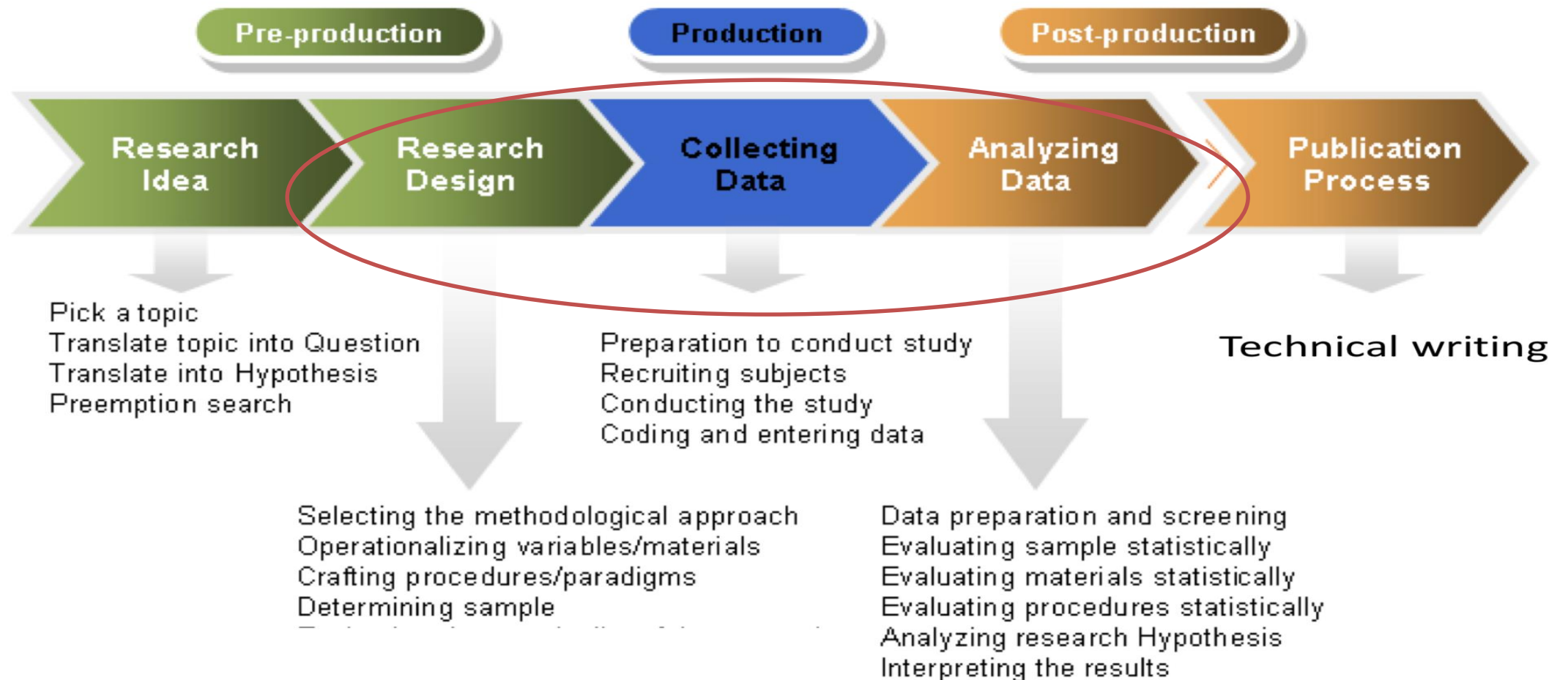




# Proposal Development : Research design and methods: Creativity and innovation

# Introduction - Research Design and Method



# Research design

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Plan of research from the point of operationalization of hypotheses to the analysis of data.

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The blueprint of your nature of investigation, data collection methods to be used, number of contacts to be made with the participants, and the reference period of study.





# Research design

- Research design involves formulating a strategy for your research.
- Once you have formulated a research design, the next step is to prepare a research plan.
- As a with a research design, research plan also gives your research a sound footing.



# Research plan should be written to address the following questions

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What do you intend to do?



Why is the work important?



What has already been done?



How are you going to do the work?

# A typical research plan has these required elements:



Specific Aims.



Research Strategy.



Resources.



Biographical Sketch.



Research Support.



Preliminary Studies.





# Research Strategy

- The Research Strategy section has three subsections:
  - Significance.
  - Innovation.
  - Approach.

# Research Strategy

## 01

### Significance + Innovation + Approach (Study Design)

- R01 = 12 Pages
- R21 = 6 Pages

## 02

### Review Criteria

- **Significance**
- Investigator
- Innovation
- Approach
- Environment
  
- Overall Impact (overall score)







Explain how the application challenges and seeks to shift current research or clinical practice paradigms



Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation or interventions



Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation or interventions

# Innovation



# Think Broadly about Innovation



New combination of expertise (unusual multi-disciplinary team) leading to new perspective



New combination of 2 previously used methods



Refinement of existing model or technology



Unique sample or opportunity provide the novelty



**Not enough to say “this method will be used” – *say why is better than alternatives***

# Writing innovation

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- Suggested length ½ - 1 page
- Does your research incorporate a new perspective on your subject?
- Does the proposed research employ novel concepts, approaches or methods?
  - “The proposed research employs a novel method that we developed . . .”
- Are the aims original and innovative?
  - “These aims are original in that . . . While they build on . . . , they are designed to advance our understanding of . . .”
- Does the project challenge existing paradigms or develop new methodologies or technologies?

# Example from a funded grant

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- 1/3 page
- Bulleted list

## B. Innovation

There are a number of innovations in the hypotheses, study design, and technical approaches of this proposal.

