National Institute of General Medical Sciences

NIGMS and NIH Grant Mechanisms for Early Career Stage Investigators

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Audience and Topics?

- Graduate Student
- Postdoc
- Early Stage Investigators
- MD and MD/PhD Investigators
- Early Career Grantees
- Mid-Career Grantees
- Resource and Center Personnel

- Navigating NIH
- Early Career Investigator Grants
- What, Why, Who Cares, How, Why Me? Why here?
- Technology Development
- BTRR (P41) => BTDD (RM1 & R24)
- Shared Instrumentation
- Helium Supplements
- Collaborative Program Grants (RM1)

Finding Your Way, Place, and Path at NIH

Part of your job as a PI is to answer the following questions:

1) Which part of NIH is interested in the science that I am interested in doing?
2) Which grant mechanisms and funding opportunities fit my needs?
3) Who will review my application?
4) How do I prepare my application?
5) Who do I talk to? When?
6) Why does it matter?
7) Do you feel lucky? Do you?

Navigating the NIH

- Identify an NIH institute that fits your research interests - www.nih.gov

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Home » Institutes at NIH

INSTITUTES, CENTERS, AND OFFICES

Institutes at NIH

List of NIH Institutes, Centers, and Offices

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NCI	NEI	NIEHS	NIGMS
NHLBI	NHGRI	NIMH	NIMHD
NIA	NIAAA	NINDS	NINR
NIAID	NIAMS	NLM	CC
NIBIB	NICHD	CIT	CSR
NIDCD	NIDCR	FIC	NCATS
NIDDK	NIDA	NCCIH	OD

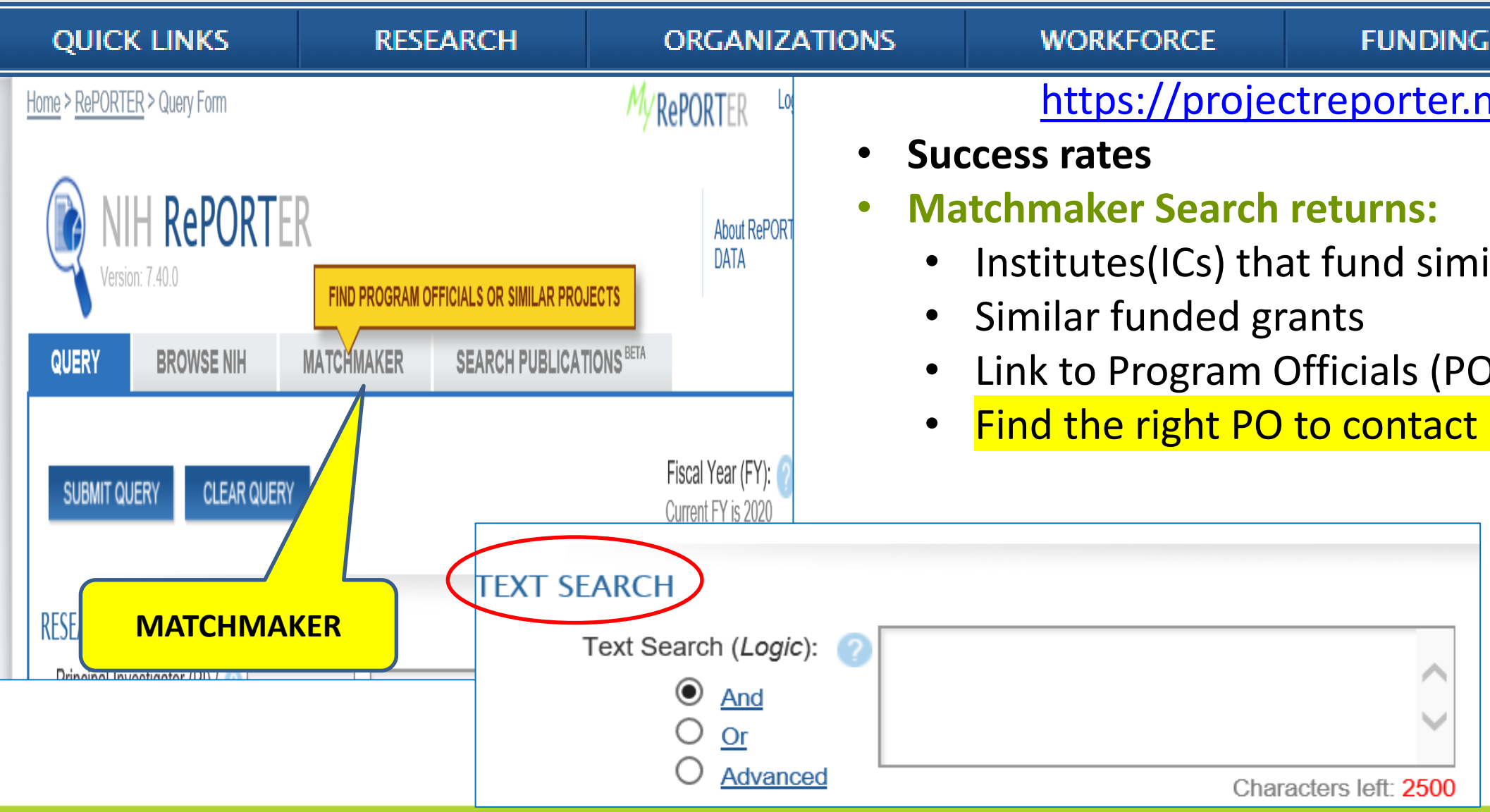
Fortunately, there is a “Post Office”

- Division of Receipt and Referral, Center for Scientific Review, NIH
- Receives Application from the Federal Commons
- Checks it for Completeness and Compliance
- Applies NIH Referral Guidelines
  - Refers the application to the most relevant Institute or Center
  - Refers it to the most relevant Initial Review Group (cluster of study sections)
  - IRG Chief refers applications to the most relevant study section and SRO
- But…the Institute or Center have to agree to Accept the Application.
- SRO who runs the study section has to agree they can review it.
- And you can help guide your application along the path you desire!

