CTMC seminar

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Disclosure

The presenters have no commercial or financial interests, relationships, activities, or other conflicts of interest to disclose related to this presentation.
Significance/Innovation/Preliminary data/Approach/Rigor/Recruitment Feasibility/Analyses

- **Significance (Scored criterion):**
  - Define the problem and demonstrate impact of solving it.
  - Common approaches include listing disease incidence, economic costs.
  - When dealing with a rare disorder explain how knowledge gained could impact more broadly
  - Define impact on treatment/diagnosis/prognostication if the project is completed.

- **Innovation (Scored Criterion):**
  - This can be technological, methodological or conceptual.
  - Most commonly development or early adoption, or first adoption of novel technology.
  - Methods: novel trial design, novel outcome measure etc.
  - Novel hypothesis that challenges existing paradigm
Approach

• Preliminary data (Scored under approach):
  • Opportunity to demonstrate that the applicant/team is capable of performing proposed plan.
  • Addresses feasibility: recruitment, feasibility of assay, technology, analytics
  • Unpublished Innovations

• Approach (Scored: most common target of criticism; Weaknesses are found here).
  • How will you accomplish your aims?
  • Clear, precise delineation of Inclusion criteria, exclusion criteria, subject enrollment mechanism, intervention.
Approach

• Primary outcome Must be clearly stated, easy to understand. Provide published or preliminary evidence that it is feasible, reproducible, sensitive and specific measure of the variable of interest (rigor).

• Secondary outcomes: Justify each.

• Refer to statistical analysis plan (rigor), with justification of expected effect size, and sample size.

• Recruitment (common problem) Provide all evidence to support your claim that you can recruit sufficient number of subjects. Be realistic, common error is to be overly optimistic.

• Address briefly inclusion of women, children, minorities. Also safety plan. Longer description in human subjects.
Environment & investigator

• Environment: Demonstrate that adequate institutional/network resources exist to support proposed research.
  • If single institution grant then list department/school/university resources (equipment/infrastructure/people).
  • If through a network then list network resources and individual site resources.

• Investigator: New Biosketch form lets you tell your story. List your strengths and weaknesses. Explain how you will address your weakness(es) (usually by using collaborators). List your areas of expertise and publications.

• Online tool to create Biosketch: My NCBI » SciENcv
Grant preparation (Admin)

- Timing, institutional support, administrative needs.
  - Multicenter grants require administrative planning, sub contract negotiation, site budgets, support letters. Plan 6-12 months ahead.
  - Prepare Budget early, revise often as you think of new items. Ask for budgets from other sites early.
  - Justify each and every item/person esp. if non modular.
  - If >500 K per year get NIH permission.
  - Make sure to meet with your Institutional officials to ensure that you have support letters as needed.
Summary statement

- Review Group: Example: NSD-K
- SRG Action: Impact Score: Range 10-90 or **
- Summary of discussion (If scored) This is what was said at the meeting about your application. This discussion determined the final score. Longer when committee is divided.

Individual critiques (Minimum of 3):

Scored criteria

- Significance:
- Investigator(s):
- Innovation:
- Approach:
- Environment:

Discussed after scores

WHAT STUDY SECTIONS HATE

• Sloppiness (grammar, spelling, organization)- ALL sections

• Too dense, play on font size and space, small images

• Overly ambitions (especially for Jr, or training grants)

• Dependent Aims!

