DEVELOPMENTAL STEPS FOR CHAPTER ELEVEN:

- 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