My application has been reviewed...so now what?

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Learning Objectives

- After this session, attendees should be able to:
  - Explain what happens after peer review
  - Identify who to speak with about their priority score and/or summary statement
  - Assess the appropriate actions if their application is not selected for award
  - Determine the actions necessary if the application is selected for award including resolving concerns from peer review and meeting just-in-time requirements
Specific Discussion Points

- Quick primer on timeline and roles
- Understanding your score
- Interpreting your summary statement
- What should I do if I’m not selected for funding?
- What happens if I am likely to be selected for funding?
  - Resolving concerns
  - Just in time requirements and procedures
  - Touch on Notice of Award
NIH Extramural Administrative Team

- Scientific Review Officer
- Program Officer
- Grants Management Specialist
**Roles and Responsibilities:**

- Manages portfolio of grants
- Conduct site visits
- Participate in IC funding priorities discussion
- Attend scientific meetings; serve on professional society and IC committees
- Plan NIH-sponsored scientific meetings
- Communicate scientific advances to the Branch, Center, and Institute Directors

**When to contact:**

Prior to application submission and after receiving a summary statement through award close out
**Roles and Responsibilities:**

- Recruits reviewers for study section meetings
- Assigns applications to reviewers; explains/interprets review criteria
- Runs study section meeting
- Calculates impact score and percentile
- Drafts narrative summaries, edits reviewer critiques (minimal edits), and releases summary statement

**When to contact:**
After application submission through release of summary statement
Roles and Responsibilities:

- Acts as an agent of the GMO
- Assures compliance with Federal laws and NIH policies and procedures
- Analyzes grant applications prior to award
- Prepares award for GMO release
- Reviews and responds to grantee prior approval and re-budgeting requests
- Assures documentation of official grant files

When to contact:
After receiving a fundable score through award close out
Review System for Grants

Scientific Review Group (SRG)
- Independent outside review managed by NIH
- Evaluate scientific merit, significance, other criteria
- Provides priority score
- Recommend length and level of funding

Output: Impact Score and Summary Statement

Advisory Council
- Assess quality of SRG process
- Offers recommendation to Institute/Center Director and staff
- Evaluates program priorities and relevance
- Advises on policy

Output: Funding Recommendations

Institute/Center Director
- Makes final decision based on Council input, programmatic priorities
- Must also pass administrative review

Output: Awards or Resubmission

3 - 7 months

1 - 3 months
Understanding Your Score

- Peer review scoring system
- What does the percentile mean?
- Why do I have a percentile but my colleague doesn’t?
- What to do when you get your score?
  - Wait until you have a summary statement to go with it before contacting your Program Officer
Understanding Your Score

• Assigned reviewers: scores for each criterion and an overall impact/priority score

• All reviewers score privately from 1 (best) to 9 (worst).

• Overall scores are averaged, rounded to one decimal place, and multiplied by 10 e.g., a 1.34 average is a score of 13.
Understanding your score

• After the meeting, reviewers may edit their criterion scores and critiques, but not the overall impact/priority scores.
  ▪ Note: Reviewers do not always edit to reflect the discussion. Depends on the reviewer and the panel.

• Your priority score in your Commons account within 3 business days after the peer review

• Your summary statement typically available within 30 days.
Understanding your score

- **Score with percentile**
- **Score with no percentile**
- **Unscored**
  - Scientific merit in the lower 50% of the applications or beyond the group likely to be competitive for funding
- **Not Recommended for Further Consideration**
  - Indication of serious concerns.
  - Usually not eligible for funding
Understanding Paylines and Percentiles

- Percentiles indicate a relative rank of your application compared to others reviewed by your study section at the last three meetings.
- Percentiles are used counter “score creep” and variation in use of review criteria by different study sections.
- Percentiles range from 1 to 99 in whole numbers.
- Smaller number is better (e.g. 10 is better than 25).
I have a percentile but my colleague doesn’t……

- Percentiles are only meaningful when there is a good comparison group such as all R01 applications reviewed by the CSR “XYZ” Study Section for the last 3 meetings

- Not meaningful when…
  - Special emphasis panel
  - Small number of one type
  - Major change in process impacts some but not all applications
Interpreting Your Summary Statement

