

## Specific Aims

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## A brief note about terminology

NIH uses the term "Specific Aims". Other agencies may refer to "Research Objectives", "Research Goals", or something similar. Regardless of the terms used, the principles are the same.

I will refer to the "Aims" or "Specific Aims". When I say this, I am referring to the entire page/section of the grant proposal.

I will also refer to "Aims Statements". These refer to the one sentence descriptions of the proposed research.

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## Before you start the Aims

To write a strong Specific Aims page, you must have a very clear research question

The research question must be:

- Interesting...to you and the scientific community
- Focused
- Feasible

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## Two frameworks for your research question

### FINER

- Feasible
- Interesting
- Novel
- Ethical
- Relevant

### PICOT

- Population
- Intervention (Factor of interest)
- Comparison
- Outcomes
- Time

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## Specific Aims

Spend a lot of time on the Specific Aims

Clear Aims → Clear Proposal

- A HUGE amount of the reviewers' impressions are based on the Aims
- It is the first thing that the reviewers will read
  - It may be the only thing that many review committee members read

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## Specific Aims: Basic Elements

Introductory paragraphs (usually 2-4 paragraphs)

Aims statements (often 3, but 1-4 is ok)

Brief overview of how the study will be done – either aim by aim or one overview

Impact statement

Address the why, what, who, how, where of the project proposal

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### Some options for structure of the aims page

Option 1	Option 2	Option 3
Introduction (2-3 paragraphs)	Introduction (2-3 paragraphs)	Introduction (2-3 paragraphs)
Intro final paragraph: general objectives	Intro final paragraph: general objectives plus <i>central hypothesis</i>	Intro final paragraph: general objectives plus <i>central hypothesis</i>
	Overview of research activities	
Aim 1	Aim 1	Aim 1
<i>Hypothesis</i>	Aim 2	Aim 2
<i>Overview</i>	Aim 3	Aim 3
Repeat for Aims 2 and 3		Overview of research activities
Impact statement	Impact statement	Impact statement

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### Specific Aims Structure - Introduction

1-3 paragraphs

Introduce topic

Sell the importance of your area

Make what you plan to do "obvious"

*Remember that grant proposals are part salesmanship—trying to convince the reader of the importance of your work*

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### Aims Introduction

The 2-3 most important paragraphs of your proposal

Must convince the reader of the significance (and possibly innovation) of your project

Must make it clear and obvious what your project is about.

But you only have a little space – every word is precious

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### Aims – Topic sentences

The most important sentence in the entire proposal is the first sentence of the aims. That first sentence sets the stage for the rest of the document.

The next two most important sentences are the topic sentences for paragraphs 2 & 3

The other important sentences are your aims statements & hypotheses.

Everything else is filling in details.

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### Aims Intro – A funnel

Think of the three intro paragraphs as a funnel

Para 1: What is the public health problem? Why is it important?

Para 2: What is the gap in knowledge?

Para 3: What are we going to do about it?



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### Aims – Paragraph 1

The goal of paragraph 1 is to state clearly why your area of study is important

One student called it – The paragraph to scare the reader (by showing how bad the disease is)

Make sure all the information is DIRECTLY relevant to what you're proposing



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## Aims – Paragraph 2

Address specific area of research more directly  
 Address the knowledge gap explicitly  
 May address the intervention in more detail  
 More focused than the first paragraph

**NO EXTRANEOUS INFORMATION**

*“Paragraph 2” may actually be 2 or even 3 paragraphs.  
 Use the space you need to make the case for what you are proposing.  
 But remember space is precious and every word must be needed.*



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## Aims – Paragraph 3 (or final paragraph)

A brief statement of what you plan to do

Possibly a statement of why your team is the best team for the project

If a central hypothesis is used, it will be here.

Remember! No extraneous information or words



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## BAI-PrEP Specific Aims (Paragraph 1)

In Asia, the HIV epidemic has shifted from people who inject drugs (PWID) to men who have sex with men (MSM). In 2021, MSM comprised 43% of new HIV cases in Vietnam.<sup>1</sup> This shift is multifactorial, including low pre-exposure prophylaxis (PrEP) uptake and persistence. In Hanoi, ~50% of MSM stop PrEP within 6 months.

