

# Specific Aims Intensive

## Part I: Overall Structure

Presenter:

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## Some basics...

- The specific aims is a 1-page summary of a grant proposal
- Central focus and most important part of the grant
- Demonstrates problem, gap in knowledge, suggests a solution
- Proposes research aims that work towards the solution





**The structure of  
a strong specific  
aims page  
demonstrates 5  
key features...**

- 1 It is an **abbreviated version of the entire grant**
- 2 The **introductory paragraph(s)** introduces the topic and captures attention
- 3 The **second paragraph(s)** proposes a solution
- 4 The **final paragraph** summarizes innovation, expected outcomes, & impact
- 5 **Headings** are used to help the reader easily identify sections

**The specific aims page is an abbreviated version of the entire grant**

## Specific Aims Page Structure

### Paragraph 1: Introduction

- What and why of the topic
- What is known? What is the gap?



### Paragraph 2: Rationale and purpose of proposed study

- Long term goal
- Preliminary work
- Study purpose & design
- Conceptual framework
- Sample & setting
- Environment & study team



### Paragraph 3: Specific Aims

- Hypotheses
- Approach
- Measures



### Paragraph 4: Innovation and Impact



## Typical NIH Grant Sections

Research Plan: Significance

Research Plan

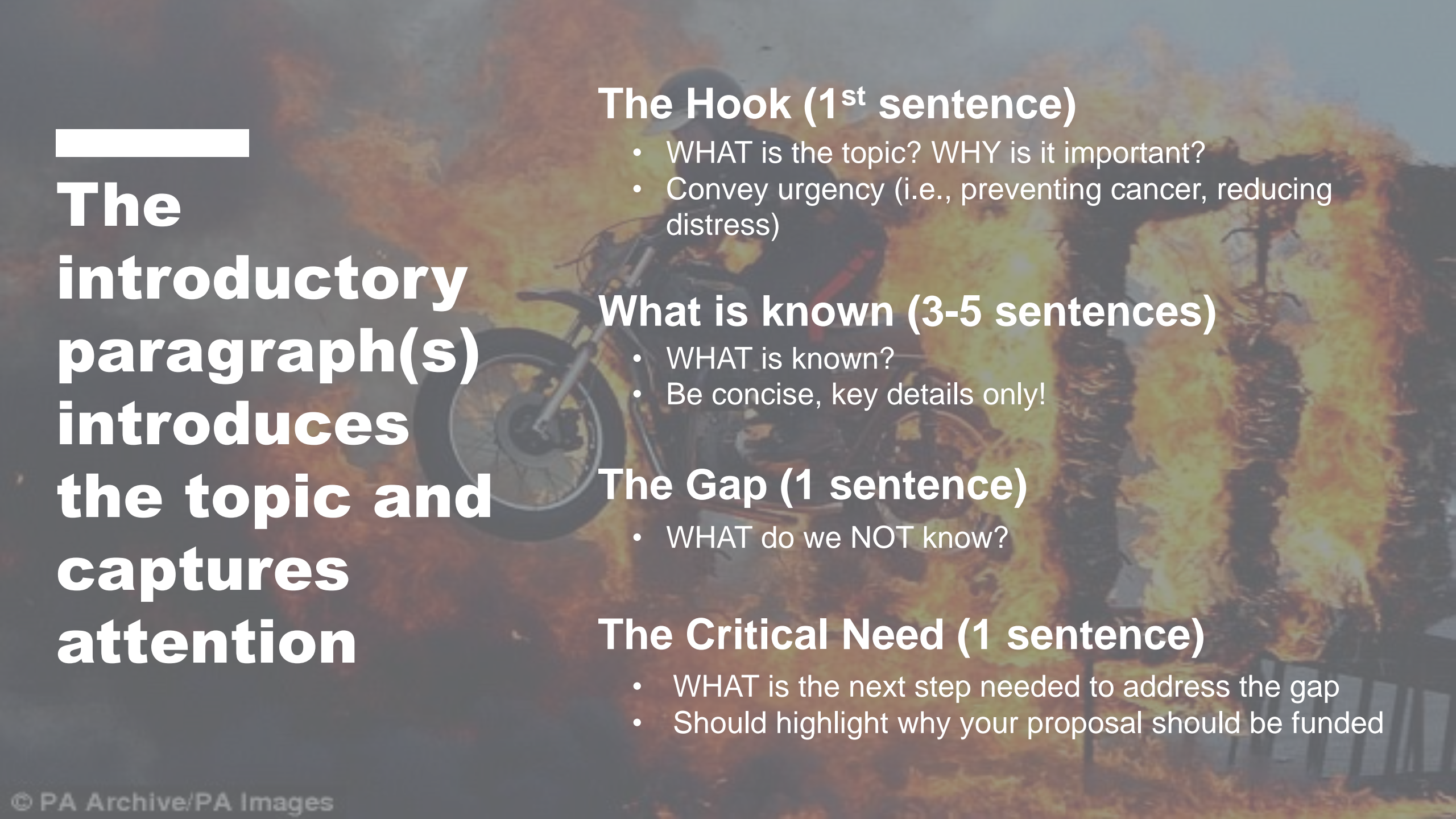
- Rigor of the prior research
- Preliminary studies
- Design
- Environment and study team
- Conceptual framework
- Sample and setting

