

DEVELOPING THE RESEARCH IDEA



Yardlee S. Kauffman and Sarah J. Billups

"The idea of finishing my project within 1 year initially seemed overwhelming. While each individual step seemed manageable, the totality of the project made me cringe and even lose sleep occasionally (honestly, quite often). Despite the valuable guidance I received from my mentors, they didn't seem to share my level of anxiety about the project. After all, it was my residency certificate that was hanging in the balance! Overall, I'm grateful for the experience because it taught me so much and really prepared me for future projects."

—Former PGY2 Ambulatory Care Resident

LEARNING OBJECTIVES

- Identify how to write a scientific research question that meets PICOTS (Population, Intervention, Comparison group, Outcomes, Timeline, and Setting) or FINER (Feasibility, Interesting, Novel, Ethical, and Relevant) criteria.
- Formulate primary and secondary study objectives.
- Formulate study hypotheses and select related outcome measures.
- Develop a research proposal and timeline.

INTRODUCTION

As you embark on your research journey, you are probably asking yourself, *Where do I begin? What needs to go into the research question?* If so, this chapter will lay out a step-wise process for building the foundation of your project:

1. Identifying a research question.
2. Searching and appraising background scientific literature.

- 3. Writing study objectives.
- 4. Specifying and defining outcomes.
- 5. Compiling these elements into a study protocol.

This chapter will equip you with the tools to accomplish these steps (Figure 1-1).

CONCEIVING THE RESEARCH IDEA

Where do good research ideas come from? Creating a focused, relevant research idea may be one of the biggest challenges for a new researcher. A great place to identify research ideas is from your own clinical practice, such as when you encounter problems but cannot find solutions in the scientific literature. You may also want to evaluate the way evidence-based care has been implemented at your institution.^{1,2} Problems may relate to a patient-specific clinical question (e.g., "What is the relationship between benzodiazepine use and emergency department utilization in the elderly?"), institutional concerns related to quality measures defined by The Joint Commission or the Centers for Medicare & Medicaid Services (e.g., "How can we increase bisphosphonate use in women who have experienced an osteoporosis-related fracture?"), resource justification (e.g., "What is the value of a clinical pharmacist as part of a diabetes-management team?"), or process improvement (e.g., "Is there a more efficient way to conduct double-checks of intravenously prepared products?").

As a resident, your clinical experience is typically limited to rotations from pharmacy school or a previous residency; you may not have been in your practice site long enough to recognize a relevant research question. Engaging in dialogue with preceptors and mentors about possible research ideas can be the first step in building your own skills in idea development. By asking research questions, you can help to build skills in identifying relevant questions. If you have to formulate your own idea, a good place to start is by reviewing the literature about a general topic that interests you. Many studies end with recommendations for future research. Another tactic is to attend

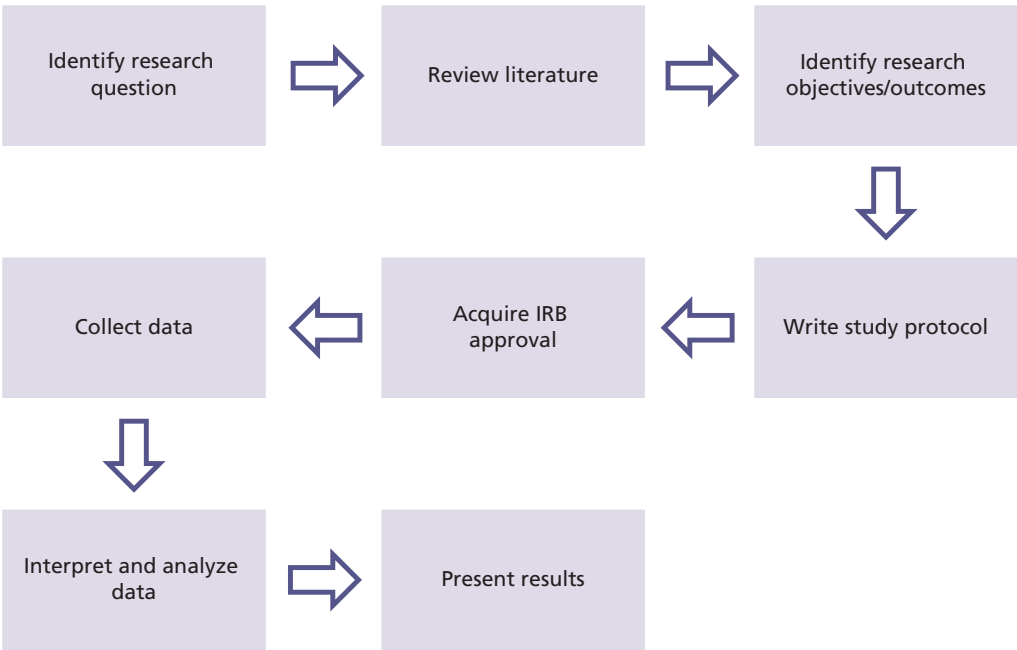


FIGURE 1-1. The Research Process

poster sessions or lectures at professional meetings where you can talk with investigators to get their ideas for needed research.^{1,2}

Regardless of where your research idea originates, the research question developed from the idea should address an unmet need or a gap in current understanding. Its answer should also contribute to improved patient care. For example, a medication adherence tool with demonstrated utility improving adherence in patients with asthma could be investigated as a strategy to increase insulin adherence in patients with Type 1 diabetes mellitus.

