ESSENTIALS FOR SUCCESS IN RESEARCH: Everything You Ever Wanted to Know About NIH Grants and Publishing in Biostatistical Journals

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Acknowledgment

Some material in this tutorial has been adapted from presentations at the ENAR Junior Researcher Workshop and elsewhere by Karen Bandeen-Roche, Michelle Dunn, Misrak Gezmu, Xihong Lin, Tom Louis, and many others.
Goal

• Provide an overview of essential information about NIH grants and publishing in statistical journals

• Essential information: Knowledge and skills that will enhance your chance of achieving success in both
Goal

Thus:

- What I will cover regarding publishing: Targeting a journal, the peer review and editorial processes, writing a good journal article, . . .
- What I will not cover regarding publishing: How to navigate an Electronic Editorial Office (EEO) portal, how to use a journal’s \LaTeX{} document class, . . .
- What I will cover regarding NIH grants: Different types of grant mechanisms, planning and writing an effective grant application, budget issues, the peer review process, . . .
- What I will not cover regarding NIH grants: Using the eRA Commons, dealing with the internal processing requirements to submit a grant at your institution, . . .
- Focus will be more on “spiritual” aspects and less on administrative aspects
The big picture

What is research?

- Activity that leads to the *advance of knowledge*

- Advances in knowledge in *(bio)*statistics can enhance the way data are collected and interpreted, form the basis for further advances, contribute to advances in *other sciences*

- *Journals* are the main mechanism by which the results of research are *disseminated*

- *Research grants* are a main mechanism by which government and other organizations *recognize and support* the importance of the advance of knowledge to society

- *Thus*: Responsibilities of a biostatistical researcher include *publishing* results of research and securing *grants* to support research
The big picture

- Success in securing research grants and success publishing in our journals are *inextricably linked*

- Success *publishing* your research means that your ideas and contributions have been judged to be *worthy advances to knowledge* in our discipline

- NIH (and other granting agencies) want to support research that will *advance science* (e.g., *biostatistical science* and *practice*)

- Thus, success *getting grants* usually results from having demonstrated a *track record* of *publishing* such advances

- Success in *publishing* often results from having support from a grant to provide the *time and resources* needed...

- And success *publishing* the results of research supported by a grant will enhance the chance that the grant will be *renewed* to support *further advances*
The big picture

A body of knowledge and skills is relevant to success in both...

- A common theme: *Effective writing*

Plan:

- *Part I*: Publishing in (bio)statistical journals (with an emphasis on *Biometrics*)
- *Part II*: Grant writing and the grant review process
Part I: Publishing in (bio)statistical journals

Main topics:

- Deciding when research is ready to publish
- Choosing a target journal
- *Biometrics* specifics
- Submission
- The review process
- Writing a good journal article
- Miscellaneous
When is research “ready” to publish?

- *Research*: Activity that leads to the advance of knowledge
- *Journals*: The main mechanism by which results of research are disseminated

*Thus ask yourself*: Objectively speaking, does what I have done represent a *significant advance* in knowledge? Will its dissemination in its current form have *impact* on the field?

- *Be honest*: Have I done enough to make a *convincing case*? Have I addressed relevant situations/special cases/etc that fellow scientists (*like me*) would want to see to be convinced? Is there *something else* I really should do/work out/study to make the case strong?

- *Do not let eagerness to publish lead you to shortchange your work*
Choosing a target journal

• What is the *message* I’d like to communicate?

• Is my work of theoretical interest? Does it address a general methodological challenge? Challenges posed by a specific study/data set? A specific application or application area? Does it focus on computational issues?

• Who would be *most interested* in my work?

• What journals tend to publish *top work* in this area and are read by researchers and/or practitioners who could benefit from my work?

• *Unsure*? Most journals have a “*mission statement*” – consider it carefully

• Ask *colleagues* for their perspectives on good outlets for certain types of work

• *Don’t*: Write to the editor(s) asking him/her/them to *pre-screen* your paper or idea
Choosing a target journal

- Look carefully at potential targets

- What is the length, scope, and style of the typical article, and does it fit with what I want to say and how I’d like to say it?

