The NIH AREA Program
The CUR Dialogues
Washington, DC
February 26, 2010

Jean Chin, Ph.D., Program Director
Division of Cell Biology & Biophysics (CBB)
National Institute of General Medical Sciences (NIGMS)
National Institutes of Health (NIH)
Department of Health and Human Services (DHHS)
ACADEMIC RESEARCH ENHANCEMENT AWARD
AREA or R15 Program

http://grants.nih.gov/grants/funding/area.htm

- Strengthening the research environment at eligible institutions
- Exposing students at such institutions to meritorious biomedical & behavioral research (including basic research)
- Providing support for meritorious research at these AREA-eligible institutions
Goals of the AREA or R15 Program

- R15 supports meritorious research
  - AREA grants are renewable
  - Research should contribute to the field
  - Results should be useful & publishable

- Students should be exposed to meritorious and peer-reviewed research
  - Students learn how to do research by doing it
  - Students may be co-authors on scientific publications

- Institutional research environment is enhanced
  - More faculty will be involved in research
  - Collaborations using complementary approaches
R15 FEATURES: PA-10-070

- Renewable grant; competing continuations
- Up to $300,000 direct cost for project period of up to 3 years plus negotiated F&A (IDC) rate
  - $250K or $300K DC requested in budget year 1
- Budgets of $250,000 DC or less are modular
  - Modular budget & budget justification
- Budgets of more than $250,000 DC are NOT
  - Detailed budget & strong budget justification
- Standard 5 NIH review criteria plus AREA-specific criteria addressing goals of program
- 12- Page limit for Research Strategy
- Three electronic receipt dates per year:
  - February 25, June 25, and October 25
The NIH R15 or AREA Program

Academic Research Enhancement Award

- For baccalaureate or advanced degree granting institutions with up to or less than $6M in NIH grants per year for 4 years over the past 7 years (excluding C, S & G grants)
- List of AREA-eligible and AREA-ineligible institutions on R15 home-page
- Most of work must be done at home institution
  - Principal Investigator (PI) may recruit students to work full-time during the summer and/or part-time during the academic year
R15 SPECIFIC REVIEW CRITERIA

- **RESEARCH**: Is the research project meritorious and appropriate for available students?

- **ENVIRONMENT**: Assess the suitability of the applicant school/academic component for an award in terms of the likely impact that an award will have on strengthening the research environment and exposing available students to research.
NIH Small Grant Program: R03
http://grants.nih.gov/grants/funding/r03.htm

- Parent R03 Program Announcement: PA-10-064
- Investigator-initiated, Parent R03s accepted only by NHGRI, NIA, NIAAA, NIAID, NIBIB, NICHD, NIDA, NIEHS, NIMH, NINDS & NINR
- R03s responsive only to specific PAs/RFAs accepted by FIC, NCCAM, NCI, NCRR, NHLBI, NIAMS, NIDCD, NIDCR, NIDDK, NIGMS & NLM
- NIH Institutes and Centers NOT accepting any R03 applications: NCMHD
Parent R03 Features

- SF424(R&R) Forms & Electronic Submission
- $50,000 direct cost per year for up to two years or $100,000 total direct cost
- New projects only; no competing continuations
- Only one resubmission (A1) allowed
- Page limit for Research Plan is 6 pages
- May support
  - pilot or feasibility studies
  - secondary analysis of existing data
  - Small, self-contained or discrete projects
  - Development of research methodology
  - Development of research technology
NIH Exploratory/Developmental Research Grant Award: R21

- Parent Program Announcement for Investigator-initiated R21 applications: PA-10-069
- Goal to encourage new, exploratory & developmental research projects by supporting the early and conceptual states of project development
- Scope of exploratory & developmental research
  - Exploratory, novel studies that break new ground or extend previous discoveries toward new directions or applications
  - High risk, high reward studies that may lead to a breakthrough in a particular area or result in novel techniques, agents, methodologies, models or applications that will impact biomedical, behavioral or clinical research
- Electronic submission through Grants.gov required
NIH Exploratory/Developmental R21 Grants

- Total direct cost for the two year period is $275,000; no more than $200K in any single year
- Possible budget: $150K (Y1) and $125K (Y2)
- New projects only; not renewable
- One resubmission (A1) allowed
- Research Strategy is limited to 6 pages total
- Parent, Investigator-initiated R21 applications accepted only by NCCAM, NEI, NHGRI, NHLBI, NIA, NIAAA, NIAID, NIAMS, NIBIB, NICHD, NIDA, NIDCD, NIDCR, NIDDK, NIEHS, NIMH, NINDS, NINR, and NLM (PA-06-181)
- Only R21s responsive to specific NIH Institute PA/RFA for R21s are accepted by FIC, NCI, NCMHD, NCRRR and NIGMS
<table>
<thead>
<tr>
<th>NIH Mechanism</th>
<th>May Renew</th>
<th>Page Limit</th>
<th>Direct Cost Limit</th>
<th>Eligibility Limits</th>
<th>Institutional Limits of Total NIH $</th>
<th>NIH IC Limits</th>
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<tr>
<td>R15</td>
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<tr>
<td>R21</td>
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<td>6</td>
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## R03, R15, R21 Receipt, Review, and Funding