Once you have an idea that meets a need and interests you, the next step is to formulate it into a well-written research question. There are three general types of research questions:

1. *Descriptive questions* seek to describe a current situation or what now exists. These questions may be answered by qualitative and/or quantitative research methods.
2. *Relational questions* examine a relationship between different phenomena and utilize quantitative research methods.
3. *Causal questions* evaluate the cause-and-effect relationship between one or more variables and an outcome of interest; these, too, employ quantitative methods.¹⁻³

Developing a Research Question Using PICOTS Criteria

Research Question, Example 1

Do patients with human immunodeficiency virus (HIV) infection have better outcomes when they take a statin?

This is a good start, but the question needs to be more focused before study design efforts can begin. The PICOTS (Population, Intervention, Comparison group, Outcomes, Timeline, and Setting) criteria are useful for ensuring that your research question contains the necessary elements, while the FINER (Feasibility, Interesting, Novel, Ethical, and Relevant) criteria help to ensure that a study is feasible and worth doing (Table 1-1).⁴⁻⁶ The PICOTS criteria are applied first to example 1 below.

TABLE 1-1. PICOTS and FINER Criteria⁴⁻⁶

PICOTS	Considerations
Population	Who will you study?
Intervention	What will you do?
Comparison Group	Will you include a control group?
Outcomes	What will you measure?
Timeline	What is the study timeframe?
Setting	What setting will you study?
FINER	Considerations
Feasibility	Is your study feasible to conduct in the allotted timeframe?
Interesting	Does your research question interest you?
Novel	Does your project fill a gap in the literature?
Ethical	Can your study be conducted ethically?
Relevant	Will your results translate to clinical practice?

Population

Your target patient population is patients with HIV, but you need to be more specific. Examining all patients with HIV is too broad and, obviously, impossible. For example, you may include any of the following variations:

- *Where is your population of interest from?* A managed care organization in California? Medicaid patients in the state of Ohio? Hospitalized patients?
- *What are the characteristics of your population of interest?* All adults? A specific age range? A specific viral load range? A specific CD4 count range? Patients with cardiovascular risk factors?
- *Is the population limited to those on antiretroviral therapy and any particular kind of therapy, or to newly diagnosed patients not taking antiretrovirals?*

The point is to *be specific*. You will need precise inclusion and exclusion criteria in your protocol to define the study population.

Intervention

Next, consider the intervention. Interventions may include a new strategy, drug exposure, service exposure, or application of a tool (e.g., pharmacist delivery of medication management services, text message reminders). A prospective trial for the example question could randomize the patient population to receive either a statin or a placebo. For an observational study to address this question, you could study an historical exposure instead of a prospective intervention:

- Taking a specific statin (e.g., atorvastatin) or statin intensity.
- Taking any statin but for a certain period of time.

Comparison Group

Do not underestimate the importance of a good control group.

- Is there an appropriate comparison group available?
- What kind of comparison (e.g., placebo, active, historical) will be used?

The value of pharmacist interventions has not been adequately demonstrated due to failure to identify a control group or a selection of one that is biased. Ideally, this group should look as much like your intervention or exposure group as possible, but it should not have received the intervention. Historical controls can be used, if necessary, but be aware they often differ from the intervention group in significant ways. If using a parallel control group (i.e., one whose exposure and outcomes occur within the same timeframe as the intervention group), you can make them more comparable by matching them on characteristics that might affect the outcome such as exposure date, age, sex, or an indicator of disease severity.

Outcomes

Make sure the outcomes you choose are meaningful, measurable, and occur frequently enough to be observable in your study.

- Specifically, what type of outcome(s) should be examined?

Ideally, you should examine outcomes that matter. Examples include morbidity, mortality, hospitalizations, or events such as fractures or heart attacks. In reality, these types of outcomes may occur so infrequently that very large sample sizes would be required to detect true differences between groups, which may limit feasibility. Sample size limitations usually require surrogate outcomes, such as low-density lipoprotein levels, CD4 counts, bone mineral density, and adherence.

Keep in mind that many other types of outcomes are relevant, including economic, humanistic, quality, or educational outcomes. In addition, not all outcomes have to be purely clinical in nature. For example, identifying if a particular intervention leads to a certain outcome can be an important question to answer.

Timeline

The duration of the follow-up period to evaluate outcomes is important.

- Is the duration 2 weeks?
- Is the duration 6 months?
- Is the duration 1 year or more?

The length of the follow-up period must be specifically stated.

Setting

The setting refers to where the study will take place, such as an outpatient physician practice, an inpatient hospital setting, or a classroom setting with pharmacy students. The revised question could be as follows:

Do Ohio Medicaid outpatients, aged 18 to 75 years, diagnosed with HIV within the past 2 years and with a CD4 T-cell count >350 cells/mm³ who initiated statin therapy within 1 year of diagnosis have improved CD4 counts 1 year after statin initiation as compared to similar patients with HIV, matched by diagnosis month, not taking a statin?

