

# Development of a Researcher

- What's New At NIH
- Types of Awards
  - Training
  - Research
- **Application Tips**

# What's New Now

- Publication Public Access
- Big Data & Data Sharing
- BRAIN Initiative
- NIDA – Cannabis / Development
- Collaborative Research on Addiction
  - ABCD – 10,000 for 10 years
  - Brain Imaging every other year
  - Data release soon as “clean”

# What's New Soon

## NOT-OD-15-103

“Enhancing Reproducibility through Rigor and Transparency” – Jan 2016

- Scientific Premise
- Rigorous Experimental Design
- Consideration of Sex and Other Relevant Biological Variables
- Authentication of Key Biological and/or Chemical Resources

# What's New Soon

## NOT-OD-15-103

“NIH expects applicants to describe the general strengths and weaknesses of the prior research being cited by the investigator as crucial to support the application. It is expected that this consideration of general strengths and weaknesses could include attention to the rigor of the previous experimental designs, as well as the incorporation of relevant biological variables and authentication of key resources. “

“For example, basing one's proposed research on previous publications that lacked statistical power, were not blinded, lacked detail on the sex of animals or authentication of cell lines would be considered a weakness of the application if it does not identify these weaknesses and propose ways to improve going forward. Likewise, conclusions drawn from prior research that used a small sample size may not adequately support the next phase of research, such as moving to a higher species of animals or to humans.”

*Grant Application ≠ Publication*

*Grant Application ≠ Research*

“Writing winning proposals is  
different from building  
winning hardware

Albert D. Wheelon

# NIH Mission Statement

“NIH’s mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability.”

*Critical Assumption:*

*Fundamental mechanism of a disease =  
Rational target for intervention  
(prevention or treatment)*

# IMPACT SCORE

Priority Score => IMPACT/Priority Score  
Score Range 10 (Best) - 90 (Worse)

Reflects the reviewers' assessment of the *likelihood* for the project to exert a *sustained, powerful influence* on the research field(s) involved

## WHY IMPACT ?

### Peer Review Regulations

“In carrying out its review under § 52h.7, the scientific peer review group shall assess the overall impact that the project could have on the research field involved, taking into account, among other pertinent factors...(review criteria)”

# Impact Scores

## Overall Impact:

The likelihood that a project will have a sustained and powerful influence on science (and/or clinical practice and/or technological developments?)

Overall Impact	High	Medium	Low
Score	1 2 3	4 5 6	7 8 9

## Evaluating Overall Impact:

Consider the 5 criteria: significance, investigator, innovation, approach, environment (weighted based on reviewer's judgment)

e.g. Applications are addressing a problem of high importance in the field. May have some or no technical weaknesses.

e.g. Applications may be addressing a problem of high importance in the field, but weaknesses in the criteria bring down the overall impact to medium.

e.g. Applications may be addressing a problem of moderate importance in the field, with some or no technical weaknesses

e.g. Applications may be addressing a problem of moderate/high importance in the field, but weaknesses in the criteria bring down the overall impact to low.

e.g. Applications may be addressing a problem of low or no importance in the field, with some or no technical weaknesses.

12/13/2012

5 is a good medium-impact application, and the entire scale (1-9) should always be considered.



# NIH Peer Review (aka Study Sections)

- Original Mission – Screen out poor science (more \$\$ than applications)
- Culture of Skepticism – What could go wrong, NOT how good it could be
- Dynamic - Innovation vs. Fear of Failure

# Application Structure

Significance – **Gap** or **Controversy**

(not discovery science = just see what happens)

Aims – What will you **RESOLVE**

Hypotheses – What will you **TEST** ?

Approach – How will you **MEASURE** it ?

Interpretation – **Alternative Outcomes & Limitations**

# IMPACT V. 2.0

Unsettle Presumptions

Defamiliarize the Familiar

Reveal what is going on beneath and behind appearances (Fundamental Knowledge)

Disorient

Propose ways to Reorient

Harvard Report on Education (quoted by David Brooks NY Times 1/27/09)

# SUCCES

- SIMPLE (Background)
- UNEXPECTED (Innovation)
- CONCRETE (Aims & Approach)
- CREDIBLE (CV)
- EMOTIONAL (Significance)
- STORY

“Made to Stick”  
C. Heath, D. Heath

# 5 P's of Successful Applications

- **PRODUCTIVITY**
  - Publications
  - Funding
- **PILOT DATA (Feasibility)**
  - Proof of Concept/Effect
  - Guarantee of detectable signal (avoid Type II Error)
  - Power Analysis
- **PRODUCTION (Factory)**
  - Mechanistic
  - Assembly Line (Directional)
  - No Negative Results
- **PERSEVERANCE (Funding)**
- **PROGRAM OFFICER (Friend)**

# 4 **F**'s of Successful Applications

- **FRESH**
- **FEASIBLE**
- **FACTORY**
- **FUNDING**

# Questions ??

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# What Else is Possible ?

