

**Obtaining your first R01  
.....in the era of sequestration and  
government shutdown**

Justin Kline, M.D.  
University of Chicago

# R01- background

- The R01 is the original and oldest grant mechanism used by the NIH
- Is the benchmark award signaling the independence of an investigator
- Can be investigator initiated or in response to a program announcement (PA) or request for application (RFA)
- Most R01s are investigator-initiated (no PA or RFA)
- R01 grants are made to support a discrete, specified project determined by the principal investigator (PI) in an area of his/her interest expertise.

# R01 – background

- R01 applications are funded in modules (typical yearly limit = \$250K)
  - In the past 2-3 years, R01 budgets have been cut by 20%-30% (ouch)
- Applications are awarded for 1-5 budget periods (i.e. years)
- Applications can be renewed by competing for an additional project period
- Only 1 resubmission of a previously reviewed R01 application is allowable
- The research plan of an R01 application must follow instructions provided in SF424 (R&R) application guide (<http://grants.nih.gov/grants/funding/474/index/htm>)
- Submission dates for new R01 applications are February 5, June 5 and October 5.

# R01 – Planning your application

- **It all starts with a strong question/hypothesis**
- For post-docs transitioning to junior faculty positions, it is helpful to have preliminary data from your prior lab that you can build upon
  - Must be independent from your mentor's funded work
- Takes time to generate strong preliminary data which are critical to convince reviewers of your proposed approach
- Consider carefully the model you will use to answer your question

# R01 – Planning your application

- Consider your publication record and grant history
  - New or early stage investigators don't need a large number of publications and awarded grants
- Allow enough time to complete the application (6-8 weeks)
- Before you start your application, contact the program officer
  - Appropriateness of your application for a particular funding mechanism, etc.
- Consult “The Grant Application Writer’s Handbook” NIH version by Stephen Russell and David Morrison

# R01 – Components

- Project summary
- Project narrative
- References
- Facilities/Resources
- Key Personnel
- Biosketch
- Budget and Justification

# R01 - Components

- Research Plan
  - Specific Aims
  - Significance
  - Innovation
  - Approach
    - Preliminary studies
    - Methods
  - Vertebrate animals
- Resource sharing

# R01 – Review Process

- Once your R01 application has been submitted, it is reviewed by the Scientific Review Group (SRG)
  - Non-federal scientists expert in your field (your peers)
- Second level of review is performed by Institute and Center (IC) National Advisory Councils
  - Comprised of scientific and public representatives expert in matters of health and disease.
- Only applications reviewed favorably by both the SRG and IC are recommended for funding

# R01 – Peer Review

- SRG led by a Scientific Review Officer (SRO).
  - Responsible for ensuring that each application is complete and receives objective and fair peer review.
- SRG members include:
  - The Chairperson – serves as the moderator of the scientific discussion and technical merit of applications
  - The reviewers – actually review and score R01 applications

# R01 – Peer Review

- Each R01 application is assigned to 3 reviewers
- Each reviewer reviews the grant and assigns it a priority score based on 5 major areas
- The overall impact/priority score reflects the reviewers' assessment of the likelihood of the project to exert a sustained and powerful influence on the field involved
- The 3 reviewers assigned to your R01 will also be responsible for discussing it before the entire SRG during the review meeting (study section)
  - Must convince your reviewers of the merit of your grant
  - They can be either a strong advocate or your worst nightmare

# R01 - Peer Review

- Scored review criteria:
- **Significance:**
  - Does the project address an important problem or critical barrier to overcome in the field?
  - If the aims of the grant are achieved, what palpable changes in the field will ensue?
  - Significance is one of the most critical scored review criteria, so take time to consider the potential significance of your project before drafting your application

# R01 – Peer Review

- **Investigator:**
  - Is the PI well suited to complete the project?
  - For Early Stage or New Investigators, do they have appropriate training? Pedigree and track record of prior publications in the field and prior grant awards are considered here.
- **Innovation:**
  - Does the application challenge and seek to shift current research paradigms by employing novel concepts, approaches or methodologies?

# R01 – Peer Review

- **Approach:**

- This review criteria is probably the most heavily considered and scored upon
- Is the overall strategy, methodology and analyses well-reasoned and appropriate to accomplish the specific aims?
- Are potential problems, alternate strategies and benchmarks of success presented in the application?
- Is the strategy feasible?

