Office of Grant & Research Development

NIH Proposal Workshop: AREA Grants
Office of Grant & Research Development

• We are here to help:
  – Assist with proposal preparation
  – Interpret guidelines
  – Proof read drafts, give feedback
  – Assist with budget development
  – Complete the submission process

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Goals of the Workshop

• Understand NIH as a funding mechanism
• Understand the submission process
• Learn how to write successful AIMS
• Become familiar with sections of an NIH proposal
NIH Mission

- Fund biomedical & behavioral research that will improve health of the nation
  - Foster innovation and creative discoveries
  - Develop and maintain resources that ensure the capability of disease prevention
  - Expand medical and associated sciences
  - Promote scientific integrity, accountability and social responsibility
NIH Structure

- Part of the Executive Branch of our government
- Director is a political appointee of the President
- Largest funder of biomedical/biosocial research
- Budget of $30 billion; 83% is for research
- NIH has a legislative responsibility to ensure a high return on the public investment in research
- Organized into 27 Institutes or Centers (I/C)
  - Each has health focus
  - Each institute awards grants
NIH Grant Programs

- Activity codes distinguish between the variety of programs
  - R-Research
  - P-Program and Project
  - K-Career Development

- Three types of funding mechanisms for grant programs
  - Parent Announcement
  - Program Announcement
  - Requests for Application
Funding Opportunities (FOA)

• **Parent Announcements**
  – Used by NIH Institutes/Centers as a common mechanism for submission
  – *Unsolicited or investigator initiated proposals*

• **Program Announcement (PA)**
  – Areas of increased priorities
  – Usually open for three years
    • PAR-special review considerations
    • PAS- specific set aside funds

• **Request for Application (RFA)**
  – Targets funds for certain topics
  – Competitive
Common Parent Announcement
Research Grant Programs

• **R01-Research Grant Program**
  – Supports specific focused projects
  – Most common funding mechanism for research institutions

• **R03-Small Grant Program**
  – Support large variety of projects-pilot feasibility studies, collection of preliminary data/analysis, small self contained research studies

• **R21-NIH Exploratory/Developmental Research Grant Award**
  – New, exploratory & developmental research project, early stages of project development, pilot/feasibility studies
R15-Academic Research Enhancement Award-AREA

• Small focused research projects for institutions that have not been major NIH recipients
• Direct costs $300,000 over entire project period
• Project limited to three years
• Preliminary data are not required

Institutions CAN submit more than one proposal provided scientifically distinct
Goals of AREA Awards

• Meritorious research
  – Research should contribute to the field
  – Results should be useful & publishable

• Expose students to research
  – Students learn how to do research through active participation
  – Students can be co-authors on scientific publications

• Strengthen research environment at institution
  – More faculty involved in research
  – Collaborations are encouraged and developed
AREA Eligibility Criteria

• PI/PD can serve on only one AREA grant at a time
• PI must have a primary faculty appointment at an AREA-eligible institution
• Standard NIH- 5 section Review Criteria applies
  – Special AREA considerations will also be evaluated
  – Quality of research
  – How students will actively participate in the research
  – If project will improve the university research environment
# AREA Submission Time Line

<table>
<thead>
<tr>
<th>Submission Cycle</th>
<th>I</th>
<th>II</th>
<th>III</th>
</tr>
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<tbody>
<tr>
<td>Submission Due</td>
<td>February 25</td>
<td>June 25</td>
<td>October 25</td>
</tr>
<tr>
<td>Peer Review</td>
<td>June or July</td>
<td>October or November</td>
<td>May</td>
</tr>
<tr>
<td>Advisory Committee Review</td>
<td>August or October</td>
<td>January</td>
<td>May</td>
</tr>
<tr>
<td>Earliest Project Start Date</td>
<td>September or December</td>
<td>April</td>
<td>July</td>
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What does NIH look for?

