

Grant Writing Seminar Series  
SESSION 2:

# Is my proposal significant? Components of a Research Question

Literature review and preliminary results, research strategy:  
significance and approach

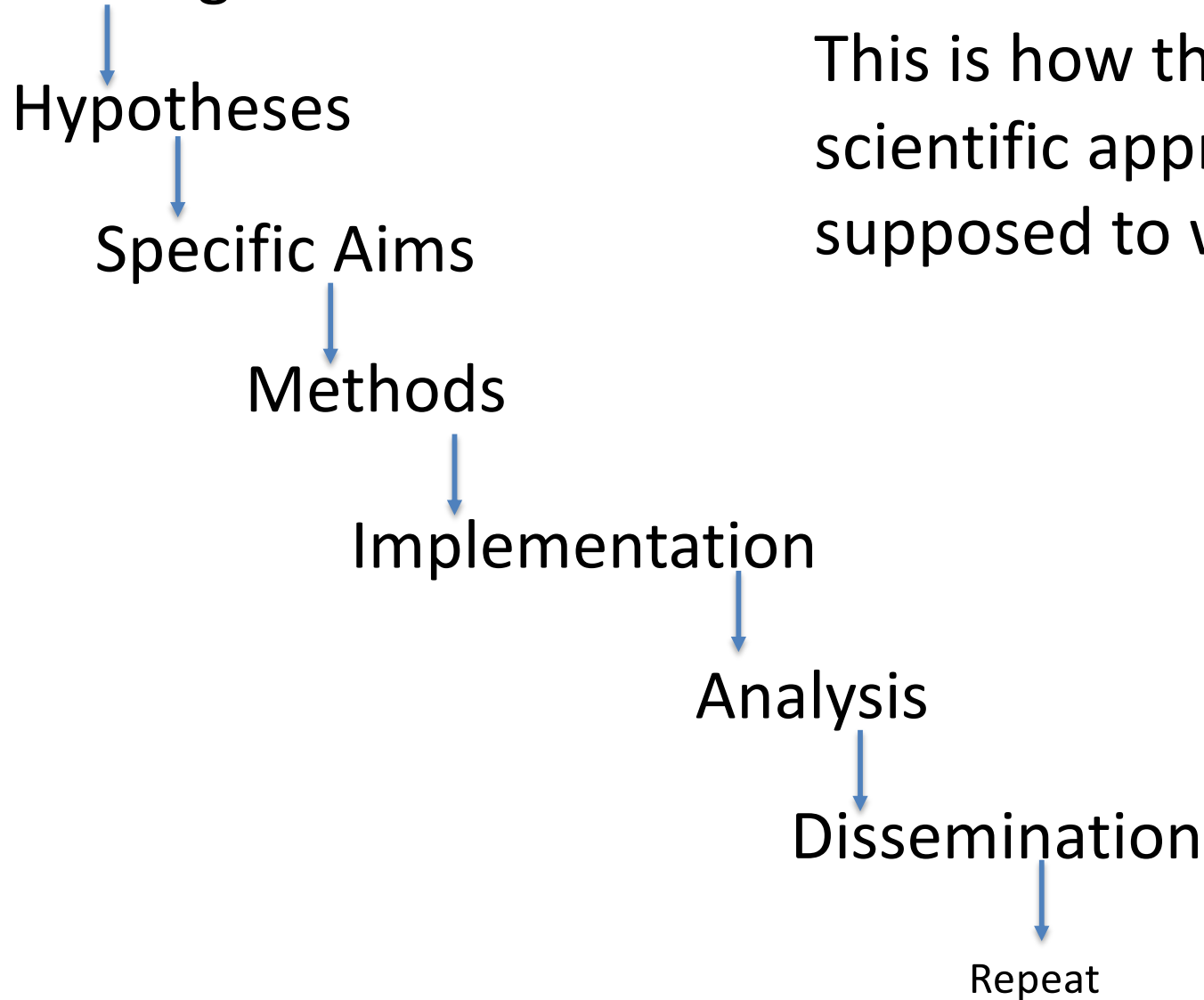
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# The application: significance, preliminary data, and approach

Hulley – chapter 19

GW Workbook – chapters 9,10,11

Background & Significance



# Review Guidelines

- Significance / Relevance
  - Is the problem important? How will science be improved?
- Investigators
  - Do investigators have appropriate experience and training to conduct research?
- Innovation
  - Does project shift current clinical practice paradigms?
- Approach
  - Are methods well-reasoned, unbiased, feasible?
- Environment
  - Are resources available to conduct project?

# Will my research get funded?



## Scoring Domains

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Significance	Innovation	Investigators	Approach	Environment
Preliminary Data				
Impact				<u>Unscored</u>
				Ethics
				Budget

*You must not be impartial. You must be the strongest advocate for your proposal.*

*It is the right study at this time to address this important problem.*

# Significance Section

- Write a condensed story that introduces reviewers to the research
- First 2-3 pages, or a brief overview with detailed write-up for each specific aim
- Provides a rationale for why you have developed your hypotheses and specific aims.

# Significance - comments

What is the basis for your research ('so what'?)

