1. Pick a Project
- Compelling topic with connection to patients and/or public health impact
- New idea that follows from published work and/or preliminary data
- Concise overarching hypothesis and/or goal
- Identify if project is innovative
  - Think through 2-3 aspects of proposal that would be new to the field – this can be a used method or an aspect of the intervention
- Feasibility of approach is established
- Something that you are passionate about and that you would enjoy doing!

2. Select Scientific Advisors
- Select at least two scientific advisors using the criteria below:
  - One advisor should know the research area well and be able to speak to the importance of the project and the planned approach
  - One advisor should know the general area of your proposed research, but not the details, representative of the range of likely NIH reviewers in study sections
  - Try to select at least one advisor with NIH study section experience
  - Bring your advisors into the R01 development early - before you are overly invested in your idea!

3. Write a Specific Aims Page for the Project
- Introductory paragraph
  - State the problem to be addressed
  - State the potential impact of the proposed research
- Specific Aims
  - Concise
  - Tied to a hypothesis (when possible)
  - Indicate, at a high level, how the proposed research will address the aim
  - No more than 3 aims (if possible)
    - The first two aims should appear achievable
    - Avoid aims that depend critically upon the success of another aim
  - Last sentence should be short and mention the positive impact of a successful project
  - Do not exceed 1 page

4. Identify Administrative Resources
- Department Business Administrator (BA)
- Department Grants Management Team
- Budget Specialist – will help with the budget
- PennERA and NIH Submission Expert – including grant components
- Identify administrative support (if available)

**Note:** These resources depend upon your department – reach out to your BA

5. Timeline - Start early!
- Determine the internal deadline with assistance from your BA or grants manager
- 6 months ahead of deadline
  - Specific Aims – Drafted
Ask advisors and mentors to review and proofread

- 3 months ahead of deadline
  - Specific Aims - “Locked”
- 1 month ahead of deadline (at least), preferably earlier
  - Research Project – Drafted
  - Ask advisors and mentors to review and proofread
- 3 weeks ahead of deadline
  - Start submission
  - Routing items:
    - Budget and Justification
    - Biosketches
    - Required regulatory components (if applicable)
- 1-2 weeks ahead of deadline
  - Between initial routing and required submission to NIH:
    - Finalize research project
    - Ask advisors and mentors to review and proofread
    - Avoid major changes in research plan during this final phase
    - Choose a preferred study section for your submission

6. Research Plan Section - Specific Tips

- Background/Significance
  - Overview of what you plan to do
  - At the end of the first paragraph, identify how the project will address a clinical/biologic issue
  - Don’t make your reader read the whole section to find out what you are doing
- Preliminary Data
  - State how each result impacts your proposed approach and/or overall project
- Approach
  - Clearly state how you will analyze your data to address specific aims and test your hypothesis.
  - A stats section can be important even if you think the analysis is easy
  - Pitfalls/alternatives sections are strongly encouraged!
- Other
  - Scientific rigor
  - Key resources/Reagents
  - Human Subjects and Vertebrate Animals
  - These are all key sections that can hurt you if they are not done well
  - Mention critical results, concepts, and considerations more than once in the research plan
    - Reviewers may miss a single instance of a critical component
  - For amended (re-submitted) grants, include an introduction (1 page)
    - Collate common reviewer concerns
    - Include some concrete change
    - Address common concerns
    - Address the concerns in the “Summary of Discussion” paragraph

7. Additional Resources

- Junior faculty in your area of research who have received their first R01 recently
- Examples of successful grants, including amended application for resubmission
- Departmental mentor review/comments
- Faculty who have been part of a NIH study section
- See additional symposium document: “Grant Writing Resources” - workshops, courses, review groups