Finding your Place

- Get to know the relevant Institute – What is its mission? Programs? Portfolio?
- What types of grant mechanisms does it offer?
- Does it have any FOAs that are a good match with your interests?
- Find a mechanism that fits your career stage and project
- Review the IC website - look at extramural divisions to identify the right Program Officer (PO) – for NIH intramural research contact the PI (corresponding AU)
- Introduce yourself! Email to set up a phone call. Send a brief description of your research and career status.
- Look for NIH staff at conferences.

Here's a useful tool – NIH RePORTER



https://projectreporter.nih.gov

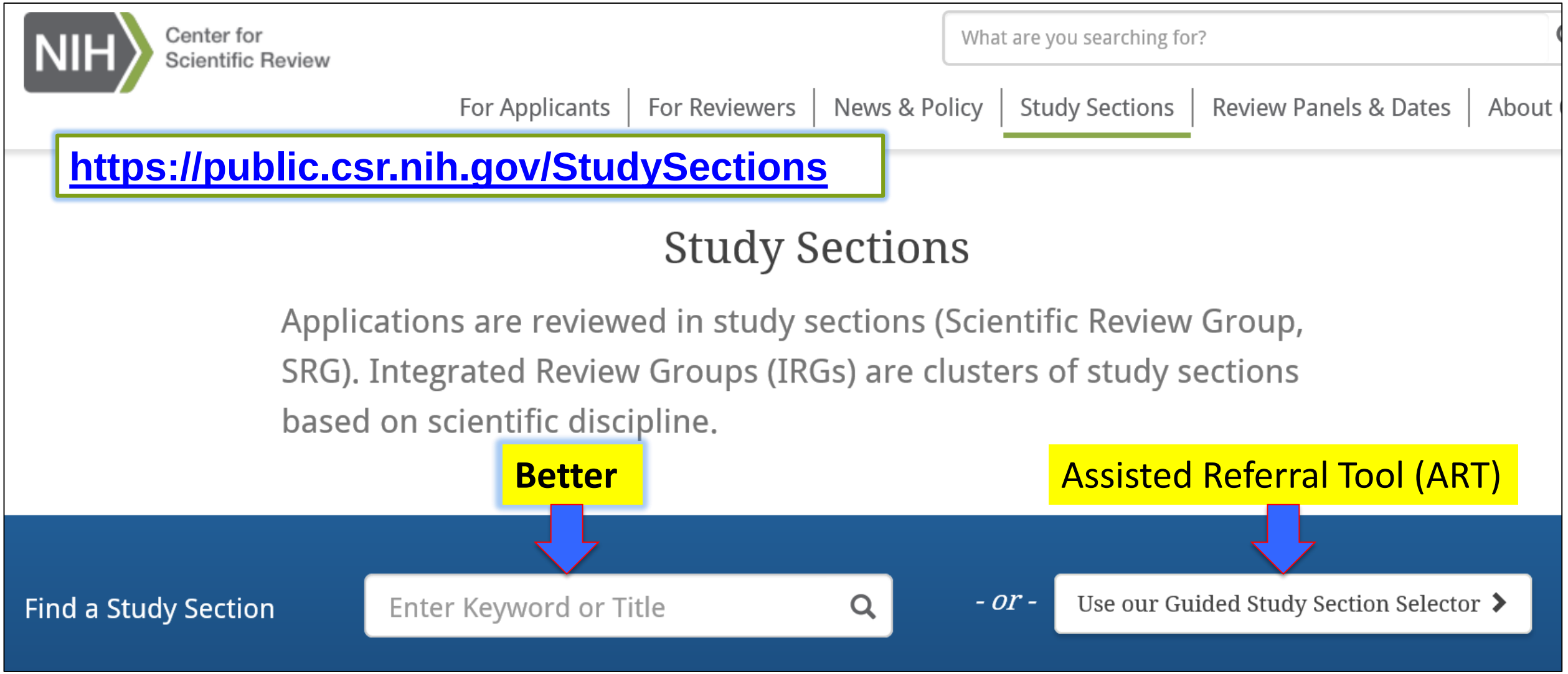
- **Success rates**
- **Matchmaker Search returns:**
  - Institutes(ICs) that fund similar research
  - Similar funded grants
  - Link to Program Officials (POs)
  - Find the right PO to contact **prior to writing**

Finding your Path – Funding Opportunity Announcements

- Investigator Initiated Research Project Grants (Parent Grant Announcement)
- Common Grant Mechanisms used by many Institutes and Centers
  - R01 typically 3-5 years, $200-$400K
  - R03 small grant 1-2 years, $50K
  - R21 Exploratory Research, 1-2 years, $250K total
  - R15 AREA up to $300K over 3 years
- https://grants.nih.gov/grants/oer.htm

- NIH Guide to Grants and Contracts
- Funding Opportunity Announcements
  - Requests for Applications (RFA)
  - Requests for Proposals (RFP)
  - Program Announcement with Special Review Criteria (PAR)
  - Program Announcement (PA)
  - Notice of Special Interest (NOSI)
  - Notices affecting FOAs (NOT)
- https://grants.nih.gov/funding/index.htm