http://grants.nih.gov/grants/funding/submissionschedule.html

<table>
<thead>
<tr>
<th>ACTIONS ON NIH APPLICATIONS</th>
<th>CYCLE I</th>
<th>CYCLE II</th>
<th>CYCLE III</th>
</tr>
</thead>
</table>
| NEW R03 & R21 RECEIPT DATES (new/resubmission) | February 16  
March 16 | June 16  
July 16 | October 16  
November 16 |
| NEW & REVISED R15 APPLICATION RECEIPT DATES AT CSR | February 25 | June 25 | October 25 |
| INITIAL REVIEW BY CSR SCIENTIFIC REVIEW GROUPS | June-July | October-November | February-March |
| SECONDARY REVIEW BY IC ADVISORY COUNCIL | September-October | January-February | May-June |
| EARLiest START DATE FOR IC FUNDING | December-January | April-May | July-August |
Biobehavioral Methods to Improve Outcomes Research (R01)


- PA-09-125
- NINR, NIGMS, NIDDK, NIDCD, NCI, NIAMS and OBSSR

- To foster biobehavioral research and develop innovative research designs, methods of measurement, and data analysis techniques
- To examine the impact of biologic & behavioral variables on individuals’ health outcomes
APPLICATION FORMAT

- 1-Page Specific Aims
- 12-Page Research Strategy with discussion of Significance, Innovation, Approach and Preliminary Studies for New Applications and/or Progress Report for Renewal Applications
- Biographical Sketch: Personal Statement on why you are well-suited to be the PI
- Resource Page for Scientific Environment
- 1-Page Introduction for Resubmissions
New NIH SCORING System

- Final score (1 for best and 9 for worst) provided by all reviewers not in conflict
- Overall priority score is the mean score from all eligible reviewer scores multiplied by 10
- Final scores will be reported in whole numbers and will range from 10 to 90
# NIH SCORING SYSTEM

<table>
<thead>
<tr>
<th>Impact</th>
<th>Score</th>
<th>Descriptor</th>
<th>Additional Guidance on Strengths/Weaknesses</th>
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<tbody>
<tr>
<td>High</td>
<td>1</td>
<td>Exceptional</td>
<td>Exceptionally strong with essentially no weaknesses</td>
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<tr>
<td></td>
<td>2</td>
<td>Outstanding</td>
<td>Extremely strong with negligible weaknesses</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Excellent</td>
<td>Very strong with only some minor weaknesses</td>
</tr>
<tr>
<td>Medium</td>
<td>4</td>
<td>Very Good</td>
<td>Strong but with numerous minor weaknesses</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>Good</td>
<td>Strong but with at least one moderate weakness</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>Satisfactory</td>
<td>Some strengths but also some moderate weaknesses</td>
</tr>
<tr>
<td>Low</td>
<td>7</td>
<td>Fair</td>
<td>Some strengths but with at least one major weakness</td>
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<tr>
<td></td>
<td>8</td>
<td>Marginal</td>
<td>A few strengths and a few major weaknesses</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>Poor</td>
<td>Very few strengths and numerous major weaknesses</td>
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**Additional Information for Scoring Guidance Table**

**Non-numeric score options:** NR = Not Recommended for Further Consideration, DF = Deferred, AB = Abstention, CF = Conflict, NP = Not Present, ND = Not Discussed

**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
Criterion Scores

- Assigned reviewers will provide preliminary overall impact or overall priority scores.
- Assigned reviewers will use the 9-point scale for the five review criteria:
  - Each assigned reviewer’s criterion scores will be reported on the summary statement.
  - Criterion scores will be reported for discussed and not discussed applications.
- Reviewers will weigh criterion scores as appropriate for each application in determining overall impact or overall priority score.
Assigned reviewers will provide preliminary overall impact or priority scores

Assigned reviewers will use the 9-point scale for the five review criteria

- Each assigned reviewer’s criterion scores will be reported on the summary statement
- Criterion scores will be reported for discussed and not discussed applications

Reviewers will weigh criterion scores as appropriate for each application in determining overall impact or priority score
OVERALL IMPACT

Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following five core review criteria, and additional review criteria (as applicable for the project proposed).
REVIEW PROCESS

- Chair will ask for initial overall impact or overall priority scores from the assigned reviewer 1, reviewer 2, and the reader
- Summary of the project aims by reviewer 1 followed by assessment by the assigned reviewers
- Discussion of the application opened to the rest of the panel
- Assigned reviewers will state their final scores
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<tr>
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<tr>
<td></td>
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<td>Low Impact</td>
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The FIVE NIH Review Criteria for Research Proposals

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

- Does this project address an important problem or a critical barrier in the field?
- If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved?
- How will the successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?
INVESTIGATOR(S)

- Are the PD/PIs, collaborators, and other key researchers well suited to the project?