Research Question, Example 2

Does a home blood pressure (BP) monitoring program improve hypertension control?

First, apply the PICOTS criteria. Consider the questions noted below.

Population

Are you interested in patients with a diagnosis of hypertension and uncontrolled BP versus controlled BP? How will you define “uncontrolled”?

Intervention

How will home BP monitoring be conducted? Will patients be asked to monitor BP using an automated home BP cuff and take measurements 3 times per week? What else is involved with the program? Will patients enter data into a database or a patient portal linked to an electronic medical record? Who will receive the data?

Comparison Group

Will you compare patients enrolled versus those who are not enrolled in the program in the same clinic or in a separate clinic? Would a historical comparator group be comparable (e.g., guidelines change)?

Outcomes

Is the outcome of interest a change in systolic and diastolic BP or achieving a specific BP goal?

Timeline

Will you measure the outcome at 6 months, 12 months, or both? Are you able to bring study participants in for a specific follow-up visit and measurement, or are you relying on self-reported measures?

Setting

In what setting will these patients receive care (e.g., ambulatory clinic, community pharmacy)? The revised question could be as follows:

Does enrollment in a pharmacist-managed home BP monitoring program increase the proportion of hypertensive patients with uncontrolled BP at baseline who achieve their target BP after 6 months, compared to similar patients at an ambulatory care clinic not participating in the program?

Additional examples of research questions that have been revised using PICOTS criteria are included in **Table 1-2**.

TABLE 1-2. Example Research Questions Revised Using PICOTS and FINER Criteria⁴⁻⁶

Initial Research Question	Revised Research Question
How effective is a clinical pharmacy service in managing patients with diabetes?	What is the impact on hemoglobin A1C for ambulatory patients with uncontrolled diabetes who are monitored by a clinical pharmacy service for 6 months compared to similar patients in a similar clinic without clinical pharmacy services?
How safe are direct oral anticoagulants (DOACs) compared to warfarin?	What is the 90-day incidence of major bleeding for rivaroxaban compared to warfarin in patients initiating therapy for atrial fibrillation?
What is the effect of text messages on medication adherence?	In patients with Type 2 diabetes mellitus, does receiving a text message reminder increase the proportion of patients picking up their next refill within 30 days when compared to similar patients who do not receive a reminder?

Developing a Research Question Using FINER Criteria

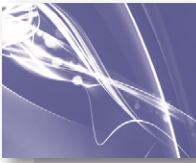
Feasibility

Is your study feasible?

Questions to consider include the following:

- Can the study population be clearly identified?
- Can you identify a large enough sample size?
- Do you have, or will you be able to obtain, appropriate data to examine the study question?
- Do you have the technical expertise? Will you need additional help (e.g., biostatistician, content expert, someone with regulatory experience)?
- What is the cost of the study? Is internal/external funding needed? If so, can you obtain it?
- Can the study be conducted in the necessary time period?

As a pharmacy resident, this is the amount of time available for the actual study once you factor in any required Institutional Review Board (IRB) approval (see Chapter 3), data requests, and preparation of a presentation and a manuscript (see Chapters 10 and 11). Look again at your research objective(s)—did you confine yourself to one to three objectives? Having too many research objectives or collecting too much data reduces the likelihood of completing the primary focus of your project. The key to completing your project by the end of your residency is keeping it tightly focused.



KEY TIP

If the answer to many of these feasibility questions is **no**, then reconsider the idea. Consult with your research team to identify how this idea could become feasible or if a different research project should be undertaken.

Interesting

Does the research question interest you?

Working on a research project can be a tedious process; if you begin the project feeling that your question is mundane or uninteresting, finishing your project will be a challenge. Your research question also needs to be interesting to a journal editor if you want to publish your work. Your residency program should provide a structure for identifying an idea that allows you flexibility in meeting this criterion. To illustrate, some residency programs may have a model in which the previous year's resident hands over a project for the next resident to continue in the following year. Alternatively, you may complete a small project that is part of a larger project—understanding the project's role in the big picture can allow you to recognize its significance. If a project does not seem interesting or ambitious, consider building the case for a larger one that the initial project could help to support.

Novel

Does the research question confirm or refute previous findings? Does it seek new conclusions? Does it fill a gap in the literature?

Confirm this with your literature search. Skimping on this step will have negative consequences when you try to publish. It may be acceptable to use a published idea and apply it with a more local focus. Is the question important to your department or hospital or important to improving the quality of patient care at your practice site?

Ethical

Can the study be conducted in an ethical manner?

For example, a retrospective study that investigates the effect of co-pay increases on adherence would be ethical, whereas a prospective study that randomly raised co-pays on some Medicare beneficiaries would place an unethical financial burden on patients. A study examining the effect of not providing counseling to patients for new medications would be unethical and unlawful. Investigative studies inherently carry more ethical risk than observational study designs. The IRB will scrutinize potential ethical issues carefully as they are charged with protecting patients.

