Study Section: Make-up

• Who are you writing for?
  – A panel of expert scientists with diverse scientific backgrounds

• Who reviews your grant?
  – Most often three assigned reviewers; probably not all experts in your area of research
Study Section: Mission

• To fulfill NIH mission, which is that the grant application receives fair, independent, expert, and timely review-free from inappropriate influences-so that NIH can fund the most promising research

• Standing study sections review R-type grants; R01, R21, R03
R01 Mechanism

• Provides support for health-related research and development based on the mission of the NIH.
• Can be investigator-initiated or can be in response to a program announcement (PA) or request for application (RFA).
• Generally awarded for 4-5 years.
• Allows an investigator to define the scientific focus or objective of the research based on a particular area of interest and competence.
• Research projects are discrete, specified, and circumscribed.
R21 Mechanism

• Is a mechanism to allow investigators to develop new concepts or techniques, or conduct defined research on innovative ideas.

• May involve 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 or clinical research.

• Proposals may also be exploratory non-hypothesis driven studies that break new ground or extend previous discoveries towards new directions or applications.
R21 Mechanism

- Preliminary data are NOT required. If preliminary data are provided, it will be evaluated.
- No new data is requested implicitly or explicitly.
- Scores reflect the scientific and technical merits of the proposal rather than whether the proposed studies meet the goals of the PA.
R03 Mechanism

• Provides limited funding for a short period of time to support investigator-initiated research
• Supports small research projects that can be carried out in a short period of time with limited resources
• Supports different types of projects including:
  – pilot and feasibility studies;
  – secondary analysis of existing data;
  – small, self-contained research projects;
  – development of research methodology;
  – development of new research technology.
Scoring

• Five criteria scores: Significance, Innovation, Investigator, Approach, Environment.

• **IMPACT SCORE:** The impact score is not an arithmetic mean of the criteria score. However, there is surely a common sense relationship between criterion score and impact score.
<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>
</tr>
<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>
</tr>
<tr>
<td>5</td>
<td>Good</td>
<td>Strong but with at least one moderate weakness</td>
</tr>
<tr>
<td>6</td>
<td>Satisfactory</td>
<td>Some strengths but also some moderate weaknesses</td>
</tr>
<tr>
<td>7</td>
<td>Fair</td>
<td>Some strengths but with at least one major weakness</td>
</tr>
<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>
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</tbody>
</table>
Evaluating Overall Impact

**Overall Impact**
The likelihood for a project to exert a sustained, powerful influence on research field(s) involved

<table>
<thead>
<tr>
<th>Overall Impact</th>
<th>High</th>
<th>Medium</th>
<th>Low</th>
</tr>
</thead>
<tbody>
<tr>
<td>Score</td>
<td>1 2 3</td>
<td>4 5 6</td>
<td>7 8 9</td>
</tr>
</tbody>
</table>

- e.g. Applications are addressing a problem of high importance/interest in the field. May have some or no technical weaknesses.
- e.g. Applications may be addressing a problem of high importance in the field, but weaknesses in the criteria bring down the overall impact to medium.
- e.g. Applications are addressing a problem of moderate/high importance in the field, but weaknesses in the criteria bring down the overall impact to low.
- e.g. Applications may be addressing a problem of moderate importance in the field, with some or no technical weaknesses.
- e.g. Applications may be addressing a problem of low or no importance in the field, with some or no technical weaknesses.

While 5 is a good medium-impact application, the entire scale (1-9) should always be considered.
General Comments

• Propose something significant, not incremental
• Good ideas do not sell themselves
• Make it exciting
• Probe for mechanism and seek new paradigm (perhaps models)
• Avoid proposing to collect more data
• Be clear of what you are proposing to do
• Do not assume much reviewer background
• Do not “stick your neck way out”
Death Critiques

• “Low impact” research
• “Incremental Advance”
• “Confirmatory research, duplicative”
• “Derivative”
Significance

• Title
• Abstract
• Specific Aims
• Innovation
• Public Health Relevance statement
Significance

• Although you will emphasize your project’s significance throughout the application, the significance section should give the most details
Significance Section

• Take your time and tell your story
• Needs to be crafted for perspective of the reviewers (be recognizant of the reviewers’ expertise and interests)
• List the basic science significance and translational significance
Significance Section

• Your chance to convince the reviewer of the importance of your project
  – To your field
  – To a public health problem
Significance Section

• Convince the reviewers how the niche you have selected for the project can push forward the frontier of knowledge in your field
Significance Is Not Disease

• The particular illness / disease you work on is not the significance of your proposal

• **Significance**: what will you do to help better understand the pathology so we come closer to preventing or curing the disease
Two Questions: The Extremes

- If 100% successful with experiments proposed, where will we be?
- If you and your lab team disappear, how will you be missed?
- Just because it hasn’t been done doesn’t mean it needs to be done
Significance Need To:

• Present the research proposed in the context of the state of your field and your long-term research plans

• Show how the proposal addresses critical research opportunities and has a promising strategy to do so
Significance Section

• Paragraph 1: Introduce the problem
• Paragraph 2: Additional background as needed
• Paragraph 3: Emphasize the significance of the idea / hypothesis proposed
• Paragraph 4: Emphasize the significance in a broader context
Summary for Significance

• Describe the importance of your hypothesis to the field
• Describe the importance of your studies to human disease
• Point out the project’s significance throughout the application
• Show awareness of the opportunities, knowledge gaps, roadblocks, and research underway in the field
• Describe how your proposal fills gap and advances field
Innovation

- A new mechanism, hypothesis-driven proposal
- A new combination of expertise (usually multi-disciplinary team), leading to new perspective
- A new combination of two previously used methods
- A refinement of existing model, technology
- Unique sample or reagent that provide opportunity for novelty
How to Write Innovation

• NIH has no guidelines regarding length; suggested ½ - ¾ page

• Does your research incorporate a new perspective on your subject?
  – Novel concepts, approaches or methods
  – Original aims and innovative
  – Challenge existing paradigm or develop new methodologies or technologies
Innovation Is Necessary But Not Justification for Research

• Model has been tested in drosophila, zebrafish, hamsters, rabbits, mice, rats, and dogs, but no one has looked at it in frogs yet
Too Much Innovation

• Be careful about arguing you’re “outside the mainstream”

• Need to balance innovation with:
  – Feasibility (preliminary results section, scope of research)
  – Credibility (training, publications)
Closing Comments

- Use readers
- Do not be defensive
- Be flexible and responsive
Significance Criterion Scores vs Overall Impact Score

The Significance Criterion – Assumes success

Assuming that all the aims are successful, does the project address a problem or critical barrier to progress in the field or have the ability to improve knowledge, technical capability, or clinical practice in a major (1-3), moderate (4-6) or minor (7-9) way?

Overall Impact

Can be influenced by all 5 criteria (significance, investigator, innovation, approach, environment) weighted based on reviewer’s judgment

The high (1-3), medium (4-6) or low (7-9) likelihood that a project will have a sustained and powerful influence on the science