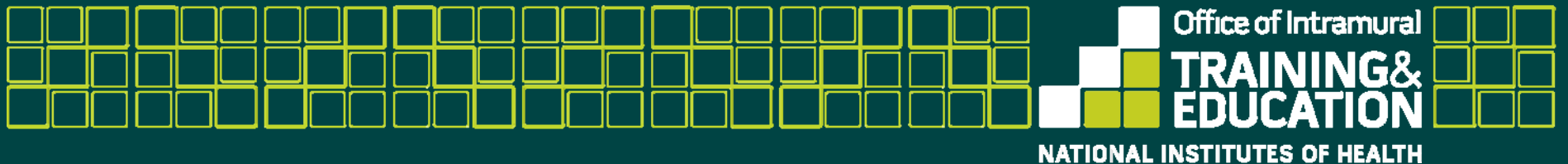
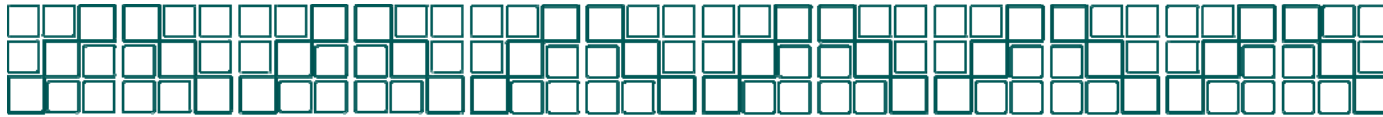


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# NIH Grants 101: Funding Mechanisms, Peer Review and Strategies for Success

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[milgrams@od.nih.gov](mailto:milgrams@od.nih.gov)





# Take Home Message

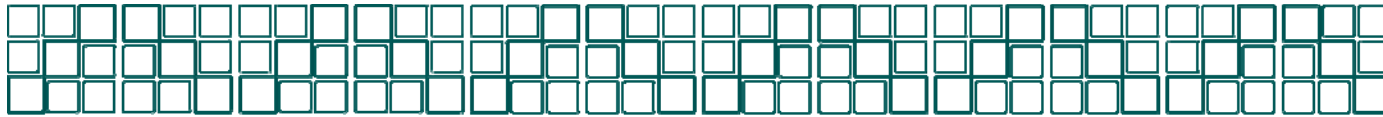
You will decrease your stress level  
and have more time to focus on  
science if you take the time to  
understand the grant writing process -  
- from first idea to final outcome

# Understanding NIH ([www.NIH.gov](http://www.NIH.gov))

- Main Federal Agency coordinating Nation's biomedical, behavioral, and social science research
- 27 Institutes or Centers
  - Different missions
  - Different budgets
  - Different activities
  - Different ways of doing things
- In addition to funding research, 21 NIH ICs have an intramural research program with basic and clinical research programs

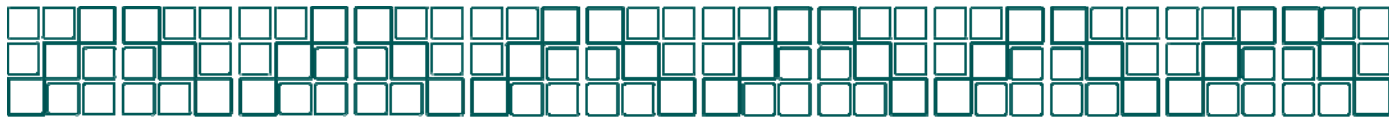
# Main Types of NIH Grants

- Research Training & Fellowships (T & F series)
- Career Development Awards (K series)
- Research grants (R series)
- Program project/center grants (P series)
- Trans-NIH Programs (Diversity supplements, GWAS studies, Director's Challenge, Loan Repayment Programs)