- What is the problem
- What do we know now
- Quickly move the text to your hypothesis
- Highlight the part of the problem you are attacking
- Show your preliminary results addressing gaps

# Significance – other comments

- You are trying to build desire for your study - **Do not be boring**
- What is the big picture
  - Facts, theoretical framework
  - Lit review can not be comprehensive. **Get to the point.**
  - Go deep only into the **most relevant research**: seminal studies and recent studies defining state of knowledge
- Rigor of existing science
  - **Highlight** problems and gaps
  - Show your judgement in the presence of uncertainty
- Impact
  - Research contribution upon completion
  - Simple statements of credible positive impacts to the field
  - Relevance to NIH



# Significance – additional comments

- Can be treated as a ‘test’ for the PI
  - Cite your publications whenever you can.
  - Provide new preliminary data
  - Demonstrate your expertise

You are telling a story...

# Your Process

- read...write....repeat
- Continuously re-evaluate your hypothesis and aims
- Search other fields for innovation to apply
- Find others with preliminary data that compliments your PD
  
- Have others read it, and acknowledge their comments
  - Content experts / mentors / peers
  - Professional writers / proof-readers
  - Educated but no content expertise

# How a reviewer sees Significance

- Do I care about this question/Impact/so what
  - Why do I not understand it?
  - Is it well written?
- Do other reviewers care about this question?
- Are preliminary data compelling?
- How does it translate to the research study?
  
- Other scoring criteria are focused on study implementation and feasibility

# Preliminary Data

- PD is almost always required, and if not required, is usually expected.
- Significance:
  - Establishes the foundation for each hypothesis and specific aim
  - “These are interesting results, and we should study this further.”
  - Clarity of data presentation is critical.
  - Includes tables, figures, or graphs. Use footnotes extensively, and map descriptive text to figures and tables.
  - Make sure your PD strongly supports your hypothesis
- Approach
  - Demonstrate feasibility or superiority of your data collection protocols
  - Repeat previously published approaches with references
  - PD may come from any member of the research team
- **The quality of the preliminary data is scored!**
  - Reviewers will look at PD carefully.
  - It should be a sample of what you think the final results might look like.
  - Do not include PD if it is of poor quality, distracting, or not relevant

# Innovation

- NIH is less interested in 'me too' research
- Depart from the status quo.
  - Use a new theory, method, approach, or intervention
  - Then explain how novel aspects increase study significance
  - Innovative hypothesis or question
  - Sometimes a strange idea is an innovative idea
- Usually one paragraph, and re-stated throughout application
- Define the status quo in the literature
- State your innovation and how it improves your project

# Approach

- Describe the overall strategy, methods, and analysis for each aim
  - What will be done
  - How will you do it
  - Who will do it (if not obvious)
  - What are the expected outcomes
  - What might go wrong
  - What are alternative approaches
- This may be the easiest section to write because you have already conducted pilot work and developed research protocols.

# Approach (for each aim)

- Introduction (1 paragraph)
  - overview /objective / hypothesis
  - statement of the rationale, approach, impact
- Research Design
  - Describe each study activity
  - Justify model systems
  - Power and sample size
  - Statistical methods
  - Preliminary feasibility data / publication quality
  - Reference published methods / common protocols /standards
  - Rigor
  - Expected outcomes (1-2 paragraphs)
  - Problems (make sure they are minor)
  - Alternatives (1 paragraph)
  - Timeline for all aims and benchmarks (make a table or figure)
  - Future directions / what is the next step



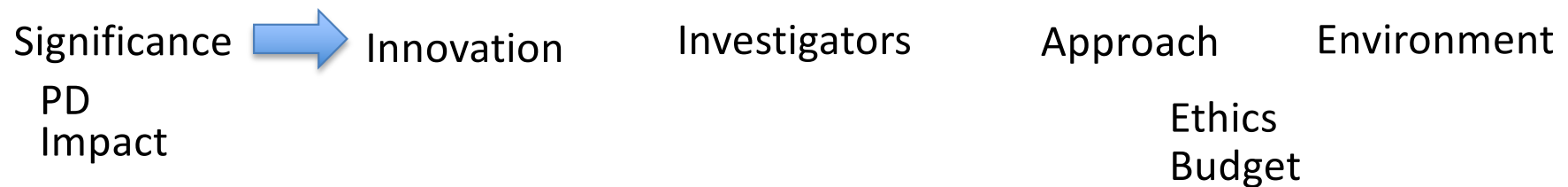
# Approach

- 8-10 pages
- Try to use equal space for each specific aim
- Simplify descriptions as much as possible
- But, include enough detail in the most critical areas
- Data analysis. Do not forget the statistical analysis – get adult biostatistical support
- Advocate for the study by demonstrating expertise, feasibility, innovation, and impact

# Other sections

- Investigators
  - Biosketches
  - One paragraph describing team interactions
- Environment
  - Facilities section
- Not scored, but discussed
  - Budget
  - Human Subjects / Animal protection

# Will my research get funded?



*Of the scored domains, Significance is sine qua non. Without significance, nothing else matters.*

*If found significant, Approach is usually most criticized. Reviewers often want more clarity and detail. They do not care about page limits.*

*Try to highlight all innovation in one place. Don't expect reviewers to know what is innovative about your proposal.*