Introduction to NIH funding opportunities and grant-writing (a work in progress...)

Tara McLaughlin, PhD, MPE,
Senior Scientist/Grant Writer (545-5065)
Hartford Hospital Research Program
March 1, 2010
Two recurring themes of grant application process

- 1. Forms (too many)
- 2. Time (not enough)
- Start planning and thinking early
- Forms, forms, forms....
  - Research plan
  - Human subjects
  - Facilities, resources
  - Letters of support
  - Biosketches
  - Budgets.....etc, etc

PLUS THEME #3: TEAM WORK IS ESSENTIAL
...Research Admin can help
Today’s talk….

- Introduction to various NIH funding types
- Examples
- NIH review criteria
- Select application components
- Scoring
- Tips, websites and other interesting “FYIs” along the way
OER Home page....a good way to spend a snow day (?)
This subpage ([http://grants.nih.gov/grants/guide/](http://grants.nih.gov/grants/guide/)) also lets you search for current funding opportunities, and
.....subscribe to get weekly funding updates via email
Introduction to NIH funding opportunities.....

- Adapted from NIH Office of Extramural Research: [http://grants1.nih.gov/grants](http://grants1.nih.gov/grants)

- NIH funds grants, cooperative agreements, and contracts – HH has been involved in applications for all of these


- **Cooperative Agreement (U series)**: There will be “substantial Federal scientific or programmatic involvement”- I.E., after the award, NIH scientific or program staff will “assist, guide, coordinate, or participate in project activities”.

- **Grant**: Provides money, property, or both to carry out an approved project or activity- no substantial NIH programmatic involvement with the recipient during the performance of the funded activities.

- NIH awards grants specifically for research and also research-related activities, including: construction, training, career development, conferences, resources.
Example Contract.....

- **National Cancer Institute** (http://rcb.cancer.gov/rcb-internet/appl/rfp/published_rfps.jsp)

- **“Tools for Electronic Data Acquisition”** (N02PC05001-78)
  - Due: 04/05/2010, Issued: 02/03/2010

- **BRIEF DESCRIPTION OF SUPPLIES OR SERVICES**
  - “The purpose of this contract is to use currently available electronic information to expand the spectrum of surveillance data available to researchers, public health practitioners, policy makers, clinicians, and the public. The overall objective of this project is to develop a robust, production level software application/tool that will access electronic data, not currently obtained and autocoded by SEER registries, transmit it to a SEER registry as an input to the registry’s data management system, be processed by the system and auto-populate data fields in the registry database. This data will then be available for analysis and reporting.”

- The RFP is a 73 page document that clearly spells out deliverables, plans (quality assurance, data collection), contractual information, evaluation criteria for awards, etc.

- Evaluation: Technical, cost, past performance and Small Disadvantaged Business (SDB) participation
NCCCP – HH example of contract application (with NCI)
Example Cooperative Agreement....
Pharmacogenomics Research Network (PGRN), U01/U19

---

**Purpose....**
- Research groups compete to become part of the Pharmacogenomics Research Network (PGRN), create network resources that serve the entire PGRN.
- **PGRN** - a consortium of interdisciplinary groups, conduct research on the genetic basis of variable drug responses, both therapeutic and adverse.
- **Scientific objectives:**
  - define pressing problems re safe and effective use of medications,
  - establish cross-disciplinary research groups,
  - apply genetic and genomic methods to sample collections,
  - discover and replicate variation in critical genes and biological pathways,
  - clarify the functional consequences of genetic variation in terms of specific drugs,
  - understand the clinical implications of genotyping to predict drug responses.

