

Precepting a Clinical Research Project and Translating it into a Manuscript

Busy Day Tool Kit Preceptor Instructions

Learner level: IPPE and APPE students, Pharmacy Practice Residents

Estimated time to complete: May take several hours/days and can be done intermittently while completing other assigned projects.

Preceptor Instructions: Select a clinical research question to address a pharmacy practice problem relevant to your institution setting and/or identify if this is a feasible longitudinal residency project. Identify opportunities to integrate IPPE and APPE students into the research process. Request that the student provide written completion of the module by answering the questions outlined in the module. Set up a time with your student to review the results of the completed module.

Resident/Student Instructions:

For Residents: Select a clinical research question to address a pharmacy practice problem relevant to your institution setting and/or identify if this is a feasible longitudinal residency project and if it is of interest to you.

For Students: Identify a research mentor and find opportunities to integrate into the clinical research process.

Precepting a Research Project and Translating it into a Manuscript

What are some of the most common types of clinical research done in Pharmacy Practice?

Retrospective studies: Mostly using the study method of “chart reviews”; are useful in anticipation of a prospective study and can be used as a pilot study of your desired outcome.

Prospective studies: Usually done in response to a retrospective study. When matched, referred to as “before and after studies” with the most common example being what was the outcome before pharmacist intervention, and what happened after (ex. Diabetes clinic A1c and blood sugar management before and after a pharmacist was introduced into clinic working under a protocol)

Descriptive Studies: Data collected (usually through surveys or other qualitative methods) do not try to answer the “why” but rather to describe a situation, subject or behavior in a population (ex. Prevalence, incidence, or experience of a group) mostly using frequency and means to discuss results.

Medication Use Evaluations (MUEs) – see separate busy day toolkit module addressing MUEs

*A more exhaustive list of clinical research study design can be found at CEBM (The Centre for Evidence-Based Medicine)

Why are clinical research projects in pharmacy practice important?

Provide value to your institution, either addressing medication safety issues or evaluating initiation of a new clinical pharmacist service

Provide value to the existing body of literature by adding new information that others may incorporate at their institution or area of practice

A longitudinal research project performed by residents is required per ASHP accreditation standards

Provide residents and students with research experience and project management skills through a longitudinal process

Provide an opportunity to write abstracts; submit to clinical meetings; deliver poster and podium presentations on a local, state or national level; and publish an article.

What is your role as a Research Preceptor?

Identifying your research team and clearly define their roles

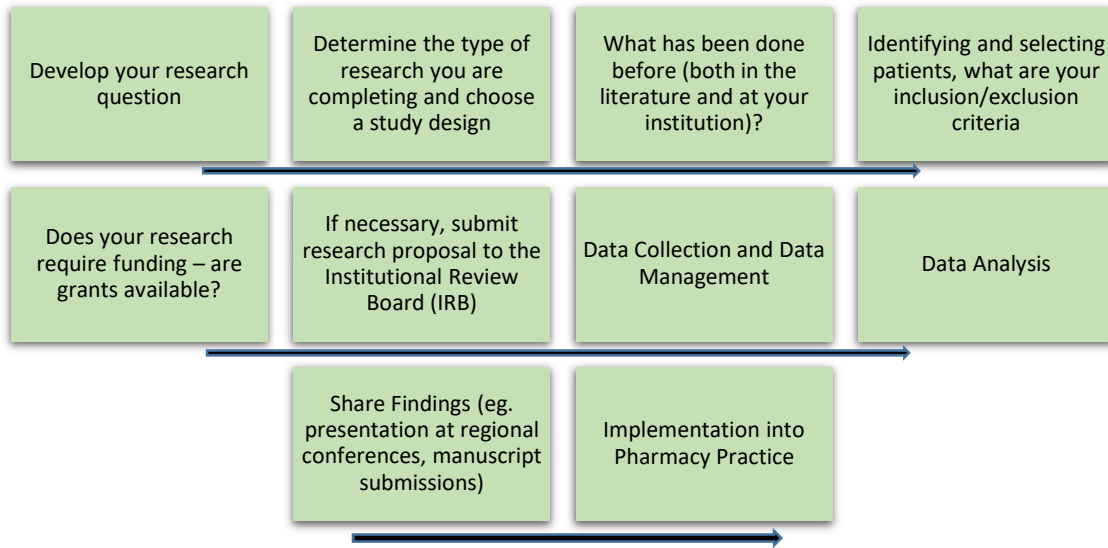
Are you serving the role of mentor or a principal investigator?