- When will I get my summary statement?
  - Usually about 4-8 weeks after the review panel meeting
  - Tips about contacting NIH staff

- Review and “digest” it

- Review the “Next Steps” guidance provided on your summary statement
  - [http://grants.nih.gov/grants/next_steps.htm](http://grants.nih.gov/grants/next_steps.htm)
  - Look under SRG Action: Impact Score on the SS

- Who do I talk with about my summary statement?
  - Program Officer, not the Scientific Review Officer
  - Colleagues and/or mentors
Interpreting Your Summary Statement

• How do I find my program officer?
  ▫ eRA Commons Account
  ▫ Upper Left Corner of the Summary Statement

• What questions do I ask?
  ▫ Likelihood of funding
    • Know that they probably won’t be able to tell you for certain but you can get a feel for it
  ▫ Thoughts about resubmitting
  ▫ Timing for funding consideration and next steps
Likelihood of Funding… it depends

October to January

*No budget yet (usually)*

- Operate under a continuing resolution previous FY $ level
- Fund a limited number of applications.
- Other awards delayed

Winter Until Spring

*Have a budget*

- Congress passes appropriations bill, president signs into law, setting NIH's budget levels
- DHHS needs several weeks to analyze budget
Likelihood of Funding… it depends

Spring to Early Summer

Budget arrives at Institutes

- Number crunching
- Each institute sets their financial management plan
- Fund grants within payline
- Fund a few grants through special funding programs

July to September

Close of fiscal year

- Number crunching
- Revisit payline if needed
- Pay deferred applications
- Special pay programs
At the start of the fiscal year, you will more likely have to wait for an award because funding is limited.

If your application missed the payline, it may get funded later in the fiscal year.

Institutes may have funding pools to use for high priority or special need areas (e.g. selective pay, Bridge awards).

Stay in touch with your Program Officer
Sample Summary Statement*

PROGRAM CONTACT: Mercy Prabhudas

Principal Investigator
MCCUNE, JOSEPH M MD, PHD

Applicant Organization: UNIVERSITY OF CALIFORNIA SAN FRANCISCO

Review Group: IHD
Immunity and Host Defense Study Section

Meeting Date: 10/14/2010
Council: JAN 2011
Requested Start: 04/01/2011

Application Number: 1 R21 AI094009-01

RFA/PA: PA10-069
PCC: I2H

Project Title: Human immune system layering and the neonatal response to vaccines

SRG Action: Impact/Priority Score: 14

Human Subjects: 30-Human subjects involved - Certified, no SRG concerns
Animal Subjects: 10-No live vertebrate animals involved for competing appl.
Gender: 1A-Both genders, scientifically acceptable
Minority: 1A-Minorities and non-minorities, scientifically acceptable
Children: 1A-Both Children and Adults, scientifically acceptable
Clinical Research - not NIH-defined Phase III Trial

*Summary statement shown with permission for training purposes
RESUME AND SUMMARY OF DISCUSSION: The investigator proposes in this application to test his hypothesis that human fetal and adult hematopoietic stem/progenitor cells (HSPC) give distinct lymphocyte lineages to yield a range of fetal/adult T cells ratio at birth. Neonates with a high ratio will generate predominant Th2 responses to routine childhood immunizations. To test this hypothesis, the investigator will analyze cord blood from infants and correlate this profile with vaccine response to hepatitis B virus (HBV). The Committee felt that the proposed work will provide new information on neonatal immune regulation. Although high risk, the work can provide the foundation to identify those newborns at risk to serious infections and to develop personalized immunization strategies relevant to the immune maturity status. Other strengths include the outstanding investigator; his accomplished collaborators; the excellent research environment and resource; the well laid-out system; the innovative techniques; and, the intriguing supporting data. Despite of minor issues with some approaches, the enthusiasm of the Committee for this application is outstanding because of its feasibility.