**Key Dates**
- Release Date: January 30, 2009
- Letters of Intent Receipt Date: May 2, 2009
- Application Receipt Date: June 2, 2009
- Peer Review Date: November 2009
- Council Review Date: January 2010
- Earliest Anticipated Start Date: April 1, 2010
- Additional Information To Be Available: February 1, 2009
- Expiration Date: June 3, 2009

**Why U series:** Substantial involvement of an NIH PGRN program director- establish steering committee, facilitate communication within network, plan network activities, work with PI to accommodate external evaluation of project

More info on PGRN:
http://www.nigms.nih.gov/initiatives/PGRN/RFAinfo
PGRN is very interesting, many diverse areas...
PGRN research areas continued

Mark Ratkin, M.D.  Pharmacogenomics of Anticancer Agents
Dan M. Roden, M.D.  Pharmacogenomics of Arrhythmia Therapy
Alan R. Shuldiner, M.D.  The Amish Pharmacogenomics of Anti-Platelet Intervention Study
Richard Weinsilboum, M.D.  Pharmacogenetics of Phase I Drug Metabolizing Enzymes
Scott Weiss, M.D.  Pharmacogenetics of Asthma Treatment

Alumni, 2000-2005
Daniel T. O'Connor, M.D.  Autonomic Pharmacodynamic Pharmacogenomics
Julio Lichino, M.D.  UCLA Pharmacogenetics and Pharmacogenomics Research Group
Mark Rothstein, JD  Pharmacogenomics & Minority Populations

Network Publications (allow connection)
This PubMed-linked listing is a compilation of publications citing the network awards.
External Scientific Panel for the PGRN, 2006-present
Governing Structure, 2007-present
Archives

This page last updated August 25, 2009
Grants, grants, grants.....

- NIH funds 204 different kinds of research-related grants- “activity codes”

- **Main types of grant funding:**
  - [Research Grants](#) (R series)
  - [Career Development Awards](#) (K series)
  - [Research Training and Fellowships](#) (T & F series)
  - [Program Project/Center Grants](#) (P series)
  - [Resource Grants](#) (various series)
  - [Trans-NIH Programs](#)
NIH announces availability of funds for grant programs through funding opportunity announcements (FOAs) in the NIH Guide for Grants and Contracts and on Grants.gov.

NIH supports two types of research: specialized studies requested through specific FOAs and investigator-initiated studies requested through general “Parent FOAs”.

Parent announcements, program announcements (PAs), and requests for applications (RFAs) are all types of FOA.

PAs and RFAs differ on receipt dates, $$, review structure, specificity of topic, offer different advantages to applicant.…. 

OER website very helpfully includes a link to a glossary
Common grant programs: Research Project Grant (R01)

- Support a specific research project performed by the named investigator(s) in an area representing his/her specific interest and competencies
- Can be investigator-initiated (uses “Parent R01”): I.e., a good idea, no specific program requirements- but research plan must relate to the stated program interests of one or more of the NIH Institutes and Centers based on descriptions of their programs.
- Program announcements and RFAs may also use R01
- NIH's most commonly used grant program
- No specific dollar limit unless specified in FOA
- Advance permission required for $500K or more (direct costs) in any year
- Generally awarded for 3 -5 years

In 2008, NIH reviewed 19,422 new R01s- 19% funded
R01 Research Plan

- Introduction (required for a resubmission or revision application) is limited to 1 page.
- Specific Aims- limited to 1 page.
- Research Strategy, including tables, graphs, figures, etc limited to 12 pages.

New page limits for research strategy in 2010—generally 6 or 12 pages, depending upon FOA—previously had been 12 or 25 pages

"Enhancing peer review"
NIH Small Grant Program (R03)

- Provides limited funding for a short period of time to support a variety of projects
  - pilot or feasibility studies, collection of preliminary data, secondary analysis of existing data, small/self-contained research projects, development of new research technology, etc.
- Limited to two years of funding
- Direct costs generally up to $50,000 per year
- Not renewable
- No preliminary data are required (may be included)
- The Research Strategy may not exceed 6 pages.

In 2008, NIH reviewed 2,930 new R03s- 22% funded
Example R03

- **Title:** Indo-U.S. Vaccine Action Program (VAP) Small Research Grant Program (R03)


- **Announcement Type**
  This Funding Opportunity Announcement (FOA) is a **reissue** of [PA-07-093](http://grants.nih.gov/grants/guide/pa-files/PA-07-093.html).