How to Find the Right Study Section - CSR



You Can Help Direct Your Application

Assignment Request Form (ARF)

- Requests for **Institute/Center** (IC) (NIH Reporter) assignment and/or **Study Section** assignment
- Identifies potential conflicts of interest and says why
- Lists areas of expertise needed to evaluate application

You should never suggest specific reviewers (it automatically puts them in conflict)

ARF *differs* from Cover Letter, which

- Explains why your application is late (only accepted for specific reasons) https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html
- *Provides notice of plans to submit a video*
- Identifies your project as one generating large-scale genomic data
- Provides pre-approvals ($500k, conference grants)

Early Career Investigators

- Early Stage Investigators
  - Within 10 years of completing PhD or residency training if MD or MD/PhD
  - Not yet received major independent NIH funding
- New Investigators
  - Not yet received major independent NIH funding
- Early Career Investigators
  - PI's seeking first renewal (or equivalent) replacement of first independent NIH grant

- Early Stage Investigator Policies
- NIH Data Book
- NIH Guide > 24 Active FOAs
- NIH Director's New Innovator Award (DP2)
- NIH Director's Early Independence award (DP5)
- NIGMS ESI MIRA (R35)
- PAR-20-117

NIH Director's DP2 Award

- Support for ESI of exceptional creativity, part of Common Fund HR/HR series, designated scientific areas.
- Enhance diversity in all dimensions.
- Preliminary data not required.
- Requires 3 person month (25%) effort
- Awards up to $1,500,000 d.c. over five years (equiv $300K per year). NCE not permitted.
- In FY2019 expected to make 33 awards for a total of $80M across all areas of NIH
- Additional awards made using IC funds
- Specific Aims (not used)
- Facilities & Resources (1 page), Equipment (not used)
- Biosketch and Current/Pending Support for PI only.
- Research Strategy Essay (10P)
  - Significance and impact; innovation; risk management; qualifications; suitability for DP2 program; statement of effort.
- No Bibliography & References – include in line of text.
- All Appls are New may not submit overlapping R01 or R35 in parallel.

NIGMS Maximizing Investigators' Research Award (R35)

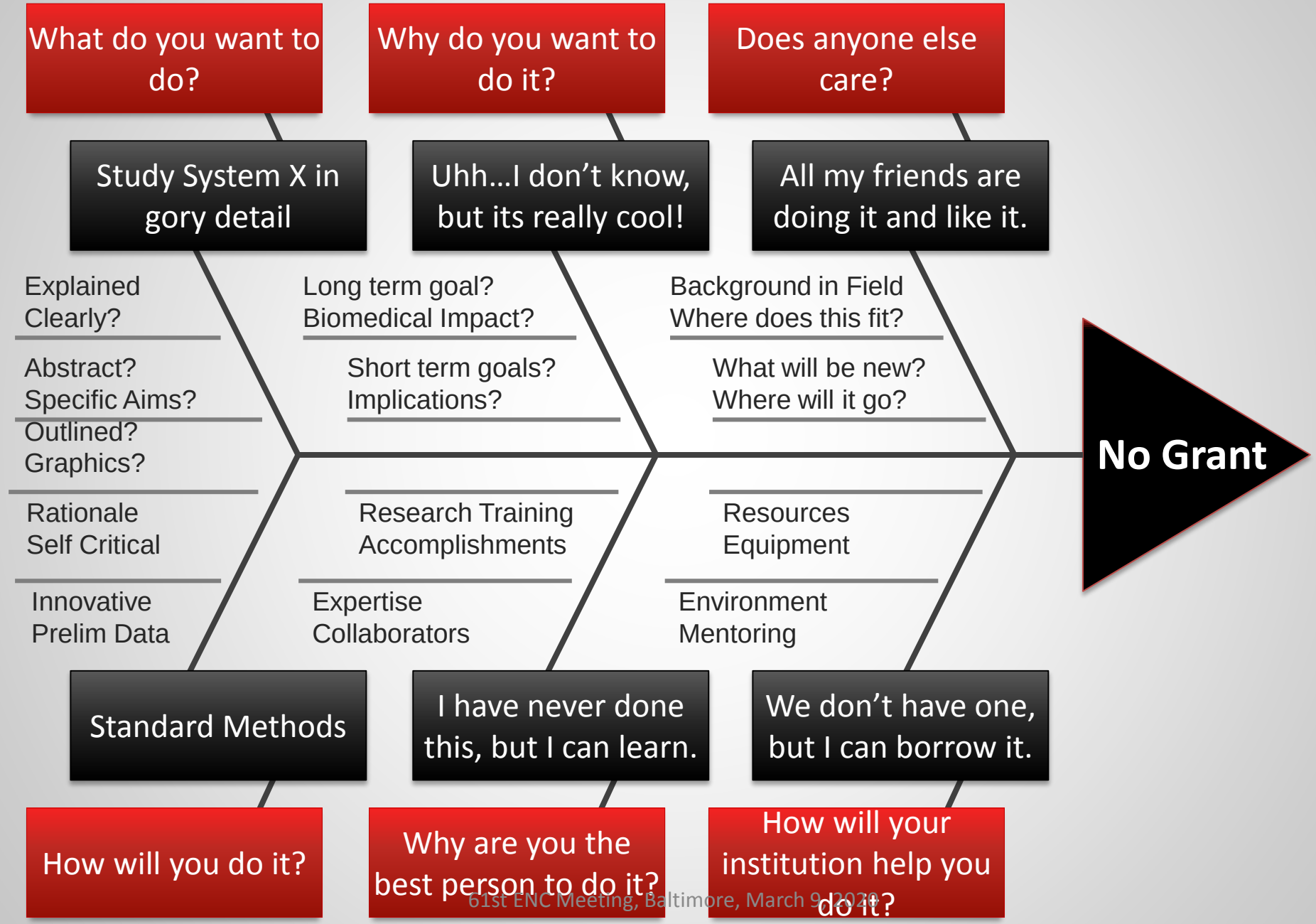
- Support for *program* of research in the lab *in the NIGMS mission.*
- Increase stability of funding; flexibility to change direction; distribute funding; reduce times spent writing and reviewing; more time for research and mentoring.
- Replaces other NIGMS support with a few exceptions.
- Requires 51% of *research* effort.
- ESI awards up to $250K d.c., Est PI up to $750K d.c. per year for 5 years, renewable.
- FY2016-2018 Ave 102 ESI, 115 Est PI awards.

