Write Winning NIH Grant Proposals
By Eva Szarek, PhD, MPM

“It’s called research not search because we have to re-search over and over”
(J.D. Robertson)

The grant application process is not science; it is the marketing of science. The June 26th half-day Grant Writing workshop introduced participants to the general outline and structuring of a grant application, with an emphasis on how to put together a K99 and other new-investigator NIH grants. John D. Robertson, PhD, an associate member of the Grant Writers’ Seminars & Workshops, LLC, with extensive experience in competitive extramural funding from both the NIH and non-federal sources, led the event.

The main points covered during the session centered on the development of the application, including aspects addressing the specific aims, central hypothesis, research strategy, innovation, and approach. The two most important aspects of the grant application are the specific aims, which garnered the most time at the workshop, and the newly created section to address innovations relating to your proposal. Dr. Robertson’s best advice focused on the specific aims, because this is the first section reviewers read and should be the executive summary to your entire grant.

The specific aims give the reviewer all the essential details about the proposal, including why the work is important, why it needs to be done, why you are qualified to solve the problem, how you will solve it, and the big picture (what is the impact in the current field?). Most importantly, you will need a “hook” sentence, one that has directional focus and addresses the target institute’s or agency’s mission. In addition to the hook sentence, the problem being proposed needs to be framed—that is, the critical need or driving force must be evident to the reviewers. For example, if your

(continued on page 3)
If you can spare two hours of your time on a Wednesday afternoon, consider checking out the quarterly NICHD Exchange meetings. I have attended two so far, and I can vouch that they are a great way to stay up-to-date on topics relevant to the NICHD community. I have walked away from each meeting with a greater appreciation for the complexities of today’s research: from what it means to have improved survival rates but long-lasting side effects to the nuances of big data. The meetings are broad enough to be interesting to both the basic and clinical researcher, and the underlying topics are relevant to young trainees as well as senior investigators. A highlight of each meeting is the in-depth discussion that follows the short introductory talks, where ideas and problems are tossed around and dissected. So set your experiment to run for a few hours and join the Exchange meetings for a thought-provoking session.

In this issue of The NICHD Connection, we cover July’s NICHD Exchange meeting, “The Next Frontier: Amassing, Warehousing, and Mining Big Data” (pg. 4) and the annual Grantsmanship Workshop, a highly anticipated event organized by the NICHD Office of Education (pg. 1). We also cover information relevant to our current and future clinical fellows with a list of useful links for each NICHD clinical program (pg 8).

Enjoy the hot weather!

Your Editor in Chief,
Shana R. Spindler, PhD
research grant is related to cancer research, your opening sentence should not begin with “Cancer is the world's leading…” This opening sentence has not taught the reviewer anything. Focus your opening statement.

The hook sentence example from the workshop is as follows:

Unhelpful: “Approximately 2 million children in the U.S. make the transition from preschool to kindergarten every fall.”

Helpful: “More than 15% of the 2 million children in the U.S. who annually transition from preschool to kindergarten lack adequate social and/or emotional skills necessary to thrive in the kindergarten environment.” This statement may not need a reference, unless you think reviewers will have their doubts. Teach the reviewer something new (…well at least try!).

The new addition of the innovation section for NIH grants is aimed at addressing the original and substantially different way of addressing the research significance. What constitutes innovation? Will your research question challenge or seek to shift current research? Does your research employ novel theoretical concepts, approaches, methodologies or instrumentation? Are any of these innovations novel to the field? These are some on the key questions one should be thinking about when writing this section.

The flow for the innovation section was presented at the workshop as follows:

(a) Document the existing strategies currently being used to address a problem (or similar problem) and their limitations or why they were unsatisfactory
(b) Include an italicized statement of potential innovation: The proposed research is potentially innovative because…
(c) Summarize the advancements that are likely to be possible with this new approach that would probably not have been possible without this innovative new approach.

The greatest challenge is to persuade your reviewers to get your science funded. Not only does your grant need to address the specific study section (the group of people in a related field assigned to review your grant), but it also needs to be reviewer friendly: use appropriate font, eliminate ambiguity, and follow the instructions. “What is research except attention and detail,” said Dr. Robertson.