- Projects of high scientific caliber
- Unique, novel projects
- Relevant to public health needs
- Alignment with Institute and Center (I/C) priorities
- Address the scientific mission of NIH and I/C’s
- Additional Criteria is considered for AREA:
  - meritorious research
  - exposure of students to research
  - enhance research environment at institution
Getting Funded

• Not every good idea gets funded!!!
• **To be successful, must understand the mission and how funds are awarded**
• You must convince NIH that your proposal will advance their mission
  – Ask yourself……..
    ? Do I have a good idea
    ? Does my idea make a difference
    ? Will it align with NIH’s mission and priorities

• Understand NIH as a funding mechanism
  – Priorities dictated by legislation, legislators
  – Proposals must align with NIH Mission
Review Process

Applications submitted
Guidelines followed, proposal accepted

Phase I
Center for Scientific Review receives, reviews, assigns proposal to peer review panel for review
Scored for Overall Impact

Phase II
Advisory Council of Institute consider review panel recommendations, determine relevance, funding decision
Phase 1 Center for Scientific Review (CSR)

- Process includes peer review, individual scoring, group discussion, group score, funding recommendations
  - Scientific Review Officer (SRO)
    » Analyze each application for content
    » Manage conflicts of interest
    » Assign applications to reviewers
    » Prepare summaries for all applications reviewed
  - Scientific Review Group (SRG) same as Study Section
    » Reviewers are experts in their fields- scientists, physicians
    » Proposals are measured against standard review criteria
    » Applications are reviewed prior to meeting (6 weeks prior)
    » Reviewers prepare written critique and assign score
    » Reviewers score at least 10-12 proposals per round
    » Not everyone on panel reviews all proposals in round
    » Over 80,000 proposals are reviewed each year
Peer Review Meeting

• Applications have been reviewed based on review criteria
  • Assigned reviewers summarize prepared critiques for group (not all individuals in study section will review your proposal)
• Open discussion
• Final scoring assigned “Overall Impact Score” and summary statement
• Not all applications are scored
  – Applications that are not scored by SRG are not discussed
Phase 2: Advisory Council/Board

- Meetings are regularly scheduled
- Panels are posted so that PI can review participants
- Board consists of individuals from Institute or Center (I/C) of potential award, scientists, public representatives, appointees
- NIH program staff examine applications, overall impact scores and percentile rankings
  - Provide grant funding plan to Advisory Board for consideration
- Proposals are considered against I/C needs and program goals
- IC Director makes final funding decision
About the Review Process

• CSR is independent from NIH

• Review panels are made up of individuals from several study sections and reviewers before grant is submitted - *predetermined*

• [http://csr.nih.gov](http://csr.nih.gov) for information on rosters, schedules

• PI’s should consider conflicts of interest, the best roster to review your proposal - *you can make requests in your cover letter*

• A good relationship with the program officer is valuable
Review Criteria-Scored for “Overall Impact”

• Significance
  – Address important problem, critical barrier, advances the field
  – If Aims are achieved, how will scientific merit be improved
  – How will success drive the field

• Investigators
  – PI/PD, collaborators well suited to project
  – Have appropriate experience, training
  – If co PI/PD’s; complementary, integrated experience
Review Criteria *continued*

- **Innovation**
  - Novel, unique
  - Changes, shift current research paradigm
  - Improvements, refinement in the field proposed

- **Approach**
  - Overall strategy, methodology, analyses well reasoned, appropriate
  - Potential problem addressed

- **Environment**
  - Scientific environment will contribute to success
  - Resources available to investigators
  - AREA considerations
# Scoring Criterion

## High Impact Table

<table>
<thead>
<tr>
<th></th>
<th>Exceptional</th>
<th>Outstanding</th>
<th>Excellent</th>
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<tbody>
<tr>
<td>1</td>
<td>Exceptionally strong essentially no weaknesses</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Extremely strong with negligible weaknesses</td>
<td></td>
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<tr>
<td>3</td>
<td>Very strong with some minor weaknesses</td>
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## Medium Impact Table

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<tr>
<th></th>
<th>Very Good</th>
<th>Good</th>
<th>Satisfactory</th>
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<tbody>
<tr>
<td>4</td>
<td>Strong with numerous minor weaknesses</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Strong with at least one moderate weakness</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Some strengths with moderate weaknesses</td>
<td></td>
<td></td>
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</tbody>
</table>

## Low Impact Table

<table>
<thead>
<tr>
<th></th>
<th>Fair</th>
<th>Marginal</th>
<th>Poor</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td>Some strengths at least one major weakness</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Few strengths with a few major weaknesses</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Very few strengths w/ numerous major weaknesses</td>
<td></td>
<td></td>
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**Overall Impact Score** = mean score from all eligible members and averaged * 10
Review Criteria and Related Proposal Sections