- New ESI-MIRA PAR-20-117
  - Encourages application early after achieving independent PI status
  - Distinct from research of mentors that will launch and sustain an independent career
  - Prelim data NOT required
  - Independent pubs NOT required
  - May submit overlapping R01 and R35 in parallel
- Recently Reissued Est PI MIRA
  - PAR-19-368
  - All NIGMS R01 equivalent can apply
  - R01 to MIRA and MIRA Renewals
  - May not submit overlapping R01 and R35

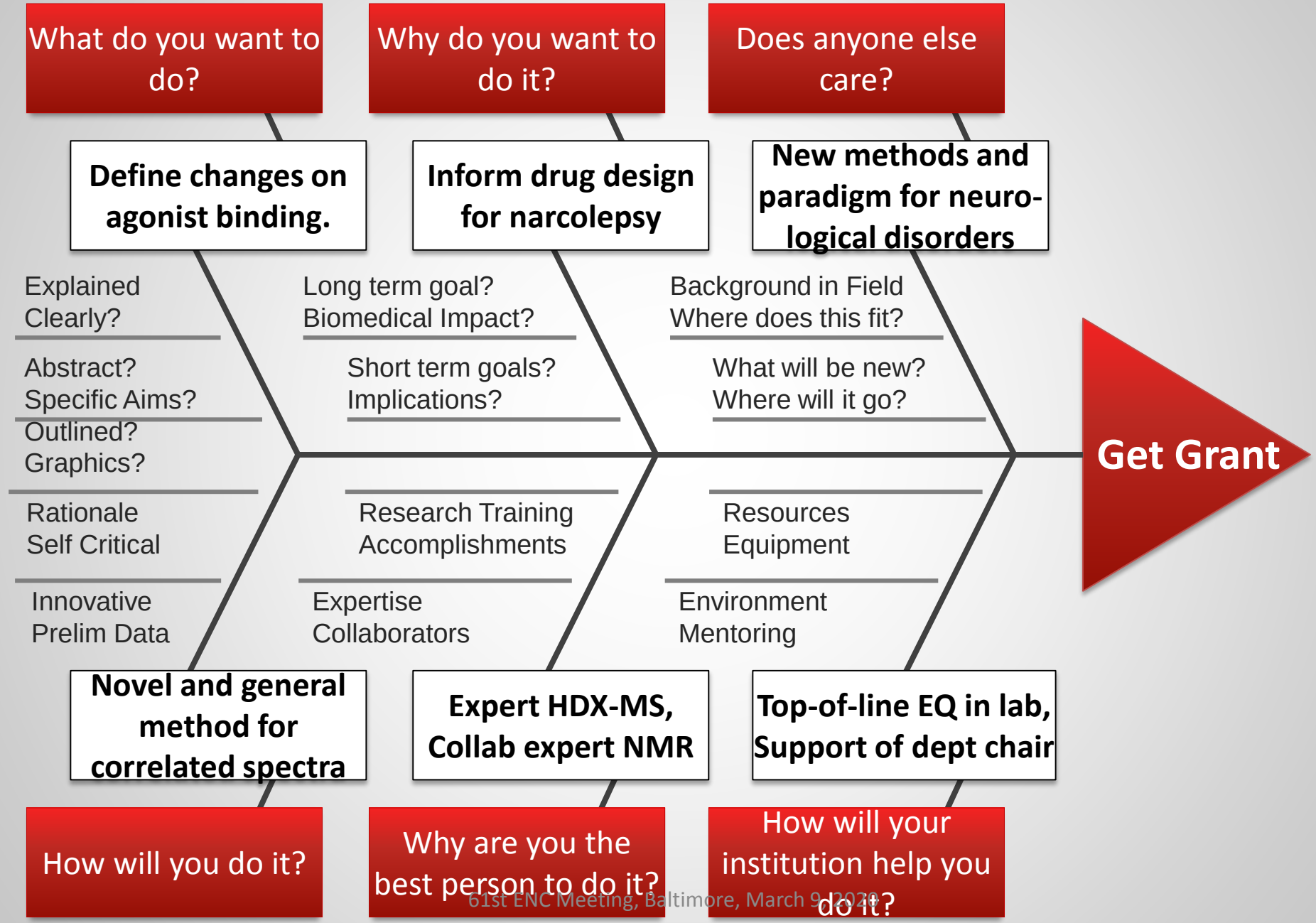
Successful MIRA Applicants

- Used headings and subheadings liberally
- Used schematics, data figures, and graphics liberally
- Showed error bars and other signs of scientific rigor
- Conveyed overall vision and motivation
- Posed specific questions or hypothesis or goals
- Experimental plans tied directly to this QHGs
- Field typical details sufficient indicate overall strategy
- Explained what, why, how, why you are the right PI, and why anyone else should care about the results?