- Examine published articles for style, level of technical detail, topics, length – published articles are the “successes”

- Review the list of Editors/Associate Editors – these are the people who may handle your paper and will have a major say in its fate

- What are the review times and times to publication; can I live with them?
Choosing a target journal

- Aim high and target “top-tier” journals

- But be realistic; the more prestigious the journal, the more difficult it will be to publish in it

- Top journals tend to accept < 25% of submissions

- Top journals have leading experts on their editorial boards, so even a “reject” will provide you with very helpful feedback that, if followed, will improve your work

- Emulating articles published in top tier journals can only improve your research and your papers
Submitting to your target journal

• Visit the journal’s web page and review the *Instructions for Authors*

• Follow *exactly* all requirements regarding format, length, conventions for mathematical expressions, numbers of tables/figures, type size, spacing, blinding, etc.

• If there is a *\LaTeX* *document class*, consider using it – much of the required formatting is “built-in”

• Include a brief cover “letter” making clear your intention and noting any extreme conflicts of interest (rare)

• *Submit the paper you think should be published* (coming up. . . )
Submitting to your target journal

- There is a *rationale* for submission requirements
- For example, the requirement of a *specific format*, with *tables/figures at the back*, is critical for Editors to be able to “*count pages*” to assess the extent of the scientific contribution against the length.
So suppose you’ve decided to target Biometrics?

- Published by the *International Biometric Society* (IBS)
- “An international society devoted to the development and application of statistical and mathematical theory and methods in the biosciences”
- *ENAR* is the *E*astern *N*orth *A*merican *R*egion of the IBS

**Sections:**

- Biometric Methodology
- Biometric Practice
- Reader Reaction
- Letters to the Editor
Biometric Methodology

- Focus on the development of new methods and results of use in the biological sciences.

- Where possible be made accessible to biologists and other subject-matter scientists by the inclusion of an introductory section outlining the application and scientific objectives on which the new methods focus.

- Discussion of real data or settings that exemplify the issue being addressed.

- Extensive mathematical derivations and proofs should be removed to an appendix (supplementary material).
Biometric Practice

- Demonstrate innovative applications of existing methods to areas in which such a method has not been previously employed; new insights or findings.

- Creatively illustrate the proper use of different methods under various explicit/implicit assumptions. Clearer guidance and understanding of the use of different methods is offered.

- Propose innovative and practical data analysis strategies, based on a combination of experience, intuition, and methodological arguments.

- Re-examine from a new perspective statistical practices that are widely used in biometric applications, providing useful alternatives to the current standard.

- May, but do not need to, contain new methodology. Must present information that goes beyond the existing literature in a way that an expert in the relevant field would regard as significantly eye-opening.
Biometrics editorial structure

- **Three Co-Editors** (CEs) with staggered, 3-year terms handle all submissions, make all scientific decisions

- One CE from each of North America, Europe, “Rest of World”

- Current CEs: Tom Louis, Geert Verbeke, Russell Millar

- **Executive Editor** (EE, me) assigns papers to CEs on basis of expertise, handles all administrative tasks (renewable 3-year terms)

- Roughly 100 **Associate Editors** (AEs)

- **Editorial Manager** Ann Hanhart

- All journal submission and communication by e-mail with Ms. Hanhart (no EEO system)
Biometrics 2010 statistics

- 602 new submissions to Methodology/Practice Sections from 39 countries/districts (58% from US) – continues to increase

- 23% of new submissions rejected outright by CEs without external review

- Overall acceptance rate ≈ 25%

- Review times very good, could be better still (long right tail); median ≈ 1.9 months

- Times to online publication are excellent once authors send the final version and copyright assignment forms to Ms. Hanhart – 8 weeks (as long as authors review galley proofs quickly)

- Times to print publication not so excellent...
Biometrics review times

Biometrics Time to Review (1/1/10–12/31/10)
Solid=First Submission, Dashed=First Revision

Survival Probability of Review

Months

0.0 0.2 0.4 0.6 0.8 1.0
0 1 2 3 4 5 6

Essentials for Success in Research, 2011 20
Length restriction

- Almost *all* top journals impose *restrictions* on the *maximum length* of submitted manuscripts
- Almost *all* top journals will return your paper to you for shortening if you exceed the limit
- *Why?*
“Papers should be typed... with one-inch margins, in 12-point size letters and no more than 25 lines per page, double-spaced throughout.

