- In accordance with the ACCME® standard for Commercial Support Number 6, all in control of content disclosed any relevant financial relationships. The following in control of content had no relevant financial relationships to disclose.

Name:	Role in Meeting:
Ruta Brazauskas, PhD	Planning Committee
Haley Montsma, BBA	Planning Committee
Aniko Szabo, PhD	Speaker

- Understand statistical issues relevant to grant applications
-

Your opinion matters!

Help us plan future meetings, by completing and submitting your evaluation forms.

Thank you.

- Statistical co-investigator on over a dozen grants
  - Basic science, human studies, clinical trials
- Wrote statistical sections for even more grants
  - and saw drafts, unfunded versions, etc
- Statistical reviewer for NIH study sections
  - Clinical and Integrative Cardiovascular Sciences [*CICS*]
  - Biomedical Methods and Research Design [*BMRD*]
  - NIEHS special panel on nanomaterials

- Specific aims and hypotheses
- Specifying the study population
- Selecting a study design
- Defining outcome measures
- Sample size calculations
- Data analysis plan

- Conceptual target population
- Operationalization
  - Inclusion/exclusion criteria

- **Ideal: differ from the study group only in the study variable**
- Straightforward situation
  - Randomized prospective study
    - Many basic science experiments fall into this category
- Subject as his/her/its own control
  - Regression to the mean can cause spurious results
  - Cross-over designs can correct for this
    - Carry-over effects
  - Within-subject change can be used as an outcome with another control group

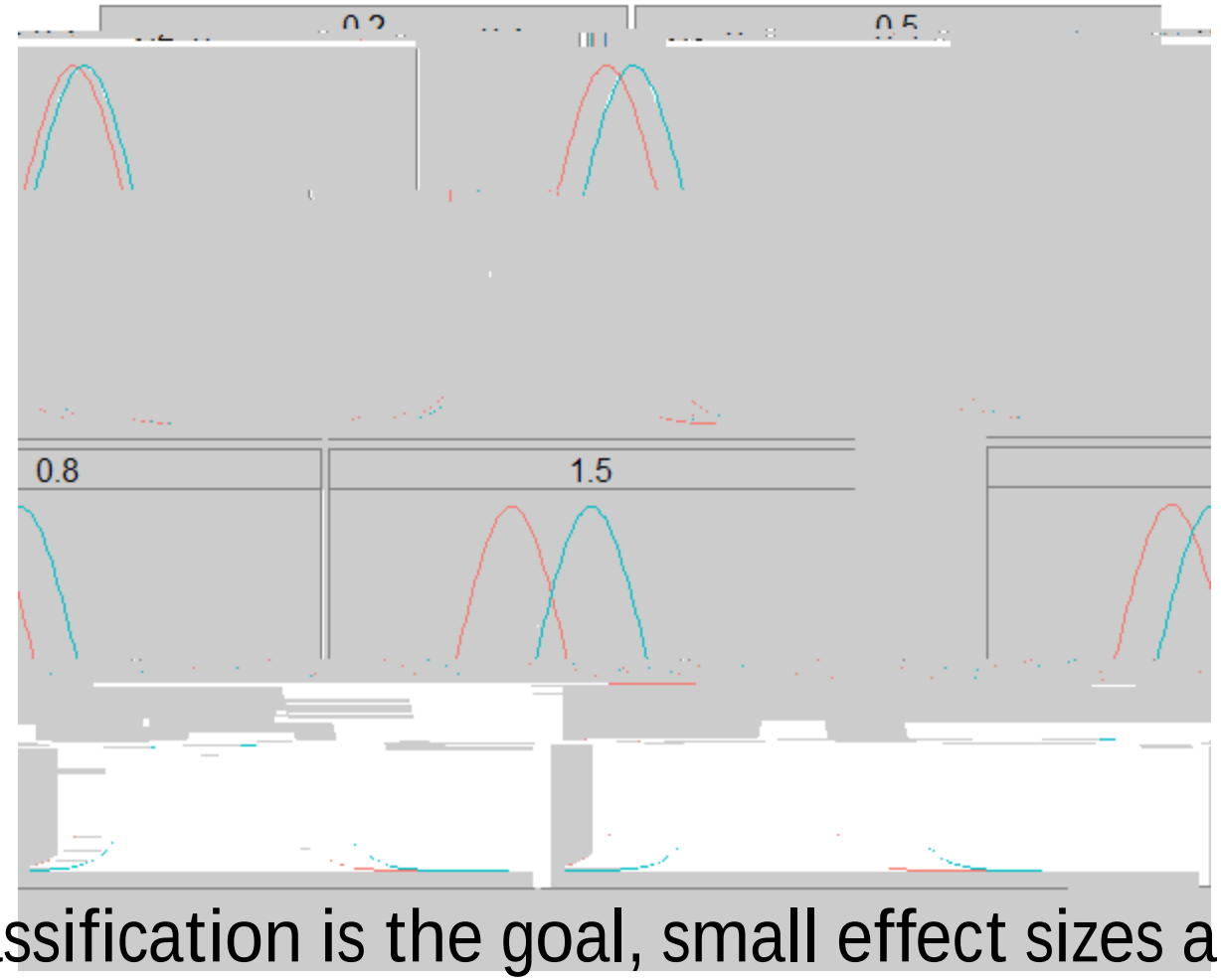
- Prospective vs retrospective
- Observational vs experimental
- Case-control studies
  - Matched vs unmatched
  - Matching can result in either gain or loss of power
  - Unmatched studies still recruit comparable controls, but there is no individual level matching
- Randomization and blinding
  - Rarely mentioned in basic science studies, though highly relevant

- Interim analysis
  - Check for statistical significance at preplanned time-points during the study
    - Significance levels have to be adjusted
  - Can be useful if there is substantial uncertainty about the expected effect
  - Rare in basic science studies, but could be useful
- Internal pilot
  - Quantities need for power calculation are estimated based on a small initial sample size
  - Needs to be planned in advance: a small adjustment of significance level might be needed

- Measureable and well defined
  - Measurement procedures
  - Timing
    - Too many repeated measurements just complicate the result
    - Two points at ends are sufficient to show change
- Separate primary versus secondary outcomes
  -

Type of Study	Sample Size	Detectable Difference	Power
Retrospective	Fixed known	Fixed Clinically / biologically important difference	Computed
Retrospective	Fixed known	Computed	Fixed (90, 80)%
Prospective	Computed	Fixed Clinically / biologically important difference	Fixed (90, 80) %
Observational	Computed	Fixed Desired precision of estimate	Not applicable

- Sample size calculation will be done by XYZ (letter of support attached)
- Plan a small pilot study that will provide the data



If classification is the goal, small effect sizes are useless

- Online calculators
  - See upcoming talk
- G*Power 3
  - Free Windows/Mac program from the University of Düsseldorf
  - Needs some statistical sophistication
- Consult your friendly neighborhood statistician

- The goal is to convince the reviewers that you can analyze the data
  - Not all details are necessary
  - Showing awareness of statistical aspects and capability to address issues is important
  - If grant contains many experiments, consider having a separate section with overall analysis approach
-

- Complicated data with no mention of statistics
- Mistakes/misinterpretations in the analysis of preliminary data
- Statistical methods do not match the study design
  - Statistical methods clearly copied from another grant
  - Matched design vs unmatched analysis
- Incorrect statistical plan
  - Plan to “sample until significance”
  - Superficial plan emphasizing minor details over substantative issues