Research Design and Methods

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Research Plan

Portray

- What you intend to do
  - Specific Aims
- Why it is important
  - Background and Significance

Research Plan

- What has been done so far
  - Preliminary Studies
- How you are going to do it
  - Research Design and Methods

Getting Started

Read instructions on how to prepare *Research Design and Methods* section



Instructions

"Describe the research design conceptual or clinical framework, procedures, and analyses to be used to accomplish the specific aims of the project."

Instructions for PHS 398 Rev. 09/2004
http://grants1.nih.gov/grants/funding/phs398/phs398.doc

Instructions

"include how the data will be collected, analyzed, and interpreted as well as the data-sharing plan as appropriate."

Instructions for PHS 398 Rev. 09/2004
http://grants1.nih.gov/grants/funding/phs398/phs398.doc

Instructions

"Describe any new methodology and its advantage over existing methodologies. Describe any novel concepts, approaches, tools, or technologies for the proposed studies."

Instructions for PHS 398 Rev. 09/2004
http://grants1.nih.gov/grants/funding/phs398/phs398.doc

Instructions

"Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims."

"provide a tentative sequence or timetable for the project."

Instructions for PHS 398 Rev. 09/2004
http://grants1.nih.gov/grants/funding/phs398/phs398.doc

Main Points That You Must Get Across

- Research design, if carried out successfully, will accomplish Specific Aims
- Methods are feasible and well developed
- Approach is original

Main Points That You Must Get Across

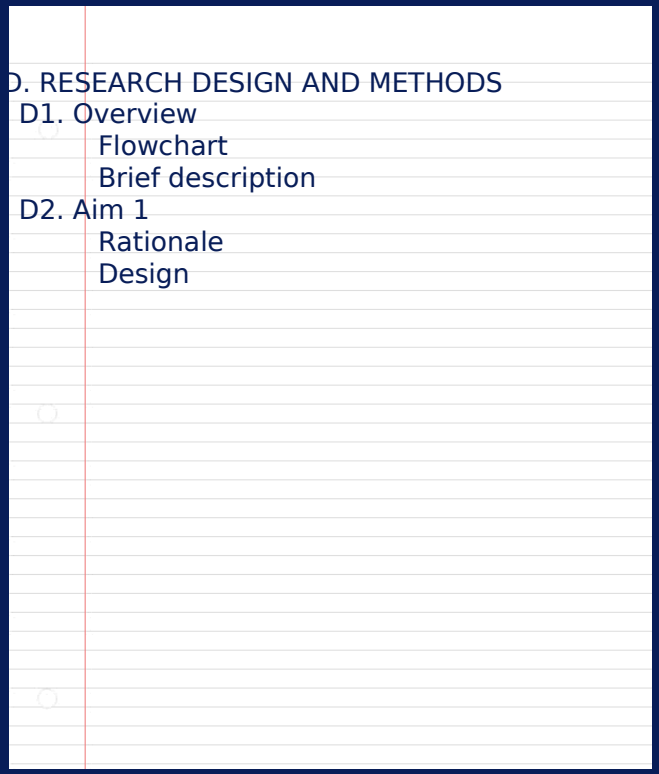
- Data will be analyzed correctly
- Enough subjects/specimens will be tested to lead to conclusive results
- Limitations are of minor concern only
- Study can be accomplished in requested time

Organization

- No one organization fits all proposals
- Try to organize in logical sequence of Specific Aims and corresponding experiments

