ABSTRACT & SPECIFIC AIMS

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Fast Facts

- Abstract & Specific Aims:
 - Create a first impression of your grant
 - WIDELY read
 - These are the only two sections distributed to reviewers during the reviewer selection process
 - Will help determine who reviews your grant
 - Often skimmed by other "unassigned" reviewers prior to or during discussion

Form Requirements/Instructions

- Abstract
 - 30 lines of text
 - Note that there is a separate section for health impact
- Specific Aims
 - A set page limit (1 page)
 - Doesn't count towards your "research strategy" page limit (6 or 12 pages)

SPECIFIC AIMS: THE BASICS

SF424 (p. I-110): Instructions (same in Fellowship Instructions)

Field Name	Instructions
2. Specific Aims	State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved.
	List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.
	The Specific Aims attachment is required unless otherwise specified in the FOA. Specific Aims are limited to one page.
	Save this information in a single file in a location you remember. Click Add Attachment , browse to where you saved the file, select the file, and then click Open .

Specific Aims: Goals

- Specific Aims should:
 - Excite the reviewer
 - Inspire confidence in the PI
- Set the framework for the rest of the application
 - Establish the specific themes or questions that guide particular projects or studies
 - Provide integration of those specific themes or questions

Specific Aims: Essential Elements

- Specific Aims should provide the following essentials:
 - Overarching Goal: What is the problem/issue and why should it be studied?
 - Theory/Rationale/Motivation: The why of the application.
 - **Approach**: What is the applicant's approach/method?
 - Specific Questions/Hypotheses: More specific goals that will be addressed in particular studies
 - **Significance/Innovation**: Why is the above of import, of significance? How will the above advance basic and applied knowledge and/or impact the nation's health? How is this application innovative?

Specific Aims: Analysis Checklist

- Is there a statement of theory, what is known, etc.?
- Is there a statement of what is unknown, the problem, etc.?
- Is there a clear goal of the planned research (should involve addressing what is unknown)?
- Are the specific questions/issues to be addressed (i.e., the specific aims) clearly identified and stated?
- Is the approach referenced in appropriate detail? (could be incorporated into each aim or could be separate; might be quite brief)
- Is it clear what will be known at the conclusion of the proposed research?
- Is it clear why that knowledge is important?
- Is the innovation of this application clear?

SPECIFIC AIMS EXAMPLE

Storkel book reading R01

Interactive Book Reading to Accelerate Word Learning by Children with SLI

Specific Aims

Children with Specific Language Impairment (SLI) need two to three times as many exposures as their sameaged peers to learn a new word (Gray, '03; Rice et al., '94). Importantly, spoken language vocabulary sets the foundation for reading success in later grades (Scarborough, '98). As a result, it is critically important to accelerate word learning in Kindergarten to set the foundation for reading, especially in children with SLI who are at increased risk for reading deficits (Catts et al., '02). Interactive book reading is a promising intervention that has yet to be optimized for children with SLI. Interactive book reading has moderate to large effects on word learning by typically developing children and children with low vocabulary due to environmental differences in input (i.e., children from low income families; Marulis & Neuman, '10; Mol et al., '09; Mol et al., '08). Moreover, the intervention can be effectively administered by a wide variety of adults (e.g., parents, teachers) with minimal training, a desirable quality given the current shortage of speech-language pathologists. The long-term goal of this research is to optimize an interactive book reading intervention (Justice et al., '05) for children with SLI. The *primary objective for this Preliminary Clinical Trial is to identify a promising treatment intensity and dosing regimen* that would move forward for further study.

Aim 1: Determine the cumulative number of exposures to target words (i.e., treatment intensity) during interactive book reading that results in children with SLI showing promising word learning outcomes.

Most studies of interactive book reading use a relatively low number of exposures to the target words. Although children with normal learning profiles benefit from this low intensity, evidence (Gray, '03; Rice, et al., '94) suggests that this low intensity will not be sufficient for children with SLI. However, there are no empirically established guidelines for what might constitute a sufficient intensity for children with SLI. This aim uses a Phase I escalation strategy (Hunsberger et al., '05) to *hone in on an adequate treatment intensity* of interactive book reading for children with SLI.