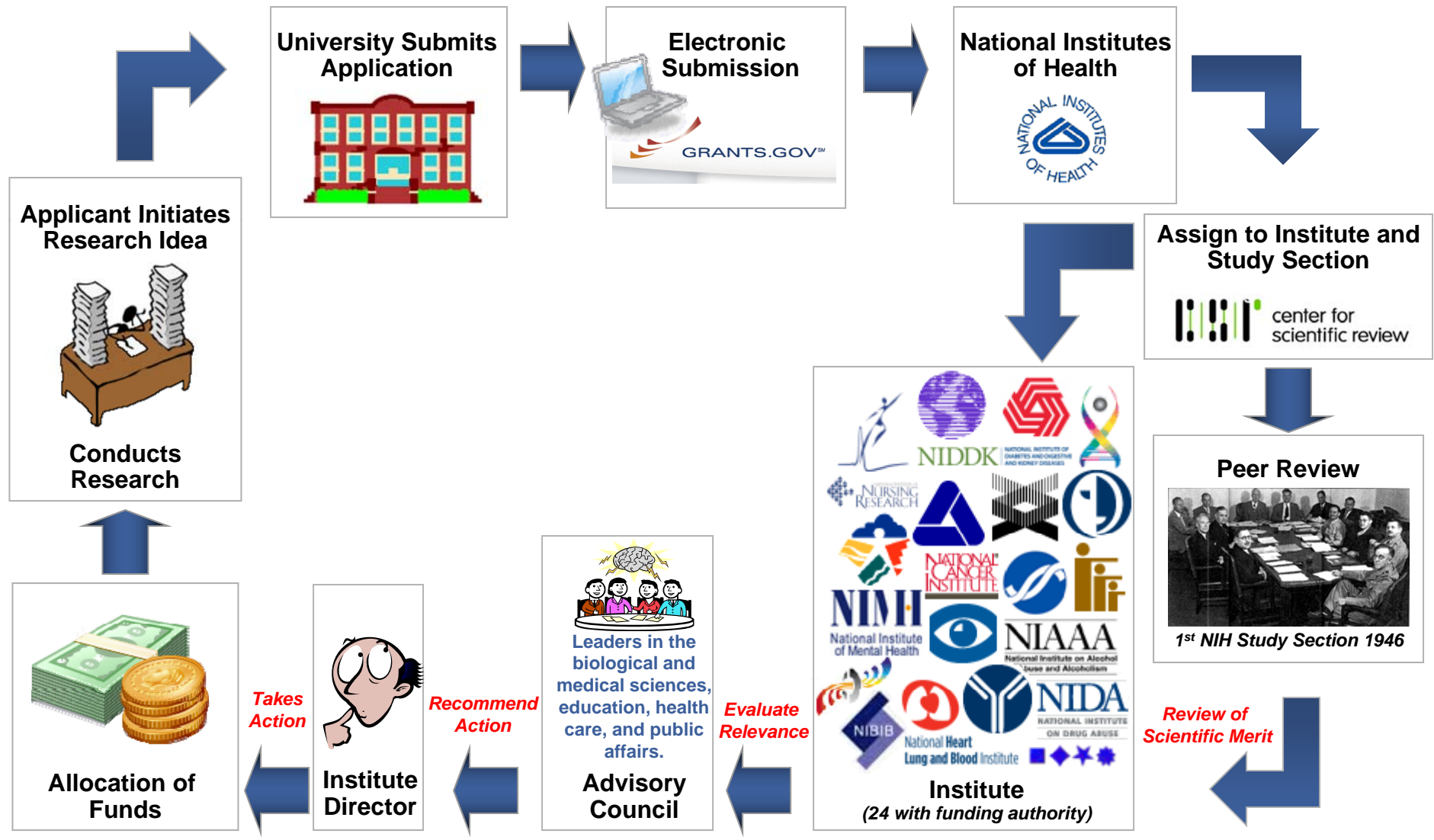


# Eligibility Issues

- Individual
  - From graduate students to senior investigators
  - Citizenship requirement for some but not others
  - Special criteria for new and early stage investigators (ESI)
  
- Institutional
  - Domestic, foreign, private, public, non-profit, for-profit are eligible to receive NIH funds with restrictions depending on the funding mechanism
  
- Just because you are eligible to apply for a specific grant does not mean you should apply for it