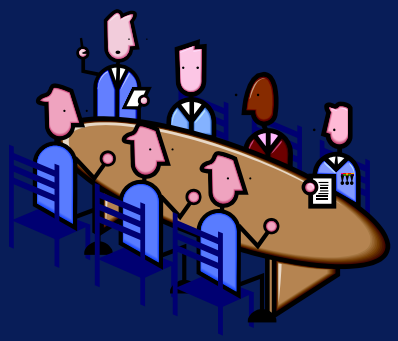
Outline

Start with an outline



Audience

- Write for reviewers and funding agency staff





Audience

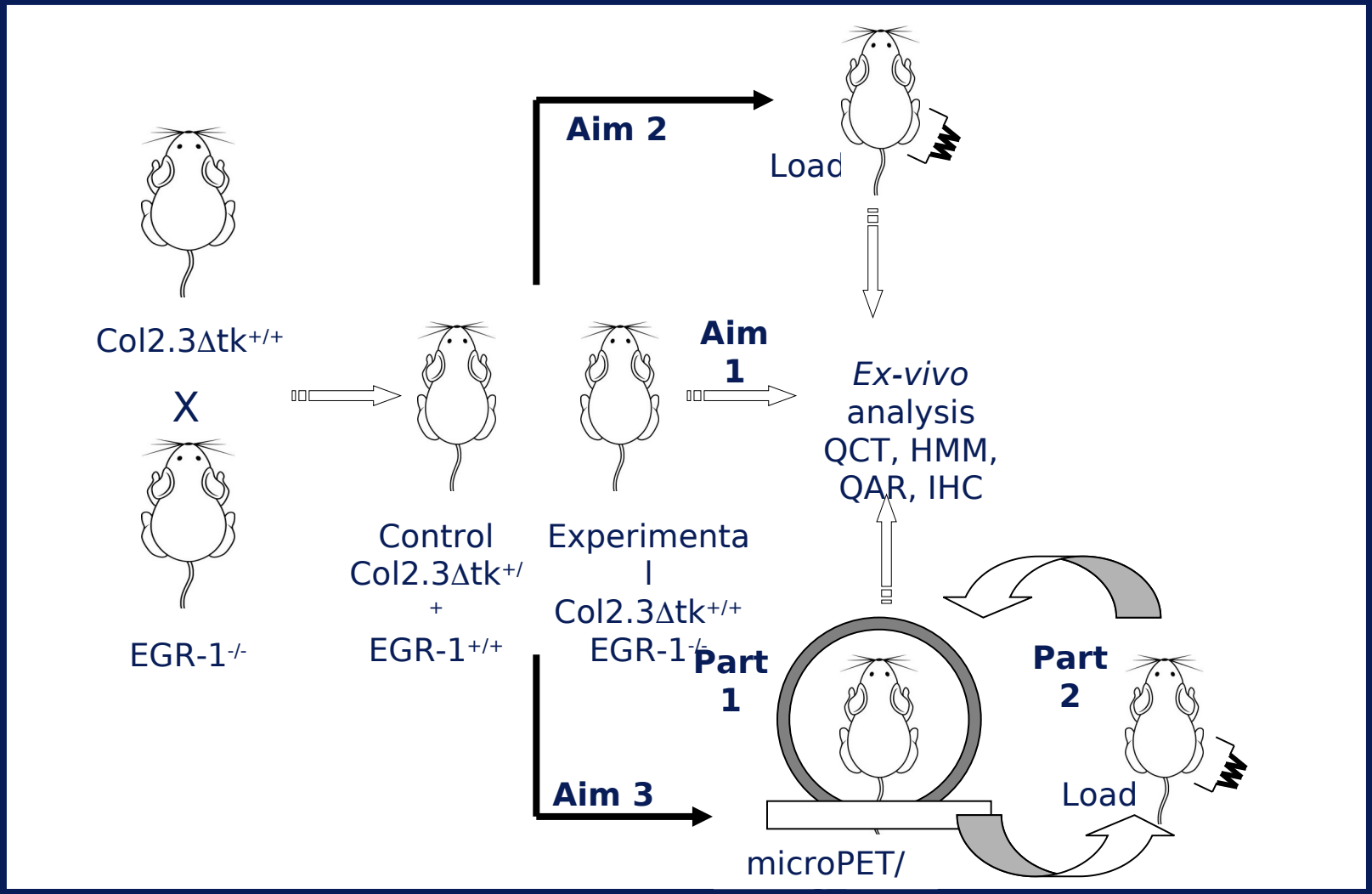
- Reviewers are informed readers but not necessarily experts in your specific area
- Funding agency (NIH) personnel want to know health impact
- Keep in mind that you need to be very clear and you need to emphasize health significance throughout

Organization

Consider giving overview at start of entire section

- Describe overall approach that will be used to achieve aims
- Consider using flowchart or table

Example of Chart



Mayer-Kuckuk

For Each Specific Aim

- Reiteration of Research Question
- Rationale
- Design, Approach
- Methods
- Anticipated Results, Interpretation
- Difficulties, Limitations, Alternative approaches

Or could include section on *Detailed Methods* common to more than one Specific Aim after description of Aims

