

Module: Writing NIH Phase I Specific Aims



Objectives

- Understand reviewer expectations
- Design Phase I aims before writing
- Draft a feasible Specific Aim



What Specific Aims Do in Review

The goal is not to describe everything you plan to do. The goal is to convince the reviewers that Phase I will answer at least one high risk technical question and justify Phase II

The aims:

- Anchor the Approach score
- Signal feasibility
- Define risk reduction

What the Specific Aims Must Accomplish

- Define the key technical uncertainty
 - What isn't known yet?
 - Why is this the right risk for NIH to fund now?

If there is no real uncertainty, reviewers see no reason for phase I
- State a clear feasibility objective
 - What will you prove can work in 6-12 months
 - What result would change confidence in the technology

Reviewers are looking for proof of feasibility not optimization

What The Specific Aims Must Accomplish

- Create a clear go / no-go decision
 - What outcome justifies moving to Phase II?
 - What result would indicate the approach should stop or pivot?

Strong aims make a reviewer's decision easy

- Reduce reviewer risk and reassure reviewers:
 - The work is focused
 - The scope is appropriate for Phase I
 - Success is measurable
 - Risks are acknowledged and manageable

What the Specific Aims Must Accomplish

Anchor the entire application

The Specific Aims page sets the expectation for:

- Approach (what experiments matter)
- Team roles (who does what)
- Milestones (what success looks like)

If the aims are weak every other section struggles

Specific Aims are not meant to:

- Describe your full development plan
- Pitch commercialization
- Show how ambitious you are
- List experiments
- Prove clinical efficacy

These are typically Phase II tasks

The goal of Specific Aims in Phase I is to make reviewers comfortable funding uncertainty – because the answer matters and the path to that answer is clear.

Phase I Reviewer Mindset

- 6–12 month feasibility
- Clear go/no-go
- One strong aim beats many weak ones



Design Aims Before Writing

- Start with uncertainty
- End with a decision
- Tie to Phase II readiness

Writing Exercise: Phase I Decision

- At the end of Phase I, we need to know whether ____ is feasible because ____.

Opening Paragraph

- Define unmet need
- State technical gap
- Explain why Phase I is needed



Specific Aims Page Structure

- Problem & gap
- Objective
- Specific Aim(s)
- Expected outcomes

Writing Exercise: Opening Paragraph

- Despite ____, a critical gap remains in _____. Phase I will address this by _____.

Writing a Phase I Aim

- Start with a verb
- Demonstrate feasibility
- Imply measurable outcome

Writing Exercise: Draft the Aim

- Specific Aim: To demonstrate ____ by ____ under ____ conditions.

Milestones & Success Criteria

- Binary metrics
- Go/no-go decision
- Risk acknowledgement

Writing Exercise: Milestones

- Success = ____
- Risk = ____
- Mitigation = ____

Expected Outcomes & Impact

- Realistic outcomes
- Phase II justification
- No hype



Key Takeaways

- One aim is often enough
- Feasibility > ambition
- Write for reviewer decisions