Research Plan:

- Analytic approach
- Statistical analyses
- Measures

Research Plan:

- Innovation
- Impact

A firefighter wearing a helmet and gear is riding a motorcycle in front of a large, intense fire. The scene is dramatic, with bright orange and yellow flames and thick smoke. The firefighter is positioned in the center-left of the frame, facing right. The motorcycle is a standard fire engine bike. The background is dominated by the fire, which appears to be consuming a structure or large pile of material. The overall atmosphere is one of urgency and danger.

**The  
introductory  
paragraph(s)  
introduces  
the topic and  
captures  
attention**

### **The Hook (1<sup>st</sup> sentence)**

- WHAT is the topic? WHY is it important?
- Convey urgency (i.e., preventing cancer, reducing distress)

### **What is known (3-5 sentences)**

- WHAT is known?
- Be concise, key details only!

### **The Gap (1 sentence)**

- WHAT do we NOT know?

### **The Critical Need (1 sentence)**

- WHAT is the next step needed to address the gap
- Should highlight why your proposal should be funded



## **Example introductory paragraph**

More than 14% of US households are food insecure, or at risk of going hungry because of the inability to afford food. Economists and social scientists have spent two decades studying the measurement of hunger, its psychological impact, and its effect on food consumption patterns. Food insecure adults tend to shift dietary intake toward nutritionally-poor, energy-dense foods, which cost less calorie-for-calorie than more nutritionally rich foods. They also tend to overconsume during episodes of food adequacy in expectation of future food shortages. Although work by ourselves and others has shown a correlation food insecurity and obesity and diet-sensitive chronic disease, the causal relations between food insecurity and obesity and other diet-sensitive chronic diseases is not well understood. Currently, a major obstacle in the field to developing effective self-management interventions to address food insecurity is the lack of understanding these mechanisms.



## Example introductory paragraph

### The Hook



More than 14% of US households are food insecure, or at risk of going hungry because of the inability to afford food.

Economists and social scientists have spent two decades studying the measurement of hunger, its psychological impact, and its effect on food consumption patterns. Food insecure adults tend to consume more energy-dense foods, which cost less calorie-for-calorie than more nutritionally rich foods. They also tend to overconsume during episodes of food inadequacy in expectation of future food shortages. Although work by ourselves and others has shown a correlation between food insecurity and obesity and diet-sensitive chronic disease, the causal relations between food insecurity and obesity and other diet-sensitive chronic diseases is not well understood. Currently, a major obstacle in the field to developing effective self-management interventions to address food insecurity is the lack of understanding these mechanisms.





## Example introductory paragraph

More than 14% of US households are food insecure, or at risk of going hungry because of the inability to afford food. Economists and social scientists have spent two decades studying the measurement of hunger, its psychological impact, and its effect on food consumption patterns. Food insecure adults tend to shift dietary intake toward nutritionally-poor, energy-dense foods, which cost less calorie-for-calorie than more nutritionally rich foods. They also tend to overconsume during episodes of food adequacy in expectation of future food shortages.