Rationale

- Directly and succinctly reiterate why you are doing this Specific Aim

Design/Approach

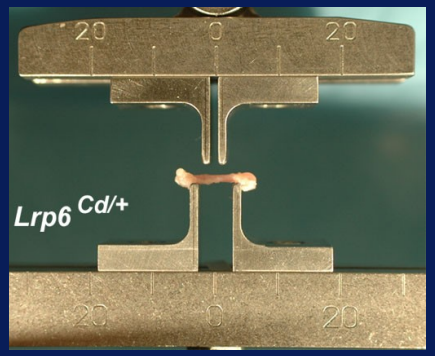
Briefly describe

- Design of study
- Choice of specimens
- Choice of interventions/independent factors and outcome assessments

Measurements

Describe techniques and equipment for measuring all variables

- Use illustrations
- Demonstrate that measurements will be accurate, precise, sensitive, specific

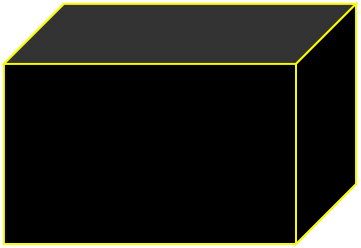


Novel Methods

- Emphasize what is new about your methods
- Point out advantages to using your proposed techniques over other approaches

Data Analysis

Describe approach for data analysis in detail

Raw Data →  → Conclusions & Interpretation

Analysis should not be **Black Box**

Data Analysis

If using analytic statistics, specify

- Statistical parameters and tests
- Assumptions of tests
- Alpha level
  - Alpha = probability of falsely rejecting null hypothesis
- Reference if statistical approach is not well known

Power Analysis

- Remember that you need to determine
  - How many specimens are needed to have a certain probability of detecting an effect?

Keep in Mind…

- Goal is to demonstrate that enough data will be collected to support analysis
- Straightforward procedure
- But is “ballpark” approach



Number of Specimens in Research Plan

State assumptions and methods used for power analysis

- Specify primary outcome variable
- Specify factor(s) or independent variable(s) of interest

Number of Specimens in Research Plan

- State proposed statistical test or interval estimation

  Examples:

  - Analysis of variance
  - Linear regression

- Note that each test has specific formula for power/number of specimens

Number of Specimens in Research Plan

- Give alpha level
  - Alpha = probability of falsely rejecting null hypothesis
- Give beta level or power
  - Beta = probability of falsely accepting null hypothesis
- Describe *effect size*

Effect Size

"...to answer the question 'What are my chances of finding it?', the researcher needs to have some idea of how big 'it' is"

J Cohen

Statistical Power Analysis for the Behavioral Sciences

Effect Size

- Ratio of expected difference to measure of variability
- Based on
  - Published work
  - Preliminary studies
  - Educated guess