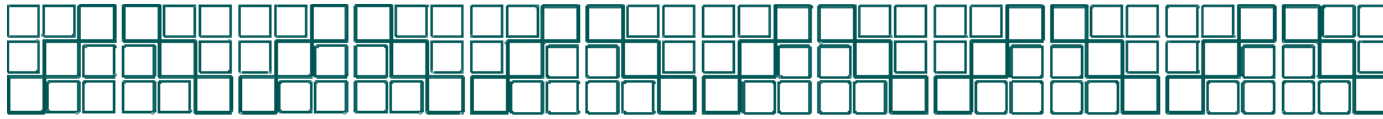


# The Big Picture

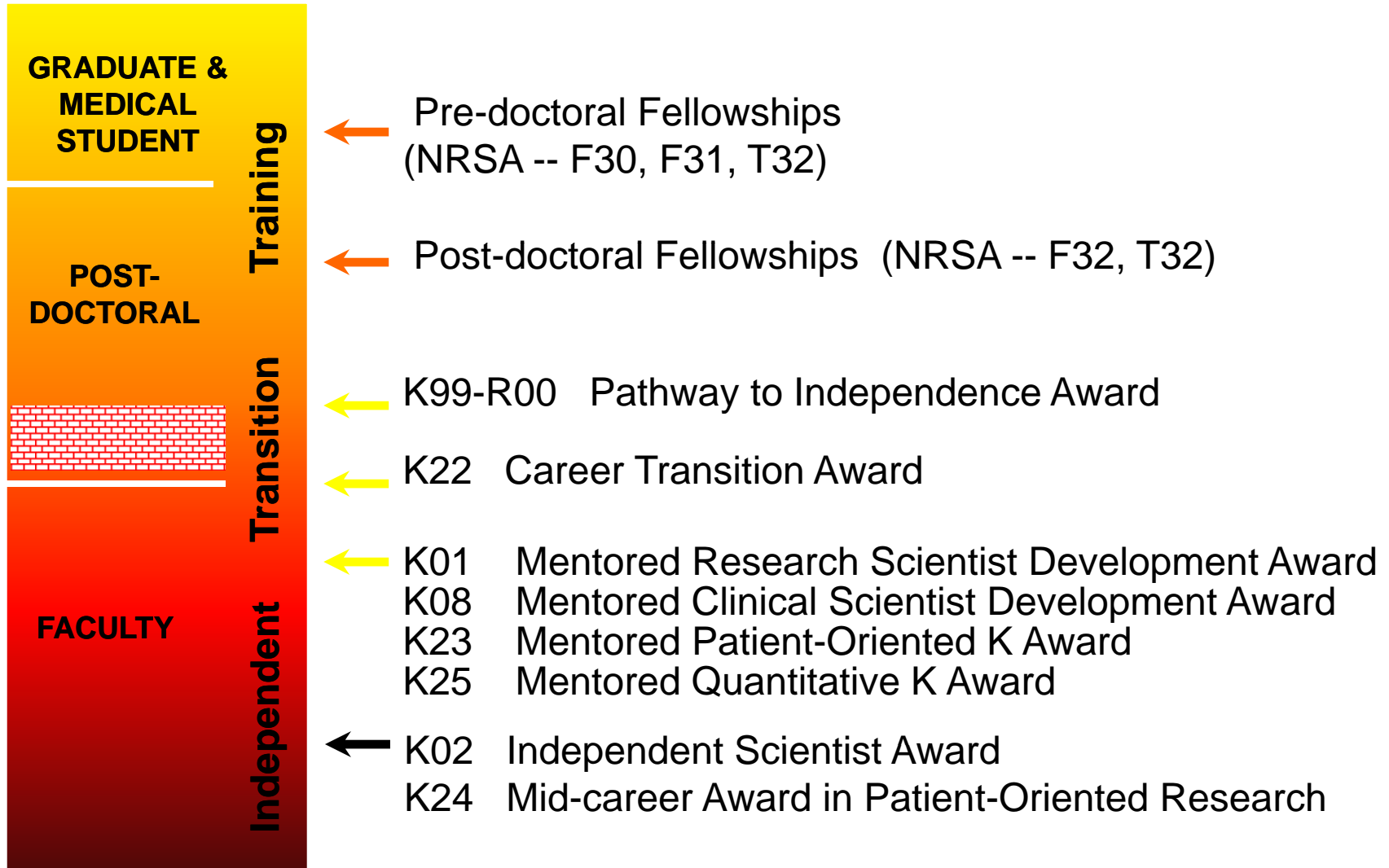


# Who Will You Interact With?

- Program Officer (PO)
  - Institute Staff
  - An important resource for applicants
  - Manages a portfolio of awarded grants
  - Monitors scientific progress made on grant
- Scientific Review Officer (SRO)
  - CSR or Institute Staff
  - Organizes and manages study section
  - Liaison between applicant and reviewers
  - Prepares summary statements
- Grants Management Officer



# Training and Career Development Awards



# Career Development Awards (K-awards)

- For basic scientists:

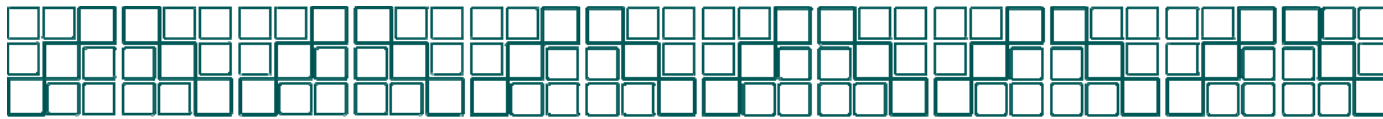
K01	Mentored Research Scientist Development Award
K02	Independent Scientist Award (for funded scientist)
K22	Career Transition Award
K25	Mentored Quantitative Career Development Award
K99	Pathway to Independence Award

- For clinician-scientists:

K02	Independent Scientist Award (for funded scientist)
K08	Mentored Clinical Scientist Development Award
K22	Career Transition Award
K23	Mentored Patient-oriented Career Development Award
K99	Pathway to Independence Award

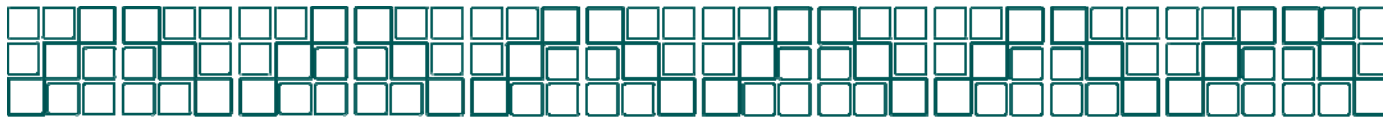
# Pathway to Independence Award (K99/R00)