• Lack of serious statistical support

• Poor justification for your approach (populations, testing instruments, outcome measures, alternative hypotheses)

• Outrageous budgets

• Lack of attention to human subjects
WHAT STUDY SECTIONS LOVE

• Clean, supported story
• Solid connection from significance, foundation (prelim data), approach, outcomes, interpretation of results
• Thoughtful discussion of limitation and how the outcome of the grant will guide discovery even if negative
• Evidence that you can do the study - recruitment (type and number), expertise in group, ...especially showing have done before.
• Clear path for next step especially if Go-No-Go grant
• Lack of serious statistical support
• Strong statistical plan
WHAT HAPPENS IN STUDY SECTION
## Scoring Descriptions

<table>
<thead>
<tr>
<th>Impact</th>
<th>Score</th>
<th>Descriptor</th>
<th>Strengths/Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Impact</td>
<td>1</td>
<td>Exceptional</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Outstanding</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Excellent</td>
<td></td>
</tr>
<tr>
<td>Moderate Impact</td>
<td>4</td>
<td>Very Good</td>
<td></td>
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<tr>
<td></td>
<td>5</td>
<td>Good</td>
<td></td>
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<tr>
<td></td>
<td>6</td>
<td>Satisfactory</td>
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</tr>
<tr>
<td>Low Impact</td>
<td>7</td>
<td>Fair</td>
<td></td>
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<tr>
<td></td>
<td>8</td>
<td>Marginal</td>
<td></td>
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<tr>
<td></td>
<td>9</td>
<td>Poor</td>
<td></td>
</tr>
</tbody>
</table>

**Non-numeric score options:** NR = Not Recommended for Further Consideration, DF = Deferred, AB = Abstention, CF = Conflict, NP = Not Present, ND=Not Discussed
<table>
<thead>
<tr>
<th>Score</th>
<th>Descriptor</th>
<th>Additional Guidance on Strengths/Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Exceptional</td>
<td>Exceptionally strong with essentially no weaknesses</td>
</tr>
<tr>
<td>2</td>
<td>Outstanding</td>
<td>Extremely strong with negligible weaknesses</td>
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<tr>
<td>3</td>
<td>Excellent</td>
<td>Very strong with only some minor weaknesses</td>
</tr>
<tr>
<td>4</td>
<td>Very Good</td>
<td>Strong but with numerous minor weaknesses</td>
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<tr>
<td>5</td>
<td>Good</td>
<td>Strong but with at least one moderate weakness</td>
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<tr>
<td>6</td>
<td>Satisfactory</td>
<td>Some strengths but also some moderate weaknesses</td>
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<tr>
<td>7</td>
<td>Fair</td>
<td>Some strengths but with at least one major weakness</td>
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<tr>
<td>8</td>
<td>Marginal</td>
<td>A few strengths and a few major weaknesses</td>
</tr>
<tr>
<td>9</td>
<td>Poor</td>
<td>Very few strengths and numerous major weaknesses</td>
</tr>
</tbody>
</table>

Minor Weakness: An easily addressable weakness that does not substantially lessen impact
Moderate Weakness: A weakness that lessens impact
Major Weakness: A weakness that severely limits impact
What Happens in Study Section

- Initial scores
- Primary Reviewer 1
  - Provides an overview of your proposal
- Scientific foundation reviewer
  - Presents the preclinical supporting data
- Assigned Reviewers 2-(10)
  - Each get their shot at what’s wrong with the grant
- Floor opens to other non-assigned reviewers
  - Questions back and forth to assigned reviewers
- Final points by assigned reviewers
- Final scores (tightening of the range sought)
- Budget
<table>
<thead>
<tr>
<th><strong>REVIEW CRITERIA AT A GLANCE – RESEARCH</strong></th>
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</thead>
<tbody>
<tr>
<td><strong>Overall Impact</strong></td>
</tr>
<tr>
<td><strong>Scored Review Criteria</strong></td>
</tr>
<tr>
<td>(Scored individually and considered in overall impact score)</td>
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<tr>
<td>PAR &amp; RFA: May add questions to each scored criterion or additional criteria</td>
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<tr>
<td><strong>Additional Review Criteria</strong></td>
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<td>(Not scored individually, but considered in overall impact score)</td>
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<tr>
<td>PAR &amp; RFA: May add new criteria or questions to each additional criterion</td>
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<tr>
<td><strong>Additional Review Considerations</strong></td>
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<tr>
<td>(Not scored individually and not considered in overall score)</td>
</tr>
<tr>
<td><strong>Additional Comments to Applicant</strong></td>
</tr>
</tbody>
</table>