Normally, newly-submitted Biometric Methodology or Biometric Practice papers exceeding 25 pages... in the style described above will be returned to the authors without review. (These page counts include acknowledgements, references, and brief appendices, but not tables and figures. The page counts do not include the title page and abstract.)

The typical accepted Biometrics paper is usually considerably shorter than 25 pages. ... Authors are encouraged to move appendices and other appropriate content to Supplementary Web Materials at the time of submission in order to achieve a shorter main paper.

Papers appearing in the journal rarely have more than six (6) tables or figures combined; about three-fourths have 4 or less.”
Biometrics length restriction

- CEs will almost always impose (non-negotiable) *length restrictions on revisions*

- Although online versions of journals are dominant, most top tier journals (including *Biometrics*) still publish a *print version*

- Space is *at a premium* (1376 pages/year, 12–14 month “backlog”)

- *Supplementary material* allows full details, additional examples, proofs, simulations, content useful but not central to the message

- Much more importantly – *shorter papers are better papers!*

- Length restrictions force authors to focus on the *key message* and the essential material necessary for communicating it
**Biometrics review process**

What happens to your paper:

- EE (me) assigns manuscript to one of the 3 CEs
- CE reviews and can decide to
  - **Reject outright** (on own or after quick consult with an expert AE)
  - **Send to AE** for review, with possible guidance on issues on which to focus, possible referees, etc.
- AE reviews him/herself and additionally send to 0–2 referees
- AE consolidates reviews and makes a **recommendation** to CE
- CE makes a **decision** based on all evidence
  - **Reject**, no opportunity to revise
  - **Revise and resubmit**, providing list of requirements (including length) and degree of hope (minor, major, at your own risk)
- Revision may undergo full review or review by CE and AE only
Biometrics review process

What you should do (and not do) when you receive reviews:

• **Calm down**, and consider them carefully; you will grudgingly admit that the reviewers have some valid points

• Almost always, misunderstanding on the part of CEs, AES, and referees is a consequence of the quality of your *writing/lack of clarity*

• The CE should be clear about the *prospects* in his/her letter; if you are unsure, send a query

• Evaluate what it will take to *respond* to the reviews and the wisdom of trying given the prospects

• Remember, papers are *almost never accepted* on first submission
Biometrics review process

What you should do (and not do) when you receive reviews:

• It is usually not a good idea to fight a rejection unless (rare) it reflects an utter lack of understanding of your work (which may well be your fault; see the previous slide)

• You do not have to do everything the reviewers ask you to do, but you should have (and state) a good reason why not

• You do need to do everything that the CE asks you to do

• Always: Prepare a point-by-point response to all comments (from CE, AE, referees) explaining how they were addressed, or in the event they were not, why not

• No matter what, be gracious

• Be timely; if > 6 months, we will treat as a new submission (ask for an extension in advance)
Writing a good journal article

“Submit the paper you think should be published:” Regardless of your target journal

- Time spent perfecting your paper before submission is time well spent

- Do not expect editors, AEs, and referees to do your work for you (how would you like it?)

- A well-written and organized paper, with careful attention paid to the clarity and quality of exposition and supported by careful citation of relevant literature, is a joy to read and review

- A poorly organized, unclear, sloppy paper is downright infuriating, and the reviews will reflect that...

- Two simple words: Spell check

- Ask a colleague to read and give you unvarnished comments
Writing a good journal article

Key elements of good writing:

• Clear statement of objective
• Scope and accessibility
• Completeness and clarity
• Organization and flow
• Tell a logical story
• Summarize
Writing a good journal article

A basic template for organizing an article:

- **Introduction** – motivation, background, summary of what is already known
- **Formal set-up** – notation, statistical model, identification of targets of inference, etc
- **Main results**
- **Supporting evidence, demonstration** – Simulation studies, application(s)
- **Discussion**
Writing a good journal article

Objective: *Introduction* section should

- Focus *immediately* on the context, e.g., “Longitudinal data sets are comprised. . .”