Although work by ourselves and others has shown a correlation between food insecurity and obesity and diet-sensitive chronic disease, the causal relations between food insecurity and other diet-sensitive chronic diseases is unclear. Currently, a major obstacle in the field of self-management interventions to address food insecurity is the lack of understanding these mechanisms.



**What is  
known**





**Example  
introductory  
paragraph**

More than 14% of US households are food insecure, or at risk of going hungry because of the inability to afford food. Economists and social scientists have spent two decades studying the measurement of hunger, its psychological impact, and its effect on food intake patterns. Food insecure adults tend to spend more on food, but tend to purchase more toward nutritionally-poor, energy-dense foods, which cost less calorie-for-calorie than more nutritionally rich foods. They also tend to overconsume during episodes of food inadequacy in expectation of future food shortages.

**The Gap**



**Although work by ourselves and others has shown a correlation between food insecurity and obesity and diet-sensitive chronic disease, the causal relations between food insecurity and obesity and other diet-sensitive chronic diseases is not well understood.**

Currently, a major obstacle in the field to developing effective self-management interventions to address food insecurity is the lack of understanding these mechanisms.



## **Example introductory paragraph**

More than 14% of US households are food insecure, or at risk of going hungry because of the inability to afford food. Economists and social scientists have spent two decades studying the measurement of hunger, its psychological impact, and its effect on food consumption patterns. Food insecure adults tend to shift dietary intake toward nutritionally-poor, energy-dense foods, which cost less calorie-for-calorie than more nutritionally rich foods. They also tend to overconsume during episodes of food adequacy in expected

### **The Critical Need**

Although work by ourselves and others has shown a strong association between food insecurity and obesity and diet-sensitive chronic disease, the causal relations between food insecurity and obesity and other diet-sensitive chronic diseases is not well understood.

Currently, a major obstacle in the field to developing effective self-management interventions to address food insecurity is the lack of understanding these mechanisms.

## The Long Term Goal

- Your overarching research goal and long-term plans
- Keep wording general

## Proposal Objectives

- Purpose statement, unlike long-term goal, is specific to the proposed work for this grant
- Briefly describe preliminary work
- Describe proposed project/solution

## Rationale

- What do you expect from this project? What does the project make possible?

## Qualifications

- Briefly state why this project, your team, and your institution are best situated to accomplish the research goals

**The second paragraph(s) proposes a solution**



## **Example second paragraph**

Our long-term goal is to improve breast milk feeding rates for premature infants in the U.S. The overall objective of this application is to better understand the behavioral factors that influence the practice of breastmilk provision to premature infants. Our expert interdisciplinary team at one of the premier academic labor and delivery medical centers proposes to recruit 75-100 postpartum women within 24 hours of birth to preterm infants and 20-30 labor and delivery clinicians to complete questionnaires about their attitudes and beliefs towards breastmilk feeding. The central hypothesis motivating this research is that systems, clinician, and patient factors in the period immediately surrounding birth are crucial for initiation and maintenance of breastmilk feeding to premature infants. The rationale for the proposed research is that understanding the most relevant factors for this practice, something that is currently unknown, is critical to designing the most effective quality intervention.



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## The Long-Term Goal

**Example  
second  
paragraph**



**Example  
second  
paragraph**

Our long-term goal is to improve breast milk feeding rates for premature infants in the U.S. **The overall objective of this application is to better understand the behavioral factors that influence the practice of breastmilk provision to premature infants.** Our expert interdisciplinary team at one of the premier academic labor and delivery medical centers **proposes to recruit 75-100 postpartum women within 24 hours of birth to preterm infants and 20-30 labor and delivery clinicians to complete questionnaires about their attitudes and beliefs towards breastmilk feeding.** The central hypothesis motivating this research is that systems, clinician, and patient factors in the period immediately surrounding birth are crucial for initiation and maintenance of breastmilk feeding to premature infants. The rationale for **The Proposed Objective** the most relevant factors, which are currently unknown, is critical to designing the most effective quality intervention.

Our long-term goal is to improve breast milk feeding rates for premature infants in the U.S. The overall objective of this application is to better understand the behavioral factors that influence the practice of breast milk feeding.

## Rationale

labor and delivery medical centers propose to recruit 75-100 postpartum women within 24 hours of birth to preterm infants and 20-30 labor and delivery clinicians to complete questionnaires about their attitudes and beliefs towards breastmilk feeding.