Fishbone Diagram – Planning and Packaging



Fishbone Diagram – Planning and Packaging



Examples

- Background, Key Gaps, Recent Progress of PI, Overview of Future Research Program, Preliminary Data, General Methods, Study Design, Data Analysis, Future Directions
- Background, Innovation, Recent Progress, Preliminary Results, Overview and Key Questions, Outlook
- Bkg, Significance, Key Gaps, Recent Progress, Goals, Approach, Strategy, Perspective
- Background, Recent Progress, Future Work
- Background, Recent Progress, Overview, Screening Protocol, Collaborative Opportunities, Concluding Remarks

More Examples

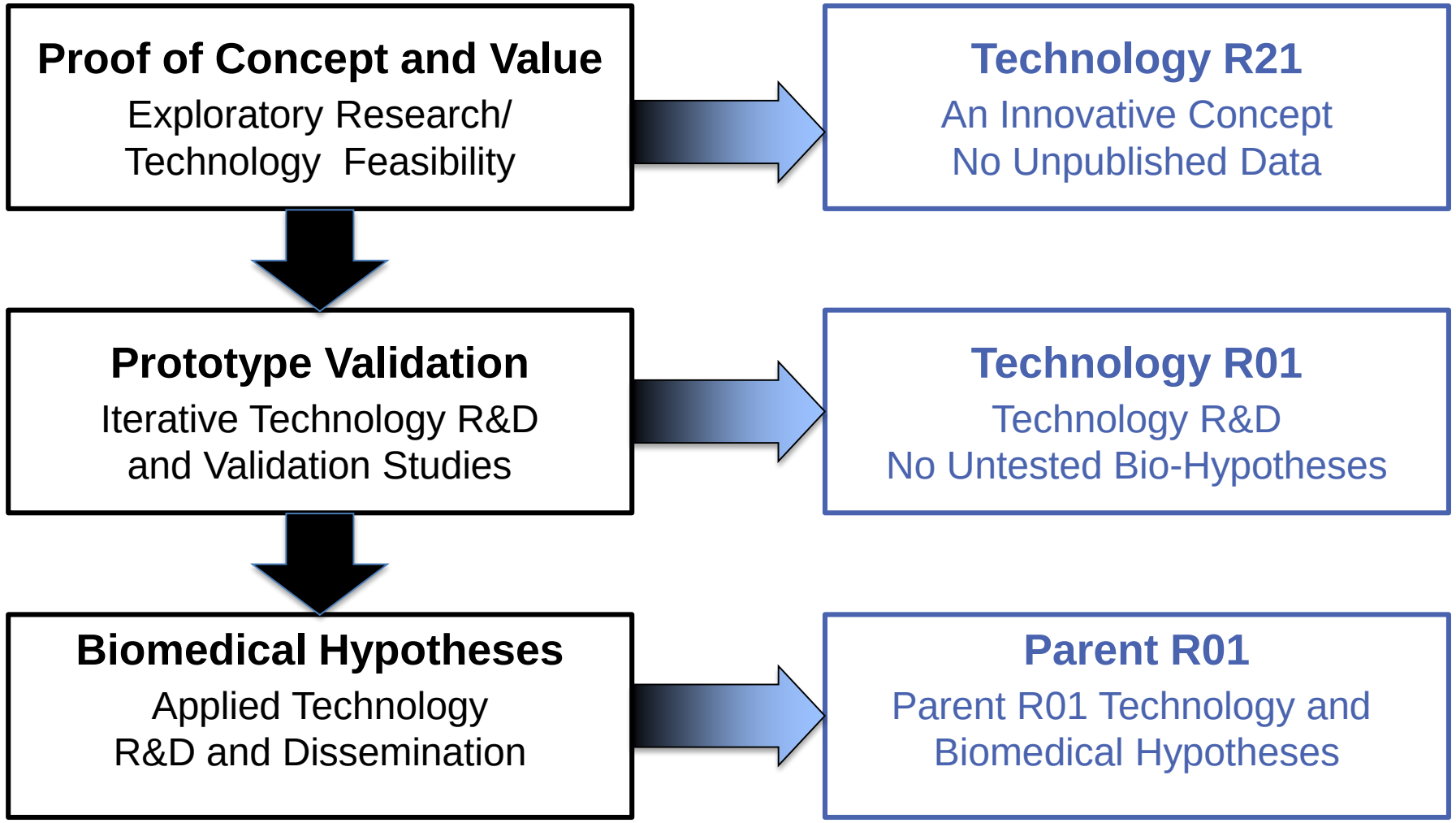
- Background, Schemes, Project 1 (Bkg, Progress, Goal 1 & Expt Plan, Goal 2 & Expt Plan), Project 2.
- Background, Progress, New Methods, Overview, Synthetic Schemes, Activity Assays, Collaborations
- Goals and Significance, Project Area 1 (Bkg & Sign; Innovation, Approach – Progress and Future Research), Project Area 2, Project Area 3, Prioritization, Summary
- Bkg & Sign, Clinical Relevance, LT-Innovation, Feasibility of Program Goals, Recruitment of Students, Establishing Clinical and Basic Science Collaborations

And More

- Background (1), Progress (1), Overview (4)
- Project 1 (Bkg & Sign, Innovation and Progress), Project 2, Project 3.
- Research Direction 1-4. Goal, Significance, Innovation, Approach, Prelim Res, Potential Obstacles. Conclusion and Outlook.
- Background, Paradigm Shift, Goal, Overview, Project 1 – Hypothesis – Predictions, Testing Predictions; Project 2; Project 3; Project 4.