Review Criteria

1. Significance
2. Investigators
3. Innovation
4. Approach
5. Environment

Related Proposal Section

1. Research Strategy
   - Significance subsection
2. Biographical Sketch/Personal Statement
3. Research Strategy
   - Innovation subsection
4. Research Strategy
   - Approach subsection
5. Facilities & Other Resources
   - Environment section
Common Reasons Proposals do not get funded:

• Lack of new or original ideas
• Diffuse, superficial or unfocused research plan
• Lack of knowledge of published relevant work
• Lack of experience in the essential methodology
• Uncertainty concerning the future directions
• Questionable reasoning in experimental approach
• Absence of acceptable scientific rationale
• Unrealistically large amount of work
• Lack of sufficient experimental detail
• Uncritical approach
Getting Started

• Have a good idea
• Think of yourself as an investigator
• Generate preliminary data
• Complete a literature review, know issues, trends in your field
• Enlist mentor guidance-consider “grant committee” to enlist feedback, support
  – OGRD can help!
• Look at successful proposals in your field
• Review funding priorities to determine where your idea fits, plan to contact Program Officer
• Start early, develop time line for all submission requirements
Develop your idea

1. Develop research question, hypothesis and strategy—**this will be the foundation of your proposal**

2. Critically analyze literature, background information—*may need to broaden your vision*
   - Is your idea original?
   - Does it have funding potential?
     - Review awarded projects to see what is funded
     - Will the project align with NIH’s Mission and I/C’s?

3. Be prepared to contact Program Officer to discuss your concept
• **Research Portfolio Online Reporting Tool**
• **Useful resource**
  – Look up grant awards
    • Institution
    • Funding mechanism
    • Award type
  – Funding amount
    • NIH spending
    • State
    • Institution
    • PI
  – Reports
Submission Process

• Grants Office submits proposals on PI’s behalf
• OGRD is available to provide support
• Internal approval process
  – Internal Approval Form
  – Investigator Significant Financial Interest Disclosure Form
  – IRB
  – IACUC
• PI’s must register with ecommons
Writing the Proposal

Your goal is to develop a focused, organized proposal

- Familiarize yourself with requirements/review components:
  - Aim 1 page
  - Research Strategy-12 pages
    - Significance subsection
    - Innovation subsection
    - Approach Subsection
  - Biosketch (Personal Statement) 4 pages
  - Facilities & Other Resources (Environment) 4 pages
  - Additional Sections not scored for overall impact
What are Aims???

- Clear and concise description of the project
- States broad long term goal(s)
- Indicates the significance/impact of the proposed project/research in the field involved
- Each Aim has a specific hypothesis and objectives to be tested
- Summarize expected outcomes
- Should be persuasive and compelling
Paragraph 1: Introduces project, educates reviewer, summarizes important knowledge, identifies gap or critical need.

- What is the big picture/relevance of your research?
- What is currently known?
- What are the gaps?
- What is the problem that you are addressing?
- What is the focus of the project/what do you hope to accomplish?
Paragraph 2: Describes long term goals, the gap/need you are addressing, your hypothesis and rationale.

- What is your overall objective for the research?
- What do you propose to test?
- What is your central hypothesis?
  - The central hypothesis must link to the objective of the research - the objective will be accomplished by testing the central hypothesis
  - Gives focus to the research you will complete
- What is your rationale for this research?
- You are proposing to?
- Why can you accomplish this?
Paragraph 3: Listing your Aims will answer the question *why you want to do this research.*

Aims will link to your overall goal. Present them in a logical manner. Aims should be conceptual—not specific and be independent from one another (so that successful outcomes are not dependent on another).

**AIM #1: State objective**
- Working hypothesis:
- What you will do:
- Expected outcome:

**AIM #2: State objective**
- Working hypothesis:
- What you will do:
- Expected outcome:

**AIM #3: State objective**
- Working hypothesis:
- What you will do:
- Expected outcome:
Paragraph 4: Will tie all together, identify the projects innovation, the overall expected outcome, how the project will validate the central hypothesis and summarize the projects significance.