- In the case of resident research projects, residents usually serve as the principal investigators and are involved in every step of the research process. The preceptor is more defined as a mentor
- For students, in many cases they will be assisting the preceptor or resident(s) on existing research projects and can be integrated at any point of the research process
 - Recognize potential barriers that may occur and help troubleshoot those barriers
 - Provide feedback as needed and identify research barriers to address promptly (ex. incomplete data collection sheets, insufficient data points, time management, etc.)
 - Edit poster, presentations, and manuscripts

Help the student or resident create an appropriate timeline and then manage their time and expectations appropriately. Specific focused aims and goals should be developed and tailored to align with the length of student or resident experience.

- For students, this might be a 6-week APPE experience and for residents a 1 year longitudinal project.
- The IPPE and APPE students can be integrated into any part of the research process and can be utilized through the layered learning model. Just ensure that the students receive adequate training to perform semi-independently.

General Considerations and Steps involved in a Research Project



Creating a Good Clinical Research Question

Identifying a research question based on institutional needs assessment, reading the literature (what is currently missing), journal clubs, or department meetings. *Identifying* if IRB approval or exemption is needed.

- If IRB approval or exemption is needed, communicate the impact of this additional step and modify the research timeline if needed.

Refining your clinical question: Defining groups and outcomes

- FINER model: Is it feasible, innovative, novel, ethical and relevant?
- PICO model: Defines a clinical question based on specific [P]atient problems or [P]opulations, the [I]nterventions, [C]omparisons (ex. Drug A vs Drug B, adherence before and after implementation of telephone refill reminders) and the [O]utcome being measured
 - Note: not all clinical questions will have a comparator/comparison

Evolution of your research question

- Be flexible during the research process, your original research question may evolve based on your initial findings
- Create clearly defined objectives when formulating methods to ensure a smooth data analysis process ex: what have previous studies used to define a “therapeutic” range for a particular study, etc.)

Data collection and organizing data considerations

Data Collection

- This is the most time-consuming portion of project, but there are several ways to help facilitate this process
- Designing an appropriate collection tool is critical to help organize the type of data you plan to collect. You should also pilot test and validate that your collection tool is reliable, and the proper variables are matched to your desired measured outcomes. Students and residents should be encouraged to “over collect” data as unforeseen trends or discoveries can potentially change the direction of your clinical question.
- It is also critical to ask if special reports need to be run (e.g. number of vancomycin orders entered by a pharmacist per protocol) or if you have access to the appropriate databases needed. It is also critical to explain the timeline of such reports and if they will increase the overall duration of the project.
- Will you need a questionnaire?

Data Management

- De-identifying data and protecting patient information are important considerations in performing clinical research. It is vital to develop a method to code data and share this “coding” dictionary with the entire research team
- Creating a data collection sheet that is easy to navigate and understandable for any of your research team and including all variables needed to measure your desired outcome

Data Analysis

- Determine if biostatistical analyses are needed and if so, what type - do you need to utilize a statistician?
 - It is helpful to involve a statistician in the data organization/collection process as they can identify appropriate data measures to record. It is recommended to identify the use of a statistician early on to help design the methodology of the study that can sometimes lead to finding more meaningful outcomes

Translating Research into a Poster, Podium Presentation or Manuscript for Publication

It is important to understand author instructions for each potential publication source as this will determine how the manuscript and data are to be presented.

Choosing to submit peer-reviewed vs. non-peer reviewed journals

The most common mistakes found in manuscripts that are rejected include:

- Multiple spelling mistakes
- Not following author instructions set forth by publication
- Inaccurate or inconsistent data reported
- Outdated review of the literature
- Mediocre writing

Opportunities within ASHP for Resident Project Publications

AJHP Resident Edition: “describe the results of research projects (e.g., experimental, observational, and descriptive studies) or rigorous quality improvement programs (e.g., medication-use evaluations) that were undertaken while they were residents.” [More information can be found at: https://academic.oup.com/ajhp/pages/residents_edition]

References

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Additional Resource

AJHP Series: Research Fundamentals - <http://www.ashpfoundation.org/ajhpresearchseries>