- To help new researchers secure a tenure-track position and launch an independent research career
  
- Eligibility:
  - Basic or clinical doctoral degree (i.e., postdoc or equivalent)
  - Domestic extramural or intramural institutions
  - US citizens or non-citizens
  - No more than 5 years postdoctoral research
  - Cannot have held independent faculty-level position



# K99/R00 Details

- K99 mentored phase (1-2 years):
  - Supports mentored postdoctoral research training
  - Provides salary + research expenses (varies by IC)
  - 8% indirect costs
  
- R00 Phase (up to 3 years):
  - Requires tenure track or equivalent faculty position
  - Launch independent research program
  - \$249,000 total costs per year (direct costs + full indirect costs)
  - Start-up should not be decreased as a result

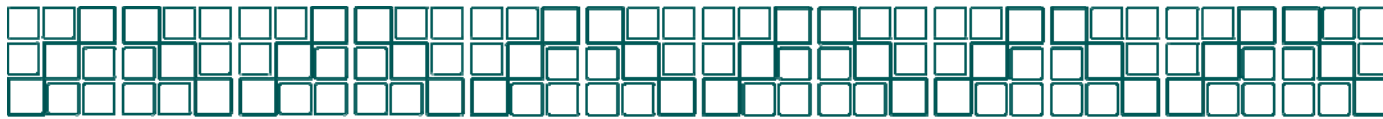


# Which K?

- Varying mechanisms with varying eligibilities, time limits, and guidelines. Some are used in many ICs while others are very limited
- To get started assess your eligibility using the NIH K KIOSK
- Follow up by contacting the appropriate NIH IC Program Officer

# NIH R Grants

- R01 Research Project Grant
- R03 Small Research Grant Program
- R13 Support for Conferences and Scientific Meetings
- R15 Academic Research Enhancement Award
- R21 Exploratory / Developmental Research Grant
- R41 Small Business Technology Transfer Grant
- R43 Small Business Innovations Research Grant

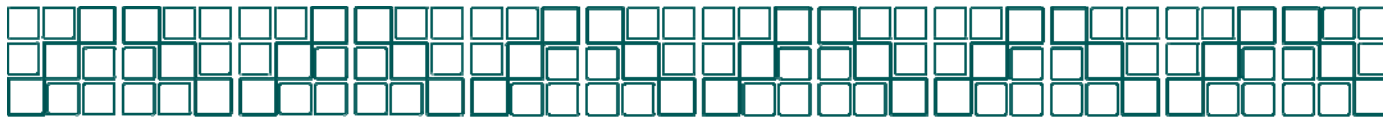


# Funding for New and Early Stage Career Investigators

- NIH policy is to fund R01s of New Investigators and ESIs at more favorable paylines
- Paylines and relative advantage differ by NIH Institute; 3%-10% more generous
- Advice for New and Early Stage Investigators
  - Apply NOW!!!
  - Apply for R01!!!!!!

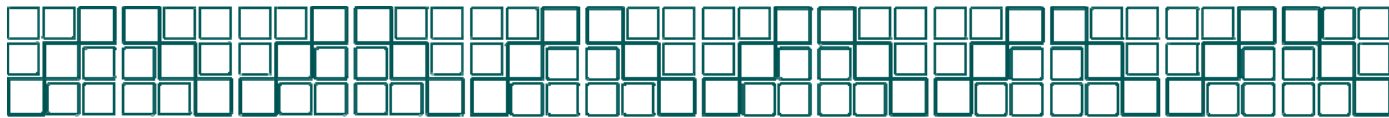
# New and Early Stage Investigators

- **New Investigator:** An application who has not previously competed successfully as PI for a significant NIH independent research award (R01)
- **Early Stage Investigator:** An applicant within 10 years of completing terminal research degree or within 10 years of completing medical residency (or the equivalent)
- Applies only to R01 applications
- New Investigators/Early Stage Investigators are clustered together for review



# Sources of Guidance

- [www.nih.gov](http://www.nih.gov) (follow links to “training” or “peer review”)
  - Office of Extramural Research (“OER” grant programs, forms)
  - Center for Scientific Review (“CSR” review policy, procedures)
  - Institute web sites
- Mentor (current and/or proposed)
- Department Chair or Administrator
- University/School Sponsored Programs Office
- Other colleagues & faculty
- RePORTER database online to look at what is already funded
- NIH Program Staff (before applying and after review)



# RePORT Expenditures and Results (RePORTER) system

[projectreporter.nih.gov/reporter.cfm](http://projectreporter.nih.gov/reporter.cfm)