Technology Stages

Funding Opportunities



NIGMS Grant Mechanisms: Technology Development

- Exploratory Research for Technology Development (R21)
  - Innovative Ideas – Proof of Concept
  - High Risk/High Reward (Potential Impact)
  - Biological motivation, but application to specific problems is not in scope
  - Preliminary Data NOT Allowed
  - $275,000 d.c. over two year award
  - Not just a small grant program
  - Not particularly for ESI & NewPI, but may be appropriate for some
  - Success rate about the same as for R01s assigned to NIGMS
- Focused Technology Research and Development (R01)
  - Focused on enabling technology, not application to a specific problem
  - Prototypes, methods, validation
  - Feasibility – Proof of Concept already established, but significant remaining technical challenges
  - Not incremental improvements
  - Preliminary results expected
  - Awards for 3-4 years (5 years for ESIs)

NIGMS Grant Mechanisms: *New* FOAs replace P41 BTRR

- Biomedical Technology Development and Dissemination Center (RM1)
  - Late stage technology development once feasibility is established.
  - Access to technology and dissemination to research community.
  - Tech Dev Projects, Driving Biomedical Projects, Community Engagement.
  - Collaborative application to biomedical problem solving, partnerships, training, data acquisition, transition plans, commercialization.
  - Up to $850K d.c. per year for 5 years (maximum 10-15 years).
- NIGMS National and Regional Resources (R24)
  - Established resources able to achieve economies of scale by supporting a substantial number of national or multi-state regional users on a service basis.
  - Funds for upgrading, maintenance, outreach, user training and support.
  - Facilities, instruments, hardware & software, research materials, tools, methods & expertise, cell lines, organisms, biospecimen banks (in NIGMS mission).
- NIH Biomedical Data Repository (U24)
- NIH Biomedical Knowledgebase (U24)

NIGMS Resources Enable Your Research

- Biomedical Technology Resources
  - Portal Site
  - http://www.btrportal.org/
  - Computing and Informatics
  - Molecular and Cellular Imaging
  - Structural Biology
  - Systems Biology
  - NIBIB-Supported BTRCs

- Carbohydrate Structure and Function
- Computing and Informatics
- Correlated Microscopy
- CryoElectron Microscopy
- Data Integration and Visualization
- Electron Microscopy
- Fiber Diffraction
- Glycomics
- Imaging
- Macromolecular Crystallography
- Mass Spectrometry
- Microscopy
- Modeling and Simulation
- Molecular Dynamics
- Proteomics
- Small Angle Scattering
- Spectroscopy
- Structural Biology
- Synchrotron
- Tomography

Shared Instrumentation Programs: S10

More info: https://orip.nih.gov/

For acquisition of

- advanced
- commercially available

scientific instruments

- used on a shared basis
- enhance NIH-funded research

ORIP publishes 3 Program Announcements

- SIG
- HEI
- SIFAR

- NIGMS participates in SIG and HEI
- One receipt day per year (May/June)
- Awards: $50K - $2M
- ~400 applications per year, ~110 awards per year

Supported technologies include:

- Spectrometers
- Sequencers
- Electron & Light Microscopes
- Cell Sorters
- Biomed. Imagers

and OTHERS

NIGMS Grant Supplements for Helium Recovery Systems

- Many instruments use liquid He and there is a world-wide shortage
- Prices are rising and delivery is becoming unpredictable
- Up to 2 NIGMS-funded PIs can apply for a combined total of $250K
- Due date March 30, 2020
- See our NOSI (NOT-GM-20-013)

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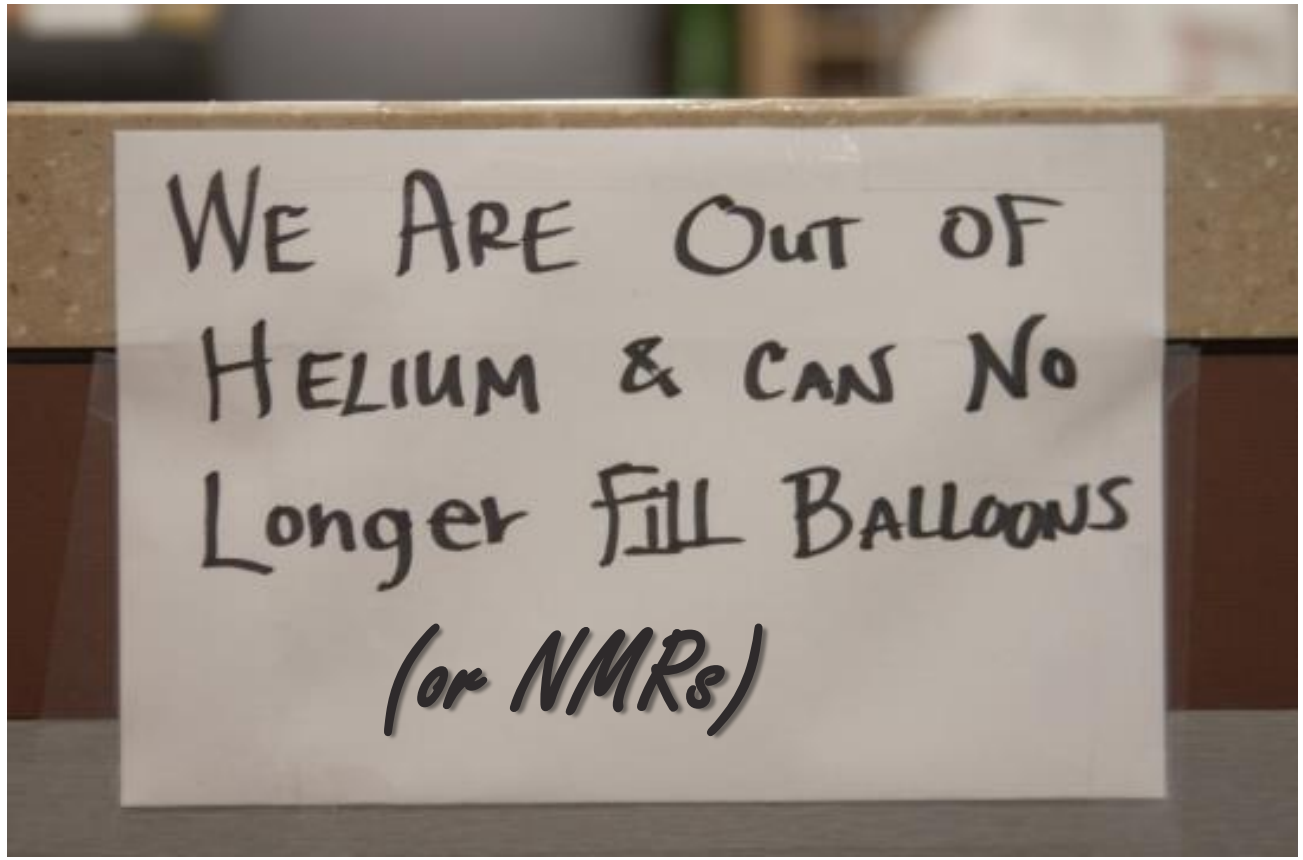