Relevant

Is the study question relevant to clinical practice and patients?

Some questions are interesting to study, but they may not be relevant given current guideline recommendations or patient needs. For example, studying the impact of an intervention to improve patient adherence in an outpatient practice may not be as pressing when providers are prescribing evidence-based therapies at a low rate in that practice setting.

CONDUCTING A LITERATURE REVIEW

A literature review should be completed in the early stages of a research project and serves three purposes:

1. Increase your scientific understanding of the area of focus.
2. Ensure that your research question is novel or clarifies ambiguity around previous research.
3. Provide ideas on how to best fill in the gaps in the current understanding of your focus area.^{4,6}

Ensuring that your work builds on existing literature and does not duplicate other research is vital to future publication. A well-written literature review helps to build a compelling case for why your project needs to be done, and serves as background for your protocol and eventual manuscript once the project is completed. To fulfill these purposes, you need to build a comprehensive search strategy.



KEY TIPS: General Literature Search Strategy

- Use at least two databases (e.g., PubMed, GoogleScholar, EMBASE).
- Check references of the “key” studies that address your research topic.
- Use the *Cited By* feature in PubMed to identify additional studies published on similar topics.
- Check with content experts to ensure relevant studies are not missed.
- Search for *gray literature*—literature that falls outside of the mainstream domains for publication. Some examples include publications that have not been indexed in PubMed or Embase, government organizations’ annual reports, and proceedings of professional meetings that align with your topic. Gray literature can be located using an internet search or Google Scholar or by searching abstracts from relevant professional meetings.
- To be as inclusive as possible in your literature search, avoid limiting searches by date.
- Develop a process for reference management up front (see the Managing References section).
- Save the search strategy and repeat the search periodically to ensure the most recent literature on the topic has been identified, especially prior to presenting the project and/or writing the manuscript.

Organizing and Evaluating Literature Search Results

Finding a method to organize and synthesize the findings of your literature search helps you organize your ideas and find key facts that you may need to reference later. This will help others understand the scope of evidence about the topic and the different types of published studies. You also

need to provide a critique about the relevance and quality of the published evidence. Consider how the study findings can be compared and contrasted and then identify strengths and weaknesses of each study. Categorize papers into different topics or headings using an Excel spreadsheet with headings for study design, methods, key findings, and critiques (see the example in **Table 1-3**).⁷ A second option is to create an annotated bibliography (see the Recommended Readings section for resources on annotated bibliographies).

TABLE 1-3. Sample Excel Spreadsheet with Study Description⁷

Study #1	Study Design	Sample Size	Eligibility Criteria	Study Intervention	Results	Critiques
Smolen JS, 2009	Phase III, randomized, multicenter, double blind, placebo controlled trial	461	Eligible patients were: Aged 18 years or older, active rheumatoid arthritis diagnosis (4+ swollen and 4+ tender joints) × at least 3 months, history of treatment with TNF-α inhibitor.	Patients were randomly assigned in a 1:1:1 ratio to placebo, 50 mg golimumab, or 100 mg golimumab every 4 weeks. Randomization was stratified by study site and baseline methotrexate use.	The proportion of patients who achieved an ACR20 response at week 14 in group I and II were (49/197, 24.9%) and (231/395, 58.5%, p<0.001), respectively.	Must have been on prior treatment.

Managing References

Managing references can be a cumbersome process. Online reference managing programs to aid in this process are plentiful; use one of them to keep track of your references (**Table 1-4**). These programs facilitate the numbering of references, especially when multiple authors provide edits, and ease the process of incorporating reviewer feedback.

TABLE 1-4. Reference Management Resource

Name of Resource	URL Address	Pros	Cons	Free
BibMe	http://www.bibme.org	<ul style="list-style-type: none"> Automatically creates citations. Easily copies and pastes citations into a protocol or manuscript from BibMe program. 	<ul style="list-style-type: none"> Only allows MLA, APA, or Chicago style citations. Must pay a fee to download citations into a Word document. 	Yes (limited)
Cite This For Me	http://www.citethisforme.com	<ul style="list-style-type: none"> Allows entry of relevant information you want to cite and downloads a finished bibliography. Creates references section entries automatically from an article title or a DOI. 	<ul style="list-style-type: none"> Saves files for only 7 days in free version. 	Yes (limited)

