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

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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.

Source: grants.nih.gov/grants/funding/r01.htm
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)**

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

Source: 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.....