# R01 – Peer Review

- **Environment:**
  - Will the scientific environment (i.e. the institution) contribute favorably to the completion of the project.
  - Are the institutional support, equipment and intellectual milieu sufficient to facilitate the completion of the specific aims?
- **Additional review criteria:**
  - Protections for human subjects
  - Inclusion of women, minorities and children
  - Biohazards
  - Vertebrate animals

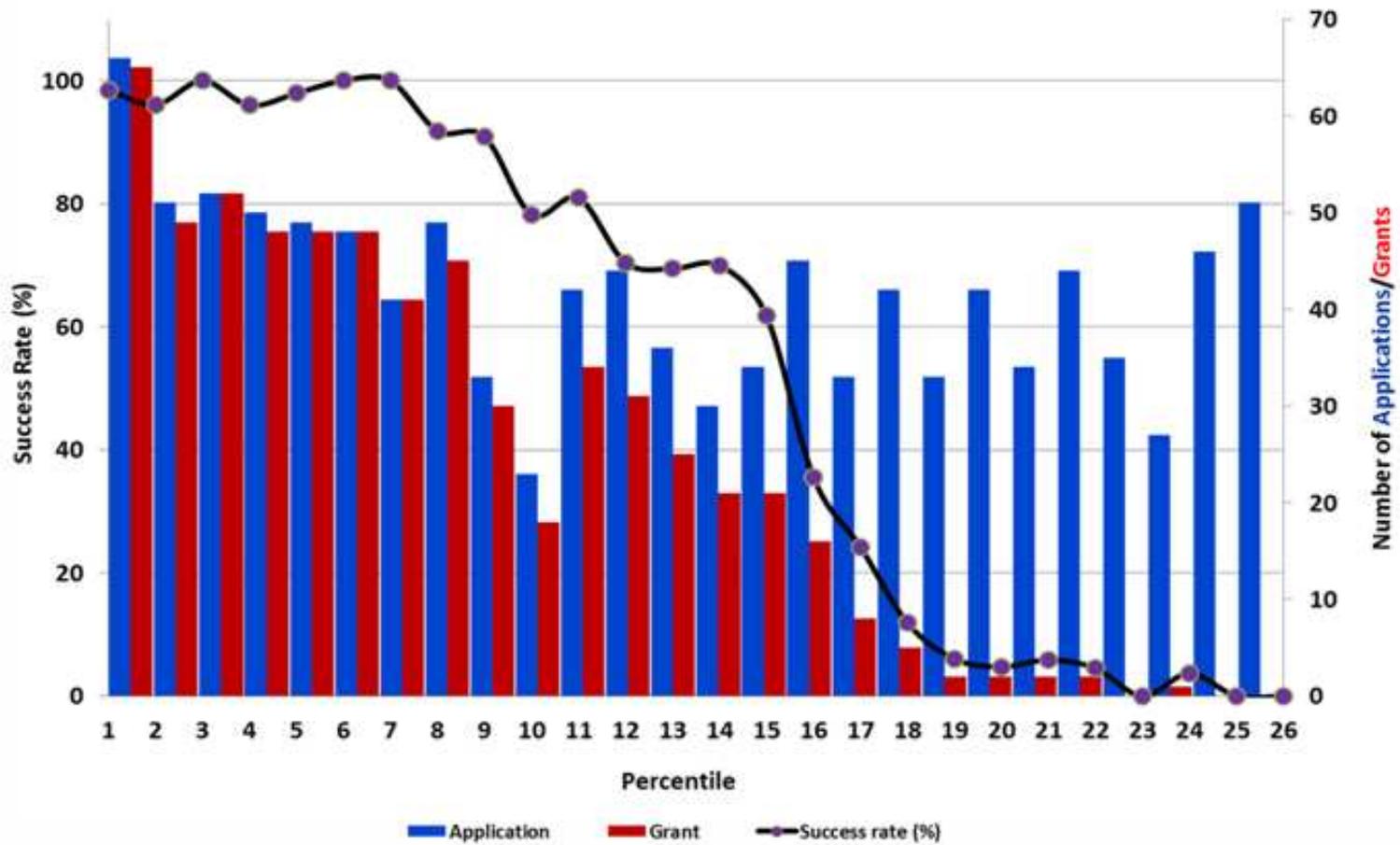
# R01 – Peer Review

- Once the review process has been completed, your R01 application will receive a overall impact score
  - An average of the scores of each reviewer present at the study section
  - Largely influenced by the 3 reviewers who present your application to the group and lead the discussion
  - Impact scores range from 1-9 (Lower is better)
  - Your overall impact score will be compared with those of other R01s reviewed at your study section and will be assigned a percentile ranking
  - Once you have received your overall score and summary statement, you should contact the program officer to discuss whether your application is potentially fundable or whether a revision is necessary (or worthwhile)

# R01 – New and early stage investigators

- The average age of an R01 award for PhD's (42) has been constant for past 10 years
- The average age for MD's and MD/PhD's has increased to about 45
- Early stage investigators (ESI)
  - Within 10 years of completing a terminal research degree (PhD) or medical residency (for MD's or MD/PhD's)
- New investigators
  - Have not successfully competed as a PI for a substantial NIH-funded grant (excludes T, F, and K awards)
- R01 applications from ESIs are given special consideration
  - Reviewers are instructed to focus more on the approach than the track record and preliminary data