- Build up *background* need to understand the problem you will tackle – Why is the problem important? What are the major challenges? What is known? What are the key references? What are the limitations of current methods? *Motivate your problem!*

- *Often*: Provide this in the context of an *application*

- *State unambiguously* what will be done in the paper to address the challenges, e.g., “In this article, we propose. . .”

- Give a “*road map*” for how things will proceed so that readers know what to expect, e.g., “In Section 2, we describe. . .”

- *Most journals*: Little or no mathematical formulæ in the Introduction
Writing a good journal article

Scope and accessibility:

• Given length restrictions, consider what you can reasonably hope to communicate effectively while making a meaningful contribution

• You can’t pack everything you know into one paper!

• Make effective use of supplementary material

• Stay focused on your theme; avoid the temptation to “go off on a tangent” on things not central to your work and message

• Accept that you can’t give a comprehensive account of all the necessary background – give enough so a reader without it would know where to go to get it

• Keep your intended audience in mind at all times!
Writing a good journal article

Completeness:

• *Everything* that is needed to understand your message should be included or cited

Clarity:

• Economical and clear *notation*, defined and not used until defined!
• *Define* all acronyms and specialized terminology on first use
• Say exactly what you mean – be *concise and precise*
• *Avoid* flowery language and “fancy” words if simpler ones will do
• Break up *long sentences* into several
• Be *parsimonious* – avoid repeating yourself, run-on sentences
Writing a good journal article

Organization and flow:

- Motivate and describe the *steps* leading to your main results in *logical order* (and do not go off on tangents stating what you might have done instead)
- State your *assumptions* up front
- Relegate detailed derivations to *appendix/supplementary material* and go right to the results
- *Organize* the exposition into logical sections, each with a clear purpose
- Give each paragraph one *main point*
Writing a good journal article

Summarize: There should always be a Discussion/Conclusions section

- *Restate* the objective and review what was done to address it
- State the *key findings* and summarize their *importance and significance*
- Note the *limitations* and explain what remains to be done
- Do all of this in *plain English* – no formulæ
Writing a good journal article

Tables and figures:

- No more than *2 significant digits* in tables
- *Stand-alone* captions
- Figures can sometimes be *more effective* than tables of numbers for communicating results (simulations, data analyses)
Writing a good journal article

Words of great philosophers:

“Tell ’em what you’ll tell ’em, tell ’em, and tell ’em what you told ’em”

“Write it, and write it again. And then read it, and read it again.”
Writing a good journal article

- Effective writing can be *learned and perfected*
- Effective writing is every bit as *important* as technical and data-analytic skills are
- A great biostatistical advance can be *thwarted* by bad writing!
- Learn to enjoy making your work and ideas as *accessible* and *easy to understand* as possible
Miscellaneous

- **Copyright assignment form**: Return as quickly as possible; your paper cannot be published without it.

- **Plagiarism**: Be sure you have made *proper attribution* to sources of ideas and material – if you reproduce wording from another source, it needs to be set off in *quotation marks* and cited.
From the editors’ perspective

Things we hate:

• When we receive papers that were obviously rejected by *Biometrika*, and the authors did not even bother to replace the ampersands (&) in the citations by “and”

• When we receive papers that were rejected by another journal, and the authors did not even bother to incorporate any of the reviewers' comments (we have ways of finding this out. . . )

• When authors think that journal conventions do not apply to them (“We realize you have a 25 page and 6 table/figure limit, but our work is especially important, so we needed 38 pages and 42 figures”)
From the editors’ perspective

Things we hate:

• Sections of manuscripts entitled “Real Data Example”

• When authors who contest a rejection do not know when to give up

• When authors come up to us at meetings and social events and want to discuss the review processes for their papers
From the editors’ perspective