The screenshot shows a web browser window displaying the NIH RePORTER Query Form. The browser's address bar shows the URL "Query Form - NIH RePORTER - NIH Research Portfoli...". The page header includes the U.S. Department of Health & Human Services logo and the text "www.hhs.gov". Below the header is the NIH logo and the text "NATIONAL INSTITUTES OF HEALTH Research Portfolio Online Reporting Tool (RePORT) REPORTS, DATA AND ANALYSES OF NIH RESEARCH ACTIVITIES". A search bar with a "GO" button is located on the right. A navigation menu contains links for HOME, FREQUENTLY REQUESTED REPORTS, REPORTS, CATEGORICAL SPENDING, REPORTER (highlighted), GLOSSARY, FAQs, LINKS, and CONTACT US. The main heading is "RePORT EXPENDITURES & RESULTS (RePORTER)". Below this, there are links for "Home > RePORTER", "RePORTER v1.0 Early Beta Version", and "Click here to provide feedback". The "Query Form" section includes a "Term Search" field with "And" and "Or" logic options, a "Fiscal Year" dropdown set to "2009", an "NIH Spending Category" dropdown, "Principal Investigator" and "Organization" text fields, and a "State" dropdown. On the right, there are dropdown menus for "Institute or Center" (set to "Admin"), "Funding Mechanism", "Award Type", "Activity Code", "Project Number" (with format "5R01CA121298-04" and a note "Use '%' for wildcard"), "Study Section", "RFA/PA" (with format "RFA-IC-09-003 or PA-09-003" and a note "Use '%' for wildcard"), and "Public Health Relevance". At the bottom of the form are "SUBMIT QUERY" and "CLEAR QUERY" buttons. A note at the bottom left states: "Note: When any field is not selected all possible values for that field will be included in the search results". The browser's status bar at the bottom right shows "Trusted sites" and "100%".

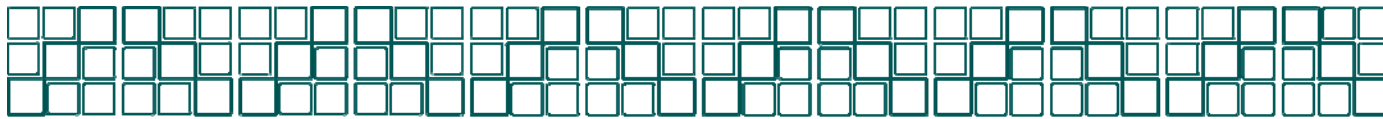
# Study Sections and Peer Review

# The Center for Scientific Review (CSR)

- Central receipt point for all grant applications
- CSR assigns applications to NIH Institute/Center as potential funding component
- Also manages ~200 Scientific Review Groups (“Study Sections”)
  - Some grants are reviewed by study sections organized by an NIH Institute

# How Applications Are Assigned To Study Sections

- Based on input from you -- in a cover letter
- Based on past review history of the application (if any)
- Based on the research area
- Depending on the type of application (R01, F32, K series, etc.)



# The Cover Letter

- Can request a specific study section, and can request a specific Institute
  - It is useful to contact the SRO or PO in advance to see if they agree with your requested assignment
  - If they agree, include the names of your contacts in the cover letter
- Can suggest the types of expertise that would be needed to review your application
  - Requests for specific reviewers will be ignored
- Can request that one or two specific individuals not be used as reviewers
  - Be prepared to discuss your reasons with the SRO

# Study Sections and Reviewers

- Study sections typically review 70-120 applications
- Applications are assigned a primary and secondary reviewer; most are also assigned one or two readers
- Reviewers are typically assigned 9 - 12 applications to review
- Reviewers write critiques for the applications on which they have primary or secondary responsibility; readers may also provide critiques
- You cannot contact reviewers, before or after review

# What Reviewers Evaluate for Research Grants

- Overall Impact
- “Core” Criteria
  - Significance
  - Investigators
  - Innovation
  - Approach
  - Environment
- Additional Issues (e.g. Human Subjects Protections)

# What Reviewers Evaluate for Training and Career Grants

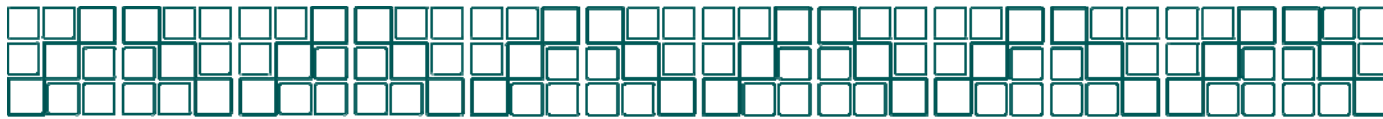
- Overall Impact
- Candidate
- Career Development Plan
- Research Plan
- Mentor(s), Consultant(s), Collaborator(s)
- Environment and Institutional Commitment
- Other criteria include: RCR plans, humans/animals, etc.



