Grant review of statistical methodology at BMRD

Jeremy M G Taylor University of Michigan

#### Outline

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- 2) BMRD, miconceptions
- 3) Recent BMRD events
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- 5) The review process
- 6) Types of grants at BMRD
- 7) The review criteria
- 8) Tips on grant writing

# Options for NIH grant support for statistical methods development

- Submit an R01/R21/R03 with you as Principal Investigator and have it reviewed by a study section
- Include statistical methodology is someone else's grant
  - Center grant
  - SPORE
  - Large R01's
- Respond to RFA's

#### BMRD

#### Biostatistical Methods and Research Design Study Section

 The Center for Scientific Review (CSR) review panel that evaluates many of the statistical methods grant applications submitted across Institutes of NIH

### NIH Study sections with expertise in statistical methods development

- BMRD (~95% of panel are statisticians)
- Others (5% 40% are statisticians)
  - GCAT (Genetics/Genomics)
  - EPIC (Cancer epidemiology)
  - BDMA (computer science, machine learning, bioengineering)
  - MABS (mathematical modeling)
  - BCHI (biomedical computing, informatics)
  - ACE (AIDS)
  - Others

#### Misconceptions about BMRD

- BMRD is "tough"
  - due to paylines and percentiling, all disciplines are subject to the same thresholds
  - all disciplines think that "their" study sections are the "toughest," but toughness is irrelevant

#### Misconceptions about BMRD

- BMRD makes investigators resubmit with more "detail"
  - across NIH, amended applications becoming more common
  - new 12 page limit for R01 Research Strategy (Significance, Innovation, Approach)
  - new review criteria place more emphasis on significance, investigators, impact, less on approach (and "detail")

#### Misconceptions about BMRD

- NIH has a limited budget for statistical methodology research
  - Not true
    - R01 and R21 grants are percentiled
    - More applications reviewed means more will get funded

#### Misconceptions about grant review

- Getting a good score is a negotiation process
  - It differs from submitting papers to a journal
  - Some reviewers will be the same, some will be different
  - Previous critique is available to new reviewers
  - Previous score is available to reviewers, but it plays a very minor role in assigning the new score

## Importance of BMRD

- Statistics is integral to a broad spectrum of biomedical research
- Ever increasing number of statisticians involved in biomedical research
- Continuing need for new methodology
- Small number of grants submitted could be interpreted as a small and not active community
- Methodology development and novel statistical applications need to be reviewed by those with high level of statistical training and experience

Number of grants reviewed by BMRD each cycle

- 2005, 40
- 2006, 39,42,40
- 2007, 49,42,43
- 2008, 49,36,37
- 2009, 23,26,28
- 2010, 50, 52

Possible reasons for reduced number of grants

- Other RFA's
- Other study sections (GCAT, BDMA)
- Statisticians have other options for funding
- Complaints about BMRD being too tough
- Anecdotal evidence of statisticians avoiding BMRD

- Possible plans to merge or eliminate BMRD were discussed
- There were efforts to raise awareness of the issue amongst the biostatistics community
- BMRD description was rewritten by Michelle Dunn and others and accepted by CSR.

### The future of BMRD

 The number of grants reviewed at BMRD needs to be maintained at around 50

#### **BMRD Updated Description**

The Biostatistical Methods and Research Design (BMRD) Study Section reviews applications that seek to advance statistical and mathematical techniques and technologies applicable to the design and analysis of data from biomedical, behavioral, and social science research. Emphasis is on the promotion of quantitative methods to aid in the design, analysis, and interpretation of clinical, genomic, and population based research studies. This includes analytic software development, novel applications, and secondary data analyses utilizing existing database resources. Specific areas covered by BMRD:

- High dimensional data methods such as those arising from genomic technologies, proteomics, sequencing, and imaging studies; development and applications of methods for data mining and statistical machine learning; statistical methods for high throughput data; biomarker identification
- Novel analyses of existing datasets: Innovative application of existing or development of new statistical and computational methodologies; application of methods in substantially new areas of application; innovative, non-routine data analysis strategies including combinations of existing methods rather than de novo development of new methods; development and evaluation of novel analytic tools to address new questions within existing data sets
- Research design: development and innovative application of randomized trial designs; sample size determination; design issues for experimental and observational studies; methods to improve study design efficiencies; methods for survey sample design; methods for comparative effectiveness studies
- Data collection and measurement: development and adaption of methods to estimate and improve data precision, reliability, and validity; methods to estimate and adjust for bias, measurement error, confounding, sampling and non-sampling error; psychometric methods
- Data analysis and modeling: development of statistical theory, analytic methods and models, computational tools, and algorithms for the analysis and interpretation of data from clinical studies, randomized trials, observational studies, epidemiological studies, human genetic association studies, environmental studies, complex surveys, large databases, and registries; methods to handle data features and anomalies such as correlation, clustering, and missing data; risk prediction and forecasting methods; causal modeling

#### **BMRD Updated Description**

This includes analytic software development, novel applications, and secondary data analyses utilizing existing database resources.

