LEARNING MILESTONES FOR CHAPTER 11:

1. Understand the APPROACH review criterion and how it relates to this section.
2. Know the five questions that your completed Approach subsection must answer.
3. Understand how the Approach subsection of Research Strategy should be formatted.
4. Adopt a succinct writing style and include only essential, meaningful detail.

Introduction

5. Copy and paste the title of your first specific aim from your Specific Aims section into a new document file.
6. Prepare a first draft of the introductory paragraph for the first specific aim. Be certain that it provides a conceptual "overview" of everything that is exciting and important about this subsection. The idea is to "hook" the interest of reviewers and make them *want* to read the details that follow.
7. Ensure that the introductory paragraph is not more than 1/4 to 1/3 of a page in length.

Research Design

8. Appreciate that inability to reproduce published research results has been an all-to-frequent problem in recent years.
9. Appreciate that NIH wants to help solve this problem by supporting rigorously designed research that takes sources of biological variation, such as sex, into consideration.
10. Some of the most important application/review changes that NIH made in 2016 pertain to design rigor and consideration of biological variables. You must provide evidence in your application of responsiveness to those changes if you want to get funded.
11. If you need additional information regarding how to increase the likelihood that your results will be reproducible, view the videos that are listed in this Chapter.
12. Consider introducing practicable aspects of Good Laboratory Practice and/or PCORI Standardized Methods to your laboratory operation as a means of helping to ensure the reproducibility of your results.
13. Read the publications at http://www.fasebj.org/content/early/2015/10/28/fj.15-279554.full. pdf+html and https://bsd.biomedcentral.com/articles/10.1186/s13293-016-0066-x to determine how sex should be considered as a source of biological variation. Download the checklist at http://www.cihr-irsc.gc.ca/e/documents/igh-checklist-integrating-fund-initiatives-bio-en.pdf, which will be of even more help.
14. If you sense a need for better grounding in experimental design, take advantage of the many authoritative resources that are available on the Internet.
15. Begin development of the Research Design for each aim by making a bulleted list of activities/studies.
16. Expand the bullets into sentences under an interest-evoking title for each set of studies/activities.
17. Include technical preliminary results if you need to establish that a method/technical procedure is feasible in your hands.

Expected Outcomes

18. Make a list of the important results that you expect from each Aim.
19. Integrate them in narrative form so that they don't come across as a list.
20. Accompany each Aim's expected outcomes with a sentence that tells reviewers how they collectively attain the objective of that aim.
21. Ensure that the expected outcomes from all of your aims collectively attain the overall objective that you have for the project.

Potential Problems & Alternative Strategies

22. Review your research plan and identify problems that could potentially develop –

probably won't – but could. List these.

23. Develop credible solutions – alternative strategies – for the potential problems.
24. Write in the conditional in this paragraph – these problems are things that *could* happen and the alternative strategies are things that you *would* turn to if the problems would arise.

Timeline and Benchmarks

25. Prepare a timetable (or narrative timeline) that summarizes when each aim will be conducted, as well as when the benchmarks that will be used to monitor progress will be reached.
26. Make certain that each benchmark is clearly named to denote what it represents in terms of measuring progress. If the table approach is used (compared to a narrative) you can either name them in the left column or, if that isn't fully descriptive, complement the name with explanatory footnotes.

Future Directions

27. Conclude the Approach subsection with a brief paragraph that is entitled "Future Directions." It should mostly focus on what you anticipate the renewal will encompass, assuming that the proposed project is completed successfully.
28. If you are writing a K Award, R03, or R21 application, use this paragraph to emphasize that the immediate follow-on proposal will be an R01, which is what NIH expects. Highlight that the non-renewable funding being sought will enable that application.

Progress Report for Renewal Applications

29. Make a decision, based on relative productivity with the current funds, whether or not to submit a renewal. The shortest path to funding may be a new application if you have not made reasonable progress during the current period of grant support.
30. Begin by offering the beginning and ending dates since the last competitive review. The ending date will be the date of submission of the renewal.
31. Summarize the specific aims for the current period of support, including any changes in them that were caused by budget cuts or change in scientific direction.
32. Use the titles of the specific aims to organize the Progress Report into subsections.
33. Use a separate paragraph to present each of your discoveries.
34. Write a fully italicized sentence at the end of each such paragraph that highlights the importance of the discovery and how it helped attain the grant's overall objective.
35. Create a list of the products – most will be publications – from the current period of support, ranked in order of greatest to least importance. Include PMCID or PMC numbers.
36. Convert the list to a PDF file and upload it into field 4 of the PHS 398 Research Plan form, Progress Report Publication List. Do not include submitted or "in-preparation" manuscripts.