Research Project Tip Sheet

Developed by the ASHP New Practitioners Forum Clinical Practice Advisory Group

Developing a Timeline

1. **Set expectations**
    a. Estimate the time needed to complete the project
        i. CITI training can take a while to complete, be sure to set aside time to complete this task
    b. Integrate firm deadlines
        i. Allows you to work backwards and integrate time for other factors including: abstract submission deadlines, poster presentations
    c. Assess time needed for feedback
        i. Work with co-authors and mentors
    d. Allow time for multiple drafts

2. **Prepare for institutional review board (IRB) submission** (approximately one month)
    a. Complete a literature review
    b. Create a detailed research plan including: Background, Aims, Study design, Data analysis
    c. Leave time to adjust research plan based on IRB feedback

3. See a proposed research timeline here

Identifying a Mentor(s)

1. **Important steps in developing and cultivating a mentor should include[1]:**
    a. Defining your specific goals
    b. Writing a description of your ideal mentor
    c. Creating a structured accountability process with a mentorship agreement
    d. Continuing to follow-up and say thank you

2. **Questions to pose when looking for a mentor could include[2]:**
    a. Do you currently admire them professionally?
    b. Are they doing what you would like to do in your career?
    c. Are they respected by their colleagues?
    d. Are they positive, optimistic, and enthusiastic?
    e. Have they established a professional network?
    f. Do you feel comfortable working with them?
    g. Do you trust that your conversations will be held in confidence?
    h. Are you willing to have them be candid with you, encourage you, and challenge you to reach your career potential?

3. See more on guided mentorship by visiting the ASHP Mentorship Resource Center

Study Methodology

1. **Developing a research question[3]**
    a. Ask yourself interesting questions in practice
        i. Question personal experiences in practice as opposed to reflecting on data: ask "why do we do this in practice?"

b. Identify a specific research question (a logical statement with unknown results or that requires validation)
    i. Ensure the question is important to four S's: size, scope, scalability, sustainability
    ii. Reflect on the purpose and objectives: ask "what do we need to know and why?"
c. Develop a testable hypothesis from the research question
    i. Specify the relationship between one or two variables
    ii. Precisely describe how the variables will be measured
d. Helpful hint: utilize the PICOT method when asking your question – P: patient population; I: intervention; C: comparator; O: outcome; T: timing
e. Consider applying the RE-AIM model to design, implement, and evaluate research interventions
f. Ensure you have an adequate patient population
    i. Large enough to answer the question and focused enough to exclude confounders

2. **Obtain departmental support**
    a. Determine the impact of your research on different departments within the institution, multidisciplinary involvement may be very helpful
    b. Important questions to consider
        i. Will you need to educate other departments regarding the protocol?
        ii. Do other departments require review by their departmental research committee prior to IRB submission?

3. **Author order**[4]
    a. Establish early in the process to set expectations for roles, responsibilities, and contributions, and to avoid misunderstandings in the process
    b. Keep in mind that all authors have responsibility for the study, with the lead author having the majority of this responsibility

4. **Design**[5]
    a. Determine if the project is classified as research or quality improvement
    b. Design the project in a way that answers your research question
    c. Keep in mind that a descriptive or observational study design may be more appropriate for a resident research project
    d. Observational
        i. Descriptive – case report, series
        ii. Cohort
            1. Retrospective or prospective in which cohorts of patients are followed through time until development of the outcome
            2. Helpful when investigating multiple outcomes associated with an exposure
        iii. Case-control
            1. Retrospective in which patients with the outcome of interest (cases) are compared to those without (controls)
        iv. Experimental (Randomized controlled trial)
            1. Patients are randomly assigned to receive a defined intervention or control
            2. Best for determining causality, though more challenging and time-consuming to conduct in clinical practice
    e. Systematic review and meta-analysis: collect research and utilize statistical methods to summarize results of multiple studies to answer the research question

f. Control for confounders in the study design to minimize bias
    i. Randomization, restriction, matching, stratification, multivariate analysis
g. Additional resources on design: ASHP Research Resource Center

5. **Data collection**
    a. Data query tools
        i. Electronic health records (working with informatics department to generate reports)
        ii. Clinical event reporting systems
    b. Measurement instruments
        i. Consider reliability, validity, and responsiveness
    c. Facilitating data collection
        i. Engagement of student pharmacists and pharmacy residents[6]
        ii. Setting expectations with training and validation: Independent sampling; periodic review; handling questions
    d. Sample data collection platforms
        i. REDCap[7]
            1. Secure, web-based application to design and facilitate manual data collection, surveys, and database development for clinical research
            2. Tutorial videos and manuals: https://cri.uchicago.edu/redcap-training/#manuals
        ii. Microsoft Excel: https://www.unmc.edu/publichealth/centers/ccorda/exceldata.html