TABLE 1-4 continued

Name of Resource	URL Address	Pros	Cons	Free
EndNote	http://endnote.com	<ul style="list-style-type: none"> • Maintains a comprehensive electronic reference list. • Is commonly used; familiar platform to many users. • Offers automatic PDF downloading. • Allows you to cite references as you write a research paper. 	<ul style="list-style-type: none"> • Has a free version with limited capabilities. • Is expensive. • Has a web interface that is not user-friendly. • Has a web sync set-up that is difficult. 	Yes (limited)
Mendeley	https://www.mendeley.com	<ul style="list-style-type: none"> • Is a cloud-based system. • Allows you to manage and share research papers. • Allows you to create a searchable library. • Allows you to cite references as you write a research paper. • Enables easy set-up. • Includes social networking. You can view what other users are reading and citing. • Finds other members with common research interests. 	<ul style="list-style-type: none"> • Can import PDFs but is a challenge. • May have performance issues, such as data syncing. 	Yes (limited)
Paperpile	https://paperpile.com	<ul style="list-style-type: none"> • Requires no account aside from an existing Google account. • Uses existing Google Drive storage and offers an extra 15 MB of storage. • Enables seamless collaborative writing because it is built around Google Drive. 	<ul style="list-style-type: none"> • Requires a Google account. • Supports only Google Chrome browser. • Has a minimal fee. 	Yes, for 30 days
ProQuest RefWorks	https://www.proquest.com/products-services/refworks.html	<ul style="list-style-type: none"> • Enables collaboration with other users. • Downloads PDFs automatically. 	<ul style="list-style-type: none"> • Requires a subscription. 	No
PubMed	http://www.ncbi.nlm.nih.gov/pubmed	<ul style="list-style-type: none"> • Is ideal for identifying biomedical literature. • Has tags with structured words about their content, and major topics help you to get better search results. 	<ul style="list-style-type: none"> • Does not include gray literature. • Searches the key words of an article, so pertinent literature can be missed if using other key words. 	Yes
Zotero	https://www.zotero.org	<ul style="list-style-type: none"> • Adds references from a web browser. • Is open source. • Is good for managing a variety of formats, including web pages. • Automatically imports PDFs and citations. 	<ul style="list-style-type: none"> • Is difficult to track articles that need to be read or followed up. • Has a set-up that may be confusing for new users. 	Yes

APA = American Psychological Association; DOI = digital object identifier; MLA = Modern Language Association; PDF = portable document format

DEVELOPING A STUDY PROTOCOL

The *study protocol* is the document that will guide the conduct of your research. This includes the study's background, research question, objectives, methods, and statistical analysis that will be used as well as outcomes to be measured.⁴ If the protocol is given to another researcher, he or she should be able to understand and replicate your study. The study protocol includes two main components—the introduction or *background* and the *methods*.

Writing the Background

Your literature review will guide and simplify writing the background section of your protocol. This portion of the protocol provides the background and rationale for the research project. The quantity of information needed in your background will vary based on the existing information on the topic. Usually, one to two pages in length is appropriate; however, your institution may prefer less material (e.g., one paragraph) for the IRB protocol (see Chapter 3). Writing a longer background will help you synthesize the current literature and provide a foundation for your manuscript once the study has been conducted. The background section should identify how your study will fill a gap in the literature and build on existing knowledge. The following information is a general overview to writing a background section.⁸

- Answer three questions:
 1. *What is known about your topic?* Describe relevant published literature (i.e., standard of care, guidelines) and provide enough information and context for the reader to become familiar with the topic without getting too broad. For example, a project on primary non-adherence to bisphosphonates should not go into an extensive background on diagnosis and epidemiology of osteoporosis, but should quickly get to the actual problem at hand.
 2. *What is not known?* Outline gaps in the literature, focusing on the gap(s) your study hopes to address.
 3. *Why is your study important?* Explain the importance of the problem or critical barrier to progress in the field that your project addresses and what contribution is expected to be made to close the gaps.
- End with the research question/purpose statement for your study.

Determining the Methods

The next section of the protocol focuses on how you will conduct the project or the methodological approach and study design. This section includes a description of the study site, inclusion and exclusion criteria, participant recruitment process, data collection methods, research instruments, study variables and outcomes, and data analysis approach. These topics will be addressed in the following chapters. Refer to the outline in **Exhibit 1-1** for more information about specific details to include in your study protocol.

WRITING OBJECTIVES, HYPOTHESES, AND OUTCOME MEASURES

Writing Objectives

After you have written your research question and conducted a literature review, you can write research objectives. The objectives form the backbone of the protocol.⁴ The *objective(s)* or *aim(s)*

identify knowledge gaps that the study will fill; identify what the study will achieve; and guide the study design, analysis, and reporting of results. A study can have multiple objectives, but one should be designated as the primary objective. The *primary objective* is the axis around which the study is designed and is key to determining the necessary sample size. Developing tightly focused study objectives is essential to conducting a successful project. Make sure you have one clear primary objective and no more than two or three *secondary objectives*. As a clinician, you have been trained to consider myriad factors in caring for your patients, but as a researcher, you must avoid diverting efforts in too many directions and subsequently losing focus on your primary objective.^{4,6,10}

Refer back to the example study questions stated earlier in the chapter. Example study objectives for those research questions are listed below.

Example 1

- *Primary objective:* Compare 6-month and 1-year changes in CD4 T-cell counts between patients who are receiving a statin compared with those who are not.
- *Secondary objective:* Compare 6-month and 1-year changes in plasma HIV ribonucleic acid counts between the study groups.

Example 2

- *Primary objective:* Compare BP control rates at 6 months in patients enrolled in a pharmacist-managed home BP program to rates in patients receiving usual care (i.e., not enrolled in a program).
- *Secondary objective:* Compare absolute change in systolic and diastolic BP between the two study groups.
- *Secondary objective:* Compare the number of visits required to achieve BP control between the two groups.