# The Scoring System

“Old” System	“New” System
Priority Score Range: 100-500	Overall Impact Score Range: 10-90 (integers only)
	Criterion Scores: 1-9 (integers only)

- 1 is still the best
- Overall impact score need not be mathematically related to criterion scores. Reviewers weight the criterion scores as they believe appropriate in assigning overall impact score.



# Scoring Guidance

Score	Descriptor	Additional Guidance on Strengths/Weaknesses
1	Exceptional	Exceptionally strong; essentially no weaknesses
2	Outstanding	Extremely strong; negligible weaknesses
3	Excellent	Very strong; only some minor weaknesses
4	Very Good	Strong but numerous minor weaknesses
5	Good	Strong but at least one moderate weakness
6	Satisfactory	Some strengths; some moderate weaknesses
7	Fair	Some strengths but at least one major weakness
8	Marginal	A few strengths; a few major weaknesses
9	Poor	Very few strengths; numerous major weaknesses

# What the Summary Statement Will Look Like

- Reviewers use a structured template
- Reviewers provide bulleted comments for:
  - Overall strengths & weaknesses
  - Strengths & weaknesses of each core criterion
  - Comments on Other Review Considerations
- Additional comments (“advice” to applicant)
- Goal: increase transparency of review process and to improve feedback provided to applicants.

# What about Not Discussed Applications?

- Applications that are not discussed by the review panel:
  - Are generally those in the lower half
  - Do not receive an overall impact score
  - Receive summary statements that include the written critiques and criterion scores from the assigned reviewers but do not include an overall impact score

# The Review process is a 2 Level System

- 1st Level: Initial Scientific Peer Review
  - Independent, outside reviewers
  - Evaluates the scientific merit and significance
  - Does NOT make funding decisions
- 2nd Level: IC National Advisory Council or Board
  - Evaluates quality of initial peer review
  - Makes recommendations to Institute staff on funding
  - Evaluates program priorities and relevance

# Strategies for Success

# Review Decisions To Make Early

- Identify a funding Institute
  - Where do you want to target your application?
  - Which Institute(s) are most interested in your topic?
  - Who are the appropriate Program Officers?
  - Note that each Institute has a different payline
- Identify an appropriate Scientific Review Group
  - Depends on Scientific Area
  - Study section rosters are available online

# Getting Started: Science Issues

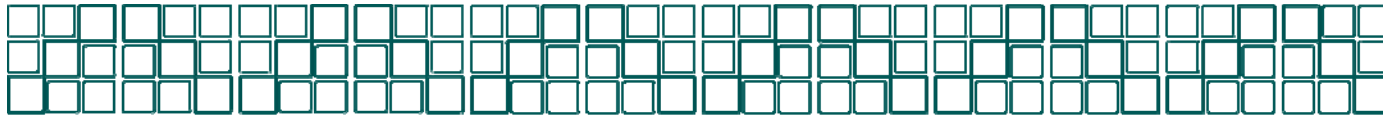
- Read the literature broadly - not deeply; save important papers for a deeper read later
- Engage your lab, mentors and collaborators in the brainstorming process
- Find outside experts to talk with - but go prepared
- Make an effort to talk with the relevant NIH Program Officer(s)
- Begin early to define, organize and plan the content
- NOTE: Early means 6 - 9 months before the deadline

# Getting Started: Administration Issues

- Download and carefully read all instructions and deadlines
- Make sure you are registered for government internet based application and award systems, particularly the eRA Commons
- Talk with lab/department administrators about budgeting, all required approvals, and routing procedures
- Begin all required approvals well in advance of the deadline - 3 months is not unreasonable at the beginning of your career
- Contact collaborators and arrange for letters as needed

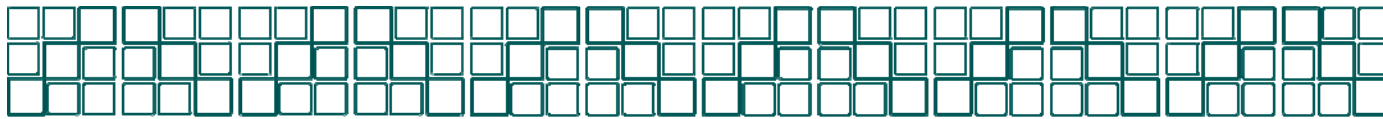
# Important Point

- It is your goal to get people excited about your research
  - Let your enthusiasm for your research be reflected in your proposal.
  - If you are not enthusiastic when writing your proposal, it is unlikely the reviewers will see anything different



# Important Point

- Your grant application will likely have several types of assigned reviewers:
  - An expert in the field
  - Someone who is smart but knows little about your field
- Therefore, your application must appeal to both audiences