The central hypothesis motivating this research is that systems, clinician, and patient factors in the period immediately surrounding birth are crucial for initiation and maintenance of breastmilk feeding to premature infants. The rationale for the proposed research is that understanding the most relevant factors for this practice, something that is currently unknown, is critical to designing the most effective quality intervention.

**Example  
second  
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Our long-term goal is to improve breast milk feeding rates for premature infants in the U.S. The overall objective of this application is to better understand the behavioral factors that influence the practice of breastmilk provision to premature infants. Our expert interdisciplinary team at one of the premier academic labor and delivery medical centers proposes to recruit 75-100 postpartum women within 24 hours of birth, 10-20 preterm infants and 20-30 labor and delivery clinicians to complete questionnaires about their attitudes and beliefs towards breastmilk feeding. The central hypothesis motivating this research is that systems of care in the period immediately surrounding birth are crucial for initiation and maintenance of breastmilk feeding to premature infants. The rationale for the proposed research is that understanding the most relevant factors for this practice, something that is currently unknown, is critical to designing the most effective quality intervention.

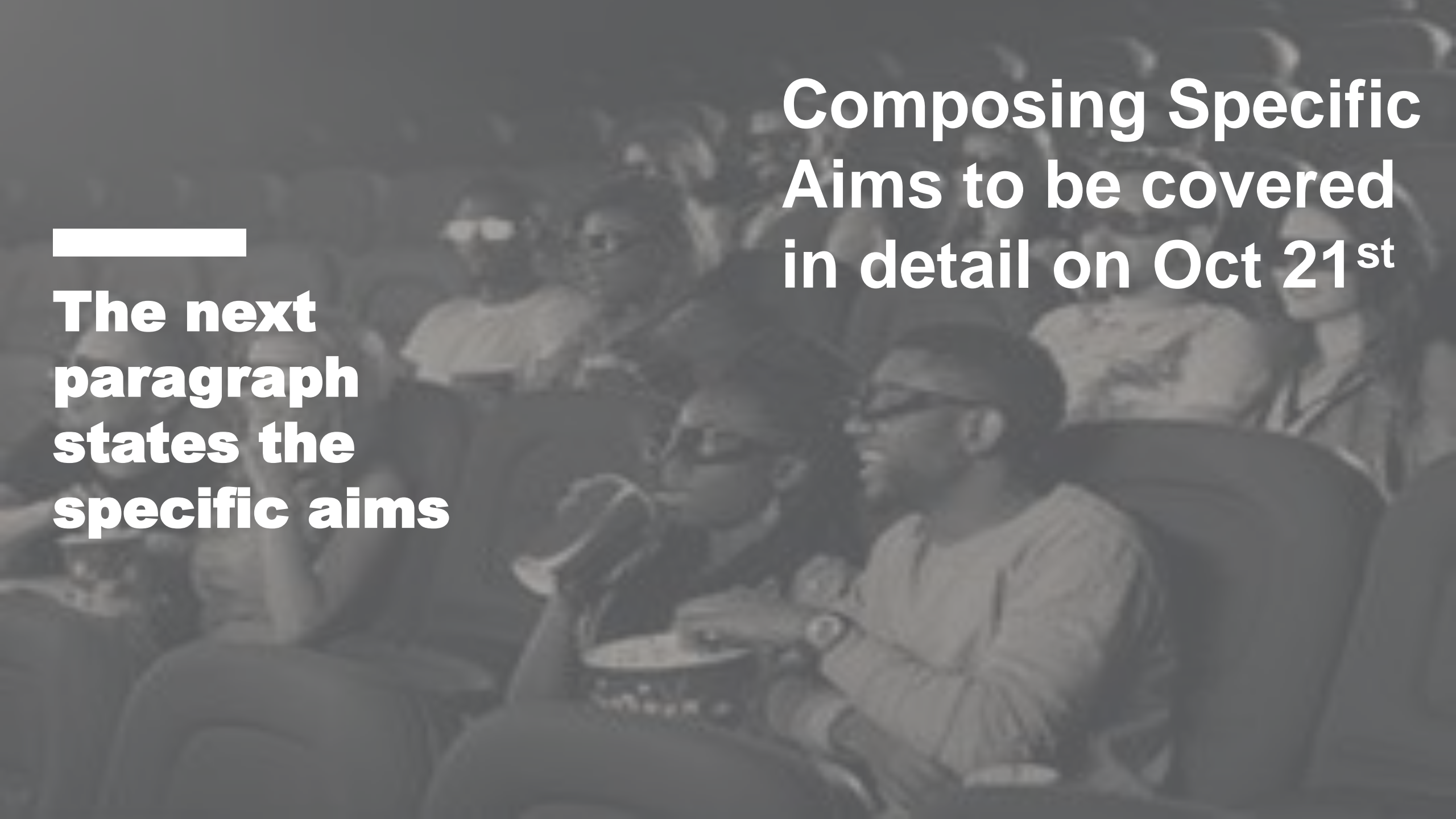


**Example  
second  
paragraph**



**Qualifications**






**Composing Specific  
Aims to be covered  
in detail on Oct 21<sup>st</sup>**

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**The next  
paragraph  
states the  
specific aims**





**The final paragraph summarizes innovation, expected outcomes, and impact**

## Innovation

- What will completion of the project bring to the field that is not currently present

## Expected Outcomes

- What do you expect as the key deliverables at the end of the project

## Impact

- Broad statement about how this project will benefit the population or problem mentioned in the opening paragraph



## **Example final summary paragraph**

The knowledge gained from this research will be used to design and test a first-of-its-kind digital health intervention using personally owned smartphones to enhance physical activity in underrepresented populations of older adults. Before the end of this K award, we will apply for an R21 grant to pilot the intervention. The culmination of this work will be an R01 application to conduct an efficacy trial and ultimately generate a novel solution to reduce physical activity and chronic health disparities in the U.S.

# Innovation



## Example final summary paragraph

The knowledge gained from this research will be used to design and test **a first-of-its-kind digital health intervention using personally owned smartphones to enhance physical activity in underrepresented populations of older adults.** Before the end of this K award, we will apply for an R21 grant to pilot the intervention. The culmination of this work will be an R01 application to conduct an efficacy trial and **ultimately generate a novel solution** to reduce physical activity and chronic health disparities in the U.S.