Formulating a Hypothesis

A *study hypothesis* is the prediction of the relationship between one or more factors and the problem under study.^{3,4,11} A hypothesis is appropriate for an intervention or evaluative study, but it is generally not applicable for a descriptive study. Hypotheses should be identified prior to the research, and state the specific relationship between the variables you plan to collect and the study outcome variables. You should have at least one hypothesis for each study objective/aim; more than one hypothesis statement can be written, but it is not required.

Hypothesis statements have many different characteristics (**Table 1-5**). First, hypotheses may be stated as a null or alternative hypothesis. A *null hypothesis* posits no difference between two or more groups under examination, whereas an *alternative hypothesis* indicates that you expect to observe a difference between groups. The null hypothesis is commonly used during statistical analysis (see Chapter 5). Second, a hypothesis statement may be nondirectional or directional. A *nondirectional hypothesis* indicates that a relationship between variables is predicted, but the direction of the outcome—higher versus lower, better versus worse, increased versus decreased—is uncertain. A *directional hypothesis* indicates the anticipated direction of the relationship between variables. Lastly, a hypothesis may be associative or causal. *Associative hypotheses* make no judgment regarding causality and suggest the only thing that can be stated with certainty is a change in one variable is associated with a change in the other. In contrast, a *causal hypothesis* is used to infer that a change in one variable (e.g., pharmacist intervention) directly causes a change in an outcome variable.^{3,4,11}

The following hypothesis statements are based on the example research questions in the previous section.

TABLE 1-5. Examples of Hypothesis Statements¹¹

Null versus alternative	<i>Null:</i> There will be no change in short-term clinical outcomes in patients with HIV who receive clinical pharmacist services compared to those receiving usual care.	<i>Alternative:</i> Clinical pharmacist services will improve short-term clinical outcomes in patients with HIV compared to those receiving usual care (i.e., no clinical services).
Nondirectional versus directional	<i>Nondirectional:</i> A social support system influences diabetes outcomes in patients with Type 2 diabetes.	<i>Directional:</i> A social support system improves diabetes outcomes in patients with Type 2 diabetes.
Associative versus causal	<i>Associative:</i> Type 2 diabetes is associated with an increased likelihood of being diagnosed with depression.	<i>Causal:</i> A new drug treatment will result in reductions in fasting blood glucose levels.

HIV = human immunodeficiency virus

Example 1

- *Hypothesis:* Patients with HIV who receive a statin will have improved CD4 T-cell counts compared to patients with HIV who are not taking a statin.

Example 2

- *Hypothesis:* Patients randomized to a pharmacist-managed home BP program will achieve greater BP control compared to patients who are randomized to receive usual care (i.e., no program).

Specifying Study Outcomes (Endpoints)

A *study outcome* is the specific phenomenon you are going to measure to represent your objective.^{3,4} In other words, the primary endpoint should be representative of the primary objective. For a quantitative study, it should be measurable and represented as a number or proportion. Also, the numerator and denominator for how the outcome will be calculated should be determined. A study outcome, for example, could be the proportion of patients in each group who express that they are adherent to their antiretroviral regimen.

The following are examples of study outcome measures using the example research questions.

Example 1

- The proportion of patients with HIV with a CD4 count >350 cells/mm³. (The numerator is the number of patients with a CD4 count >350 cells/mm³, and the denominator is the total number of patients with HIV and a CD4 count measured in the past N number of days.)

Example 2

- The mean change in systolic BP from baseline to 6 months follow-up.

COLLABORATING WITH YOUR RESEARCH TEAM

Research is a collaborative, interdisciplinary process; therefore, you will likely require others' cooperation to complete your project successfully. As a pharmacy resident, you may have been assigned an individual mentor or team of collaborators to work with on your project. In future research endeavors, the need for a team and members to be included on the team will vary. When working

with a team, it is helpful to define the roles and responsibilities of each team member at the beginning of the project. For some projects, the level of involvement for each person will vary with some people taking responsibility for certain tasks or contributing expertise at specific phases of the project (e.g., data analyst extracting data from medical records during data collection phase). In other projects, it may be expected that all team members share the responsibilities throughout the course of the study. Working in a team setting can be rewarding; however, team dynamics can be challenging to manage. It is necessary to maintain open communication and flexibility to prevent potential misunderstandings and ensure that everyone is engaged, as needed. The initial team meeting should include a discussion of the following items:

- Establishment of ground rules for respectful team dynamics
- Identification of who needs to be on the team and their respective roles on the project
- Communication preferences
- Frequency of team meetings
- Authorship and authorship order
- Goal journal submissions



KEY TIPS: Successful Collaborations

- Schedule meetings proactively at regular time intervals, especially while developing the protocol. You can always cancel if meetings are not needed.
- Create an agenda for each meeting.
- Take minutes to record decisions made and work to share; send minutes to participants after the meeting, including action items, who is responsible, and by what deadline.
- Create a central place to store study-related documents (e.g., literature, protocol) so that all team members have access to all documents (e.g., Google Drive, Dropbox, Box).

