Eunice Kennedy Shriver National Institute of Child Health and Human Development

New Home for NICHD:
6710 Rockledge Drive, Bethesda, MD, 20817

Clinical Trial Workshop & Mock Study Section NICHD Young Investigators Conference 2016

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Outline

- Clinical Trial Workshop
  - Purpose and process
- Mock study section
  - Purpose and process
  - Review criteria and scoring scale
  - Other issues such as conflict of interest and confidentiality

Clinical Trials Workshop

- Real-life experience of designing a RCT
- The reasons for your intervention choices:
  - What intervention and why?
  - Inclusion and exclusion criteria? Why?
  - Study end points? Why those?
  - Study feasibility

At the end of t he Workshop. . .

- You will have designed a randomized control trial ready to be launched, with justifiable rationale for all your choices
- Format: open-ended discussion led by two faculty.

Mock Study Section: Purpose

- A real-life experience of the review process, and to help you prepare better applications
  - Three applications have been distributed
    - R01, R03, and K23 (or K08)
  - Instructions provided
- Mock study-section will be conducted similar to the real study section

What are “Study Sections”?

- CSR—Gateway for all applications to be received
- CSR convenes non-NIH scientists to review applications.
- More than 20,000 scientists review ~70,000 applications each year, about 70% are reviewed by CSR Study Sections
- Study sections are organized around topic themes

Study Section Meeting Process

- Scientific review officer (SRO)
- Chair runs the meeting
- Members are both regular, ad-hoc, or mail-in
- SRO's Administrative assistant
- Program Officers are "visitors"
- Meetings are closed to the general public

Mock Study Section Meeting

- SRO: meeting to order: confidentiality, conflicts of interest explained
- The Chair asks the assigned reviewers to give their “initial level of enthusiasm” or the “impact score.”
- Each reviewer presents the strengths and weaknesses.
- Open discussion: statistician’s input
- Other scoring criteria; Humans and animal safety; Inclusion of gender, minority and children; Biohazard
- The assigned reviewers restate their impact scores
- <u>All members score confidentially</u>
- Budget (non-scoring criteria) appropriate or not?

Training Review Criteria at a Glance (for Parent Announcements)

	Fellowship (F30, F31, F32, F33)	Career Development (K01, K02, K07, K08, K23, K24, K25, K99)	Institutional Training (T32, T35, K12)
Overall Impact	Overall Impact/Merit	Overall Impact	Overall Impact
Scored Review Criteria (Scored individually and considered in overall impact score)	✓ Fellowship Applicant ✓ Sponsors, Collaborators, and Consultants ✓ Research Training Plan ✓ Training Potential ✓ Institutional Environment & Commitment to Training	✓ Candidate ✓ Career Development Plan/Career Goals & Objectives/Plan to Provide Mentoring ✓ Research Plan ✓ Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s) ✓ Environment & Institutional Commitment to the Candidate	✓ Training Program and Environment ✓ Training PD/PI ✓ Preceptors /Mentors ✓ Trainees ✓ Training Record Other T programs use other criteria
Additional Review Criteria (Not scored individually, but considered in overall impact score)	✓ Protections for Human Subjects ✓ Inclusion of Women, Minorities, & Children ✓ Vertebrate Animals ✓ Biohazards • Resubmission • Renewal	✓ Protections for Human Subjects ✓ Inclusion of Women, Minorities, & Children ✓ Vertebrate Animals ✓ Biohazards • Resubmission • Renewal • Revision	✓ Protections for Human Subjects ✓ Inclusion of Women, Minorities, & Children ✓ Vertebrate Animals ✓ Biohazards • Resubmission • Renewal • Revision
Additional Review Considerations (Not scored individually and not considered in overall score)	✓ Training in the Responsible Conduct of Research • Applications from Foreign Organizations • Select Agents • Resource Sharing Plans ✓ Budget & Period of Support	✓ Training in the Responsible Conduct of Research • Select Agents • Resource Sharing Plans ✓ Budget & Period of Support	✓ Recruitment & Retention Plan to Enhance Diversity ✓ Training in the Responsible Conduct of Research • Select Agents ✓ Budget & Period of Support
Additional Comments to Applicant	Additional Comments to Applicant	Additional Comments to Applicant	Additional Comments to Applicant

Research Review Criteria at a Glance
(for Parent Announcements)

