

Approach Section:

The “Meat” of the Proposal

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Purpose of the Approach section:

To describe the research project as proposed to be carried out in the PI's laboratory: a logical flow of experiments designed to complete each Specific Aim

To describe the Preliminary Studies that justify/support the experiments designed for each Specific Aim

To explain the Specific Aims page & convince the Reviewer that the work should and can be done by the PI's research team

The Approach should be well-organized

Overall Organization of each section – present proposal in an organized manner

Typical Section Headings for an NIH proposal:

3. Research Strategy

(A) Significance

(B) Innovation

(C) Experimental Approach

C.1 Title of Specific Aim 1 (SA1)

C.1.1 Rationale *[subheading]*

C.1.2 Experimental Design *[subheading]*

C.1.3...

C.2 Title of SA2

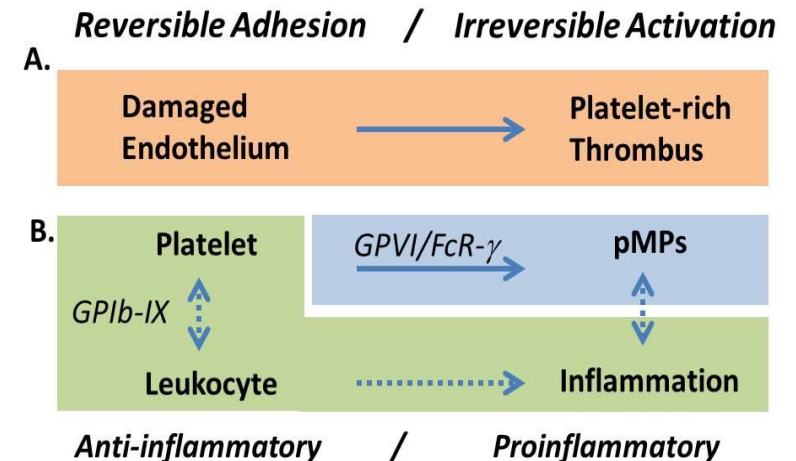
Variations in the organization

(C) Experimental Approach

- Use introductory overview to set the stage for Aims that follow. As an example:

This application focuses on a series of events paralleling the platelet paradigm in thrombosis but impacting inflammation (**Fig 1B**). Studies outlined for **SA1** will focus on leukocyte phenotypic changes during the progression of inflammation that are platelet GPIb-IX dependent (**Fig 1B**, green shading). Outlined studies for **SA2** highlight the transition of the platelet to an activated state that coincides with the release of proinflammatory pMPs and exacerbation of inflammation (**Fig 1B**, blue shading). As such, the transition of the platelet from an “unactivated” to “activated” state represents an analogous “switch” or “turning point” in the progression of the inflammatory response. **SA3** will validate the results of **SA1** and **SA2** by focusing on the dysregulated inflammation found in severe human sepsis.

- Can include a figure to show model you are testing. Cartoons or schematic diagrams are very effective.



Critical Components of the Approach section

- **If possible, include Preliminary Studies – including references to publications from PI’s laboratory supporting Experimental Design**
 - Preliminary Studies justify the Rationale for proposing a particular Aim
 - Ideally, have at least 1 Figure of preliminary data to support each Specific Aim – Figures are important!
 - Emphasize importance of preliminary data. For example, state: “Building on our intriguing preliminary results, we will do such-and-such...”
 - Preliminary Studies can be in an introductory section of the Approach or embedded to support each Aim

Critical Components of the Approach (cont.)

- **Include *Rationale*** (objective) for each specific Aim
Explain how achieving Aim addresses overall hypothesis of the proposal
- **Provide *Experimental Design*** for each Aim – Describe experiment(s) to be done to achieve Aim
- **Include *Methods*** – including references to publications from PI's laboratory supporting ability to use or perform necessary, specific techniques
- **Include *Time-Line*** – for the entire project to show realistic planning and feasibility of all Specific Aims
- **Include *Future Studies or Future Goals*** – what will this project lead to; make sure that this initial investment will pay off in future, for an INBRE applications future goals would be “papers and/or R15/R16 submissions”
- **Include Undergraduate Student Participation**

Recommended Content for Each Specific Aim:

- **Rationale** – objective or purpose of the Aim
 - Include Preliminary Studies to justify the Rationale
- **Experimental Strategy or Design**
- **Methodology and Analyses to be used to accomplish the Aim**
 - Methods can be incorporated in Strategy/Design
 - Include how data will be collected, analyzed and interpreted – Be sure to include statistical analysis!
- **Expected Outcomes or Results**
 - Describe Benchmarks for success in accomplishing each Aim
- **Potential Problems and Alternative Strategies**
 - Convince Reviewers that PI can anticipate technical difficulties and has alternative approach

Variations:

- **Experimental Strategy or Design**
 - Aim can have its own hypothesis, related to overall hypothesis
 - Aim can be subdivided into Sub-Aims
 - Preliminary data can show feasibility of approach/technique
- **Potential Pitfalls and Alternative Interpretations**
 - Convince Reviewer that PI knows the field and is open-minded



**Project Timeline – at the end of the Approach section, to show that have realistic view of what can be accomplished
Here’s a Template :**

Specific Aims and Sub-Aims	Year 1	Year 2	Year 3	Year 4	Year 5	
1.1	■	■	■	■		
1.2		■	■	■	■	
1.3			■	■	■	
1.4				■	■	■
1.5					■	■
2.1	■	■	■	■		
2.2	■	■	■	■		
2.3			■	■	■	■
2.4				■	■	■
2.5					■	■
3.1			■	■	■	■
3.2			■	■	■	■
3.3				■	■	■
3.4					■	■

Most common problems with Experimental Approach:

- Not enough detail on approaches, especially untested ones
- Too much unnecessary experimental details
- Not directly testing hypothesis
- Lack of appropriate controls
- Experiments not directed towards mechanisms
- No discussion of alternative models or hypotheses
- No discussion of potential pitfalls
- No discussion of data interpretation (statistics)
- SABV – sex as a biological variable
- No timeline included

Additional Components to include as needed:

If you need these things and don't properly describe them – a major weakness in the proposal and all your other efforts are wasted.

Human Subjects

Vertebrate Animals – *recommended to contact Dr. Ware if you anticipate vertebrate animal use*

Select Agents (biological hazards)

Resource Sharing

Authentication of Key Biological and Chemical Resources

Letters of Collaboration

For examples of Funded Grants and Summary Statements, go to:

<https://www.niaid.nih.gov/grants-contracts/sample-applications> (*link*)

See R01, R21 and R15 examples.

Summary Statement – critical review of NIH proposal, whether scored or unscored