- Why is this innovative
- How will this validate the hypothesis
- How is this significant

Once you have developed your Aims, you will be able to complete all sections of the proposal
Develop your research plan

- Aims- have been developed, foundation of your research strategy
- Research Strategy (3 sections):
  - Significance
  - Innovation
  - Approach- *how you are going to accomplish your Aims*
    - Discussion of each specific Aim
    - Include timetable for activities
Significance Subsection (½ - ¾ page)

1. **Does project address important project/critical barrier?**
   - State existing knowledge, critical literature analysis current relevant data
   - Discuss existing research that you are doing, the gaps and the contribution you are making

2. **If aims are achieved, how will science be improved?**
   - Statement of significance, rationale of proposed project-*how aims will be achieved*
   - How your research will further the field

3. **How will the successful completion of aims change the field, have a broader impact?**
   - What is the potential contribution of your research in the field
Innovation Subsection (½ – ¾ page)

1. Well reasoned, logical, appropriate to project, document citations as to what the norm has been
2. State why the project is innovative-how project shifts current paradigm, explain new approaches
3. Discuss the positive impact, the concrete benefit that is expected
4. Must be able to argue why the project is innovative

Adapted from: Russell, SW, Morrison, DC, The Grant Application Writers Workbook NIH Version
Approach Subsection (10-11 pages)

• Narrative portion of what will be done
• Will relate back to Aims- For each Aim you will indicate:
  – What will be done
  – What are the means to accomplish this
  – Rationale-why you are doing what you are doing
  – What problems may be encountered
  – Alternative strategies would be needed to address problems
  – Expected outcomes

• Include timeline for approach that addresses each Aim

Adapted from: Russell, SW, Morrison, DC, The Grant Application Writers Workbook NIH Version
Approach Section: complete for each Aim

• For each Aim, include:
  – Introductory paragraph
  – Justification and feasibility
    • Review of relevant literature
    • Preliminary studies
  – Research design
    • How you will measure/analyze
  – Expected outcomes
  – Potential problems and alternative strategies
• Address future directions
Investigator/Biosketch-Personal Statement

- Use standard form
- Purpose is to establish credibility of PI/PD
- Include Biosketch for all collaborators reconsider “weak links”
- If new investigator, must sell yourself
- In Personal Statement, goal is to highlight accomplishments and the value of your experience for the project
- Include experience supervising students
- Indicate what peer reviewed publications involve supervising students
Environment-separate attachment (4 pages)

- Gives reviewers information about institution and capability to achieve aims
- How committed is the institution to the project, investigator
- How well equipped are the institution/facilities to enable the proposed research
- Be specific and objective
- Discuss physical resources
- Include other resources - training, travel, other supports
- List major equipment items available
Environment-AREA Specific

- AREA grants additional information is requested
  - Student profile
  - Special characteristics of school/academic component that make it appropriate for and AREA grant—considering the goals of the program
- If applicable, description of resources that will be utilized if other sites are used
- Statement of institutional support for the project
- Remember to include information about students
Additional Criteria

*not scored individually but considered in Overall Impact Score*

- Evaluated for scientific and technical merit
- Items discussed as applicable
  - Protection for Human Subjects
  - Inclusion of Women and Minorities
  - Vertebrate Animals
  - Biohazards
  - Renewals
  - Resubmissions
  - Revisions
Additional Review Considerations

not scored individually not considered in overall score

- Select Agent Research
- Resource Sharing Plans
  - Data sharing plan
Budget
additional review consideration, not scored in Overall Score

• Includes detailed budget and justification
• To accomplish your project, what do you need money for??
  – Should be reasonable and justifiable
• Faculty, staff
  – Usually the largest budget expense (60-80%)
• Students
• Equipment
• Supplies
• Travel
Additional Submission Components

• Project Summary/Abstract
  – 30 lines or less
  – Succinct and accurate description of proposed work
    • Long term objectives, specific aims, research design and methodology to be used

• Project Narrative (Public Health Statement)
  – 2-3 lines
  – Relevance of the project to public health
  – How it fulfills NIH’s mission
Additional Submission Components

- **Cover Letter**
  - Optional but strongly suggested
  - The only item that reviewers do not see
  - Focus on issues related to review
  - Use to request assignment to a specific awarding component and group and why
  - Use to request that certain individuals *not* review your proposal and why

- **Letters of Support**
  - Show commitment of others, institution, collaboration
Tips

• Be focused
  – Identify hot button issues that are important to target audience
• Communicate with Program Officer often to discuss issues, questions-building relationship
• Discuss potential pitfalls and alternate strategies in proposal
• Use clear and concise writing style-remember brevity
• Avoid jargon, use simple words
  – Paragraphs should flow into each other
  – Choose words wisely, positive, powerful words
• Proofread
• Have others read your proposal- mentor, “grant committee, OGRD is here to help!”
Questions