And last but not least: create a writing schedule with set completion dates that you will stick to. Efficient time management is one of the most important ways you can gain that edge over your competitors, not only by making sure your writing is succinct and the information relates specifically to your topic, but also by guaranteeing that you have written an aesthetically pleasing grant application with sufficient time for your referees to write you that glorious reference letter.

What are you waiting for…get writing!!!

GRANT FUNDING NIH LINK: http://grants.nih.gov/grants/grant_tips.htm

GRANT WRITERS' WEBSITE: http://www.grantcentral.com/whoweare.html
By Shana R. Spindler, PhD

“What would Yoda say to investigators about sharing data?” asked Dr. Rohan Hazra, medical officer in the Maternal and Pediatric Infectious Disease Branch. “Train yourself to let go of everything you fear to lose.”

A few decades ago, the idea that we could store terabytes of data on our personal computers seemed unfathomable. But it just goes to show that scientists benefit from being forward thinking, because what might seem impossible today could easily be the norm tomorrow. So what do we do when the impossible becomes, in fact, reality?

With the ability to collect, store, and access large datasets from research spanning tens of years, scientists and doctors must establish dataset ground rules and—quite frankly—a new culture of data sharing. Four experienced researchers who are involved with large datasets met on July 10, 2013 in an NICHD Exchange meeting to discuss the role that “big data” will play in the future of NICHD and science in general.

The term “big data” refers to the vast amounts of structured and unstructured data accumulated from large and encompassing studies that requires nontraditional techniques to process and analyze. In Dr. Rohan Hazra’s introductory talk, he likened the process of establishing how to use big data to the rules of early childhood: share everything and play fair.

Several achievements in the past few years have set the stage for big data sharing. The Big Data to Knowledge (BD2K) initiative (https://commonfund.nih.gov/bd2k/overview.aspx) and the Yale Open Data Access (YODA) project (http://medicine.yale.edu/core/projects/yodap/index.aspx) are good examples of facilitating the use of big data and successfully sharing data, respectively.

The goals of sharing big data are noble. Sharing large datasets encourages diversity of analysis, promotes new research, avoids duplication, and honors research as a public good. Not to mention it saves money and time and increases the power of statistical arguments.

However, before researchers rush onto the big data scene, several concerns must be considered. Erroneous secondary analysis of datasets, privacy and confidentiality issues, proprietary interests, academic credit, and the balance of data preservation with administrative burdens all must factor into the equation. To address these pitfalls, researchers must “collect data with sharing issues in mind all along,” said Dr. Hazra.

Captain Steven Hirschfeld, director of the National Children’s Study (NCS), emphasized a standards-based approach to big data. The NCS is an NICHD-led study to investigate the environmental and genetic effects on the growth, development, and health of children from birth until age 21 years. Drawing upon his experience with the NCS, Captain Hirschfeld approaches big data with a “big picture” point of view, where data exists in the life cycle of approach, acquisition, analysis, and use.

Ultimately, different groups will have varying end-point requirements of the data, and Captain Hirschfeld aims to satisfy the needs

(continued on page 5)
of all data users via the integration of multiple standards for each step of the data life cycle. He also acknowledged that data access must be structured, robust, and tightly controlled.

When the Division of Epidemiology, Statistics, and Prevention Research (DESPR) of the NICHD standardized access to their extensive dataset collection, they established an internal Biorepository Access and Data Sharing (BRADS) committee to oversee the process. Dr. Jennifer Weck, Scientific Program Specialist with DESPR and chair of the BRADS committee, continued the Exchange meeting with the “theory versus practice” of dataset and biospecimen sharing.

Because DESPR researchers established their datasets to answer specific questions, Dr. Weck noted that finding a common data structure for diverse projects, establishing common dataset search terms, examining data ownership issues, and establishing ethical guidelines for the additional use of biospecimens have been areas of data sharing that are tricky to navigate. To address some of these issues, the BRADS committee reviews all requests for access to the BRADS data, and biospecimen use requires a material transfer agreement with a 10-page proposal reviewed by the committee as well as outside experts.

Problems do arise, said Dr. Weck, such as sufficient review of proposals, specimen use costs, and compliance with data submission. The BRADS program addresses these issues with an oversight committee and reviewers, alongside an in-house data management and web development team.