### Scored Review Criteria
- Significance
- Investigator(s)
- Innovation
- Approach
- Environment

### Additional Review Criteria
- U01-BRP only:
  - Partnership and Leadership
- All:
  - Protections for Human Subjects
  - Inclusion of Women, Minorities, & Children
  - Vertebrate Animals
  - Biohazards
  - Resubmission
  - Renewal
  - Revision

### Additional Review Considerations
- U01-BRP only:
  - Technology Transfer
- All:
  - Applications from Foreign Organizations
  - Select Agents
  - Resource Sharing Plans
  - Authentication of Key Biological and/or Chemical Resources
  - Budget & Period of Support

### Additional Comments to Applicant
- Additional Comments to Applicant

Responses for items with emphasis (italics) are required.

*Last updated June 1, 2016*
Review Criteria

Each scored 1-9

- **Overall IMPACT** (Total Score – not average)
- **Significance** – (incremental advance vs change the field)
- **Investigators** – (experience, experts, stats)
- **Innovation** – (Too little, too much)
- **Approach** – (90% of the review)
- **Environment** – (mostly covered if at academic facility)

- Human Subjects (target diversity and genders)
- Other (training grant etc.)
- Budget

Overall Impact Score 1-9 x 10 = final score (e.g. 30); Final Percentile Rank – how many grants scored better than yours (e.g. 50%) in the study section – rank of your grant and pay line based on percentile, not your grant score.
OMG – NOT DISCUSSED (ND)

MY PROPOSAL WAS NOT SCORED!!!!

• Does not mean the idea is doomed
• Proposals had enough flaws to push score into non-competitive
• Read reviews carefully and respond to EVERY comment
ITS OK, YOU CAN RE-APPLY
## David Wright

**#5 3B | Bats: R, Throws: R | New York Mets**

**Birth Date**: December 20, 1982 (Age: 33)
**Birthplace**: Norfolk, VA
**Experience**: 12 years
**College**: None
**Ht/Wt**: 6-0, 206 lbs.

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**2016 Season**

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<tr>
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**Career**

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<tr>
<td>0.298</td>
<td>235</td>
<td>956</td>
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How to handle potential problems

• The best way is to not have them happen in the first place!
• Read the instructions and then read them again
• Know the deadlines at your institution
  • The way you handle this will set the stage for the help you receive in the future
  • Good manners, playing by the rules will put you in good graces
  • These people run on overtime ALL the time
• Expect technical problems - they will happen
• No one is as invested in your grant as you are
Submitting Your Competing Grant Application

The majority of competing applications now require electronic application submission. The Funding Opportunity Announcement (FOA) to which you are applying will identify whether you must submit electronically or use paper submission. Note that paper submissions require use of the PHS 398 application form, while electronic submission requires the SF424 (R&R) application. Make sure to read instructions in the Funding Opportunity Announcement and the application guide to determine submission requirements.

Submitting Your Competing Grant Application

- **Submission dates.** The FOA provides discrete application deadlines or will refer to NIH’s standard due dates.
- **Late applications.** NIH expects applications to be submitted on-time. The NIH Policy on Late Submission of Grant Applications applies both to paper and electronically submitted grant applications.

Electronic Application Submission

- **Do your homework.** Take the time to understand the process. Electronic submission involves two separate systems working together – Grants.gov and eRA Commons. The Applying Electronically website and the application guide will walk you through every step of the process.

- **Develop a submission plan.** Institution administrators and principal investigators should work together to come up with a submission plan. Think about:
  - What funding opportunity announcement should be used?
  - Who will be responsible for completing the different forms within the application?
  - How will the application file be shared between different contributors (e.g. email attachment, placed on shared drive, copied to portable media)?
  - When must the forms be completed in order to allow time for the actual submission?