Aim 2: Determine the extent of benefit when the adequate treatment intensity is administered to children with SLI.

Treatment at the adequate intensity will be administered to a greater number of children with SLI and will be compared to a control condition to *confirm that the intensity is adequate*. Moreover, the breadth of change will be explored. Specifically, prior studies show that both *proximal* (i.e., learning the taught words) *and distal outcomes* (i.e., measures beyond the taught words) improve with interactive book reading. Lastly, in prior studies of other populations, there was variation in the degree of improvement resulting from interactive book reading that was dependent on pre-treatment test scores. Thus, this aim also will *explore the pre-treatment characteristics that are most related to treatment response*.

Aim 3: Determine the best combination of the number of exposures within a book (i.e., dose) and the number of exposures via repeated readings of a book (i.e., dose frequency) for children with SLI.

The same cumulative number of exposures can be achieved in different ways. For example, 12 cumulative exposures could be achieved by hearing a target word 6 times in a book that is read on 2 different occasions or by hearing a target word 2 times in a book that is read on 6 different occasions. Crucially, theories of learning and empirical data converge on the prediction that one of these combinations (i.e., the one that maximizes dose frequency) will result in better word learning outcomes, <u>even though</u> the number of cumulative exposures is the same (Childers & Tomasello, '02; McGregor et al., '07; Riches et al., '05). This aim *identifies the most promising dosing regimen for children with SLI* and links these 'active ingredients' of the treatment to theory.

This Preliminary Clinical Trial is one of the first studies to systematically examine different intensities and dosing regimens for interactive book reading and to document the extent of benefit associated with the treatment. This information will set the foundation for either (1) further optimization or (2) rigorous efficacy testing of interactive book reading for children with SLI, a population critically in need of an effective word learning treatment. Children with Specific Language Impairment (SLI) need two to three times as many exposures as their sameaged peers to learn a new word (Gray, '03; Rice et al., '94). Importantly, spoken language vocabulary sets the foundation for reading success in later grades (Scarborough, '98). As a result, it is critically important to accelerate word learning in Kindergarten to set the foundation for reading, especially in children with SLI who are at increased risk for reading deficits (Catts et al., '02). Interactive book reading is a promising intervention that has yet to be optimized for children with SLI. Interactive book reading has moderate to large effects on word learning by typically developing children and children with low vocabulary due to environmental differences in input (i.e., children from low income families; Marulis & Neuman, '10; Mol et al., '09; Mol et al., '08). Moreover, the intervention can be effectively administered by a wide variety of adults (e.g., parents, teachers) with minimal training, a desirable quality given the current shortage of speech-language pathologists. The long-term goal of this research is to optimize an interactive book reading intervention (Justice et al., '05) for children with SLI. The *primary objective for this Preliminary Clinical Trial is to identify a promising treatment intensity and dosing regimen* that would move forward for further study.

- Yellow = problem (kids with SLI have trouble learning words)
- Pink = impact/importance of problem (places them at risk for other problems)
- Green = potential solution *(interactive book reading)*
- Blue = long-term goal and specific objective of this proposal (figure out how to use this treatment with this population)

Aim 1: Determine the cumulative number of exposures to target words (i.e., treatment intensity) during interactive book reading that results in children with SLI showing promising word learning outcomes.

Most studies of interactive book reading use a relatively low number of exposures to the target words. Although children with normal learning profiles benefit from this low intensity, evidence (Gray, '03; Rice, et al., '94) suggests that this low intensity will not be sufficient for children with SLI. However, there are no empirically established guidelines for what might constitute a sufficient intensity for children with SLI. This aim uses a Phase I escalation strategy (Hunsberger et al., '05) to *hone in on an adequate treatment intensity* of interactive book reading for children with SLI.