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## BAI-PrEP Specific Aims (Paragraphs 2-4)

The epidemic shift is also driven by alcohol use, which affects MSM's behavioral decisions and PrEP use.<sup>2,3</sup> Heavy alcohol use is normative in Vietnam—men often feel pressure to drink and drink to excess. MSM often report unhealthy alcohol use,<sup>2</sup> defined as a spectrum of use from risky/hazardous (drinking more than the recommended daily, weekly or per-occasion amounts resulting in increased risk for health consequences) to alcohol use disorder.<sup>4</sup> In Hanoi, 63% of MSM attending a sexual health clinic reported unhealthy alcohol use (Preliminary Studies). Unhealthy alcohol use brings consequences—affecting every step of the HIV prevention and care cascade,<sup>5</sup> including reduced PrEP persistence and adherence.<sup>2,6</sup> Despite these negative impacts of unhealthy alcohol use, alcohol reduction interventions for MSM are rare.<sup>7</sup>

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## BAI-PrEP Specific Aims (Paragraphs 2-4)

...Despite these negative impacts of unhealthy alcohol use, alcohol reduction interventions for MSM are rare.<sup>7</sup>

One promising strategy to prevent HIV among MSM is the brief alcohol intervention (BAI), which is based on cognitive behavioral therapy and motivational enhancement therapy.<sup>8</sup> In our randomized controlled trial (RCT), REDART, we showed that the BAI, comprising two individual face-to-face sessions and two booster telephone sessions, increased viral suppression among Vietnamese people with HIV (PWH) with unhealthy alcohol use. PWH on antiretroviral therapy (ART) with concomitant unhealthy alcohol use, received either the BAI or standard of care (SOC).<sup>8</sup> Viral suppression at 12 months was 92% in the BAI arm compared to 77% in the SOC arm. This effect was mediated through reduced alcohol use and increased ART adherence. The BAI was cost-effective<sup>9</sup> and participants found the BAI components clinically and culturally acceptable.<sup>10</sup>

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## BAI-PrEP Specific Aims (Paragraphs 2-4)

... The BAI was cost-effective<sup>9</sup> and participants found the BAI components clinically and culturally acceptable.<sup>10</sup>

Extending the use of the BAI from ART to PrEP for HIV prevention is a logical step. Effective PrEP use requires persistence in care and adherence to the prescribed regimen, whether daily oral, event-driven (known as 2+1+1),<sup>11</sup> or injectable. For many MSM, risk behaviors vary over time.<sup>12</sup> If risk decreases, a switch to event-driven PrEP or PrEP discontinuation may be appropriate. We refer to matching of current risk to PrEP use, as risk-aligned PrEP use, also known as prevention-effective adherence.<sup>13-15</sup> Persistence, adherence, and risk-aligned PrEP use may all be affected by unhealthy alcohol use.<sup>16-18</sup> Offering the BAI to MSM with unhealthy alcohol use at the time of PrEP initiation could improve PrEP outcomes through a mechanism similar to that seen in REDART—reduced alcohol use and improved medication adherence.

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### BAI-PrEP Specific Aims (Paragraph 5)

We propose an effectiveness-implementation type 1 hybrid RCT<sup>19</sup> to compare the BAI to SOC among MSM with unhealthy alcohol use who are initiating or reinitiating oral, event-driven, or injectable PrEP in Vietnam. We hypothesize that the BAI will improve a) PrEP persistence, b) PrEP adherence, and c) risk-aligned PrEP use. The type 1 hybrid design ensures rapid scale-up if the RCT is successful. Our specific aims are to:

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### Specific Aims –“Paper test”

After reading the introduction paragraphs, a reviewer should be able to state what the aims statements are going to be—at least relatively closely—without looking at the actual aims statements

(If you covered the aims statements with a piece of paper, the reader should be able to guess the aims.)

*You want the reader to be able to anticipate what you're planning to do.*

**NO SURPRISES!!!**

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### Aims Statements Structure

When you write the brief aims statements (objectives):

Be *clear, concise, and complete*

Remember:

It's easy to feel like your Aims are “clear”, when they're not

It's easy to feel like your Aims are “specific”, when they're not

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### Aims statements

Use active verbs to describe what you'll do: compare, measure, describe, adapt, evaluate.

If an aim is exploratory, it is ok to be clear about that: “To explore...”

Scientifically, aims that are too dependent can be a problem.

- If one aim fails, and you cannot proceed with a subsequent aim, the aims are too dependent

- In other words, you should be able to do Aim 3, even if Aim 2 is unsuccessful

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### Aims statements

The scope of the project, as reflected in the aims statements, must match the funding available and the type of grant mechanism.

A trial development award (e.g., NIH R34) must focus on development of an intervention and usually will conclude with a pilot study

A large award (e.g., NIH R01) must involve a trial or observational study of substantial size

A career development award (e.g., NIH K43) must involve appropriate training and related research activities. The aims will focus only on the research.