DESCRIPTION (provided by applicant): The development of the mammalian immune system is typically thought to occur in a linear fashion, from immaturity to maturity as a function of antigen exposure. Previous findings in birds and in mice, however, indicate that this view is oversimplified. Thus, in these species, the developing immune system appears to be "layered" in a manner that is...
Sample Summary Statement*

CRITIQUE 1:

Significance: 2
Investigator(s): 1
Innovation: 1
Approach: 1
Environment: 1

Overall Impact:
The research in this application should lead to a paradigm shift in our understanding of the development of the neonatal immune system, particularly the shift from a tolerogenic phenotype utero to a highly responsive phenotype after birth. The hypothesis is clearly presented, and the experiments are expected to unequivocally prove or disprove the hypothesis. Either way, the results will be of great interest. If the hypothesis proves to be true, it may become possible to identify those newborns at the highest risk for serious or life-threatening infections, and to tailor immunization strategies to an individual’s immune maturity status.

*Summary statement shown with permission for training purposes
Sample Summary Statement*

Significance: Strengths
The limited ability of the neonatal immune system to effectively resist infections is a major cause of morbidity and mortality. Understanding the reasons for this would allow us to identify the highest risk for infections, might allow us to tailor organization approaches approach and might ultimately lead to immune modulatory approaches. The clear demonstration of layering in the human developing immune system would challenge the prevailing paradigms of immune system development.

Weaknesses

Investigator(s): Strengths
The PI has a long and highly accomplished record in this field, and is exceptionally well-suited for these studies.

Weaknesses

Innovation: Strengths
The application of the concept of layering to the developing human immune system is innovative. The hypothesis that temporal differences in the layering process might lead to variation in balance of Th1 vs Th2 type responses is highly innovative. The development of a transcriptional signature for fetal versus adult lineage T cells is highly innovative.

Weaknesses

Approach: Strengths
The extensive preliminary data, all of which is highly relevant to this proposal, is a clear demonstration of the application. The extremely clear presentation of the experimental approach is another strength. The inclusion of multiple collaborators at different sites as sources for cord blood is good. The well-thought-out and clear data analysis plan is a strength. The overall synergy between the aims and between the sub-aims is remarkable. The expected results and their interpretation are clearly presented.

Weaknesses

Environment: Strengths
The environment at UCSF and the associated clinical sites is essentially perfect for this study.

*Summary statement shown with permission for training purposes
Sample Summary Statement*

Protections for Human Subjects:
Acceptable Risks and/or Adequate Protections
No concerns

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Inclusion of Women, Minorities and Children:
G1A - Both Genders, Acceptable
M1A - Minority and Non-minority, Acceptable
C1A – Children Included, Acceptable no concerns

Vertebrate Animals:
Not Applicable (No Vertebrate Animals)

Biohazards:
Acceptable no concerns

*Summary statement shown with permission for training purposes
What if I’m *not* selected for funding?

- Understand your summary statement
- Discuss options with your Program Officer
- Discuss options with colleagues and/or mentors
- Evaluate your options
- Prepare to re-apply, if applicable
What if I’m *not* selected for funding?

- Assess peer review results and read summary statement carefully
  - Can you readily fix reviewers concerns?
  - Can you clarify things that reviewers misunderstood?
  - Did reviewers have conceptual problems that you can address?
What if I’m not selected for funding?

- **Talk to your Program Official**
  - Are there options for special funding??

- **Ask the PO about**
  - Reviewer support for your idea
  - Additional insight from the review
  - Any issues with the presentation
What if I’m *not* selected for funding?

- **Hard to fix Problems – When to go in a new direction**
  - Low-impact research topic.
  - Philosophical issues, e.g., the reviewers do not think the work is highly significant.
  - Hypothesis is not sound or not supported by the data.
  - Work has already been done.
  - Methods proposed were not suitable for testing the hypothesis.
What to do if I _am_ being considered for funding?