Clearly, big data is not a one-person job. “Data science really requires a team approach,” said Dr. Regina Bures, final speaker of the Exchange meeting. Dr. Bures manages portfolios on population health and the environment for the Population Dynamics Branch in addition to her managing role in the Educational Programs for the Demography and Population Science Research Grant Program. Dr. Bures emphasized the need to encourage cultural change through funding policies, data sharing policies, and the education of researchers across all disciplines.

The take-home message from the meeting: it is important to be forward thinking and thoughtful now in the design of data collection and analysis because there’s a big world out there full of big data.

*During the discussion session, one of the audience members asked how to deal with consent for the use of biospecimens when a study included thousands of people who are no longer available for contact. After some discussion, the panel members agreed that the ethicists’ consensus is that researchers cannot use biospecimens for additional research without consent from the donating individual, although different institutes have varying guidelines on this practice. Food for thought in the design of biospecimen consent forms from this point forward…
A Warm Welcome To Our New NICHD Clinical Fellows

The NICHD Connection would like to introduce our newest clinical fellows. Welcome to the family!

RODRIGO R. CORREA, M.D.
Program: Adult Endocrinology
Residency: Jackson Memorial Hospital—University of Miami, Miami, FL
Medical School: Universidad de Panama, Panama

OVIDIU A. GALESCU, M.D.
Program: Pediatric Endocrinology
Residency: SUNY Downstate, Brooklyn, NY
Medical School: Universitatea de Medicină și Farmacie Carol Davila, Romania

SMITA JHA, M.D.
Program: Adult Endocrinology
Residency: North Shore Medical Center, Salem, MA
Medical School: Bangalore Medical College, India

(continued on page 7)
GEORGE PATOUNAKIS, M.D.
Program: Reproductive Endocrinology and Infertility
Residency: Thomas Jefferson University Hospital, Philadelphia, PA
Medical School: UMDNJ–Robert Wood Johnson Medical School, Piscataway, NJ

TORRIE PLOWDEN, M.D.
Program: Reproductive Endocrinology and Infertility
Residency: Tripler Army Medical Center, Honolulu, HI
Medical School: The George Washington University School of Medicine, Washington, DC

DONALD ROYSTER, M.D.
Program: Reproductive Endocrinology and Infertility
Residency: San Antonio Uniformed Services Health Education Consortium (SAUSHEC), San Antonio, TX
Medical School: Uniformed Services University of the Health Sciences (USUHS) School of Medicine, Bethesda, MD

ZHIYOU ZHANG, M.D., PH.D.
Program: Pediatric Endocrinology
Residency: Richmond University Medical Center, Staten Island, NY
Medical School: Tianjin Medical University, Tianjin, China
Useful Links for Current and Future NICHD Clinical Fellows

NIH CLINICAL FELLOWS CORNER
The NIH Clinical Fellows Corner website centralizes links to tools, resources, and programs relevant to the clinical fellow community. Information about the Clinical Fellows Committee and Office of Clinical Research Training and Medical Education (OCRTME) are also available from this site.

Useful Links:
» http://www.cc.nih.gov/clinicalfellows
» http://www.cc.nih.gov/clinicalfellows/training.html
» http://www.cc.nih.gov/clinicalfellows/it_tools.html
» http://www.cc.nih.gov/clinicalfellows/committees.html

NIH IRB PROTOCOL Navigators Training Program
The NIH IRB Protocol Navigators Training Program is a set of 10 videos within the National Human Genome Research Institute’s “GenomeTV” YouTube series. According to the description on their site, “Protocol navigation is the complex process of providing administrative and regulatory assistance to progressively move a protocol through its lifecycle from conception to termination. Successful protocol navigation requires knowledge of the protocol review cycle and expertise in Institute and NIH policies and procedures, as well as the Federal regulations and guidances related to clinical research.”