- If Early State Investigators or New Investigators, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)?

- If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?
INNOVATION

- Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or inventions?

- Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense?

- Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?
APPROACH

- Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project?
- Are potential problems, alternative strategies, and benchmarks for success presented?
- If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?
- If the project involved clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?
ENVIROMENT

- Will the scientific environment in which the work will be done contribute to the probability of success?
- Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed?
- Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?
Preparation by the Institution

- Are the Faculty, Business Office, Deans all supportive of faculty research & knowledgeable about the NIH application process?
  - Know the guidelines, review criteria & flexible points

- Does the Institution provide and support an environment for faculty to succeed?
  - Start up packages for equipment, supplies & students
  - Credit for student involvement in research

- Do tenure decisions include credit for independent and/or collaborative research?
  - Some projects require team work & more expertise
More Institutional Preparation

- Help NIH applicants with the Resource page, equipment available and student profiles
  - Environment is a review criterion
  - Resources available to accomplish the aims

- Do not pressure applicants to apply if their projects are not ready for peer-review
  - Only 2 submissions allowed per project
  - Quality over quantity; submit best proposal

- Use the Cover Letter to help the Receipt and Referral Staff make assignments
  - NIH Institute & NIH study section assignment
More Preparation by the Institution

- Mentor new faculty & critique their research & application
  - Discuss what reviewers look for, like or dislike
  - Faculty should be very familiar with all the NIH Review Criteria questions

- Support faculty researcher to attend national and important meetings in their fields
  - Present research and interact with other researchers
  - Attend NIH grant workshops
  - Encourage faculty to contact NIH staff by e-mail with specific aims and rationale on a one page (not visit)
Preparation by the Investigator

- Is your expertise suitable for the project and approaches proposed?
  - Are you asking the important, next questions in the field? Do you have the appropriate expertise?
  - Does your research fit the NIH research goals?

- Have you generated preliminary data at your current institution with your students and other staff?
  - Is your data supportive of your research proposal?
  - Are your tools & reagents prepared & ready?

- Have you recruited and trained the necessary students and technicians?
  - Are they enthusiastic and engaged? Are you?
Research Strategy

- Get feedback early on your one-page Specific Aims page
- Understand the NIH review criteria & the review criteria questions
- Write a clear, reviewer-friendly proposal on your exciting research project
- Be self-critical, rigorous, persistent, and enthusiastic about your research
- In the resubmission, respond thoroughly and diplomatically to all review comments, concerns, issues and suggestions
Manuscripts versus Grant Proposals

Manuscripts
- What experiments you did and why
- Enough details so others can do them
- Retrospective; looking back

Grant Proposals
- What experiments you plan to do, why and what their significance might be
- Discussion of potential pitfalls and possible alternatives, results, their interpretation, and potential impact
- Prospective; looking forward
General Questions

- Does the AREA Program target New Investigators or Early Stage Investigators (ESIs)?
  - ESIs of R01 proposals are targeted by NIH
  - The R15 program does not target ESIs or New PI

- Does NIH favor translational and interdisciplinary research over basic, fundamental research?
  - NIGMS supports basic research & model organisms
  - NIH wants & needs a balance of research approaches: investigator-initiated, single PI, collaborative or team, transformational, translational and interdisciplinary research
  - Impact and significance of the research needs to be justified, rationalized and discussed
More General Questions

- When and why should a project be submitted to NIH vs NSF?
  - NIH and NSF share many research goals in chemistry, biology, biochemistry, biophysics, bioengineering, bioinformatics and biomath.
  - NIH focuses on biomedical and behavioral research, both clinical & applied as well as basic, fundamental and non-disease research using model organisms such as bacteria, plants, flies, worms & others (GM).

- Why is the entire, requested AREA budget in Year 1 only and not spread out over 2-3 years?
  - R15 is a multi-year funding mechanism, funded in Y1.
Application Assignments & Cover Letter

- The Division of Receipt and Referral at the Center for Scientific Review (CSR) will make two assignments for your applications, but you may request specific assignments
  - An NIH Institute or Center (IC) for programmatic and funding consideration
  - An Initial Review Group for review of scientific merit by a Scientific Review Group or Study Section

- Include a COVER LETTER with the following:
  - Research goals and hypotheses/questions and specific aims
  - Biological system or model used or studied (microbe vs animal)
  - Major methods and approaches proposed (biological and/or computational)
  - Areas of review expertise (NOT names of reviewers)
  - Potential conflicts (name & reason, i.e., direct competitor)
  - +/- Requested NIH Institute/Center +/- Study Section Choices