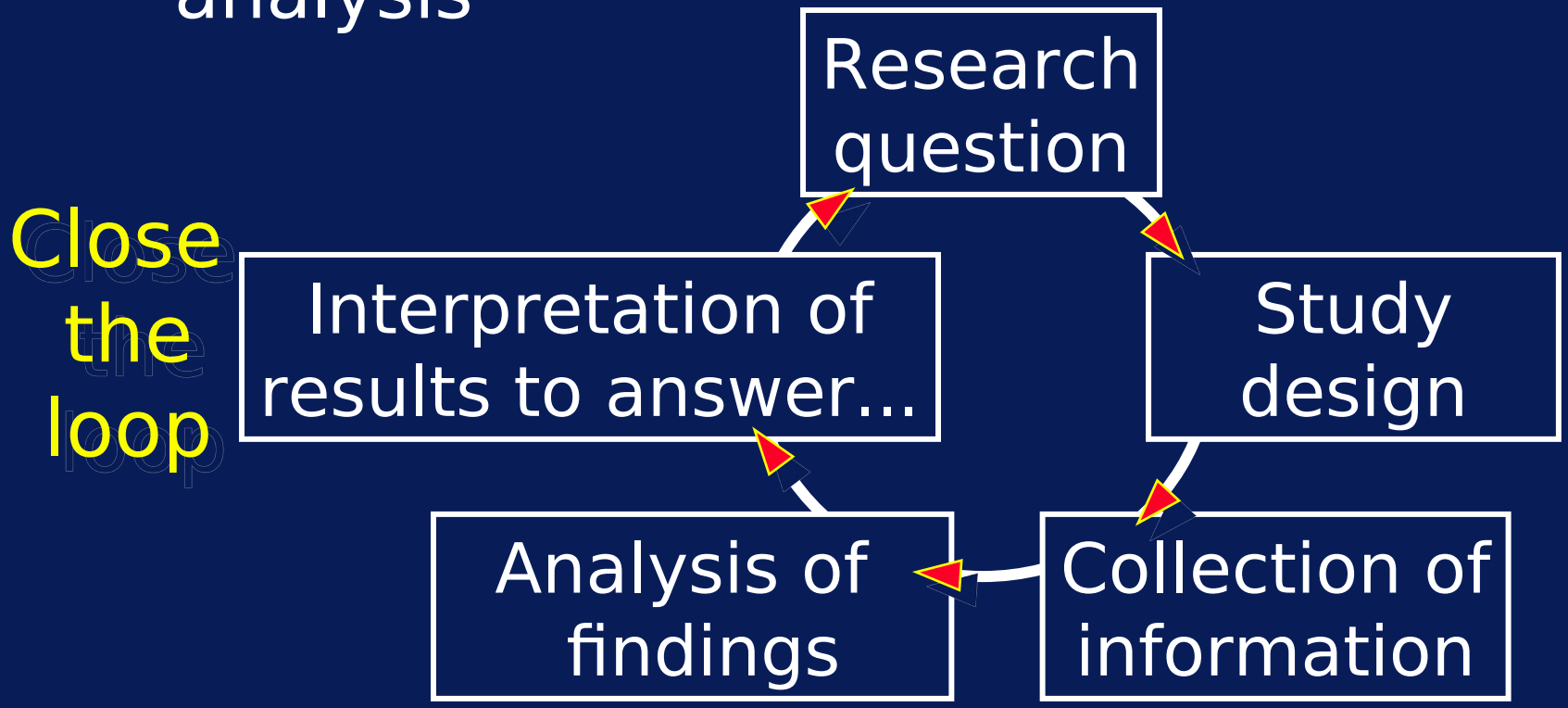
Use an effect size of scientific or clinical importance

Number of Specimens

- Calculate number
  - Hand calculation
  - Computer programs, e.g., nQuery, PASS
- If using educated guess for effect size, determine number for several effect sizes
- Adjust for loss of laboratory animals if applicable

Expected Results and Interpretation

Remember to discuss expected results and interpretation of analysis



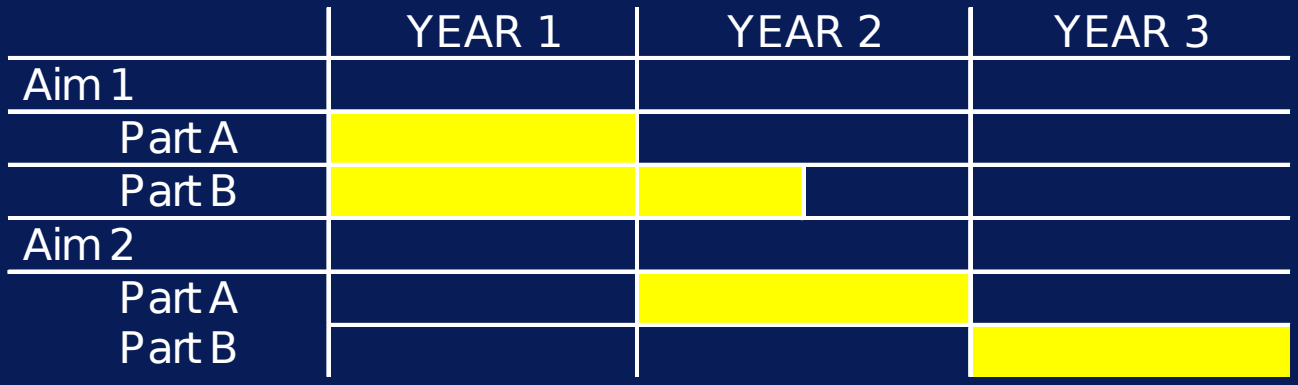
Limitations

- Include segment on potential difficulties & limitations at one of following locations
  - Under each Specific Aim
  - End of entire *Research Design and Methods* section
  - As they occur in methods
- Use limitations to point to future studies