- **Prepare to submit.** Electronic submission requires institutions to register with Grants.gov and NIH eRA Commons (Grants.gov registration; eRA Commons registration). Principal Investigators (PIs) also will need to make sure they are registered with the eRA Commons (Creating PI Account).

  Registration can take 8 weeks or more – start early!

- **Verify successful submission.** Your Authorized Organization Representatives submits your SF424 (R&R) application to Grants.gov. The NIH will retrieve your application and process it into our own electronic system, the eRA Commons. Part of that process includes actually assembling the data and PDF attachments submitted into a cohesive application. You will be able to login to eRA Commons to see if any “errors” or “warning” were identified for your submission. An application must be error-free to complete the electronic submission process.

  You are responsible for checking eRA Commons to ensure successful submission of your application!
View your assembled application. Once an error-free application is received, NIH holds that application for two days (Monday-Friday, excluding Federal holidays) to allow submitters and PIs a chance to view the final assembled application in eRA Commons. This is your first opportunity to see the application just as a reviewer will see it – take advantage of it!

- See Check Assembled Application for details.

Paper Application Submission

- Confirm submission requirements. The majority of competing applications now require electronic submission; however, there still are a few grant programs that accept paper. Check your opportunity announcement carefully for submission requirements prior to using the paper PHS 398 application format.

- Pack it. Use one package (including all copies) per application.

- Send it. All applications and other deliveries must be submitted either via courier delivery or via the US Postal Service (USPS) to the NIH at:

  Center for Scientific Review  
  National Institutes of Health  
  6701 Rockledge Drive, Room 1040 - MSC 7710  
  Bethesda, Md. 20892-7710 (regular USPS or USPS Express mail)  
  Bethesda, Md. 20817 (other courier/express mail delivery)

  Phone: 301-435-0715

- Address Labels (MS Word - 42 KB)
- Address Labels (PDF - 30 KB)

- Do not hand deliver your application. Applications delivered by individuals to the Center for Scientific Review will not be accepted.

- Related NIH Guide Notices:

  - Reminder and Clarification – Delivery of Competing Grant, Cooperative Agreement, and Fellowship Applications (April 2003)
  - Mail Address to the National Institutes of Health (November 2001)

Finding Help

- Grants Information. The Grants Information office provides general information to the biomedical research community about NIH extramural research and research training programs, grant application procedures and process, and other general research grant information.

Grants Information  
Division of Communications and Outreach  
Office of Extramural Research  
National Institutes of Health  
E-mail: grantsinfo@nih.gov  
Telephone: (301) 710-0267
A little bit about reviewers...

• They are looking at things cold
• They are working under pressure just like you
• They do not have the benefit of lengthy discussions with the research team
• They do not have time to read the proposal over and over again
• Burden of proof is on the proposer
• If information cannot be found quickly it will be considered missing
• They are looking for problems
Responding to reviewer comments

• Reviewers may not be from same discipline
  • Check section roster and PubMed/Google them
  • May need to speak to a wider audience
  • Identify common themes among reviewers
• Don’t take it personally – it’s not about YOU
• Take feedback seriously
• Get advice from agency staff – ASAP
• Get senior mentor/colleagues to help interpret comments and frame response
  • Reserve one person to “cold” react to your resubmission
  • Preferably someone who sits on a study section
  • Respond accordingly
Sulking is normal...
but get over it quickly
What happens next?

• Expect to make a second submission
  • Leave plenty of time to overhaul in response to study section and colleagues
  • Do not rush to resubmit, put the pink sheets away for a week
  • Never let your outrage show in the response
  • Thank the reviewers for their valuable comments even if you think they are wrong (the reviewer is ALWAYS right)
  • Respond to ALL comments in the Response section and the text
• Look for sources of bridge funding
• Diversify - never write a proposal that you only intend to submit to one place
Questions?