Section Analysis: Approach and Preliminary Studies

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LESSONS FOR SUCCESS
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- **Projects must be high in impact, significance, and innovation**
- **However, all is lost when an approach is either not feasible or does not lead to data that will accomplish the aims of the project**
- **Statistical plan is important for assessing the likelihood that the project will yield interpretable results; in the Summary Statement, the Approach generally receives the most attention.**

Summary of Review Considerations

- All grants: Does the research plan address scientific significance, originality, and feasibility?
  - Note: Evaluating probability of a sustained and powerful impact
- Training grants: Will the research training plan provide the applicant with individualized and supervised experiences that will develop research skills needed for his/her research career?
- Training and Impact; strong research plan is absolutely ESSENTIAL

Some Considerations

- Approach links clearly to the theoretical and clinical questions (e.g., significance and innovation)
- Impact is a combination of significance and approach
- Difficulties with conceptual background become apparent in the development of the experiments

Some Considerations

- Statistical plan, including Power Analysis (often commented on in Summary Statement)
- Preliminary data (feasibility and pilot data); how used to explicate analysis plan
- Reliability (e.g., of coding, tests, procedures, fidelity of administration)

Some frequently occurring weaknesses/strengths

- **Feasibility**
  - **Of recruiting participants, especially if clinical populations**
  - **Of completing work (how ambitious)**
  - **Of lack of success with one Aim (often Aim 1) leading to difficulties with later Aims (aims overly contingent on one another)**

Some frequently occurring weaknesses/strengths

- Aims overly diffuse and unrelated; Approach not clearly tied to Specific Aims
- Inclusion and **integration** of appropriate scientific team (including statistical consultation, expertise when when adding a new methodology)
- Potential problems, alternatives, benchmarks
- Authentic pitfalls (demonstrate thinking it through and not naïve)

Some frequently occurring weaknesses/strengths

- Reviewer does not understand or misunderstands the Approach (What should you do?)
- Clarity is the responsibility of the PI, not the reviewer
- Power of pictures, data figures; easy to read!

Discussion Point: Page Limits

- How can a new investigator (or a not so new one) convey all that is needed in their Approach section(s) within the bounds of the page constraints?
  - e.g., careful use of preliminary studies
  - e.g., concise, clear, and delimited questions and allied analyses

Power Analysis (thanks to Elena Plante)

- Where should the power estimate go?
  - **Preliminary Studies**
    - With pilot data for each task
  - **Approach**
    - **Participant number & description**
      - If all studies use one general method
      - If similar effect sizes are expected across studies
    - **Before each individual study**
      - If individual studies use different methods
      - If different effect sizes are expected
    - **In a Statistical Plan section**

Example: From a Subjects section

Numbers of Subjects and Statistical Power

Studies involving children will use a minimum of 25 children per group (50 children total). Power calculations based on the most similar studies completed during the last grant cycle indicate that this N size should provide a minimum of 80% power to detect significant effects at $p < .05$. Adult samples tend to show larger between-group effects for similar tasks, requiring fewer subjects. Therefore, these studies will use a minimum of 20 adults per group (40 subjects total) to maintain the same power. Although these estimates are used for planning purposes, we routinely check effect sizes when approximately two thirds of the data have been collected so that data from additional subjects can be included if effect sizes are smaller than anticipated. Our recruitment sources (i.e., available school programs) are sufficiently large to allow this measure of flexibility.

Power estimate #1

Power estimate #2

Verification plan

Resource availability

Power Analysis Resources

- Common to many stat packages
- Cohen, J. Statistical Power Analysis for the Behavioral Sciences. Lawrence Erlbaum Associates.
- Kraemer, H.C. & Thielman, S. How many subjects? Statistical power analysis in research. Sage.
- NCSS Statistical Software. PASS Power Analysis and Sample Size. Author.

SAMPLE GRANT
LAURENCE LEONARD

Broad theoretical level

"Many common errors in SLI across different languages….can be logically related to an assumption of inappropriate extraction of nonfinite subject-verb sequences. There is now emerging evidence that children with SLI are, in fact, prone to extract nonfinite subject-verb sequences from larger structures in the input. However, the next crucial step for this proposal – demonstrating that this inappropriate extraction is related to a failure to grasp the structural dependencies in larger structures – has not yet been taken."

Overview linking questions to theory

Broad theoretical level

"This perspective could lead to a wholly new approach to treatment. Specifically, intervention might be directed at comprehension, to help children learn the structural dependency between nonfinite sequences and early appearing finite verb information. A new approach is sorely needed, given that previous intervention attempts have produced only modest results at best."

Translational implications

Specific questions/hypotheses

- Will typically developing children make use of early-appearing finite information in questions that serve as cues to information appearing later in the questions, while children with SLI fail to make use of this information?
  - e.g., Are the dogs running?
- Will children's sensitivity or insensitivity to this early-appearing finite information serve as a significant predictor of their consistency/inconsistency in using the same tense/agreement forms in their own speech?

Specific analyses

To address Specific Aim 1, we will compare the three groups of children on the looking-while-listening measures. First, we will examine the children's mean RT in shifting gaze from distractor to target using an ANOVA with participant group as a between-subjects variable. We expect a significant interaction, with the the TD-A and TD-Y groups showing faster RTs in the finite-cue condition than in the no-finite cue condition, whereas the children with SLI will show no RT difference between the two cue conditions.

Specific analyses

For the second analysis, using mean percentage of looking at the target in the pre-noun time window, we expect a similar interaction. Judging from the effect sizes in our pilot work, we have determined that an n of 18 for each group in each experiment will have power greater than .80 at $p < .05$.

And how to handle complex findings

To address Specific Aim 2, we will use regression analyses……we ask if the children's mean percentage of (pre-noun) looking to the target in the finite-cue condition serves as a predictor of the child's use of copula or auxiliary forms.

Primary Prediction

Alternate Predictions

We will also include the children's scores on the Sentence Structure subtest of the CELF-P2 as well as the children's digit span scores. The former serves as a general language comprehension measure that does not focus on the kinds of structural ties hypothesized to be related to the children's inconsistent use of copula and auxiliary forms.

Alternate Prediction

Alternate Predictions

The latter (digit span) serves as a measure of verbal short-term memory. This measure is included because a failure to grasp the structural ties between an early appearing finite form and a later appearing noun may be due to a failure to retain the finite information.

In this analysis we seek to determine if our looking measure predicts unique variance in the children's copula and auxiliary use scores over and beyond the variance explained by the Sentence Structure and digit span scores.

Alternate Prediction 2

Summary of Example

- Fairly standard design (between groups; ANOVA and regression)
- Theory linked to hypotheses linked to experiments and statistical approach
- Alternative accounts considered

Critiques are Wonderfully Helpful!!!!

- The quantitative measures developed by the Principal Investigator have thus far been used only to evaluate group differences. The current proposal provides the opportunity to extend this research to see if these measures are also reflect individual differences. This opportunity will be lost without a more complex statistical analysis more appropriate to the multivariate and longitudinal design.

Section Analysis of Approach

*********Handouts*********

- Hearing
  - Location: Main Conference Room
- Language
  - Location: Board Conference Room
- Speech
  - Location: Main Conference Room