- **Key Dates**
  - **Release/Posted Date:** February 26, 2010
  - **Opening Date:** May 16, 2010
  - **Letters of Intent Receipt Date(s):** Not Applicable
  - **Application Due Date(s):** Standard dates apply, please see [http://grants1.nih.gov/grants/funding/submissionschedule.htm](http://grants1.nih.gov/grants/funding/submissionschedule.htm)
  - **Peer Review Date(s):** Standard dates apply, please see [http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewaward](http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewaward)
  - **Council Review Date(s):** Standard dates apply, please see [http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewaward](http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewaward)
  - **Earliest Anticipated Start Date(s):** Standard dates apply, please see [http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewaward](http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewaward)
  - **Expiration Date:** May 8, 2013
Example R03 continued

- Support collaborative vaccine-related research projects to reduce the burden of infectious diseases in India, the U.S., the South Asian region and globally.
- Applications from organizations/institutions that propose to research through well-established collaborations with Indian investigators on the following: dengue, influenza (including avian influenza), HIV/AIDS, and tuberculosis.
- Basic, translational, clinical, or epidemiological vaccine research may be proposed. Clinical trials not supported.
- Possible research topics:
  - Discovery, demonstration of the proof of principle, development of novel manufacturing processes, evaluation of the safety and efficacy and demonstration of the effectiveness of the use of new and improved vaccines
  - New vaccine delivery technology
  - Epidemiology of disease in the human population.
- Research strategy- 6 pages
- Budget – direct costs up to $50,000 per year for two years
Exploratory/Developmental Research Grant (R21)

- Encourages exploratory/developmental research
- Supports early and conceptual stages of project development
- Exploratory, novel studies that break new ground or extend previous discoveries toward new directions or applications.
- High-risk, high-reward studies that may lead to breakthroughs, novel techniques, agents, methodologies, models or applications
- Will impact biomedical, behavioral, or clinical research
- Can be investigator initiated or submitted in response to FOA
R21 continued....

- Project period of up to two years
- The combined budget for direct costs for the two year project period may not exceed $275,000. No more than $200,000 may be requested in any single year.
- Research Strategy may not exceed 6 pages.
- Preliminary Data not required

....but critical for R01!

In 2008, NIH reviewed 10,642 new R21s- 16.5% funded
Example R21....

- “Secondary Analyses in Obesity, Diabetes, Digestive and Kidney Diseases- PA-09-131”

- National Institute of Diabetes and Digestive and Kidney Diseases

- Example of how ....
- **FOA may be reissued:** Reissue of PA-05-094 previously released April 22, 2005.
- **Updates may be posted:** “The following update relating to this announcement has been issued:
  - **March 13, 2009** - This PA has been reissued as (PA-09-131).”

- **FOA have expiration dates:**
  - Release/Posted Date: March 13, 2009
  - Opening Date: May 16, 2009 (Earliest date an application may be submitted to Grants.gov)
  - Expiration Date: May 8, 2012

- **Check back to original FOA for notices**

- **Key dates:** some FOA follow standard NIH submission dates posted to website, other announcements list the due dates specifically
Purpose of PA-09-131 was to support.....

- Analysis of existing data sets relevant to diabetes and endocrine and metabolic diseases; digestive diseases and nutrition, including obesity and eating disorders; and kidney, urologic, and hematologic diseases.

**Scope:**

- a) secondary analyses of data related to the epidemiology of disease areas of NIDDK;
- b) important and/or innovative hypotheses explored through analysis of existing data sets;
- c) secondary analyses designed to inform and support subsequent applications for individual research awards;
- d) rapid analyses of new databases and experimental modules to inform the design and content of future studies;
- e) the archiving of datasets to be made publicly available for research purposes related to disease areas of NIDDK, including both epidemiological studies and multi-center clinical trials.

HH team from HH Brownstone submitted to this PA in October, 2009: Expand and perform secondary analysis on special database from HH Brownstone Clinic, focus on quality care indicators for patients with diabetes.
Scored review criteria (5) for Research, Research Centers, SBIR/STTR:

- **1. Significance.** Address an important problem or a critical barrier to progress in the field? Improve scientific knowledge, technical capability, and/or clinical practice?