## **Example final summary paragraph**

The knowledge gained from this research will be used to design and test a first-of-its-kind digital health intervention using personally owned smartphones to enhance physical activity in underrepresented populations of older adults. Before the end of this K award, we will apply for an R21 grant to pilot the intervention. The culmination of this work will be an R01 application to conduct an efficacy trial and ultimately generate a novel solution to reduce physical activity and chronic health disparities in the U.S.



**Expected  
Outcomes**



## Example final summary paragraph

### Impact



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**Headings are used to easily identify specific aim sections**





How we wished  
people looked  
when they read  
our grants...



How people  
actually look  
when they  
read our  
grants...



# Headings are used to easily identify specific aim sections

## **SPECIFIC AIMS**

**Problem:** Many of the 2.8 million family caregivers (FCGs) of persons with advanced cancer<sup>1</sup> are underserved, particularly African-Americans and rural-dwellers in the Southern U.S.. Most have poor access and awareness of community-based palliative care services<sup>12,13</sup> and have received no formal support or training<sup>8,14</sup> despite providing assistance to their relatives an average of 8 hrs/day.<sup>15</sup> This problem is widely recognized as a public health crisis<sup>17-19</sup> and a nursing and palliative care (PC) priority.<sup>20-22</sup>

**Consequences:** Providing complex care and witnessing a close friend or family member struggle with advanced cancer can result in marked distress and high caregiver burden, particularly as their care recipients near end of life (EOL).<sup>23-25</sup> Patients receiving support by distressed and unprepared caregivers may result in suboptimal home care leading to poorer patient quality of life (QOL) and higher healthcare utilization.<sup>18,26,27</sup>

**Gap:** FCGs play a vital role in supporting patient's day-to-day QOL<sup>28-31</sup> in the community and hence there is a critical need to support them; however few scalable, early, community-based PC interventions have been tested to support underserved FCGs for advanced cancer patients living in the Southern U.S.<sup>32,33</sup>

**Rigor of the prior research:** Reports from NCI and NINR caregiving summits,<sup>34,35</sup> systematic reviews,<sup>32,33,36</sup> and the National Academy of Medicine<sup>19</sup> have highlighted major limitations of cancer caregiver interventions, including a lack of attention to underserved populations and cost, poor scalability, over reliance on highly-trained professionals (e.g., nurses, psychologists, behavioral therapists), lengthy sessions over a short duration, and a lack of demonstrated impact on patient outcomes and healthcare utilization.