DEVELOPING A STUDY TIMELINE

To keep your research project on track and check feasibility, it is important to create a timeline. Most residency research projects occur over 1 year, so it is helpful to work backward from the residency completion date to ensure that you allocate time appropriately to complete your study and draft the manuscript or final study report. Allot extra time for IRB approval and data collection in case of unanticipated setbacks. Ask about the IRB meeting dates before starting the research process and target the date you plan to submit your project for review. It is important to know those dates so you can allot time for the approval process or revise your proposal, if needed. Revise the timeline, as required, if setbacks occur, and ensure that all research team members agree about project expectations. Additionally, allow sufficient time (e.g., 1–2 weeks) for mentors to provide feedback about your study implementation plan and documents. Better yet, ask how much notice they need to review documents so that you can accommodate their schedules. Incorporating a plan for publication into the timeline is beneficial, and expectations for publication should be discussed with your research team.⁵ A sample timeline is provided in **Table 1-6**.

TABLE 1-6. Sample Study Timeline¹⁰

Month	Project Goal	Activity	Expected Completion Date	Person Responsible
July	Research question	<ul style="list-style-type: none"> • Review research ideas with preceptor/director. • Identify research question. • Define objectives and hypothesis. • Complete literature search. • Complete human subjects training for IRB. • Identify collaborators/research team. • Determine all permissions/approvals required. 		
Aug	Study protocol	<ul style="list-style-type: none"> • Complete draft of study protocol and share with study team for feedback. 		
Sept–Oct	Institutional Review Board (IRB) submission	<ul style="list-style-type: none"> • Review IRB requirements. • Submit for IRB review. 		
Sept–Oct	Manuscript preparation	<ul style="list-style-type: none"> • Write up background and study methods section of your manuscript. 		
Nov–Jan	Data collection	<ul style="list-style-type: none"> • Determine data sources and data characteristics. • Develop data collection form (i.e., paper, electronic). 		
Jan–Mar	Data analysis	<ul style="list-style-type: none"> • Prepare data for analysis and analyze data. 		
Apr	Research project presentation	<ul style="list-style-type: none"> • Prepare abstract for submission to residency or other professional conference. 		
May–Jun	Manuscript preparation and submission	<ul style="list-style-type: none"> • Identify target journal. • Revise background/methods, as needed, and write results and discussion of manuscript. • Share manuscript draft with study team for feedback. • Revise and submit manuscript for publication.* 		

*It is not unusual for revisions to extend beyond the completion of your residency. Consider building this extra work into your timeline.

A Gantt chart is another tool to aid project planning (**Table 1-7**). A *Gantt chart* includes all research activities in the order they are expected to occur and plots how much time will be allocated for each activity. Consider including additional columns for who is responsible for completing each milestone or additional rows with greater detail for activities that support accomplishing each milestone.¹²

TABLE 1-7. Gantt Chart¹²

Week	1	2	3	4	5	6	7	8	9	10	11	12	Etc
Conduct background/ literature review													
Identify collaborators/ research team													
Determine all permissions/ approvals required													
Develop the study protocol													
Prepare study documents/ instruments													
Obtain IRB approval (or waiver)													
Collect data													
Analyze and interpret data													
Identify target journal for submission and authorship order													
Write up study background and methods													
Write up results													
Write up discussion													
Complete first draft													
Revise draft													
Submit manuscript													

IRB = Institutional Review Board



KEY TAKEAWAYS

- Identify the knowledge gap your study will address by critically evaluating the literature and consulting with colleagues.
- Write the research question using PICOTS and/or FINER criteria.
- Search for existing information on the topic and refine the research question.
- Identify a strategy for referencing the relevant literature.
- Develop a study protocol and outcome measurement strategy.
- Create and implement a study timeline.

CONCLUSION

Implementing a research project begins with writing a well-crafted research question. The PICOTS and FINER criteria are useful tools to guide the development and refinement of your question. Once the question is finalized, formulating a search strategy to uncover relevant literature will guide further refinement of your research question and writing of the study protocol. Regular meetings with your study team to draft and finalize the study protocol, especially the background and methods, will ensure that your project has a strong foundation.