- **2. Investigator(s).** Suitability of PD/PIs, collaborators, and other researchers. Experience, training appropriate? If established, is there an ongoing record of accomplishments, advancement in the field(s)? Integrated expertise for multiple PIs- complementary team?

- **3. Innovation.** Does it challenge and seek to shift current research or clinical practice paradigms- novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions?

For R01: **New Investigator**- PI who has not yet competed successfully for a substantial, competing NIH research grant is considered a New Investigator. **Early Stage Investigator (ESI)**- Within 10 years of completing his/her terminal research degree or is within 10 years of completing medical residency.
Criteria, continued....

4. Approach. Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims? Are potential problems, alternative strategies, and benchmarks for success presented?

Clinical research: 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children (must be justified in terms of the scientific goals and research strategy proposed)

5. Environment. Will the scientific environment contribute to the probability of success? Institutional support, equipment and other physical resources? Are there unique features of the scientific environment- access to special subject populations, or collaborative arrangements?

Criteria are scored individually and considered in overall score- other criteria also possible in FOA- listed towards the end of the FOA
Some Key Application Components (R01): Research Plan

- **Introduction**
  - Usually only for Resubmission or Revision; limited to 1 page
  - Resubmission: Intro summarizes additions, deletions, changes, includes response to issues/criticisms raised in review
  - Revision: Request support for expansion of scope for a funded project - Intro addresses how expansion will influence specific aims, research design and methods of current grant

- **Specific Aims**
  - Concise statement of project goals: list specific objectives- i.e., test a hypothesis, develop a technology, solve a specific problem- state impact research will have on the field
  - Limit 1 page
Research Plan, cont.

- **Research Strategy (12 pages for R01)**
  - Significance
  - Innovation
  - Approach
    - Methods
    - Preliminary Data
    - Progress Report (for Renewal and Revision)

- **Inclusion Enrollment Report (if applicable)**
  - If renewal or revision and if clinical research must address enrollment of subjects and ethnicity/race, sex/gender

- **Human Subjects**
  - Protection of Human Subjects: Involvement, Protection against risks at research sites (IRB), Sources of data, Special protections for children
  - Inclusion of women and minorities: if not included why?
  - Targeted/Planned Enrollment
  - Inclusion of Children: if not included why?
Preliminary Data.....

- Usually considered critical for R01
- Results of pilot study or previous work of PI that supports the present application
- Your publications, those of other researchers, unpublished data, or some combination
- Establishes applicant’s experience and competence, provide support for the study hypotheses and research design
- HH Small Grant: Competitive program, one goal is to provide seed money to collect preliminary data in support of further grant application

For New Investigators: less importance is placed on preliminary data. NIH is on the lookout for new investigators- advantageous to self identify in the application!
Project summary/Abstract
- Summary of proposed activity suitable for the public, stand-alone description: states long term objectives and specific aims, research design and methods - make reference to how project addresses mission of NIH
- Must do all of the above in 30 lines of text

Project Narrative
- Two or three sentence description of relevance of project to public health

Facilities and other resources
- Laboratory, Animal, Computer, Office, Clinical, Other – capacities, proximity, availability for project
- Are there unique features of scientific environment that will increase project’s chances for success?
- Institutional support of and investment in PI’s development if an ESI – e.g., training, administrative support, protected time for research with salary support

Equipment
- List major items of equipment available for project - location, capabilities
Scoring: New procedures....