- **Federal**
  - NIH Staff
    - Program
    - Review
    - Policy
  - SAMSHA – Services & Treatment Support
  - Military
  - Intelligence
  - USAJOBS.GOV
    - Check every day – only 5 day window for applications
- **Private Research**
  - “Big Pharma”
  - “Small Pharma”
  - Private Research Laboratories (Allen Brain Institute; HHMI)
- **Bio-Technology & BioEngineering**
  - Brain Computer Interface
  - Cognitive Training & Rehabilitation
- **Business & Finance**
  - Marketing
  - Leadership
- **Science Writing**



# What's New At NIH

- Budget
- BRAIN Initiative
- Public Access Policy
- Big Data & Sharing
- Application Tips

# DATA

Big Data to Knowledge (BD2K)  
FY14

Data Sharing / Open Access  
Human Connectome Project  
NIDA Supplements PAR-12-204

# Public Access Policy

NIH will delay processing of an award if publications arising from it are not in compliance with the NIH public access policy.

Effective July 1, 2012 for non-competing continuation grant awards

<http://publicaccess.nih.gov/>

Use My NCBI to enter papers onto progress reports. Papers can be associated electronically using the Research Performance Progress Report (RPPR), or included in the PHS 2590 using the My NCBI generated PDF report.

Create a My NCBI account using your eRA Commons ID, or link your current account with your eRA Commons account.

# Budget, Pay Lines, & Scores Oh My !



# F- Awards Pre/Post-Doctoral Training (NSRA /Kirschstein)

## TYPES:

F30 – Pre-Doctoral Dual Degree

F31 – Pre-Doctoral Types

- Diversity
- MD/Ph.D.
- Pharm.D./Ph.D
- Nursing

Training beyond usual degree program requirements

F33 – Senior Fellowship

Mostly Salary

- New Skills
- Pre-Doctoral
  - Training beyond usual degree program requirements
- Post-Doctoral
  - New Skills

Limited Research Funds

- Document source of research funds

<https://grants.nih.gov/training/extramural.htm>

# K- Awards Mentored/Career Development

## TYPES:

- Degree: Health Care or Research
- Subjects: Humans/Patients or Pre-Clinical
- Career Level:
  - Junior-Mentored, New Skills
  - Mid-Career
    - Buy Time from other duties (teaching/clinical)
    - Mentoring
    - New Skills
    - Not a substitute for research salary support
- ~~Senior~~

## Mostly Salary

- Major % Effort
- Cannot draw salary from other Federal research awards

## Limited Research Funds

- Document source of research funds

<https://grants.nih.gov/training/extramural.htm>

# Research Awards

## TYPES:

- R- Awards
  - R03 – Small Grant
    - \$75K - \$150K 1 -2 years
  - R21 – Exploratory/  
Developmental
    - \$275K over 2 years
  - R21/R33 Phased Innovation
  - **R01 – Gold Standard**
    - Typically 5 years
- Big Awards (P)
  - P01 – Program Project
  - P30 – Research Cores
  - P50 – Centers

## Salary & Research Funds

- Single or Multiple PI
- Consortia / Collaborations

## Budget

- Modular \$250K Direct Costs
- Need Permission if  
> \$500K Direct Costs

# Funding Opportunity Announcements

## TYPES:

- PA – Program Announcement
  - Broad focus
  - PAR – Special Review
  - PAS – Set aside of funds
- RFA – Request for Applications
  - Set aside of funds
  - Special Review
  - One Shot
  - Narrow focus

## Salary & Research Funds

- Single or Multiple PI
- Consortia / Collaborations

## Budget

- Modular \$250K Direct Costs
- Need Permission if > \$500K Direct Costs

**TIP: Always quote directly from FOA text, especially if special requirements or topics !! Reviewers not required to read PA's and may not read RFA in depth.**



# *INNOVATION*

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions?

Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense?

Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

# APPROACH

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project?

Are potential problems, alternative strategies, and benchmarks for success presented?

If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the project involves clinical research, are the plans for 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, justified in terms of the scientific goals and research strategy proposed?

# INVESTIGATORS

Are the PD/PIs, collaborators, and other researchers well suited to the project?

If Early Stage Investigators or New Investigators, do they have appropriate experience and training?

If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)?

If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project\*? (\*Moved from Approach)

# ***SIGNIFICANCE***

Does the project address an important problem or a critical barrier to progress in the field?

If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved?

How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

# Barriers to Innovation aka Challenges for Iconoclasts

- Perception -- seeing things for what they are instead of what past experience or other people say
- Fear -- fear of failure and fear of public ridicule
- Social Intelligence – “Everybody knows”...selling your ideas to non-iconoclasts

# REVIEW CRITERIA

Core criteria order:

(\* - receive individual score 1- 9)

**Significance\***

Innovation\*

Approach\*

Investigator(s)\*

Environment\*

Additional review criteria & considerations  
expanded