# Specific Aims

- Provides an overview of the details - tells what your proposal is about, and how you will get there
  - start with 1 - 2 paragraph general overview
  - then list AIMS, each clearly defined
  - end with a brief statement of what you will learn if successful
- The reader must finish this section convinced that the proposed research is significant and that you have a feasible approach
- The aims should be clearly and concisely stated; many also include sub-aims
- Typically 2 - 4 related aims. Later aims should NOT depend on the success of previous aims

The specific aims page is your  
hook

Make it as perfect as possible

# Significance

- The place to clearly state the importance of the proposed research
  - A proposal with a strong research plan will generate little enthusiasm if the problem is not seen as significant
- Looks both backward and forward
  - How we got “here” and where we need to be
- Points out any controversies and discrepancies that your work will address
- Should be appropriately referenced with an honest and balanced discussion of others’ work

# Significance

- The issue is not: ‘why this disease is important.’
- The issue is: ‘why this intervention is important for this disease’ or ‘what is important about this basic research.’
- For clinical research grants, you must explain how your study will make a difference to patients

Changes in review were designed to place more focus on **impact** and less on details of approach

**Impact** combines significance and feasibility

## Feasibility = Preliminary Data

- To show that you can do what you say you are going to do
- To generate excitement and enthusiasm for the proposed studies
- To show you are a careful scientist who understands the value of controls and does not over-interpret data
- Typically contains several figures with clear legends; figures should be large enough for reviewers to easily read

# Research Approach

- Organized by specific aims, not by techniques
- Include an overview of approaches and the rationale for experiments
- Define controls (positive and negative) for all experimental approaches
- Show you have thought through issues of feasibility, sample size, data analysis, etc.
- Include a discussion of expected outcomes, data interpretation, potential problems, and alternate approaches

# Strong Research Plans:

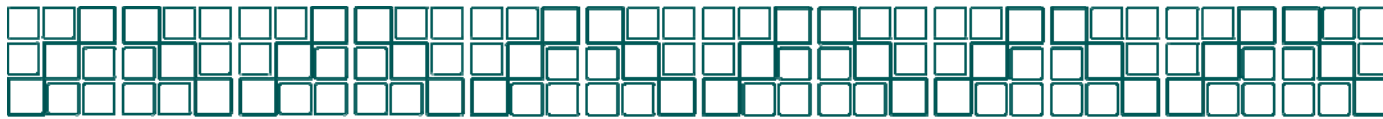
- Explicitly state the rationale for the proposed studies
- Never assume reviewers will intrinsically appreciate or understand what you intend
- Use flow diagrams for overview, and for complex experiments and protocols
- Include well-designed, easy to follow tables and figures
- Address priorities if patients, reagents or resources will be limited
- Include a discussion of how the data will be analyzed and interpreted
- Include realistic discussions of pitfalls and provide alternate approaches

# What To Cover In A Training Plan

- Additional technical training, not incremental advances in what you already know
- Didactic training
  - Depends on your educational level and background
  - Traditional and non-traditional ways
- Professional training
  - In anything you will need to be successful as an independent scientist
  - Including communication, teaching, management, and leadership skills
- Job Search information
  - Who will help and when
  - Availability of institutional resources

# Strong Training Plans:

- Goes beyond the “standard stuff”
  - Standard is lab meetings, journal clubs, attending the obvious National/International meeting
- Are based on your career goals and not a standard institutional template or IDP
- Demonstrate that there is a meaningful interaction between the mentor and the mentee
  - Meaningful letters and specifics help
- Involves a mentoring team when appropriate
  - New mentors
  - Work diverges from mentor’s expertise
  - Career goals are outside the mentor’s expertise
- Show some evidence that you mean what you say



# Common Criticisms

- Rationale for hypothesis or methods not sound
- Models over-hyped as relevant to the human situation
- Diffuse, unfocused or superficial examination of the field
- Unexciting science - an incremental advance for the field
- Mediocre preliminary data that are over-interpreted
- Lack of experience in required methodologies
- Unrealistic amount of work
- Lack of sufficient experimental detail
- Too many irrelevant experimental details
- Insufficient discussion of pitfalls and alternate approaches
- Lack of knowledge of published work
- Lacks evidence that the fellow and mentor worked together
- Lack of detail in the training plan; letters from mentors lack depth

# What Reviewers Really Say

- This is the first of three very long aims that could make its own proposal. The subaims just go on and on.
- An important question and an elegant approach; however there is no discussion of how many targets are expected, and most importantly, what criteria will be used to select which targets to pursue.
- The role of these senior scientists needs to be defined.
- This is a horizontal contribution to the field.
- The investigator does not pay sufficient attention to feasibility issues, including the enrollment of research subjects and careful attention to inclusion issues.
- Insufficient information is given to indicate how the CART analysis will be implemented, and no discussion of power analysis is given. These omissions are particularly unfortunate.