**Our intervention:** To fill this gap, we have developed and are successfully pilot testing ENABLE Cornerstone, a lay navigator-led, community-based, telehealth early PC intervention for underserved rural and African-American FCGs of newly-diagnosed advanced cancer patients. Evolving out of our prior trials and community stakeholder formative evaluation work,<sup>14,37-43</sup> this multicomponent intervention is based on Pearlin's Stress-Health Process Model<sup>44</sup> where lay navigators, overseen by an interdisciplinary outpatient palliative care team, employ health coaching techniques and caregiver distress screening to behaviorally activate and reinforce psychoeducation on managing stress and coping, getting and asking for help, improving caregiving skills, and decision-making/advance care planning over 6 brief in-person/telephonic sessions plus monthly follow-up from diagnosis through early bereavement.<sup>45</sup>

**Study design:** Our expert interdisciplinary research team proposes a hybrid type I randomized effectiveness-implementation trial<sup>46,47</sup> to test the effectiveness and evaluate costs of ENABLE Cornerstone on demonstrating reduced FCG and patient distress and better QOL compared to usual care with a sample of 294 rural-dwelling and African-American family caregivers of newly-diagnosed advanced cancer patients. To maximize recruitment, we will recruit from two community cancer centers in Birmingham, AL and Mobile, AL.

**Specific Aim 1: Test the effect of ENABLE Cornerstone on caregiver outcomes.**

**Hypothesis<sub>Primary</sub>:** Compared to usual care, ENABLE Cornerstone participants will report lower distress as measured by the Hospital Anxiety and Depression Scale<sup>48</sup> over 24 weeks.

**Hypothesis<sub>Secondary</sub>:** Compared to usual care, ENABLE Cornerstone participants will report better a) QOL (Caregiver QOL Index-Cancer)<sup>49</sup> and b) lower burden (Montgomery-Borgatta Burden Scale)<sup>50</sup> over 24 weeks.

**Specific Aim 2: Test the effect of ENABLE Cornerstone on patient outcomes.**

**Hypothesis:** Compared to usual care, ENABLE Cornerstone participants' care recipients will report lower distress as measured by the Hospital Anxiety and Depression Scale, better QOL (PROMIS Global Health),<sup>51</sup> and lower healthcare utilization over 24 weeks.

**Specific Aim 3: Evaluate implementation costs and the cost effectiveness of ENABLE Cornerstone implementation on caregiver and patient outcomes, including healthcare utilization.**

**Exploratory Aim:** Explore mediators and moderators (e.g., coping, social support, preparedness) of the relationship between the intervention and FCG and patient outcomes.

**Innovation & Impact:** In response to PAR-19-352, this high impact research directly addresses the call to test "interventions designed to support caregivers of adult cancer patients." Our intervention is innovative because it uses lay navigators to support an underserved caregiver population from diagnosis over the illness trajectory, as opposed to other difficult-to-implement FCG interventions that rely on advanced practice healthcare professionals providing lengthy sessions over a brief duration.<sup>32,33</sup> If effectiveness is established, the ENABLE Cornerstone intervention offers a highly scalable and reproducible model of formal caregiver support that would be primed for a large, national, multisite implementation trial.



# Summary

- The specific aims page is the MOST important piece of the grant
- It should outline and summarize the entire grant
- The introductory paragraph needs to introduce the topic, capture attention, and highlight the gap in what's known
- The second paragraph states the overall purpose and objectives of the current grant
- The final paragraph summarizes innovation, outcomes, and impact
- Headings help readers easily identify sections
- All specific aims pages are unique and there is a lot of flexibility in how key elements are organized

# Thank you!! Questions?

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## Next Specific Aim Intensive Dates:

October 21<sup>st</sup> 1-2:30pm CST (presenter: Dr. Marie Bakitas)

November 18<sup>th</sup> 1-2:30pm CST (presenter: Dr. Carolyn Pickering)

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