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- Methods for Comparative Effectiveness Research

#### Why these changes?

- Clarification of areas statisticians are heavily involved and can make a contribution
  - bioinformatics, genomics, imaging, genetics, data mining, high dimensional data, health services, comparative effectiveness research.
- Signal to CSR that BMRD has broad expertise
- Mention software development
- Explicitly mention novel analysis of existing data
- The core of BMRD will remain the development, evaluation and application of innovative statistical methods

#### Reviewers perspective of the process

- Meet three times per year
- Receive assigned grants (about 10) 5 weeks before meeting
- Post preliminary critiques and scores on website about 4 days before meeting
- One day meeting (50 grants to review)
  Half not discussed (based on preliminary score)
  - Half discussed (12-25 mins each)

#### At grant review meeting

- Three reviewers will have thoroughly read it
- A few others will have looked at it beforehand
- Most will scan it during the discussion
- The three reviewers present their scores and opinions on strengths and weaknesses
- Others discuss or give opinions
- The three reviewers give their final overall scores everyone else assigns (in secret) a score

What type grants should BMRD see? And what is likely to score well. Some examples.

- Methodology work
  - Clear area or areas of application
  - Rigorous development and comparison with other approaches
  - Develop and test software
  - Statistical generalizability
  - Potential for large improvement
  - Impact

# What type grants should BMRD see? And what is likely to score well. Some examples

- Substantive contributions lead by statisticians with high statistical content
  - Answer burning scientific question
  - Sophisticated statistical methods are required
- Heavy statistical computing
  - Develop and evaluate different novel preprocessing or normalization schemes for large complex raw biomedical data
  - Software required

#### Recent changes to grants

- Grant applications are shorter
  - Grants are easier to write now
  - Good grants are not necessarily easier to write
- Grant sections are different (significance, innovation, approach)
  - Pay more attention to impact and significance and pay less attention to approach

- What do impact, significance, investigator and innovation mean for statistical grants?
- Overall impact
  - the likelihood of the project to exert a sustained powerful influence on the field.
  - Could be field of statistics with the potential to impact applications or field of application

- Significance
  - Does the project address an important problem or a critical barrier to progress in the field? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?
  - Could be an important problem in statistics with clear application to the NIH mission
  - Could be an important health problem (hard to judge)

#### Investigator

- Are the investigators well suited to the project?
- For junior investigators do they have appropriate experience and training? Does the CV look promising?
- For senior investigators have they demonstrated an ongoing record of accomplishments that have advanced their field? The track record matters.
- An investigator who has very little prior research in the proposed area is unlikely to score well in this criteria.

#### Innovation

- Does the application challenge and seek to shift current research by utilizing novel theoretical concepts, approaches or methodologies.
- Are the concepts, approaches or methods novel to one field of research or novel in a broad sense?
- Could be statistical novelty. Could be novel area of application. Could be both.
- A continuation of someone's long term research program may not score well on innovation unless there are new ideas.

- Overall impact is all that matters for the final score
- The 5 criterion scores are just guides
- Overall impact not equal to average of 5 criteria scores.

#### Tips on grant writing - I

Keep in mind the review process:

- Will get reviewers familiar with your area, but probably not an exact match.
- Make sure to clearly point out what will be innovative.
- Make sure to clearly point out the implications of the work.

#### Tips on grant writing - II

What makes an excellent BMRD application:

- Strongly motivated by a real problem.
  - Helps to clearly spell out datasets and collaborators.
- Widespread scope of work.
- Makes novel contributions to the discipline of biostatistics.

#### Tips on grant writing - III

- If methods already exist for your problem you need to compare with them and there needs to be a likelihood of more than epsilon gain
- If you are going to develop software you need a believable plan
- It may be a good idea to include the nonstatistical collaborator in the budget

#### How not to get an NIH grant

- Assume the reviewers will understand all the implications of your work.
- Assume you will get three reviewers intimately familiar with your exact area of research.
- Propose proving deep theoretical theorems that will one day undoubtedly be useful.
- Don't bother to mention that you have access to real data
- Spend many pages giving a tutorial on basic concepts
- Argue with the reviewers in a resubmission

#### When your grant isn't funded

- It is competitive, you are part of the 85% majority.
- Everyone thinks their brand or style of statistics is the right one and the important one, but opinions do differ
- Reviews can be quite terse, just lists strengths and weaknesses that drove the score
  - Not always clear how to revise

#### When your grant isn't funded

- Contact the program officer who may be able to provide some insight
- Don't give up
  - the reviewers may be different next time
  - do pay attention to the critiques
- Seek advice from senior colleagues

# Thanks to others whose slides or ideas I borrowed

- Michelle Dunn
- Marie Davidian
- Chuck McCulloch
- Giovanni Parmigiani