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### Example Aims Statements (SNaP)

1) To compare standard Implementation Mapping (IM) to *tailored* Intervention Mapping (TIM) to scale-up SNaP in HIV test sites in Vietnam.

2) To measure the incremental costs of IM compared to TIM for SNaP implementation in Vietnam.

3) To explore the key characteristics of high and low performing HIV test sites for SNaP implementation in each study arm.

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### Example Aims Statements (VITAL R34)

- 1) To adapt the proven Friendship Bench protocol to be optimized for people living with HIV in Vietnam.
  
- 2) To evaluate the feasibility, fidelity, and acceptability of the adapted FB as well as preliminary indicators of its impact in improving CMDs and HIV care and drug use treatment outcomes.

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### Example Aims Statements (K43)

- 1) To assess the mental health needs of WWUM in Haiphong Province.
- 2) To adapt the FB to the specific needs of Vietnamese WWUM.
- 3) To assess the feasibility, fidelity, and acceptability of the adapted FB for CMDs among WWUM and preliminary indicators of its impact in improving CMDs, meth use, HIV risk behaviors and PrEP and ART uptake in a two-arm randomized trial, comparing FB (n=50) with usual psychiatric care (n=25).

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### Specific Aims Structure - Hypotheses

Hypothesis driven work will be viewed as stronger

Hypotheses can be either:

- Specific to each aim
- More global and stated clearly in the introduction

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### Central Hypotheses

Typically given in 3<sup>rd</sup> paragraph (or last paragraph before Aims)

Covers the overall goal of the study

- in other words, a guiding hypothesis that will be addressed by completing all of the aims of the study

#### *SNaP Central Hypothesis*

We hypothesize that, compared to standard Intervention Mapping, tailored Intervention Mapping will: a) increase site fidelity to SNaP, b) increase PWID ART uptake, and c) be cost-effective.

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### Aim-by-aim Hypotheses

Given after each aim

Set off on new line with *Hypothesis*:

No more than 2 at most for each aim; usually just one

If you cannot specify a hypothesis for each aim, it is often better to have a central hypothesis

The aim-by-aim hypotheses should be directly testable with your analytical methods

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### Specific Aims Structure - Overview

Often helpful to describe briefly how you will accomplish each aim

May be included:

- With each aim
- As a part of the last paragraph of introduction
- After the aims statements

Describe study design, intervention, outcomes

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## Overview example (Aim 1, SNaP)

**1) To compare standard Implementation Mapping (IM) to tailored Intervention Mapping (TIM) to scale-up SNaP in HIV test sites in Vietnam.** We will conduct a two-arm, pragmatic cluster randomized implementation trial among HIV test sites in Vietnam. HIV test sites (n=42) will be randomized to receive one of two implementation strategies: a) IM—a standard, one size fits all multifaceted implementation package identified through Intervention Mapping, or b) TIM—a tailored implementation package using Intervention Mapping with tailoring to each test site. The primary outcomes are HIV test site-level EBI fidelity (implementation outcome) and ART uptake effectiveness (outcome). Secondary implementation outcomes include penetration, acceptability, and cost. Secondary effectiveness outcomes include viral suppression and MAT use. We will conduct outcome assessments at 12 and 24 months.

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## Specific Aims – Impact Statement

At the end of your aims page, consider adding a paragraph that addresses the overall impact of your proposed work

What will the world gain by funding this proposal?

Be specific...and don't over-promise

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## Impact Statement example (SNaP)

In HPTN 074, our team successfully implemented and evaluated SNaP, one of the most promising EBI for PWID to date. Our experienced team is perfectly positioned to conduct this implementation evaluation. This study will provide critical guidance to Ministries of Health worldwide regarding the most effective, cost-efficient approach to SNaP implementation. With this guidance, widespread implementation has the potential to significantly reduce mortality and improve health for HIV-infected PWID in resource-limited settings

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## Specific Aims – When are they done?

When complete, the Aims should answer:

- 1) Why is this topic important?
- 2) How will your research advance knowledge about this topic? What gap will be filled?
- 3) What are you going to do?
- 4) Where will you do it?
- 5) How will you do it? (Briefly)

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## Specific Aims – Key points

The single most important part of any grant (even when the grant mechanism uses a different name, such as “objectives”)

Space is limited—every word must be chosen carefully, every word must do its job

Tell the story of why your work is important in the introduction

Give enough information about what you will do to allow the reader to judge the feasibility and potential value of the proposed research

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Thank you!!!

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