Specialty Pharmacy Outcomes Research Overview and Pearls

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Advisory Group on Outcomes and Value

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1. Generate/Identify Research Idea
   a. Ideas may come from strategic goals, gaps (or successes) in patient care, or collaborations with internal and external stakeholders.
   b. Develop a research question using PICOT method (Population, Intervention/Exposure, Comparison, Outcome, and Time).

2. Define the Scope and the Scale of the Project
   a. Perform a literature search to discover existing state of understanding.
      i. Refer to the ASHP HSSP Outcomes Literature Library for articles.
   b. Determine initial outcomes to evaluate.
   c. Evaluate project feasibility and resource requirement.

3. Engage Stakeholders
   a. Develop research team and outline responsibilities and timeline
   b. Engage with other stakeholders that may need to be involved (will vary - managers, non-IRB research review boards, compliance, office of intellectual property, etc.)

4. Finalize Study Protocol
   a. Finalize primary and secondary outcomes.
   b. Meet with statistician or create stats plan.
   c. Develop data dictionary listing all data needed to perform the study that clearly defines each metric and how it is collected.
   d. Establish study timeline.
   e. Determine initial plan on how results will be disseminated.
      i. Consider multiple deliverables if the project can support them.

5. Obtain IRB approval
   a. Requirements may vary between institutions. Work with local IRB for details.

6. Project Kickoff
   a. Set target deadlines for each remaining step of the research process.
   b. Review team responsibilities.
   c. Before kickoff, review the checklist below to ensure that you are ready.

7. Data Collection
   a. Request discrete data that will be extracted by analyst (if applicable).
   b. Thoroughly train all data collectors and perform regular data quality checks.
   c. Document discrepancies, deviations, or other changes that may occur.

8. Data Analysis
   a. Review and clean data. Organize data for analysis.
   b. Perform statistical analysis.
   c. Review data and determine key points from the findings.

9. Dissemination of Knowledge Gained
   a. Present and publish using scientific platforms (e.g., posters, presentations, publications).
   b. Develop public mediums for dissemination (e.g., online magazines, social media).

10. Reflect on Study Methods and Findings
    a. Determine if further practice changes are needed.
    b. Review ways to improve study design moving forward (e.g., better method of data documentation).
    c. Develop subsequent research questions.
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