CONSIDERATIONS AND STEPS IN DESIGNING A RESEARCH STUDY

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1	Develop your idea into a research question	You have a great idea. Now you want to develop it into a research question. For a good research project, your question should be currently unanswered, incompletely understood, and/or in need of re-assessment. Also, the question needs to be answerable. There are a lot of good questions, but not all are answerable. Bonus for a question that addresses a particularly salient, timely, or costly problem. Ask yourself (and others): Is there sufficient knowledge about your research question to generate a hypothesis? If so, is your hypothesis testable? Or is your question more suited to a hypothesis-generating or descriptive project?
2	Review the literature	Be exhaustive! Don't assume you "found it all" in just 1 or 2 searches. Consult a librarian for assistance in developing thorough search strategies. Ask experts for advice and for important citations. Read meta-analyses and other reviews to build your knowledge of the body of evidence. Prepare a summary of the literature - build a table that documents all the outcome measures and findings that have been reported. Be prepared to summarize the current literature in a "pitch" to your colleagues.
3	Revise your research question if/as needed	Considerations based on your lit review: Did you find that your question has already been answered? You might think you came up with an interesting and novel question, but it may have already been addressed or settled. Does existing knowledge identify a knowledge gap your research could fill? Are there outcome measures or other insights that have not previously been addressed? Can your research question address these unknowns? Will you have access to all that you need to answer the question?
4	Design the study, develop your methods	Think about what is required to answer your question. What samples or data will you need and from whom (or what)? How many do you need? How will you obtain the samples or data? How will you ensure unbiased sampling/data collection? How will you examine/analyze the samples or data (what methods will you use)? Where will you conduct your analyses? What is your time frame from start to finish? What statistical approaches are needed to interpret your results? Who do you need on your study team?
5	Write your research proposal	Use a structured approach to draft an initial proposal. (e.g., introduction/background, materials and methods, anticipated results, discussion/conclusion). Be prepared to articulate the potential impact of the proposed work, particularly clinical impact. Also define the public health problem that will be addressed if your work is successful. READ, RE-READ, and RE-READ your proposal. Have others read your proposal and provide comments; improve your proposal based on their suggestions.
6	Address any funding issues	Consider: Do you have access to everything you need (e.g., equipment, space, etc)? If you propose an animal study, how will you pay for acquisition of the animals, their housing, their food, etc? If acquiring tissue, is there a cost? Will you need to rent or pay for equipment or reagents to analyze your samples? If conducting a clinical study in humans, will you need to pay participants? Will you need to pay a study coordinator? If an intervention, how will you pay for the experimental agent being tested?
7	Obtain appropriate institutional approval	Studies in humans require human subjects Institutional Review Board (IRB) approval. Learn what is required at your institution to acquire IRB approval. Consult with IRB staff to see if you need approval. If so, is someone available to help you? Studies in animals also require approval, usually from your Institutional Animal Care and Use Committee. Acquisition of data and tissue may require approval and/or a materials transfer agreement, depending on the source and whether identifiers are associated with it.