Things we like:

• Authors who respect the journal conventions at the time of submission

• Authors who take the time before submission to perfect their papers and who proofread them carefully

• Authors who offer thoughtful and complete responses to all of the reviewers’ comments and concerns

• Authors who conform to page limitations and other requirements imposed by the Co-Editor in preparing revisions
• Writing papers with a high chance of success is a skill that is learned over time from both successes and disappointments

• Effectively communicating your work requires time, attention to detail, and commitment to excellence

• Our journals are a primary mechanism by which advances in our field are vetted and disseminated

• The editorial process is not perfect, but it is generally fair and effective at identifying worthy advances and making sure they are communicated in the best way possible

• A great way to learn: Serve as a referee!
Questions
Part II: Grant writing and the review process

Main topics:

• The National Institutes of Health (NIH)
• NIH research grant mechanisms and funding opportunities
• Deciding when to write a research grant
• Writing an effective NIH grant application
• Submitting your grant application
• The peer review process
• Post-review
• Tips for success
The National Institutes of Health

- A federal agency that conducts and supports research focused on *improving health* in the US
- Budget of over *$30 billion*, over 80% of which is awarded through *competitive grants* to outside researchers (*extramural* research)
- Comprises 27 *Institutes and Centers* each with its own research focus and agenda – *24 of these* fund grants
  - *National Cancer Institute (NCI)*, *National Institute of Allergy and Infectious Diseases (NIAID)*, *National Heart, Lung, and Blood Institute (NHLBI)*, . . .
  - *Center for Scientific Review (CSR)* . . .
## NIH grant mechanisms

<table>
<thead>
<tr>
<th>Code</th>
<th>Grant Description</th>
<th>Duration</th>
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<tbody>
<tr>
<td>R01</td>
<td>Traditional Research Project Grant</td>
<td>3–5 years</td>
</tr>
<tr>
<td>R21</td>
<td>Exploratory/Development Grant</td>
<td>2 years</td>
</tr>
<tr>
<td>R03</td>
<td>Small Research Grant</td>
<td>2 years</td>
</tr>
<tr>
<td>R15</td>
<td>Academic Research Enhancement Award</td>
<td>3–5 years</td>
</tr>
<tr>
<td>K25</td>
<td>Mentored Quantitative Research Development Award</td>
<td>3–5 years</td>
</tr>
<tr>
<td>K99/R00</td>
<td>Pathway to Independence Award</td>
<td>5 years in 2 phases</td>
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</table>

- Information on these and other grant mechanisms
  
  [Link](http://www.grants.nih.gov)

- Detailed solicitation for R01 Research Project Grants
  
  [Link](http://grants.nih.gov/grants/guide/pa-files/pa-10-067.html)
NIH funding opportunities

- **Omnibus**: Unsolicited, *investigator-initiated* research grants
- **Request for Applications (RFA)**: Specific, targeted research priority for particular Institute(s) with set-aside pot of funds, usually time-limited
- **Program Announcement (PA)**: Statement of interest in a research area by Institute(s), usually on-going
- Information on RFAs, PAs at [http://www.grants.nih.gov](http://www.grants.nih.gov)
Administrative issues

- **Deadlines**: Three regular *cycles* for submission of most grant mechanisms; see
  http://grants.nih.gov/grants/funding/submissionschedule.htm
- **RFAs** may have different, specific deadlines
- **Forms and instructions** – SF424 (R&R)
- **Familiarize yourself** with the requirements on *page limits*, *margins*, *spacing*, etc, and follow them *exactly*
- **Familiarize yourself** with the *internal processing* procedures for submission at your institution
- Have your institution register you with **eRA Commons**
  https://commons.era.nih.gov/commons/
  (Check *status*, *scores*, *Summary Statement*)
Why write a research grant?