	Research and Research Center (R, DP, RC, P, etc)	SBIR/STTR (R41, R42, R43, R44)	Academic Research Enhancement Award (AREA) (R15)
Overall Impact	*Overall Impact*	*Overall Impact*	*Overall Impact*
Scored Review Criteria (Scored individually and considered in overall impact score) PAR & RFA: May add questions to each scored criterion or additional criteria	✓ *Significance* ✓ *Investigator(s)* ✓ *Innovation* ✓ *Approach* ✓ *Environment*	✓ *Significance* ✓ *Investigator(s)* ✓ *Innovation* ✓ *Approach* ✓ *Environment*	✓ *Significance* ✓ *Investigator(s)* ✓ *Innovation* ✓ *Approach* ✓ *Environment*
Additional Review Criteria (Not scored individually, but considered in overall impact score) PAR & RFA: May add new criteria or questions to each additional criterion	R01-BRP only: • Partnership and Leadership All: ✓ *Protections for Human Subjects* ✓ *Inclusion of Women, Minorities, & Children* ✓ *Vertebrate Animals* ✓ *Biohazards* • Resubmission • Renewal • Revision	• Phase II • Fast Track ✓ *Protections for Human Subjects* ✓ *Inclusion of Women, Minorities, & Children* ✓ *Vertebrate Animals* ✓ *Biohazards* • Resubmission • Renewal • Revision	✓ *Protections for Human Subjects* ✓ *Inclusion of Women, Minorities, & Children* ✓ *Vertebrate Animals* ✓ *Biohazards* • Resubmission • Renewal • Revision
Additional Review Considerations (Not scored individually and not considered in overall score)	R01-BRP only: ✓ *Technology Transfer* All: • Applications from Foreign Organizations • Select Agents • Resource Sharing Plans ✓ *Budget & Period of Support*	• Select Agents • Resource Sharing Plans ✓ *Budget & Period of Support*	• Select Agents • Resource Sharing Plans ✓ *Budget & Period of Support*
Additional Comments to Applicant	Additional Comments to Applicant	Additional Comments to Applicant	Additional Comments to Applicant

Scores

- Criteria score
  - Scores for individual review criteria given 3 assigned reviewers only
- The Impact or Priority Score (PS)
  - The average of scores by all member
  - Reflects the overall strength of the application
  - <u>Ranked to make funding decisions (some mechanisms are given “percentile” score based on priority score</u>
  - <u>Not an average of criteria score!</u>

The Impact/Priority Score

- The SRO obtains the average, multiplies by 10 and includes it in the summary statement.
- The final score ranges from 10-90
- It is NOT the average of the criteria scores

Overall Impact-Priority Score

Score	Descriptor	Comments
1	Exceptional	Exceptionally strong with essentially no weaknesses
2	Outstanding	Exceptionally strong with negligible weaknesses
3	Excellent	Very strong with some minor weaknesses
4	Very Good	Very strong with many minor weaknesses
5	Good	Strong but with at least one moderate weakness
6	Satisfactory	Some strengths, but with some moderate weaknesses
7	Fair	Some strengths, but with at least one major weakness
8	Marginal	A few strengths and a few major weaknesses
9	Poor	Very few strengths, and many major weaknesses

Example of Criteria Scores

Reviewer	Significance	Investigator	Innovation	Approach	Environment
Primary	5	1	7	2	1
Secondary	2	1	5	2	1
Reader	6	2	8	2	1

- **Priority Score was 45**

What did the criteria scores say?

- You are a terrific investigator. (Scored “two 1s and one 2”)
- You are working in a great university (Scored three “1s”)
- The overall methodology is not so bad, either. (Scored three “2s”)
- There is nothing new in the proposal; and it does not matter whether you do the study or not. So, basically, it stinks (Scored 5/6 were worse than 5)

- “It is not worth doing—so, it is not worth doing well.”

The Summary Statement

SUMMARY STATEMENT
(Privileged Communication)

PROGRAM CONTACT:
TONSE RAJU
(301) 402-1872
rajut@mail.nih.gov

Release Date: **03/25/2013**

Application Number: [redacted]

Principal Investigator
[redacted]

Review Group: **ZRG1 EMNR-P (55)**
Center for Scientific Review Special Emphasis Panel
RFA Panel: Studies in Neonatal Resuscitation

Meeting Date: **02/27/2013** ***RFA/PA:*** **PAR11-222**
Council: **MAY 2013** ***PCC:*** **PPB -TR**
Requested Start: **07/01/2013**

Project Title: [redacted]

SRG Action: **Impact Score: 38 Percentile: 29 #**
Next Steps: **Visit http://grants.nih.gov/grants/next_steps.htm**
Human Subjects: **10-No human subjects involved**
Animal Subjects: **44-Vertebrate animals involved - SRG concerns**

Project Year	Direct Costs Requested	Estimated Total Cost
1	243,847	370,647
2	263,144	399,979
3	250,128	380,194
4	261,773	397,895
5	287,084	436,368
TOTAL	1,305,976	1,985,083

ADMINISTRATIVE BUDGET NOTE: The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.

NEW INVESTIGATOR

When you re-apply

- Read the summary statement thoroughly
- Discuss with your colleagues/mentors, and NIH Program Officer about the best way to respond to the critiques
- Pay attention to the criterion scores
- Respond to each item clearly, but politely (Thank the reviewers for their thoughtful review)
- Highlight the changes

NIH is Not an ATM
It is a Partner in Science

- Talk to the Program Official before and after applying, and before re-applying
- When you receive major awards or publish important papers
- Press releases by your institution as well as by NIH
- Such communications help the NIH
- Your academic success is our success!

Useful Websites

- http://cms.csr.nih.gov
  - See a mock study section video
  - Standing IRGs and their membership
- http://enhancing-peer-review.nih.gov/
  - New peer review items
- **Research Portfolio Online Reporting Tool (*RePORT*)**
  - *http://report.nih.gov/index.aspx*

Thank You

Questions?