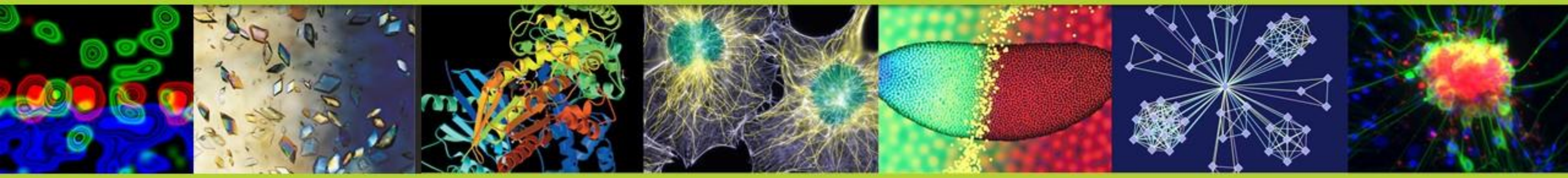
NIGMS Collaborative Program Grants for Multidisciplinary Team Science (RM1) – Recently Reissued (PAR-20-103)

- Support for highly integrated research teams to address ambitious and challenging questions important to the NIGMS research mission
- Coordinate application, review, and funding of research to achieve outcomes that cannot be supported by individual research grants
- Multiple PI application from 3-6 investigators
- Single set of well-integrated specific aims, no subprojects, but can be multi-institutional with subcontracts (Research Plan limit 30 pages)
- Team Management Plan (limit 6 pages)
- Optional developmental funds for addition of ESI's in future years.
- Budget up to $1.5M d.c. per year for 5 years, up to $250K d.c. development funds in years 2-5, maxium of one renewal permitted.

National Institute of General Medical Sciences

Review Basics and Other Tips

From presentations by Ruth Grossman (NIGMS) and Michele McGuirl (NIGMS) at the Biophysical Society meeting in San Diego



Review Basics – Study Sections

- **Scientific Review Officer (SRO)** manages each study section
- **Standing study section** − 12-25 **appointed** members from the relevant scientific community, plus temporary (ad hoc) members recruited as needed
  - Reviews R01s, R21s, R03s, some R15s
- **Special Emphasis Panel (SEP)** − members from the scientific community serving on a **one-time only basis**
  - Because of member conflicts, subject matter, or IC request (CSR)
  - Some mechanisms or FOAs use **recurring SEPs** to review (SBIRs/STTRs, some R15s, Fellowships, NIGMS MIRA and ESI MIRA) (CSR)
  - ICs have mostly SEPs, with a few standing study sections
- **CSR reviews 80% of applications, ICs review 20%**

Tip: Look in the FOA, Section V #2, for locus of review

Before the Review Meeting

SRO assigns each application to 3 qualified reviewers, who look for:

- **Fit to Mechanism & Good Science**
  - Exciting ideas with significance and impact
  - Whether PI notes limitations of the study
- **Grantsmanship**
  - Brevity with things that everybody knows
  - Ideas they can understand - Don't assume too much
  - A concise, well-written application
  - Appropriate amount of work proposed for timeline

Tip 1 – Always have a senior investigator (or several) look at your application before submitting

Tip 2 – Write to the review criteria (Section V) in the FOA

NEVER CONTACT STUDY SECTION MEMBERS

During the Review Meeting

Applications are clustered by type (R01s, R21s, R03s), ESI status, Clinical Trial

- Your Career Stage is considered for R01 review if **eRA Commons** indicates that you are a New Investigator or Early Stage Investigator

Approximately 50% of applications are discussed

- Three assigned reviewers present critiques and preliminary scores for each application, followed by a panel discussion and confidential final scoring

Application scores in CSR standing study sections are *percentiled*

- To align scores across different study sections

After the Review Meeting

SRO prepares summary statement for every application

Summary statement = official record of the deliberations of the panel

Available ~ one month after the review meeting

All applications receive:

- Scores for each review criterion (if applicable)
- Critiques from assigned reviewers
- Administrative notes, if any

If your application is discussed, you also will receive:

- An overall impact/priority score (and percentile ranking)
- A summary of discussion – ‘resume’ – drafted by the SRO
- Budget recommendations of the panel

Who Can Answer Your Questions?