- Contribute to the *advance of knowledge* in the statistical and health sciences

- *Resources and time* for research

- Form of *peer review*

- Contribute to the *research enterprise* (and bottom line) of your institution

- *Fact of life*: Is an *expectation* in many institutions

- A great way to force you to *organize your ideas* and to think concretely about your research
Deciding when to write a research grant

- Realization that models/methods in your research area are applicable to specific health science challenges
- Have identified issues in your collaborative work that need new solutions (and you have good collaborators willing to advise/work with you)
- A RFA or PA is issued to which your research expertise and collaborative experience is relevant
- Have established a track record of publication that demonstrates your qualifications and potential for success
Planning to write a research grant

• Begin 3–6 months in advance of your target deadline

• Talk to relevant Institute Program Directors/Officers for biostatistics research

• E.g., Michelle Dunn at NCI or Misrak Gezmu at NIAID

• Talk to successful recipients

• Examine successful applications – many senior researchers are willing to share

• You are the Principal Investigator (PI); identify Co-investigators to collaborate with you
Specific Aims

What will be accomplished?

• One page

• Concrete outline of specific problems to be tackled and brief discussion of why they are important and need study

• For statistical methods grants: Usually 3–5 specific aims; may or may not be related to a common theme

• Each aim may have interrelated sub-aims, e.g.,
  – Development of new inferential methods for a specific problem
  – Extension to a more complicated setting
  – Application to specific data sets

• Attention grabbing introductory narrative followed by enumerated aims, each with a short motivating and descriptive blurb
Research Strategy

What will you do, and why?

- 12 pages total, three required sections
- Significance
- Innovation
- Approach
- In addition: Comprehensive bibliography and references cited
Significance

- *Importance* in terms of advancing health sciences research and improving biostatistical practice (not just statistical theory)
- *Specific applications* that motivate the need for the work
- Why what is available is *inadequate* or *non-existent*, needs *improvement*
- *Review of relevant literature* – cite key work
- Not *technical*; a high-level case for the *impact* of the work
- ~ 2 pages, can subdivide by aim
Innovation

- Convincing argument that the ideas are *new* and not straightforward extensions
- Emphasize *relevance* to new and emerging problems
- *Novel integration* of existing methods and substantive science
- $\sim$ 1–2 pages
Approach

- **Preliminary studies**: What you have *already done* that is important and relevant to the proposed research
- Demonstrate your *qualifications*
- Describe *relevant collaborations* with health scientists
- Cite your relevant *published/accepted papers*
- ~1–2 pages max on preliminary studies
Approach

- What will you do?
- Focus on what you *will* do, *not* what you have already done
- *Limited space*: present ideas *clearly* and *precisely*, *simple notation*
- *Big picture* of what you will do for each aim...
- ...but with enough detail to show you have a *well-planned*, *concrete*, *systematic strategy* for how to address each aim
- Brief *preliminary results* (e.g., a small simulation in a simple case), description of *analytical approach* you will take
- *Contingency plans*
- *Timeline*
- Use remaining pages
Some guiding principles

- Emphasize the (genuine) relevance to substantive health sciences research
- If you have subject-matter collaborators, include them as Co-Investigators or Other Significant Contributors; if you do not, consider teaming with such individuals
- No “theory for theory’s sake”
- Clarity
- Specificity about what you will do and what will be accomplished and its likely impact
- The same elements of effective writing we discussed for journal articles apply here
Submitting your grant application

**Cover letter:** Specific outline in SF424 instructions

- The particular *Institute(s)* that might be interested, e.g., NCI, NIAID, etc.

- Note if you are responding to a particular *Program Announcement* (PA) or *Request for Applications* (RFA).

- People who *should not* review your application due to professional conflicts (*very rare*).

- *Under no circumstances* name people who you think *should* review your application (*NIH* will determine who does...).

- Request assignment to a particular *study section* for review.