- Address new questions regarding multi-scale transfer of strain and stress. While some evidence of tissue inhomogeneity exists, there is very little understanding of the origin, prevalence, or impact of PG-rich  $\mu$ -domains within fibrous  $\mu$ -domains, and no information on how these domains impact the tissue-level mechanical function. Elucidating the crucial role of  $\mu$ -domains in load-bearing is an innovative pursuit.
- Mechanotransduction. We will evaluate cell response to mechanical perturbations within distinct  $\mu$ -domains using real-time and novel single-cell measurement tools (*in situ* calcium signaling and RNA fluorescence *in situ* hybridization). We will tie micromechanics to local cell behavior for cells ensconced in native tissue and in 3D engineered constructs that reproduce this complexity.
- Establish new state-of-the-art experimental measures. Our team and our integration of micro-mechanical measurements, FE modeling, and single-cell biological response, represent a unique and powerful approach and interdisciplinary collaboration.
- Integrate native tissue structure and TEC platforms. Our approach utilizes both native and engineered systems, including engineered  $\mu$ -domains, to inform one another in order to develop novel insight into the role of microstructure in governing macroscopic tissue behavior and cellular responses to loading.



# Another example from a funded grant

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- 1<sup>st</sup> paragraph of 1 page Innovation section:



*The studies we propose will capitalize on **innovative state-of-the-art technology** in high-resolution microMRI, image registration, and computational modeling to quantify and evaluate internal disc stress and strain fields **with unmatched capability**. ...Our proposal, which integrates experiments and modeling, where both approaches inform each other, **is a powerful and distinctive approach**. Simultaneous development of both experimental and modeling techniques to quantify disc internal stress-strain fields noninvasively, especially at tears, **provides capabilities not previously achieved**.*



## Make Sure Your Research Question is Unique

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Search Online database to see if anyone else has been funded to carry out similar research

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E. g - <http://report.nih.gov>

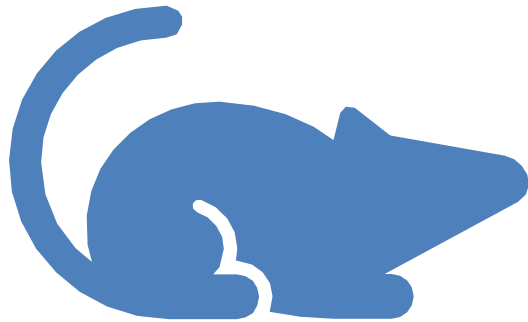


# Innovation is Necessary, But Not Justification

- “This model has been tested in rabbits, mice, rats, drosophila, dogs, cats, chickens, zebrafish and hamsters, but no one has looked at it in a frog yet.”

# But.....

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“This model has been tested in rabbits, mice, rats, drosophila, dogs, cats, chickens, zebrafish and hamsters, **but no one has looked at it in humans or better yet patients with the condition of interest.**”

.... is a different story



# Too Much Innovation

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- Be careful about arguing you're "outside the mainstream"
- Need to balance innovation with:
  - Feasibility (preliminary data, scope of research)
  - Credibility (training, publications)



Grant writing is different from other technical writing



Read by only a few people

Tired and fitting this service into busy schedules  
But get excited by good ideas presented well



Persuasive writing – tell a story and draw the reviewer in



Win their interest in going to bat for your proposal, do not beat them into submission

# Final Thoughts on Innovation

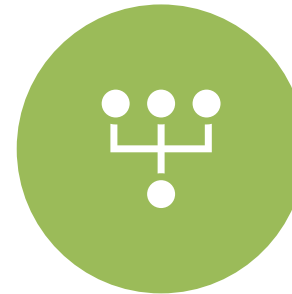


# Study Approach

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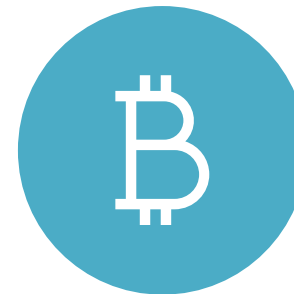
Heartbeat of proposals.



Vital because it describes the work to be done and details the methodologies or tasks for performing the work.



Clarity is essential because Language in the approach often becomes part of the contract specifying services to be performed by the research team.



Approach tells the value for the money to be spent .

## Approach

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If the research tasks or services are complex, the approach explains how the elements of the project inter- relate and why each activity is essential to the job.

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Activities described in the approach form the basis for managing and budgeting .

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Accuracy in describing activities is important to ensure timely completion of the project without cost overrun.





## When writing your study design and method —

- Either
  - Address Significance, Innovation, and Approach for each Specific Aim individually or
  - Address Significance, Innovation and Approach for all of the Specific Aims collectively if the applicant has multiple Specific Aims.
- State strategies that will be used to ensure a robust and unbiased approach, as appropriate for the work proposed.
- State how relevant biological variables, such as gender, minority, stigma for studies in human subjects will be addressed .



## When writing your study design and method..2

- State the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project.
  - Unless addressed separately, it will include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.
- Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.



## When writing your study design and method ..3

- Describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work if the project is in the early stages of development.
- Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised.
- Discuss in full the use of select agents or product, if applicable..



- Subsection
  - Study direction
  - Study site (s)
  - Study population
  - Study procedures
  - Study measurements
  - Data quality and management
  - Data analysis
  - Expected Outcomes
  - Potential Problems & Alternative Approaches
  - Timeline

**Finally  
Research  
design and  
method**



# NIH guidelines for this section



Describe

- Overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project.

Discuss

- Potential problems, alternative approaches, and benchmarks for success anticipated to achieve the aims.

Describe

- If the project is in the early stages of development, describe any strategy to establish feasibility and address the management of any high-risk aspects of the proposed work.

Include

- For new applications, include information on Preliminary Studies as part of the Approach section.



# Questions and Answers