- Not highlighted = succinct statement of Aim
- Yellow = general problem (current version of interactive book reading won't work for this population)
- Pink = more specific problem (don't really know what will work)
- Green = solution pursued in this aim + tiny bit about approach (Let's figure it out!)

Aim 2: Determine the extent of benefit when the adequate treatment intensity is administered to children with SLI.

Treatment at the adequate intensity will be administered to a greater number of children with SLI and will be compared to a control condition to *confirm that the intensity is adequate*. Moreover, the breadth of change will be explored. Specifically, prior studies show that both *proximal* (i.e., learning the taught words) *and distal outcomes* (i.e., measures beyond the taught words) improve with interactive book reading. Lastly, in prior studies of other populations, there was variation in the degree of improvement resulting from interactive book reading that was dependent on pre-treatment test scores. Thus, this aim also will *explore the pre-treatment characteristics that are most related to treatment response.*

- Aim 2 = succinct statement of Aim 2
- Aim 2 is pretty closely linked to Aim 1 so there is not as much problem details
- Yellow = what will be learned through this aim

Aim 3: Determine the best combination of the number of exposures within a book (i.e., dose) and the number of exposures via repeated readings of a book (i.e., dose frequency) for children with SLI.

The same cumulative number of exposures can be achieved in different ways. For example, 12 cumulative exposures could be achieved by hearing a target word 6 times in a book that is read on 2 different occasions or by hearing a target word 2 times in a book that is read on 6 different occasions. Crucially, theories of learning and empirical data converge on the prediction that one of these combinations (i.e., the one that maximizes dose frequency) will result in better word learning outcomes, <u>even though</u> the number of cumulative exposures is the same (Childers & Tomasello, '02; McGregor et al., '07; Riches et al., '05). This aim *identifies the most promising dosing regimen for children with SLI* and links these 'active ingredients' of the treatment to theory.

- Aim 3 = succinct statement
- Yellow = issue (not really a problem)
- Pink = theory/prediction
- Green = goal/outcome of this aim

This Preliminary Clinical Trial is one of the first studies to systematically examine different intensities and dosing regimens for interactive book reading and to document the extent of benefit associated with the treatment. This information will set the foundation for either (1) further optimization or (2) rigorous efficacy testing of interactive book reading for children with SLI, a population critically in need of an effective word learning treatment.

- Conclusion or summary of the aims
- Yellow = summary of the outcome or the predicted accomplishments of this research
- Pink = next step/future direction
- Comment: Little bit of a snooze here. Abstract has more powerful conclusion. Should have been incorporated here.

ABSTRACT: THE BASICS

SF424 (p. I-61): Instructions (same in Fellowship Instructions)

7. Project Summary/Abstract

The Project Summary must contain a summary of the proposed activity suitable for dissemination to the public. It should be a self-contained description of the project and should contain a statement of objectives and methods to be employed. It should be informative to other persons working in the same or related fields and insofar as possible understandable to a scientifically or technically literate lay reader. This Summary must not include any proprietary/confidential information. Please click the **Add Attachment** button to the right of this field to complete this entry.



The **Project Summary** is meant to serve as a succinct and accurate description of the proposed work when separated from the application. State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project (i.e., relevance to the **mission of the agency**). Describe concisely the research design and methods for achieving the stated goals. This section should be informative to other persons working in the same or related fields and insofar as possible understandable to a scientifically or technically literate reader. Avoid describing past accomplishments and the use of the first person. Finally, please make every effort to be succinct. This section must be no longer than 30 lines of text, and follow the required font and margin specifications. An abstract which exceeds this allowable length may be flagged as an error by the agency upon submission. This would require a corrective action before the application will be accepted.

As noted above, do not include proprietary, confidential information or trade secrets in the description section. If the application is funded, the Project Description will be entered into an NIH database and made available on the NIH Research Portfolio Online Reporting Tool (RePORT, available at <u>http://report.nih.gov</u>) and will become public information.

