CFA Brown Bag R&R Update

April 19, 2019
Annual Reports

- Instructions updated on OR site last week:
  - Use narrative template as guide for format
  - Use scoring to know when to stop

- If you are unsure of how to tie chart strings to grant titles, contact Andy with group name and chart string
  - [https://report.nih.gov/](https://report.nih.gov/)
  - [https://www.nsf.gov/awardsearch/](https://www.nsf.gov/awardsearch/)
  - DoD, DoE, etc. requires you to contact research groups

- Okay to email reports to Jeff or Andy
  - If you are requesting FSM funds, submit to Jeff as there is a pre review before reports go to FSM review panel

- STAY BRIEF!
Rigor and Reproducibility

- All funding agencies clearly concerned with R&R as part of the review process
- NIH leading or articulating criteria for reviewers and submitters
- Nationally, cores are formalizing response to ensure cores are supporting the new point of emphasis

Goal:

1. CONDUCT SOUND RESEARCH
2. GIVE NU FACULTY A COMPETITIVE ADVANTAGE WHEN PROPOSING AND CARRYING OUT RESEARCH
## NIH Review

<table>
<thead>
<tr>
<th>4 AREAS OF FOCUS</th>
<th>WHAT DOES IT MEAN?</th>
<th>WHERE SHOULD IT BE INCLUDED IN THE APPLICATION?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rigor of the Prior Research</td>
<td>A careful assessment of the rigor of the prior research that serves as the key support for a proposed project will help applicants identify any weaknesses or gaps in the line of research. Describe the strengths and weaknesses in the rigor of the prior research (both published and unpublished) that serves as the key support for the proposed project. Describe plans to address weaknesses in the rigor of the prior research that serves as the key support for the proposed project. <em>See related FAQs, blog post</em></td>
<td>Research Strategy&lt;br&gt;➢ Significance&lt;br&gt;➢ Approach</td>
</tr>
<tr>
<td>Scientific Rigor (Design)</td>
<td><strong>Scientific rigor</strong> is the strict application of the scientific method to ensure robust and unbiased experimental design, methodology, analysis, interpretation and reporting of results. Emphasize how the experimental design and methods proposed will achieve robust and unbiased results. <em>See related FAQs, blog post, examples from pilots</em></td>
<td>Research Strategy&lt;br&gt;➢ Approach</td>
</tr>
<tr>
<td>Biological Variables</td>
<td><strong>Biological variables</strong>, such as sex, age, weight, and underlying health conditions, are often critical factors affecting health or disease. In particular, sex is a biological variable that is frequently ignored in animal study designs and analyses, leading to an incomplete understanding of potential sex-based differences in basic biological function, disease processes and treatment response. Explain how relevant biological variables, such as the ones noted above, are factored into research designs, analyses, and reporting in vertebrate animal and human studies. Strong justification from the scientific literature, preliminary data or other relevant considerations must be provided for applications proposing to study only one sex. <em>See related FAQs, blog posts, article</em></td>
<td>Research Strategy&lt;br&gt;➢ Approach</td>
</tr>
<tr>
<td>Authentication</td>
<td>Key biological and/or chemical resources include, but are not limited to, cell lines, specialty chemicals, antibodies and other biologics. Briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies. These resources may or may not have been generated with NIH funds and: • may differ from laboratory to laboratory or over time; • may have qualities and/or qualifications that could influence the research data; • are integral to the proposed research. The authentication plan should state in one page or less how you will authenticate key resources, including the frequency, as needed for your research. Note: Do not include authentication data in your plan. <em>See related FAQs, blog post, examples</em></td>
<td>Other Research Plan Section&lt;br&gt;➢ Include as an attachment&lt;br&gt;➢ Do not include in the Research Strategy</td>
</tr>
</tbody>
</table>

**This chart is based on general instructions for research grant applications submitted for January 25, 2019 due dates and beyond. It should only be used as a guide. For all applications, please read the applicable Funding Opportunity Announcement (FOA) & Application Guide for specific instructions.**

Scientific Premise

- Applicants should consider scientific premise of proposed research
- Discussion of strengths and weaknesses of prior research crucial to support application
- Consideration of strengths and weaknesses could include:
  - Attention to rigor of previous experiments
  - Methodology, analysis, and interpretation
  - Relevant biological variables
  - Authentication of key resources