Before You Submit Your Application

- A Program Officer at an NIH Institute or Center
- A Scientific Review Officer at CSR or an IC

After You Submit Your Application

- Your Scientific Review Officer

After The Review Meeting

- Your Assigned Program Officer (best after Summary Statement is released, PO name is at top of face page)
- http://grants.nih.gov/grants/next_steps.htm (link on face page of summary statement)

GrantsInfo: GrantsInfo@nih.gov or (301) 435-0714

Early Career Reviewer (ECR) program at CSR

NEW! Required Qualifications (as of January 2020):

- Two or more years in faculty appointment or equivalent, Assistant Professors or equivalent only
- Active independent program of research
- 1 senior-authored research publications in peer-reviewed journals in past 2 years plus 1 since doctorate
- No R01 or equivalent grant
- No service on any NIH study section (except by mail)
- Submitted a grant proposal as PI/PD to the NIH and received the associated summary statement (any grant mechanism other than F30, F31, F32)

Apply! Instructions at www.csr.nih.gov/ECR

Tip – contact the SRO of the standing study section most appropriate for your area of expertise OR contact an IC SRO

Key NIH Grants and Review Web Sites

NIH Central Grants and Funding Website

https://grants.nih.gov/grants/how-to-apply-application-guide.html

NIH Center for Scientific Review

http://www.csr.nih.gov

Insider's Guide to Peer Review for Applicants:

http://www.csr.nih.gov/applicantresources/insider

NIH Office of Extramural Research

http://grants.nih.gov/

FOA & Application Tips

- **Read the Funding Opportunity Announcement and related Notices**
  - See especially Sections IV. Application Information & V. Review Information
  - Separate FOAs for Clinical Trials (not allowed, required, or optional) - Don't apply to the wrong one!
- **Follow the instructions in the FOA and the Application Guide – FOA tops the Guide**
  - Include everything that is requested and nothing that isn't
- **Use the correct forms – Forms "F" is here** (use after May 25, 2020)
  - Don't rely solely on a past awardee's experience or grants for format and content
- **Apply before the due date and use the 2-day application viewing window to fix things**
  - Check for formatting errors and issues with attachments (duplicates, old versions, etc)

Investigators & Collaborators

What Reviewers Look For	What You Should Provide
Your qualifications	• Productivity • Publications, awards, honors • Adequate prior training for the work • Evidence of independence
Your personal statement (part A of the biosketch)	• Well-written and compelling narrative tailored to the application
Current & pending funding	• If other grant titles are similar to this application, clarify the differences to avoid overlap concerns
Role of Collaborator – essential or window dressing?	• Complementary expertise • Evidence of prior teamwork • Personalized Biosketch or Letter of Support
Collaborator commitment	• Contribution/Role specified in Letter of Support • Frequency and plans for interactions

Specific Aims

What Reviewers Look For	What You Should Provide
Overview with a Clear Hypothesis (or Goal)	• Big Picture → Knowledge Gap → Specific Inquiry • Long-term goal of lab vs "aims of this study"
Aim 1, Aim 2, Aim 3…	• Challenge → Approach (→ Impact) • Each aim should test the hypothesis (or lead to a specific accomplishment that will complete the goal) • Aims should be synergistic but independent
Potential Impact	• "If Successful" summary of what will be learned

Research Strategy

What Reviewers Look For	What You Should Provide
Interesting & significant questions	• Project that sets you up for longevity/success • Using up-to-date approaches • Summarize pivotal work, address controversies fairly
Innovation	• Innovation can be in the concept, questions or methods • Claiming to shift paradigms can backfire
Hypothesis-driven study (or clear goals and outcomes)	• If big data study, describe selection criteria for narrowing and moving to next level • If computational, how will results be validated?
Feasibility	• Focused study can be completed in award period (ambition is good but avoid being overly-ambitious) • Provide preliminary data or strong basis in literature • Rigor in data collection & analyses, avoid bias
Anticipated results, pitfalls & alternative strategies	• Interpretation of expected results, likely problems & solutions

Environment & Resources

What Reviewers Look For	What You Should Provide
Quality & reputation of institution	• Biosketch - Personal Statement ○ How institution type fits your career goals
Institutional Commitment	• Start-up $, instruments, protected time • Describe facilities & equipment available for this project • Networking and mentoring programs for you and your mentees
Human Subjects, Vertebrate Animals, Biohazards	• Properly formatted, complete sections • Poor descriptions can influence reviewer scores
Resource Sharing Plan(s) & Authentication of Key Resources	• REQUIRED elements – don't omit! • Pay attention to detail, make a good impression

Common Problems in Applications

Problems with "Good Science"

- Absence of a scientific rationale
- Lack of experience in the essential methodology
- Questionable reasoning in experimental approach
- **Uncritical approach, no potential pitfalls or alternative approaches**
- Uncertainty concerning future directions

Problems with "Grantsmanship"

- Diffuse, superficial, or unfocused research plan
- Lack of sufficient experimental detail
- **Lack of knowledge of relevant published work**
- Unrealistically large amount of work

Critically Revise, Especially if Summary Statement Says:

- Aims: Unfocused… inter-dependent… don't address the hypothesis…
- Overly ambitious project
- Not enough expertise for the work
- Lack of significance or innovation – the last remaining questions in a mature field
- At best, an incremental advance
- Densely written and poorly organized
- Reads like a laundry list of experiments - No idea of where this project will lead or what we'll learn from it
- Lack of controls, no data to back up the hypothesis, not feasible

Thank you!

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