The attachment must be in PDF format. (See <u>Section 2.6</u> for additional information on preparing attachments.)

Abstract: Goals

- Abstract should:
 - Invite and encourage the reviewer to read the grant
 - Excite the reviewer about the research
 - Inspire confidence in the PI

Abstract: Essential Elements

- Abstract should provide the following essentials:
 - Overarching Goal: What is the problem/issue and why should it be studied?
 - **Approach**: What is the applicant's approach/method?
 - **Significance/Innovation**: Why is the above of import, of significance? How will the above advance basic and applied knowledge and/or impact the nation's health? How is this application innovative?

Abstract: Analysis Checklist

- Is there a statement of theory, what is known, etc.?
- Is there a statement of what is unknown, problem, etc.?
- Is there a clear goal of the planned research (should involve addressing what is unknown)?
- Is the approach to address the goal noted, briefly described, etc.?
- Is it clear what will be known at the conclusion of the proposed research?
- Is it clear why that knowledge is important?

ABSTRACT EXAMPLE

Storkel book reading R01

Interactive Book Reading to Accelerate Word Learning by Children with SLI

Abstract

Children with Specific Language Impairment (SLI) are known to have difficulty learning new words, which places them at greater risk for future reading impairments and academic failure. Surprisingly, there are few interventions for word learning by children with SLI that have undergone rigorous efficacy and/or effectiveness testing. The long-term goal of proposed research is to optimize an intervention with moderate to large effects on word learning by other populations of children for children with SLI. The intervention of interest is interactive book reading, where an adult uses oral reading to a child as a foundation for teaching new words. The first step towards the long-term goal is this Phase I/II Preliminary Clinical Trial, which is defined as a preliminary study addressing core design and clinical issues necessary to the future conduct of a Phase III/IV Definitive Clinical Trial that, in turn, establishes the efficacy/effectiveness of the intervention. Aim 1 uses a Phase I escalation strategy to hone in on an adequate treatment intensity of interactive book reading for children with SLI. The intensities to be tested are informed by empirical word learning studies showing that children with SLI need two to three times as many exposures as their typically developing peers to learn new words. Aim 2 examines the extent of benefit associated with the adequate treatment intensity in terms of both proximal (i.e., learning the taught words) and distal outcome measures (i.e., learning beyond the taught words) and in terms of the variation in response to treatment based on pre-treatment language skills. Aim 3 is based on the idea that there are different ways of achieving the same treatment intensity. For interactive book reading, intensity is a function of the number of exposures to target words within a book (i.e., dose) and the number of exposures to target words via repeated readings of a book (i.e., dose frequency). There is strong evidence from experimental studies and theory suggesting that a regimen that maximizes dose frequency will yield better word learning outcomes than a regimen that maximizes dose, even when the overall intensity is equivalent. Aim 3 will identify the best combination of dose and dose frequency for word learning by children with SLI. The likely impact of this research is that an adequate intensity and promising dosing regimen of interactive book reading will be identified for children with SLI, for whom there are few (if any) proven treatments for word learning. Moreover, the types of outcomes that can be attained through manipulation of intensity and dosing regimen will be identified, determining whether further optimization of the treatment is needed to meet the significant word learning challenges faced by children with SLI. Lastly, the resulting findings will contribute to theories concerning the number of exemplars needed to support learning as well as theories of learning from input versus memory consolidation. Specifically, the work pushes the limits of these theories by providing evidence from children with SLI learning large numbers of words over several months. supplementing prior data from typically developing children learning small numbers of words over a few weeks.