Beginning with the summer 2009 review cycle, assigned reviewers have been instructed to score each of five review criteria, and the overall impact/priority of each application, on a 9-point rating scale. Scoring and Review Changes: Enhancing Peer Review at NHLBI - Scoring and Review Changes - Microsoft Internet Explorer. New Scoring System:

<table>
<thead>
<tr>
<th>Impact</th>
<th>Score</th>
<th>Descriptor</th>
<th>Additional Guidance on Strengths/Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>1</td>
<td>Exceptional</td>
<td>Exceptionally strong with essentially no weaknesses</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Outstanding</td>
<td>Extremely strong with negligible weaknesses</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Excellent</td>
<td>Very strong with only some minor weaknesses</td>
</tr>
<tr>
<td>Medium</td>
<td>4</td>
<td>Very Good</td>
<td>Strong but with numerous minor weaknesses</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>Good</td>
<td>Strong but with at least one moderate weakness</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>Satisfactory</td>
<td>Some strengths but also some moderate weaknesses</td>
</tr>
<tr>
<td>Low</td>
<td>7</td>
<td>Fair</td>
<td>Some strengths but with at least one major weakness</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>Marginal</td>
<td>A few strengths and a few major weaknesses</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>Poor</td>
<td>Very few strengths and numerous major weaknesses</td>
</tr>
</tbody>
</table>

Non-numeric score options: NR = Not Recommended for Further Consideration, DF = Deferred, AB = Abstention, CF = Conflict, NP = Not Present, ND = Not Discussed.

Minor Weakness: An easily addressable weakness that does not substantially lessen impact
Moderate Weakness: A weakness that lessens impact
Major Weakness: A weakness that severely limits impact

Applications that are not discussed at the meeting will not be given an overall impact/priority score, but the applicant, as well as NIH staff, will see the preliminary scores for each of the review criteria as additional feedback on their summary statement. The Scoring System and Procedure document was provided as guidance to all reviewers.
Rationale for changes....

Rationale for the New NIH Grant Application Scoring System

The prior scoring system of 1.0 to 5.0 in 0.1 increments served NIH well for many years, but its weaknesses became increasingly evident as the quality and quantity of applications increased and NIH budgets to fund grant applications tightened. The new scoring system is being implemented to address the following issues:

- For even the most experienced reviewers, it is difficult to make 41 reliable discriminations of application merit. Based on measurement science, prior experience, and feedback from various constituencies, a 9-point rating scale with descriptors associated with each rating option was adopted.
- Reviewer ratings became increasingly positive, compressing the score range, and effectively reducing the usefulness of scores for NIH funding decisions. In the new scoring system, the descriptors associated with each rating were designed to encourage use of the full scoring range.
- To provide additional feedback to applicants, program staff, and other consumers of the summary statement, assigned reviewers also provide rating of the specific review criteria using the same 9-point scale.

"Enhancing peer review"
Writing tips.....

http://grants.nih.gov/grants/writing_application.htm

- Follow instructions in FOA regarding organization of proposal
- Be organized and logical: Assess your thought process- the parts of the application should fit together.
- Make one point in each paragraph. Keep sentences to 20 words or less. Write simple, clear sentences.
- Before writing, think about budget- how is it related to research plan? Everything listed must be justified by the work you've proposed to do.
- Use the active, rather than passive, voice. For example, write "We will develop an experiment," not "An experiment will be developed."

Inverted pyramid structure: Starts out with broad topic, narrows down concepts, point out “holes” in the literature that your project will address
Avoid jargon, be consistent with terms, references and writing style.

Spell out all acronyms on first reference

Use sub-headings, short paragraphs, bullets and numbered lists for effective organization

Use diagrams, figures and tables to assist in conveying complex information

Have an independent expert, neutral third-party review the application

If more than one investigator is contributing to the writing, have one overall editor.

Zero tolerance for typographical errors, misspellings, grammatical mistakes or sloppy formatting - reflects poorly on the PI’s potential to carry out the research

Follow your passion…..easier to prepare a grant if you care about the topic
Finally:
Team work and planning are crucial.

- Process is complicated- many aspects not touched upon today.....
  - Biosketches
  - Budgets
  - Letters of support
  - Administrative
- RAdmin can help
  - Grant-writer
  - Scientists
  - Grants administrators
- We also help with other research grant applications- e.g., foundations, investigator initiated pharmaceutical trials

CONTACT RESEARCH ADMIN EARLY