- Usually, *CSR* coordinates the review and makes the assignment.
Study section

- Members with expertise in a particular scientific area
- Meet face-to-face three times a year
- Coordinated by a Scientific Review Officer (SRO), an NIH official with expertise in the scientific area
- The SRO assigns members as reviewers for each application
  http://www.csr.nih.gov/committees/rosterindex.asp
- Evaluates scientific merit of grant applications
- DOES NOT decide which applications are funded
Study sections of interest

- **Biostatistical Methods and Research Design** *(BMRD)*
- **AIDS Clinical Studies and Epidemiology** *(ACE; statistical methods relevant to HIV research)*
- **Biomedical Computing and Health Informatics** *(BCHI; large clinical database development/data mining)*
- **Biodata Management and Analysis** *(BDMA; computational biology, bioinformatics)*
- **Epidemiology of Cancer** *(EPIC; research designs, genetics/genomic methods)*
- **Genomics, Computational Biology and Technology** *(GCAT; microarray, population genetics, gene mapping)*
- **Modeling and Analysis of Biological Systems** *(MABS; modeling complex biological systems)*
- **Social Sciences and Population Studies** *(SPSS; econometrics, survey methods)*
The review process

- **Internet Assisted Review (IAR)** in eRA Commons is *portal* for pre-, during-, and post-meeting activities
- SRO assigns “primary reviewer,” “secondary reviewer,” and “reader” (Reviewers 1, 2, 3) to each application (mindful of conflicts) who will submit *critiques* and *preliminary priority scores* in **IAR** before the meeting
- All members may read all applications prior to meeting
- Assigned reviewers *cannot see* critiques/scores of other assigned reviewers until 3 days before meeting; can think about them...
- Applications with *average preliminary scores* across assigned reviewers in “lower half” are candidates for “streamlining” – will *not be discussed* at the meeting (applicants receive critiques)
The review process

- The study section *Chair* runs the meeting (assistance from SRO)
- Applications from *Early Stage investigators* grouped in discussion order
- Each application discussed for *15-20 minutes*; those *in conflict* leave
- Three reviewers give *preliminary scores*
- *Reviewer 1* summarizes application and his/her critique
- *Reviewers 2 and 3* add additional comments
- Application is discussed by *all members present*
- Also discussed: *Human subjects research issues*
- Assigned reviewers give *final scores* and *all members* then score
- Reviewers may *modify critiques* post-meeting to *better reflect discussion*, final scores
- *Chair*: Keep focus on *big picture* rather than minutiae, summarizes
- *Budget request* not discussed until *after* scoring of *scientific merit*
Review criteria

Specific aspects:

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

Overall impact:

- Likelihood of the project to have a sustained, powerful influence on the research field(s) involved
## Scoring

**9-point scale:** For *each specific review criterion* and *overall impact*

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<thead>
<tr>
<th>Impact Level</th>
<th>Score</th>
<th>Description</th>
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<tbody>
<tr>
<td>High Impact</td>
<td>1</td>
<td>Exceptional</td>
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<tr>
<td></td>
<td>2</td>
<td>Outstanding</td>
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<tr>
<td></td>
<td>3</td>
<td>Excellent</td>
</tr>
<tr>
<td>Moderate Impact</td>
<td>4</td>
<td>Very good</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>Good</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>Satisfactory</td>
</tr>
<tr>
<td>Low Impact</td>
<td>7</td>
<td>Fair</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>Marginal</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>Poor</td>
</tr>
</tbody>
</table>

- Final *priority score* = average of *overall impact* scores of all members $\times 10$ (10–90)
Post-review

- **Score** in *eRA Commons* within days

- **Summary Statement** with *critiques* and *summary of discussion* written by the SRO within a month

- For R01s, a *percentile* is also assigned – where you sit relative to all scored applications in the current and previous 2 cycles (**low is good**)

- **Funding**: Determined by the “*payline*” for the grant mechanism at the assigned Institute – for R01s is a *percentile* cut-off

- **Special paylines** for *Early Stage Investigators*

- **Funding** determined by *percentile + program/policy considerations* and *availability of funds*

- If **not funded**: Allowed one *resubmission* – talk to the *Program Director/Officer*

- **Resubmission**: Modify to *respond to issues* raised in critiques and describe in a *1-page Introduction*; be *gracious*
What makes a successful application?

- **Impact**: Does the research address important problems in a way that will move *biostatistical science* and *practice* and the substantive *health science* forward in a *significant way*?