Abstract

Children with Specific Language Impairment (SLI) are known to have difficulty learning new words, which places them at greater risk for future reading impairments and academic failure. Surprisingly, there are few interventions for word learning by children with SLI that have undergone rigorous efficacy and/or effectiveness testing. The *long-term goal* of proposed research is to optimize an intervention with moderate to large effects on word learning by other populations of children for children with SLI. The intervention of interest is interactive book reading, where an adult uses oral reading to a child as a foundation for teaching new words. The first step towards the long-term goal is this **Phase I/II Preliminary Clinical Trial**, which is defined as a preliminary study addressing core design and clinical issues necessary to the future conduct of a Phase III/IV Definitive Clinical Trial that, in turn, establishes the efficacy/effectiveness of the intervention. Aim 1 uses a Phase I escalation strategy to hone in on an *adequate treatment intensity* of interactive book reading for children with SLI. The intensities to be tested are informed by empirical word learning studies showing that children with SLI. need two to three times as many exposures as their typically developing peers to learn new words. Aim 2 examines the extent of benefit associated with the adequate treatment intensity in terms of both proximal (i.e., learning the taught words) and distal outcome measures (i.e., learning beyond the taught words) and in terms of the variation in response to treatment based on pre-treatment language skills. Aim 3 is based on the idea that there are different ways of achieving the same treatment intensity. For interactive book reading, intensity is a function of the number of exposures to target words within a book (i.e., dose) and the number of exposures to target words via repeated readings of a book (i.e., dose frequency). There is strong evidence from experimental studies and theory suggesting that a regimen that maximizes dose frequency will yield better word learning outcomes than a regimen that maximizes dose, even when the overall intensity is equivalent. Aim 3 will identify the best combination of dose and dose frequency for word learning by children with SLI. The likely impact of this research is that an adequate intensity and promising dosing regimen. of interactive book reading will be identified for children with SLI, for whom there are few (if any) proven treatments for word learning. Moreover, the types of outcomes that can be attained through manipulation of intensity and dosing regimen will be identified, determining whether further optimization of the treatment is needed to meet the significant word learning challenges faced by children with SLI. Lastly, the resulting findings will contribute to theories concerning the number of exemplars needed to support learning as well as theories of learning from input versus memory consolidation. Specifically, the work pushes the limits of these theories by providing evidence from children with SLI learning large numbers of words over several months, supplementing prior data from typically developing children learning small numbers of words over a few weeks.

- Yellow = general problem (kids with SLI have trouble learning new words)
- Pink = more specific problem that will be explicitly addressed in this grant (few effective treatments)
- Green = long-term goal (adapt a known treatment for use with this population)
- Blue = current step towards long-term goal (preliminary clinical trial)
- Aims in brief

(peach – adequate intensity, purple – extent of benefit, gray – best combination)

 Orange = outcomes & impact (more of this probably should have been re-iterated in the aims)

GENERAL TIPS

General Tips

- Many people write these two sections as an "after thought" = not a good idea!
 - START here and SHARE with mentors immediately!
 - Sets the stage for the rest of the application
- Both sections should be concise (e.g., ~¹/₂ -1 page for each)
 - Delete anything that is unnecessary and get to the point
 - Try to have new information in each statement
- Both sections should be powerful and compelling
 - Avoid generic empty statements: "The findings will have implications for treatment"

General Tips

- Write for a "semi-naïve" audience
 - Try to avoid jargon or provide short, clear definitions of crucial terms
 - For jargon/technical terms, pick a single term and stick with it throughout the application
 - Avoid acronyms!!
- Ask others to review these two sections extracted from the rest of the grant
 - Gives you a sense of how a reviewer will react to the sections
 - If your "internal" reviewers are not *excited* about the research, revise!

Mentor Group "Charge"

- Critique YOUR aims and abstracts in mentor groups
 - · Watch your time: Spend half on one protégé and half on the other
 - Decide whether to tackle aims or abstract first (may not have time for both)
 - Analyze each person's aims and/or abstract (refer to analysis handout)
- Create a plan for revision
 - Aims? Abstract? Both?
 - Be realistic: You have other homework!
- Decide on timeline for revision
 - Revise tonight or tomorrow AM
 - Pick a deadline on Tuesday for sending revised items to the group Exchange e-mail addresses
- Follow-up discussion on Wednesday Morning (breakfast)