6. **Statistical analysis**
    a. Access to a statistician?
        i. Yes: meet early in the process to discuss study design, outcomes, and incorporate into the project timeline[8]
        ii. No: determine which statistical software your institution utilizes (if any) to familiarize yourself
    b. Resources that provide a great overview of biostatistics
        i. Statistics at Square One (bmj.com)
        ii. Annals of Emergency Medicine "Introduction to Biostatistics" six-part series: Introduction to biostatistics: Part 1, basic concepts - ScienceDirect
        iii. Canadian Medical Association Journal "Basic statistics for clinicians" four-part series: Basic statistics for clinicians: 1. Hypothesis testing. (nih.gov)
        iv. Overview of Biostatistics Used in Clinical Research (*AJHP*)
        v. Essentials of Practice-Based Research for Pharmacists (Data Analysis video)
        vi. ASHP Basic Statistics and Pharmaceutical Statistical Applications, third edition
    c. Free resources for statistical analysis
        i. Quick Calcs at GraphPad Software
        ii. Power and Sample Size | Free Online Calculators
        iii. R: The R Project for Statistical Computing (r-project.org)
    d. Sample statistical packages
        i. GraphPad
        ii. Stata: Software for Statistics and Data Science | Stata
        iii. SPSS Statistics | IBM
    e. Don't forget about Microsoft Excel! There are many ways to use Excel for statistical analysis…
        i. Pivot Tables, Descriptive Statistics, Analysis of Variance (ANOVA), Moving Average, Rank and Percentile, Regression, Random Number Generator, Sampling, etc.

ii. Using Excel For Statistical Analysis: Tips And Techniques (digitalvidya.com)
iii. Statistics in Excel | How to Use Excel Statistical Functions? (educba.com)

7. **Additional funding support**
   a. An introduction to grants[9]
      i. Plan plenty of time for grant preparation and ensure you review your institution's grant requirements
      ii. Submit your application to the grants administration office in advance of submission to the funding agency
   b. ASHP Foundation – awards, grants, and resources: https://www.ashpfoundation.org/

Study Dissemination

1. **Manuscript preparation/submission[10]**
   a. Choice of journal:
      i. Choose a journal in which you wish to publish your work at the time of conceptualization of clinically relevant scientific work
      ii. Develop a thorough understanding of scope of the journal and instructions for authors before you begin preparing your manuscript
      iii. Consider the journal's impact factor; proactively seek information from mentors and journal websites to avoid predatory journals
      iv. Consider whether the journal is open-access (may need to pay a heftier amount once your manuscript is accepted for publication)
   b. Writing the manuscript:
      i. Broad sections include abstract, introduction, methods, results, and discussion. Create a skeletal framework for your manuscript, keeping in mind journal requirements
      ii. Ensure content is logical and clearly flows from one section to the other
      iii. Appropriately cite the sources for all claims made in your manuscript
         1. Review journal's citation formatting requirements
         2. Multiple resources exist to facilitate storing and organizing, citing, and formatting of references: EndNote (purchase required), Mendeley (free access)
         3. Citations are easily generated and adjustable dependent on journal citation preferences
      iv. Include acknowledgements (e.g., for technical assistance, assistance with formatting, translation, scholarly discussions, etc.) and conflicts of interest
      v. Seek out review from advisors who were not involved in the research
   c. Manuscript submission:
      i. Compile all files associated with manuscript (image files, tables, charts, supplemental information etc.) in a single folder before submitting
      ii. Use a cover letter to highlight the relevance of your work and why it would be of interest to the journal's readers
      iii. If including any third-party material in submission, ensure necessary permission has been obtained
      iv. Include the name and affiliation of all co-authors
   d. For more information on *AJHP* manuscript submission instructions visit https://academic.oup.com/ajhp/pages/General_Instructions

2. **Peer Review Process**[11]
    a. Manuscript is submitted to journal
    b. Initial check by editorial board to ensure that the manuscript is relevant to the focus and scope of the journal and is making a useful contribution to existing literature
    c. Sent to 2-3 reviewers based on their expertise, availability, and absence of conflicts of interest
    d. Reviewers provide comments to authors
    e. Final decision on each manuscript. Typical ratings include: accept, minor revision, major revision, or reject
    f. Decision letter sent to authors via email
    g. Important considerations during peer review process:
        i. Originality & relevance of content
        ii. Correct structure based on journal of submission
        iii. Ethical issues e.g., plagiarism, conflicts of interest, duplicate publication, concerns surrounding research involving animals/humans, etc.

3. **Abstracts and Posters**
    a. Research meetings with calls for abstract presentations and submit to those most applicable to the study topic and audience
    b. Prepare a concise abstract touching on brief background/purpose, intervention, number of observations, end points, and results according to the specifications of the meeting/organization
    c. Poster Presentations[12-13]
        i. Review poster requirements, dimensions, and display methods
        ii. Display the most relevant details, highlighting results, as opposed to re-writing the abstract
        iii. Minimize text and instead utilize images, graphs, tables, or flowcharts as able
        iv. Check out this podcast for more information!

4. **Presentation "Do's and Don'ts"**
    a. Do consider your audience to best tailor your presentation approach: live or virtual poster session? Platform presentation? Pharmacy or non-pharmacy audience? Visit the ASHP Research Resource Center for more resources!
        i. Check out platform presentation tips here
    b. Do be prepared for and anticipate questions from the audience
    c. Do practice, but do not sound too rehearsed!
    d. Do not have distractions – including mannerisms, or backgrounds for virtual presentations

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