Rigorous Experimental Design

Scientific Rigor:
Strict application of scientific method to ensure robust and unbiased experimental design, methodology, analysis, interpretation and reporting of results

- Full transparency in reporting permits others to reproduce and extend the research
- Journal guidelines aligned with application instructions to reinforce transparency
- Robust and unbiased results are reproducible under well-controlled and reported experimental conditions

Updated Application Instructions:

Relevant Biological Variables

5.5.3 Research Strategy:

Approach

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately in the Resource Sharing Plan, include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.
- Describe the experimental design and methods proposed and how they will achieve robust and unbiased results.
- Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
- If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work.
- Explain how relevant biological variables, such as sex, are factored into research designs and analyses for studies in vertebrate animals and humans.
  - For example, strong justification from the scientific literature, preliminary data, or other relevant considerations, must be provided for applications proposing to study only one sex.
  - Please refer to NOT-OD-15-102 for further consideration of NIH expectations about sex as a biological variable.

Other Research Plan Attachment:

Authentication of Key Biological and/or Chemical Resources
Briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies.

Key biological and/or chemical resources may or may not be generated with NIH funds and:
1) may differ from laboratory to laboratory or over time;
2) may have qualities and/or qualifications that could influence the research data; and
3) are integral to the proposed research.

These include, but are not limited to, cell lines, specialty chemicals, antibodies, and other biologics.

Standard laboratory reagents that are not expected to vary do not need to be included in the plan. Examples are buffers and other common biologicals or chemicals.

Reviewers will assess the information provided in this Section. Any reviewer questions associated with key biological and/or chemical resource authentication will need to be addressed prior to award.

Information in this section must focus only on authentication and/or validation of key resources to be used in the study; all other methods and preliminary data must be included within the page limits of the research strategy. Applications identified as non-compliant with this limitation will be withdrawn from the review process (see NOT-OD-15-095).

http://grants.nih.gov/reproducibility/index.htm
Example of How Research Has Been Impacted

Apparent Effects (Noise) vs. Cohort Size

Small cohort sizes increase the chance of an apparent effect in the SOD1 mouse model of ALS.

https://grants.nih.gov/reproducibility/module_1/presentation_html5.html
Resources:

- Learn about the NIH Initiative to Enhance Reproducibility through Rigor and Transparency. (Video)
- Principles and Guidelines for reporting preclinical research https://www.nih.gov/research-training/rigor-reproducibility/principles-guidelines-reporting-preclinical-research
- NIH Rigor and Reproducibility: https://www.nih.gov/research-training/rigor-reproducibility
- NIH Grants and Funding page on Rigor and Reproducibility: https://grants.nih.gov/reproducibility/index.htm
- Grant Application instructions: https://www.nih.gov/research-training/rigor-reproducibility/updated-application-instructions-enhance-rigor-reproducibility
- https://grants.nih.gov/reproducibility/index.htm#guidance
- Get involved: Association for Biomolecular Resource Facilities (ABRF) Committee for Core Rigor and Reproducibility (CCoRRE) https://abrf.org/committee/committee-core-rigor-and-reproducibility-ccorre
Goal is that this becomes a community based activity.
Three Areas of Focus

- **Data Management**
  - In collaboration with NUIT
  - Team leads: Dina Arvanitis and Chad Haney

- **Best practices for service based / collaborative data generation cores**
  - Team leads: Paul Thomas and Leah Welty

- **Best practices for instrumentation / user based data generation cores**
  - Team Leads: Ben Myers and Jessica Hornick
Timeline

- Now- Requesting volunteers to serve on teams: https://weinberg.co1.qualtrics.com/jfe/form/SV_8q1Z85OsvBndu0B
- May 2019: Finalize teams
- June-Aug 2019: 2-3 meetings to identify key practices that the group feels are needed in order to meet R&R requirements and identify examples of those practices
- September/October 2019: Teams present out to the cores at next core colloquium

Expect total time commitment to be 10-15 hours

Ongoing- Output of these teams will lead to:
- Development of Rigor and Reproducibility page on CFA website
- Prioritization of investment in tools needed to implement best practices
- Expectation that cores develop plans to implement best practice
- Expectation that cores document in a way that faculty will benefit when submitting proposals