- **Resolve concerns**
  - E.g., human subject protections, vertebrate animal protections, inclusion of women, minorities, and children
- **Complete Just-In-Time Requirements**
- **Restricted Awards**
Resolving Concerns

• A concern is a Bar to Award:
  ▫ Human and Animal Subjects Protection Concern code = 44
  ▫ Inclusion of women, minorities, and children concerns = U (unacceptable) code

• How to resolve concerns
  ▫ Read your summary statement
  ▫ Determine the issue(s) e.g., source of materials, identifiers, risks, protections, informed consent, missing inclusion information, poorly justified sample
  ▫ Contact your Program Officer
  ▫ Submit requested materials via the just-in-time module
  ▫ Resolution may take a few weeks

• Restricted award may be issued
  ▫ Typically at the end of the fiscal year
  ▫ Activity with concern may NOT commence without resolution
Other potential bars to funding

- Lack of assurance code = 20

- Research Misconduct
  - Institutions are required to establish and maintain an assurance that certifies they have a process for responding to allegations of research misconduct.
  - This does not appear in the summary statement
  - Generally due to institution not updating ORI their research misconduct assurance or not having a misconduct assurance in place (usually new institutions, first time grantees)
Just in Time Requirements

- **What is just in time information?**
  - Information that NIH requests after the initial peer review
  - Information NIH needs to make an award but doesn’t require in your application
  - Application within the range of possible funding; JIT request doesn’t mean that your application will be funded.
Just in Time Requirements

- How will I know to submit just in time?
  - **Standard email from NIH.**
    - The NIH issues automatic just-in-time emails for all applications that get an overall impact/priority score of 40 or less. These requests should arrive to you and your business office within 15 days after you get your percentile rank.
  - **Personalized email from individual institute or center.**
    - Grants Management staff issues personal just-in-time requests when funding is likely.
Just in Time Requirements

• What is just in time information?
  ▫ Current Other Support for all key personnel (may need update after 120 days)
  ▫ Human subjects: IRB approval date or Institutional Assurance
  ▫ Documentation of required education in Protection of Human Subjects Research Participants for key personnel
  ▫ Animal Research: IACUC approval date
Just in Time Requirements

• What is just in time information?
  □ Confirm administrative information such as Entity Identification Number (EIN)
  □ Confirm F&A agreement date and rate
  □ Responses to Summary Statement Concerns
  □ Patient Care Costs
Just in Time Requirements

• Where do I send the information?
  ▫ Electronic Submission of Just-in-Time Information
    NIH Guide Notice NOT-OD-12-101
  ▫ Your business official will submit through eRA Commons.

• Be prepared
  ▫ Know what we will ask for and when to send it
  ▫ Contact person: Grants Management
After the Award… Now What?

- Understand what’s in your Notice of Award
- Post-review reporting requirements
- Research Progress Performance Report (RPPR)
Notice of Award (NoA)

- Legally binding document
- Award data and fiscal information
- Grants payment information
- Terms and conditions of award
  - Terms and Conditions in FOA
  - Terms and Conditions in your NoA
  - Used to clarify information, provide programmatic structure, or restrict how you can use funds.

Where to get information?
- eRA Commons; use the Status module or Issued Notice of Award query.

*Your institution accepts the terms and conditions of award when you spend the money*
Differences Between Request and Award

- Peer review may have recommended changes to budget, performance period, or your research plan.
- Overlap may cause funding levels to be lower.
- Programmatic reduction
  - Some ICs reduce award budgets when the annual appropriation doesn’t allow funding at council approved levels.
Reporting After Award

• Annual Research Progress Performance Report (RPPR)
• Annual federal financial reporting
• Subaward reports
• Invention reporting
• Yearly audits (as applicable)
• Closeout reporting
Additional Reporting related to the research

• **Examples:**
  - Clinical Research and/or Trials
    - Protocols registered in Clinical trials.gov
    - Inclusion enrollment reporting at least annually
    - Institute/Center-specific reporting requirements
  - Human subjects IRB approval every year
  - Animal subjects IACUC approval every 3 years
  - Data Sharing
  - Model Organisms
  - Public Access
Resources for Investigators

• NIH Grants Process Overview
  ▫ Homepage:  http://grants.nih.gov/grants/grants_process.htm
  ▫ Award Management page:  http://grants.nih.gov/grants/managing_awards.htm
  ▫ NIH Grants Process: The Big Picture (YouTube)
    https://www.youtube.com/watch?v=rNwsg_PR90w

• Policy pages dedicated to specific topics
  ▫ Examples:  Human subject protections, inclusion of women, minorities, and children, animal protections, peer review, public access, etc.

• Institute/Center-specific resources
  ▫ Grants process
  ▫ Funding plans
  ▫ Reporting and award requirements