time.

eIRB Training
ORSP will schedule training and post a User’s Guide to eIRB and eIRB FAQs at www.wfu.edu/rsp/irb/.

COMPLIANCE HOTLINE – 1-877-888-7888, to anonymously report suspected violations of laws, regulations, rules, policies, procedures, ethics, or other information you feel uncomfortable reporting to a supervisor or faculty administrator. The operator, who is not a university employee, will report your concerns to the University Compliance Office.
NIH REVIEW REORGANIZATION PROPOSED
from ASBMB Today (January 2007) www.asbmb.org/

Dr. Toni Scarpa, director of the NIH Center for Scientific Review, discussed study section changes.

How is the new study section structure working out, and do you foresee further changes soon?
“The reorganization of our Integrated Review Groups (IRG) and their respective study sections was a major effort. . . Significantly positive effects include . . . it (1) realigned peer review with changes in science by making the study sections broader, (2) removed ‘entitlements’ from narrowly focused study sections, and (3) diluted the presence or the appearance of the ‘old boys’ network’.

“Does it work well now? Yes, in many cases. However, a number of study sections . . . remain too narrowly focused, while others became far too broad . . . and unwieldy, with up to 70 reviewers.

“What are we going to do? In addition to the mandatory external reviews of each IRG every 5 years, we have taken two important steps. (1) Early in 2006, we initiated new rigorous workshops for reviewing one of our IRGs every month . . . if problems are identified, they are fixed immediately. If they are substantial, we work up a proposal with the . . . community in that scientific area and present a plan to the NIH Peer Review Advisory Committee. (2) In 2007, we will hold 6 . . . workshops focused on our scientific review areas. Leaders from professional societies, disease groups, and study section chairs will . . . provide input on whether specific areas are being appropriately reviewed and to discuss possible alternatives.”

Are there plans for electronic reviewing?
“Yes. . . Many have pointed out that our R01 application is 2-5 times longer than those used by similar funding institutions. . . . A major driver is the desire to recruit and retain the best reviewers. At the moment, we are using 18,000 a year, and the large majority are ad hoc. On average, a reviewer spends over 7 hours just to read an R01 application. If it were shorter, reviewers could review more; . . . the study sections could have fewer reviewers, and we could be more selective in recruiting ad hoc reviewers. It could focus more on significance and impact and less on experimental detail.

“We have established a new NIH committee to consider a shorter R01 application. . . . A request for information was posted in the NIH Guide, seeking input from the scientific community (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-014.html). During the first 3 days, NIH received 1,200 responses, with 80% in favor of shortening the application.”

“. . . . we are making progress in shortening the time between application submission and the posting of scores and summary statements. . . . we are conducting a pilot where over 600 new investigators who submitted applications in February 2006 were eligible to reapply for the next review round in July rather than . . . November. The pilot is ongoing, but the preliminary data are very encouraging: 14% took advantage of the shortened cycles to reapply in the next round, saving 4 months. We are still collecting and examining the data. If all goes well, we will offer this option to all new investigators and then to all R01 applicants, which should be possible since almost all NIH applications will be submitted electronically by February 2007. Ultimately, it would be important to provide our first response (scoring and reviews) no later than 4 months from the date of application.”
WFU Funded Research
1 November 2006 - 28 February 2007

ANTHROPOLOGY
Kenneth Robinson
- Archaeology Investment, Fountainhead Spring, Fayetteville, NC, supplement #1, Fayetteville Public Works Commission, $1,359.30

- Fountainhead Spring, Fayetteville, NC, Supplement #2, Fayetteville Public Works Commission, $2,640.80

- Testing, Tot Hill Farm Road Parking Lots, Randolph County, NC, Uwharrie National Forest, $2,508.60

- Historical and Industrial Archaeology of the Idols Hydro-electric Facility, City of Winston-Salem, $54,698.08

- Survey, Bear Creek Force Main, Davie County, NC, Grey Engineering, Inc., $14,993.97

- Survey, Ray’s Creek Outfall, Franklin County, NC, Hobbs, Upchurch & Associates, $14,977.72

- Archaeological Survey, Area Surrounding Eudor Furnace, Lee County, NC, City of Sanford, $42,330

BIOLOGY
Clifford Zeyl, Evolutionary Advantage, Recombination, and Adaptation in Experimental Yeast Populations, National Science Foundation, $93,000

CHEMISTRY
Rebecca Alexander, Research Infrastructure in Minority Institution Grant (RIMI), National Institutes of Health, $7,716

S. Bruce King, Nitric Oxide-Producing Reactions of Hydroxycyurea, National Institutes of Health, $267,213

Abdou Lachgar, Design and Self-Assembly of Cluster-based Materials, National Science Foundation, $120,000

COMMUNICATION
Ananda Mitra
- Alcohol-Related Problems Among College Students, National Institutes of Health, $11,296

- Rapid Response, National Institutes of Health, $11,296

COMPUTER SCIENCE
V. Pau’l Pauca
- Systematic Development of Quantum Computational Software, Targacept, Inc., $15,000

- Systematic Development of Quantum Computational Software, North Carolina Biotechnology Center, $45,000

Todd Torgersen, Innovative Methods for High-Resolution Imaging and Feature Extraction, Army Research Office, $84,926

ENGLISH
Connor O’Callaghan, Visit by Poet Adam Zagajewski to Wake Forest University, North Carolina Humanities Council, $1,200

HEALTH & EXERCISE SCIENCE
Peter Brubaker, ACTION: A CHF Trial Investigating Outcomes of Exercise Training, National Institutes of Health, $3,171

Gary Miller, Does Weight Loss Following Laparoscopic Roux-en-Y Gastric Bypass Improve Physical Function? National Institutes of Health, $17,401

Walter J. Rejeski, Lifestyle Interventions and Independence in Elders (LIFE), National Institutes of Health, $7,334

LAW SCHOOL
Robert Walsh, Professionalism Program, North Carolina State Bar, $7,000

PHYSICS
David Carroll
- Targeting the Glycocalyx (capsule/exopolysaccharide) to Reduce Bone/Implant-Related Infections, Orthopaedic Research Education Foundation, $39,696

- Self-Assembled Soft Optical NIMS, Air Force Office of Scientific Research, Multidisciplinary University Research Initiative (MURI), $115,677

George Holzwarth, Kinesin Force-velocity Curves When 1, 2, or 3 Motors Transport a Single Load, National Institutes of Health, $5,013

Daniel Kim-Shapiro, Nitrite and Nitric Oxide in Sickle Cell Blood, National Institutes of Health, $103,680

WFDD
Jay Banks, WFDD Digital Conversion, Corporation for Public Broadcasting, $75,000