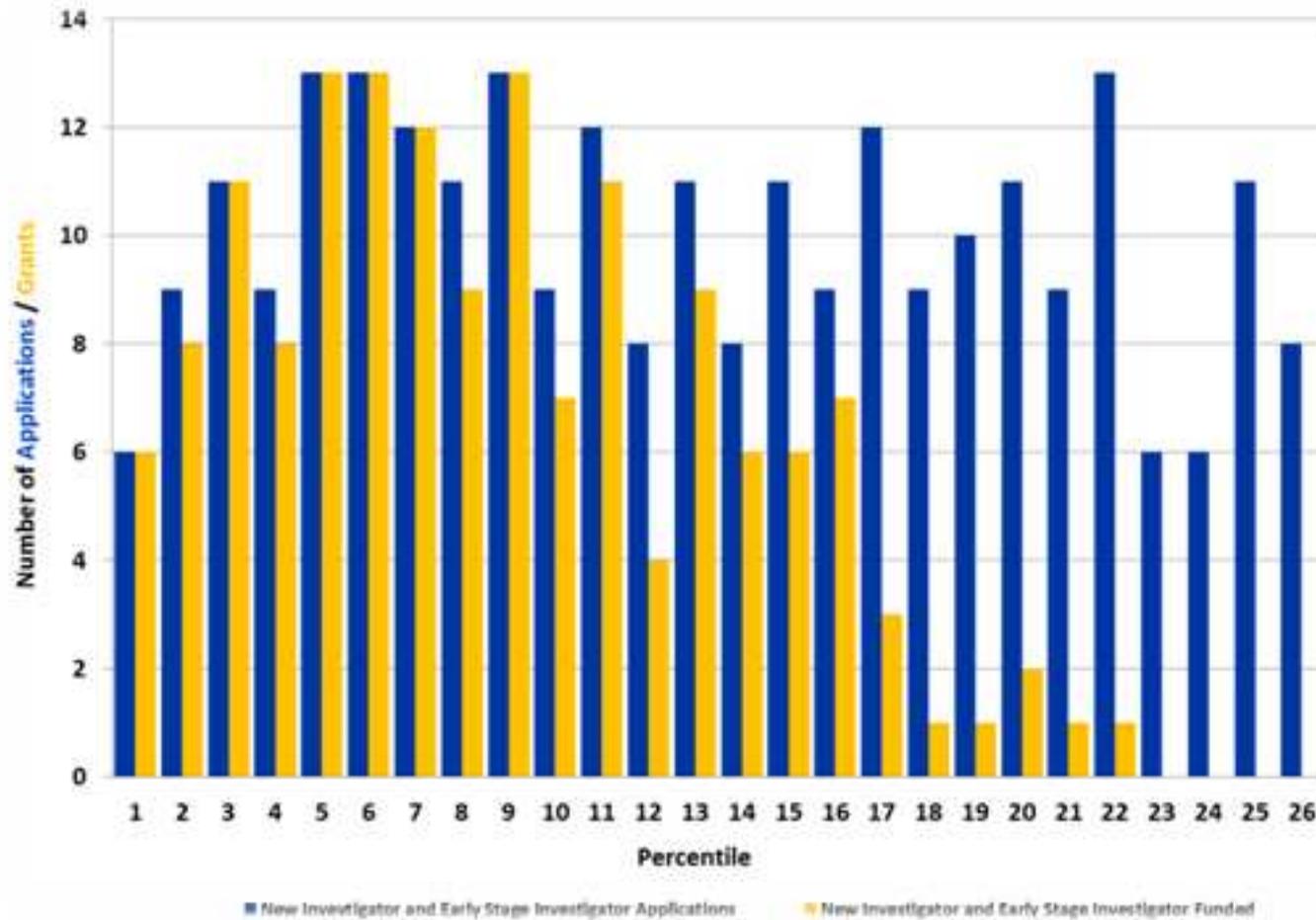
# R01 – Funding FY 2012



All investigators

Source: nci.nih.gov

# R01- Funding FY 2012



New investigators

Source: nci.nih.gov

# R01 – Funding FY 2012

**Table 1: Fiscal Year 2012: Success rates (unsolicited R01s)**

	Total Applications	Number With Percentiles Of 25 or Better	Number With Percentiles Of 10 or Better	Funded	Success Rate
R01 - All Investigators	4,143	1,029	462	618	<b>15%</b>
Experienced Investigators - Total	2,849	777	356	466	16%
Type 1	2,345	556	245	316	13%
Type 2	504	221	111	150	30%
*New Investigators	1,294	252	106	152	<b>12%</b>
**Early Stage Investigators	564	129	59	86	<b>15%</b>

Source: [nci.nih.gov](http://nci.nih.gov)

# Final tips

- Take time to consider the potential significance of your project to the field
  - Projects that are largely repetitive are NOT likely to be funded
- Talk to the PO before applying to make sure your application is appropriate for the funding mechanism
- Allow enough time to draft the application
  - Make sure to avoid minor errors (i.e. proofread your grant multiple times)
  - Have colleagues read your grant and offer their feedback
- When your grant is reviewed and you receive your summary statement, take the recommendations seriously when planning your revised application.

Good Luck.....