Useful Links:
» http://www.youtube.com/playlist?list=PL1ay9ko4A8skercaqlHgd9E4-qP96StRc

MATERNAL-FETAL MEDICINE FELLOWSHIP TRAINING PROGRAM
This three-year training program co-sponsored by Wayne State University and the Perinatology Research Branch of NICHD is housed at the Detroit Medical Center and the Wayne State University campus in Detroit, Michigan. Fellows in this program learn specialized patient care in maternal-fetal medicine, prepare for a career in academic medicine, and take a multi disciplinary approach to complications in pregnancy.

Useful Links:
» http://www.nichd.nih.gov/about/org/dir/osd/tp/mfmftp/Pages/overview.aspx
» http://www.med.wayne.edu/prb/fellowship_training_program.html?mainMenuItemToSlide=1

(continued on page 9)
Useful Links for NICHD Clinical Fellows
(continued from page 8)

MEDICAL GENETICS TRAINING PROGRAM
This fellowship is offered through the Program in Developmental Endocrinology and Genetics (PDEGEN) with the NIH Medical Genetics fellowship program and can be combined with training in Pediatric Endocrinology and/or internal medicine and Endocrinology.

Useful Links:
» [http://www.nichd.nih.gov/about/org/dir/osd/tp/mgtfp/Pages/overview.aspx](http://www.nichd.nih.gov/about/org/dir/osd/tp/mgtfp/Pages/overview.aspx)

NICHD-NIDDK INTERINSTITUTE ENDOCRINE TRAINING PROGRAM
This Interinstitute Endocrine Training Program (IETP) contains participants from the NICHD, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), and the National Institute of Dental and Craniofacial Research (NIDCR). As stated in the NICHD Division of Intramural Research (DIR) overview of the program, “Clinical training occurs largely in the first year. At any one time, fellows are responsible for five to ten patients on the inpatient service of the NIH. The trainee has complete responsibility for all aspects of the patient’s care, under the supervision of the endocrine faculty. Fellows make daily rounds, discuss patients with the attending physicians, and participate in management decisions related to both patient care and clinical investigation… The remaining two years are spent primarily in laboratory or clinical research under the direction of a senior investigator in one of the several endocrinology branches of the NIH. During this research period, active clinical experience continues through two weekly continuity outpatient clinics and participation in clinical conferences.”

Useful Links:
» [http://www.nichd.nih.gov/about/org/dir/osd/tp/iietp/Pages/overview.aspx](http://www.nichd.nih.gov/about/org/dir/osd/tp/iietp/Pages/overview.aspx)

(continued on page 10)
Useful Links for NICHD Clinical Fellows
(continued from page 9)

PEDIATRIC ENDOCRINOLOGY TRAINING PROGRAM
This three-year program provides training in clinical patient management and guidance in the development of research skills. The program is based at the NIH Clinical Research Center in Bethesda, MD, although multiple other institutes participate, including The Johns Hopkins University, Children's National Medical Center, and Georgetown University (GU), the co-sponsoring institute.

Useful Links:
» [http://www.nichd.nih.gov/about/org/dir/osd/tp/peitp/Pages/overview.aspx](http://www.nichd.nih.gov/about/org/dir/osd/tp/peitp/Pages/overview.aspx)
» [http://pe.nichd.nih.gov](http://pe.nichd.nih.gov)

REPRODUCTIVE ENDOCRINOLOGY AND INFERTILITY TRAINING PROGRAM
The Reproductive Endocrinology and Infertility Training Program is a graduate medical education program that aims to advance basic, translational, and clinical science in reproduction by training clinicians to be researchers and future leaders in the field of reproductive endocrinology. The program accepts applications through the Society for Reproductive Endocrinology and Infertility ([http://www.socrei.org/REIApplication](http://www.socrei.org/REIApplication)).

Useful Links:
» [https://www.nichd.nih.gov/about/org/dir/osd/tp/reitp/Pages/overview.aspx](https://www.nichd.nih.gov/about/org/dir/osd/tp/reitp/Pages/overview.aspx)
» [http://www.socrei.org/REIApplication](http://www.socrei.org/REIApplication)
NICHD FIGS Grants Incentives, Check Them Out!

The objective of the NICHD Fellows Intramural Grants Supplement (FIGS) program is to encourage fellows in the Division of Intramural Research to apply for competitive funding from intramural NIH or outside organizations and agencies, in order to develop their skills in grantsmanship, and in support of their career development. Award recipients are also contributing to the DIR by bringing in additional funding and resources, and as such merit recognition from the Institute.