Timetable

Include timeline or timetable at end of *Research Design and Methods*

- Give enough detail for evaluation
- Make certain it is reasonable



Ending

- Close *Research Design and Methods* with overall statement about significance of studies
- Be enthusiastic

Tips on Clarity and Style

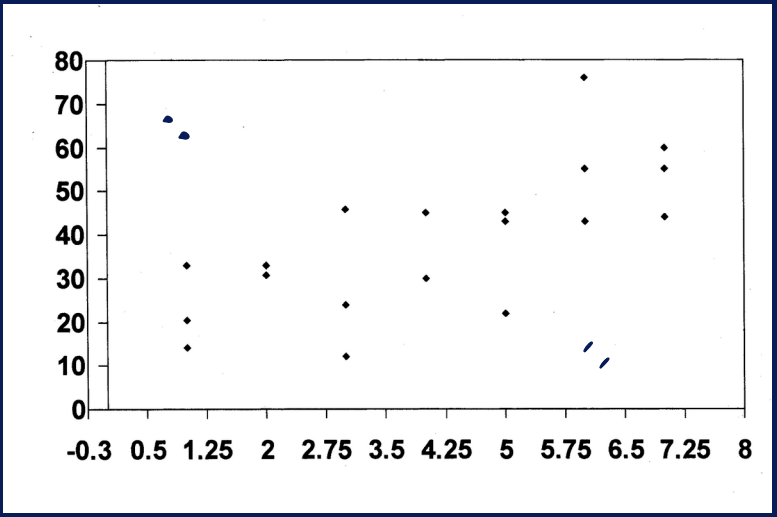
Make appearance conducive to easy reading on paper and on screen

- Neat
- White space
- 11-12 point font



Tips on Clarity and Style

- Proofread
- Make figures, tables, and legends legible



Length

Stick to page length recommendations

- RO1:

Research Plan must be <=25 pages

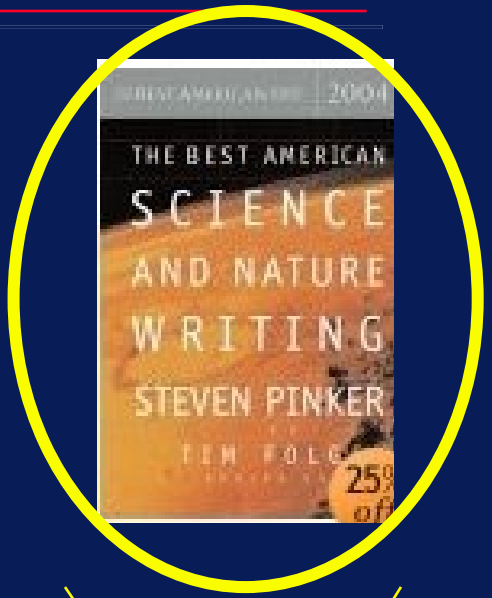
- Specific Aims: 1
- Background: 3
- Preliminary Studies: 6-8
- => Research Plan/Methods: 13-15

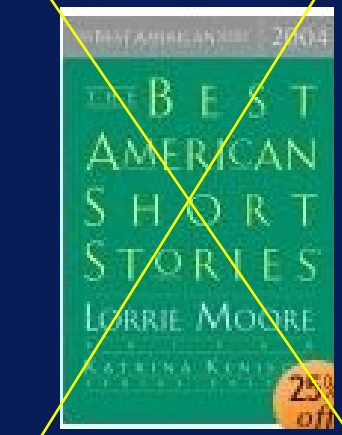


Informative Writing

Target readers' understanding

- Inform the reader
- Explain what is difficult to understand
- Say only what needs to be said

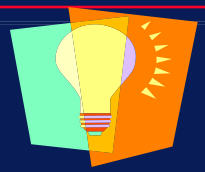




Avoid

- Overly ambitious research plans
- Contingent *Specific Aims*
- Complex, emerging techniques without establishing familiarity or including expert
- Too little detail on data analysis
- Under-powered studies

Summary: Successful Research Design and Methods



- Bright idea
- Well developed and clearly described methods
- Appropriate data analysis
- Large enough sample size
- Plenty of time to do the work
- Only minor limitations
- Clear pathway to strong conclusions