# How to Approach a Negative Review

- Give yourself the time and space to feel sad and angry, but appreciate that your colleagues, students, lab members are watching
- Avoid calling or writing your program officer until you have calmed down
- Then read the reviewer's comments **CAREFULLY**
- You will need to decide whether or not the reviewers show any enthusiasm for your application.
- Talk with:
  - A senior scientist with experience reading critiques
  - Your program officer



# Amended Applications

- Can submit one amended application
- Must respond to reviewers' criticisms
  - Do not have to agree or make the suggested changes, but must respond to the comments
  - Do not attack the reviewers' competence, abilities, etc. This will only hurt your cause.
- No guarantees that amended application will score better than previous submission
  - Different reviewers
  - Different panel of applications

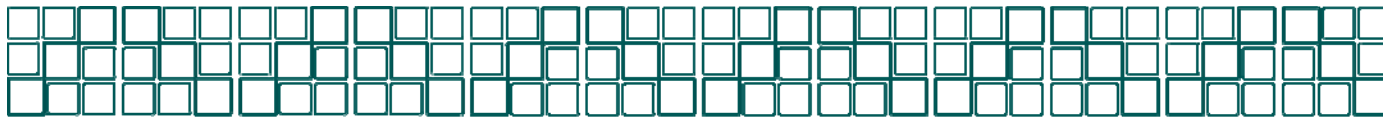
## An example - absolute agreement

Reviewer 1 accurately pointed out that we had not sufficiently discussed the detergents used to prepare cell lysates for our assays. We now expanded this discussion in AIM 3 of the revised application.

Reviewer 2 pointed out that we lacked a clear way to address the relevance of these protein interactions in an animal model. There are no universally accepted animal models for CF lung disease, but we now include studies in mouse tissues and/or well-differentiated human primary airway epithelial (WD-PAE) cell cultures to further explore the physiological relevance of the interactions we identify.

# An Example - Graciously Disagreeing

We wholeheartedly agree with Reviewer 2 that unfocused research can indeed lead to “a quagmire of proteins”. However, we have several strategies in place to ensure that we do not go down such a path. Specifically, ..... As proof of principle, our progress since June 2004 clearly indicates that we can rapidly identify important proteins for further analysis. Therefore we have retained the protein interactions screens described in AIM 3 of the original application.



# The Psychology of Grant Review

- Reviewers are:
  - Over-committed, over-worked and tired
  - Inherently skeptical and critical
  - Often only peripherally interested in your work
- Make their job easier with:
  - Well-organized, clearly written prose
  - Lots of section headings and breaks in the writing
  - Repeat important points at several places in the application
  - Well designed flow diagrams, charts, figures
- And avoid irritating them by:
  - Exceeding page limits, using small fonts and narrow margins
  - Putting information in the wrong section
  - Omitting or mislabeling references/figures
  - Submitting an application that is sloppy or full of typographical errors

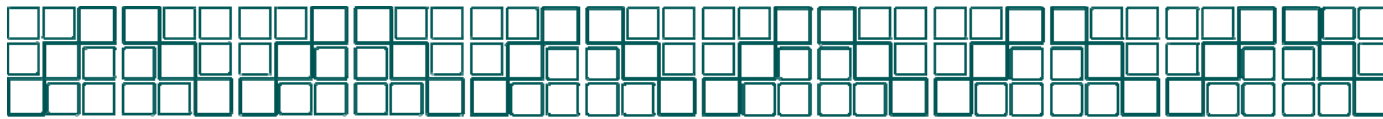
# It's About More Than The Science

## ■ Observation I:

- Strong writing can not compensate for bad ideas, but weak writing easily ruins good ideas

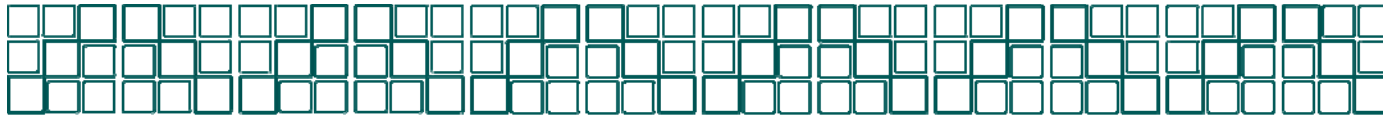
## ■ Observation II:

- You can learn to write well; find outstanding resources as early as possible



# Conclusion

- Only some of the deserving R01 applications can be funded, unfortunately
- Maximize your chances for success by
  - Planning ahead
  - Remembering your target audiences
  - Showing the reviewers that you've thought about your project
  - Preparing a reader-friendly application
  - Remaining optimistic, and letting your enthusiasm for your science come through



# Helpful Web Resources

- NIH Home page <http://www.nih.gov/>
- NIH Grant Application Basics (Includes guides, tips, and tutorials) [http://grants.nih.gov/grants/grant\\_basics.htm](http://grants.nih.gov/grants/grant_basics.htm)
- Information on Study Sections <http://cms.csr.nih.gov/>
- Science magazine GrantsNet  
<http://sciencecareers.sciencemag.org/funding>