- **Innovation**: Is the work novel, clever, original rather than just straightforwardly extending previous work?

- **Involvement**: Is the PI involved in *collaborations* and the *health science area* in a significant way and does s/he demonstrate *knowledge* of the area?

- **Applications and dissemination**: Will the new methods be *demonstrated* on interesting data where they can lead to new insights? Will *public-use software* be developed?

- **Clarity**: Nothing *annoys* a reviewer more than not being able to figure out what you are planning to do!
Common factors behind a poor score

- *Unfocused* Research Strategy
- More discussion of what *has* been done than what *will* be done
- Lack of *innovation*
- Lack of *experience/expertise* in the health science area
- Failure to demonstrate knowledge of *literature and relevant work*
Summary

- Writing a research grant is a major undertaking
- Successful grant writing can be learned, takes practice
- Careful planning and attention to detail are essential
- Clarity and focus are essential
- A great way to learn: Collaborate on a grant application with an experienced colleague
Administrative details

Some other parts of application: Besides Specific Aims and Research Strategy

- Project Summary/Abstract
- Project Narrative
- Personnel
- Budget and Budget Justification
- Biographical Sketch
- Facilities and Resources
Administrative details

**Project summary/abstract and narrative:** Like an *abstract*

- Summarize the research and its relevance to *public health*
- Describe *relevance* in terms a layperson could understand

**Personnel:**

- *Principal Investigator* (PI) is responsible for overseeing the project
- *Key personnel* – PI, Co-Investigators, postdocs, computer programmers, technicians, consultants
- *Other Significant Contributors*
- *Research Assistants* (aka graduate students)

**NIH Biographical Sketch:** Needed for all *key personnel, other significant contributors*

- Includes a *Personal Statement* on qualifications for participating in *this particular project*
Administrative details

Budget: Direct costs

- Salary ("person-months" effort; usually $ \leq 6$ months for PI), fringe benefits
- Travel, supplies (e.g., a PC/laptop), tuition, computing time
- Typically $100,000$–$250,000$ per year

Modular grant application: If direct costs $\leq 250,000$ per year

- *Simplified system* – request funding in $25K$ increments (1 "module" = $25K$)
- Specify only percent effort, any special purchase – *no detailed budget* required
- A short *justification* of the efforts, other line items requested is required
Administrative details

**Budget:** *Facilities and Administration* (aka F&A, indirect costs, overhead)

- Support for institutional *infrastructure* – buildings, phones, copying, libraries, postage, computer network, . . .
- Calculated as a *percentage* of direct costs at your institution’s *negotiated rate*

**Total Costs:** *Direct costs + F&A*

- Additional considerations if the project involves personnel at *other institutions* ("*subcontracts*")
- Typical *project period* 3–4 years; 5 years is unusual
Administrative details

**Internal processing:** The grant is made to your institution, not to you!

- Application must be approved by your institution – approval of authorized university official
- Learn what is involved at your institution well in advance!
- *Must budget time for this*!

**Submission:** MUST be submitted by the deadline! No exceptions!
Human subjects research: Typically, BMRD research does not involve human subjects, but you must address this!

- Your research does not involve human subjects if subjects are not living or you do not have individual-subject data
- Your research does not involve human subjects if you and all personnel have no access to identifying information
- Your research does not involve human subjects if you have a documented agreement with the provider of the data that you will not have access to identifying information (unless that provider is one of the personnel on your grant!)
- Read the instructions regarding human subjects research carefully!
Administrative details

Progress report: Funds are allocated on *yearly basis*

- To receive next year’s funds, must document progress, publications
- Be sure you follow the directives of the *NIH Public Access Policy* throughout the project period – [http://publicaccess.nih.gov/](http://publicaccess.nih.gov/)

Renewal: Can submit a *new application* proposing to continue the project

- *Not guaranteed!* Must undergo *peer review* as for new applications
- Must add (brief) *Progress Report* documenting results of previous project period in the *Approach* section of Research Strategy plus *Progress Report Publication List*
- New research ideas and continuation of previous ones