ELIGIBILITY:
Postdoctoral, visiting, and clinical fellows

TERMS:
- The grant for which the fellow applies must be for a competitive award of $30,000 or more
- The fellow must be the primary applicant on the grant application; or, in exceptional cases, the co-investigator

AWARDS:
For submissions, they must be made through the Office of the Scientific Director (OSD) and signed off on by the Scientific Director prior to going forward (see NICHD Grants Administration Policy). The fellow must provide confirmation of receipt of the application by the awarding agency to the Office of Education/OSD/DIR/NICHD.

A $250 one-time stipend increase (limited to 2 applications maximum per year), processed at the time of the fellow’s renewal.

For applications that result in an award, the fellow receives a one-time $1,000 stipend increase.

All stipend increases will be funded centrally through the OSD, typically at the time of the fellow’s renewal. In the case of a trainee on an FTE, a one-time award will be made, in lieu of the stipend increase, and subject to approval of the award justification by the Office of Human Resources, NIH.

Note: In the case of the Pharmacology Research Associate Program (PRAT) offered through NIGMS, FIGS applies only if the application results in an award; no supplement will be given for applications.

RESOURCES:
Fellows are encouraged to consult the OITE web site for a list of potential funding sources. In addition, http://sciencecareers.sciencemag.org/funding through Science Careers lists many grant opportunities. Note that a fellow in the intramural program of NIH may not be eligible for all awards, and the fellow should consult with the funding agency to determine his or her eligibility in advance of submitting an application. Certain funders may be ineligible as well, because of their intellectual property clauses (IP) or because of potential conflicts of interest. Fellows may also consult the NICHD Office of Education for guidance.
August Announcements

CONTINUE PREPARING FOR YOUR GRANTS SUBMISSIONS:
MOCK STUDY SECTIONS

Planning to apply for a NIH grant, and want to learn what happens to your application after you hit “SUBMIT”? In partnership with NICHD Division of Extramural Research, the Office of Education is offering a workshop for our intramural fellows on Tuesday, September 17th, from 9 am to 12 noon.

NICHD Program Officers, Drs. Susan Taymans and Stuart Moss
NICHD Scientific Review Officer, Dr. David Weinberg

As you prepare for your academic careers—working towards securing funding for your research program, this workshop will cover how a study section works, the roles of program officers and scientific review officers and how they can be helpful to you, and the process after your grant is reviewed. To gain an understanding of the distinctions among grant applications, the kinds of scientific comparisons that are made, and how scoring is modified based on the discussion, it will also include a mock study section with six reviewers, scoring three types of NIH applications: K99/R00, R01, and R03. In addition to three experienced reviewers, two postdocs and one Assistant Clinical Investigator from NICHD will participate in the mock session.

Note there are 40 spots available, if you would like to attend, please send Yvette Pittman (yvette.pittman@nih.gov) an email.
August Events

THURSDAY, AUGUST 8, 9 AM – 3 PM
Summer Poster Day for summer interns
Natcher Conference Center (Building 45)
More info at https://www.training.nih.gov/summer_poster_day

THURSDAY, AUGUST 22, 12 – 1 PM
“Lunch and Chat Session: Preparing for Industry Careers”
Brad Fackler, MBA / OITE

After completing your training at NIH, are you thinking of pursuing a career in industry?
The Office of Education is offering a brown bag lunch session with Brad Fackler, OITE’s Industry Career Advisor. This is a great opportunity for you to learn about the application process, tips for resume and cover letter writing, and job searching strategies for industry careers. Also, you can learn what fellows could do throughout their training to prepare for the competitive job market, and of course, hear firsthand what OITE’s Career Services can offer you while preparing to obtain a job in industry.

If you would like to attend, please send Yvette Pittman (yvette.pittman@nih.gov) an email.
ACTUALLY, MY PRINCIPAL INVESTIGATOR AND I HAVE A GREAT RELATIONSHIP.

IN FACT, JUST THE OTHER DAY HE SAID I WAS HIS "P.F.F."

YOU MEAN, "B.F.F.?"

"POSTDOC FELLOW FOREVER."