REFERENCES

1. Lipowski EE. Developing great research questions. *Am J Health-Syst Pharm*. 2008;65:1667–1670.
2. Haynes RB. Forming research questions. *J Clin Epidemiol*. 2006;59:881–886.
3. Smith KM. Building upon existing evidence to shape future research endeavors. *Am J Health-Syst Pharm*. 2008;65:1767–1774.
4. Aparasu RR. *Research Methods for Pharmaceutical Practice and Policy*. London, UK: Pharmaceutical Press; 2011.
5. Aparasu RR, Bentley JP. *Principles of Research Design and Drug Literature Evaluation*. Burlington, MA: Jones & Bartlett Learning; 2015.
6. Hulley S, Cummings S, Browner W, et al. *Designing Clinical Research*. 3rd ed. Philadelphia, PA: Lippincott, Williams & Wilkins; 2007.
7. Smolen JS, Kay J, Doyle MK, et al. Golimumab in patients with active rheumatoid arthritis after treatment with tumour necrosis factor alpha inhibitors (GO-AFTER study): a multicentre, randomised, double-blind, placebo-controlled, phase III trial. *Lancet*. 2009 Jul 18;374(9685):210–221.
8. Welch HG. Preparing manuscripts for submission to medical journals: the paper trail. *Eff Clin Pract*. 1999;2:131–137.
9. NEJM Resident 360 Website. Sample research protocol template. https://resident360.nejm.org/content_items/1839. Accessed July 15, 2019.
10. Weber RJ, Cobaugh DJ. Developing and executing an effective research plan. *Am J Health-Syst Pharm*. 2008;65(21):2058–2065.
11. Farrugia P, Petrisor BA, Farrokhyar F, et al. Research questions, hypotheses, and objectives. *Can J Surg*. 2010 Aug;53(4):278–281.
12. Wilson JM. Gantt charts: a centenary appreciation. *Eur J Oper Res*. 2003;149:430–437.

RECOMMENDED READINGS

The references listed below outline how to develop research ideas and a plan as well as write research questions.

Research Planning

- Al-Ryami A. How to prepare a research proposal. *Oman Med J*. 2008;23(2):66–69.
- Weber RJ, Cobaugh DJ. Developing and executing an effective research plan. *Am J Health-Syst Pharm*. 2008;65(21):2058–2065.

- Planas LG. Intervention design, implementation, and evaluation. *Am J Health-Syst Pharm*. 2008;65:1854–1863.
- Smith FJ. *Conducting Your Pharmacy Practice Research: A Step-by-Step Guide*. 2nd ed. London, UK: Pharmaceutical Press; 2010.

Research Questions

- Lipowski EE. Developing great research questions. *Am J Health-Syst Pharm*. 2008;65:1667–1670.
- Smith KM. Building upon existing evidence to shape future research endeavors. *Am J Health-Syst Pharm*. 2008;65:1767–1774.
- Raich AL, Skelly AC. Asking the right question: specifying your study question. *Evid Based Spine Care J*. 2013;4(2):68–71.

Databases

- PubMed (Medline). <https://www.ncbi.nlm.nih.gov/pubmed/>. Accessed March 31, 2020.
- Google Scholar. <https://scholar.google.com>. Accessed March 31, 2020.
- EMBASE. <https://www.elsevier.com/solutions/embase-biomedical-research>. Accessed March 31, 2020.
- International Pharmaceutical Abstracts. <https://www.ovid.com/product-details.109.html>. Accessed March 31, 2020.
- Cochrane Collaboration. <http://www.cochrane.org/>. Accessed March 31, 2020.
- ClinicalTrials.gov. <https://clinicaltrials.gov/>. Accessed March 31, 2020.

Web Resources

- ASHP Foundation. Essentials of a Practice-Based Research for Pharmacists. <https://www.ashpfoundation.org/research>. Accessed March 31, 2020.
- Gantt Charts. <https://www.teamgantt.com>. Accessed March 31, 2020.
- Annotated Bibliography Guide. <http://guides.library.cornell.edu/annotatedbibliography>. Accessed March 31, 2020.
- Annotated Bibliography Example. http://www.ucdenver.edu/academics/colleges/pharmacy/AcademicPrograms/clinical-pharmacy-toolkit/Documents/annotatedbibliography_clinical-pharmacy-integration-into-pcmh.pdf. Accessed March 31, 2020.

EXHIBIT 1-1. Study Protocol Outline⁹

- I. Title Page
 - A. Protocol title, principal investigator, co-investigators, date
 - B. Affiliations for all investigators
- II. Abstract (optional)
 - A. Brief one-page summary of proposed research; this section may be shorter depending on institution requirements
- III. Background and Rationale
 - A. Significance of research question
 - B. Last sentence should be the study purpose/main research question
- IV. Study Objectives (Aims)/Hypothesis
 - A. Primary objective
 - B. Secondary objective(s)
- V. Methods
 - A. Study design (e.g., prospective, retrospective, randomized, cohort); include statement that IRB approval will be obtained
 - B. Study setting and population
 - i. Brief description of study setting
 - ii. Inclusion/exclusion criteria
 - C. Study procedures
 - i. Describe subject identification and/or recruitment
 - ii. Describe informed consent process (written or verbal) (if applicable)
 - iii. Describe subject enrollment process (if applicable)
 - iv. Describe procedures for intervention, methods for blinding, randomizing, detailed description of what will occur once subject is deemed eligible for study (if applicable)
 - v. Describe criteria for assignment to study versus control group (exposure)
 - vi. Describe data collection, including all required data elements, sources, date ranges, and storage
 - D. Outcome measures
 - i. Primary outcome
 - ii. Secondary/tertiary outcomes
- VI. Analytical Plan
 - A. Sample size calculation (if applicable)
 - B. Methodology for measuring and evaluating each outcome
 - C. Statistical analysis plan
- VII. Study Timeline
- VIII. References
- IX. Appendixes (separate documents)
 - A. Data collection tools, consent forms, patient information letters, surveys, etc.

IRB = Institutional Review Board

