Developing and executing an effective research plan

Article *in* American journal of health-system pharmacy: AJHP: official journal of the American Society of Health-System Pharmacists · December 2008

DOI: 10.2146/ajhp070197 · Source: PubMed

2 authors:

Robert James Weber
Northwestern University
98 PUBLICATIONS **1,746** CITATIONS

SEE PROFILE

Daniel Cobaugh
American Society of Health-System Pharmacists
97 PUBLICATIONS **4,171** CITATIONS

SEE PROFILE

Developing and executing an effective research plan

ROBERT J. WEBER AND DANIEL J. COBAUGH

Purpose. Practical approaches to successful implementation of practice-based research are examined.

Summary. In order to successfully complete a research project, its scope must be clearly defined. The research question and the specific aims or objectives should guide the study. For practice-based research, the clinical setting is the most likely source to find important research questions. The research idea should be realistic and relevant to the interests of the investigators and the organization and its patients. Once the lead investigator has developed a research idea, a comprehensive literature review should be performed. The aims of the project should be new, relevant, concise, and feasible. The researchers must budget adequate time to carefully consider, develop, and seek input on the research question and objectives using the principles of project management. Identifying a group of individuals that can work together to ensure successful completion of the proposed research should be one of the first steps in developing the research plan. Dividing work tasks can alleviate workload for individual members of the research team. The development of a timeline to help guide the execution of the research project plan is critical. Steps that can be especially time-consuming include obtaining financial support, garnering support from key stakeholders, and getting institutional review board consent. One of the primary goals of conducting research is to share the knowledge that has been gained through presentations at national and international conferences and publications in peer-reviewed biomedical journals.

Conclusion. Practice-based research presents numerous challenges, especially for new investigators. Integration of the principles of project management into research planning can lead to more efficient study execution and higher-quality results.

Index terms: Methodology; Pharmacists; Quality assurance; Research

Am J Health-Syst Pharm. 2008; 65:2058-65

Pharmacists play an important role in the development of evidence that supports safe and effective medication use.[1-3] This evidence comes from numerous research domains including practice-based investigations of the medication-use process, biopharmaceutical sciences research, and pharmacoeconomic and pharmacoepidemiologic studies.[4] Clinical pharmacists, in both academic and nonacademic settings, often pursue studies that will help them answer important research questions that are identified in their practice. Successful completion of these studies is often difficult because of the complexities of undertaking rigorous research in the patient care setting.[5-9] For new investigators with limited research experience, conducting rigorous practice-based research can be a challenge.

Successful execution of practice-based research relies on development and execution of a well-organized research plan. The key components of a research plan include the research question and specific aims, methods and research implementation, data management and analysis, and presentation and publication of findings.

Project management is a discipline that combines concepts from a variety of fields (e.g., engineering, construction) and focuses on organizing and managing resources to complete a project within a defined scope and time period.[10] Activities necessary to effectively plan and execute a project include project team establishment, defining the project scope, timeline development and progress tracking, approvals and endorsements by the required institutional committees and stakeholders, resource alloca-

ROBERT J. WEBER, M.S., is Chief Pharmacy Officer, University of Pittsburgh Medical Center; and Associate Professor and Chair, Department of Pharmacy and Therapeutics, University of Pittsburgh School of Pharmacy, Pittsburgh, PA. DANIEL J. COBAUGH, PHARM.D., FAACT, DABAT, is Senior Director, Research and Operations, Research and Education Foundation, American Society of Health-System Pharmacists, Bethesda, MD.

Address correspondence to Dr. Cobaugh at the Research and Education Foundation, American Society of Health-System Pharmacists, 7272 Wisconsin Avenue, Bethesda, MD 20814 (dcobaugh@ashp.org).

 1079-2082/08/1101-2058$06.00.
DOI 10.2146/ajhp070197

The Research Fundamentals *section comprises a series of articles on important topics in pharmacy research. These include valid research design, appropriate data collection and analysis, application of research findings in practice, and publication of research results. Articles in this series have been solicited and reviewed by guest editors Lee Vermeulen, M.S., and Almut Winterstein, Ph.D.*

tion, directing project activities, managing problems, and ensuring quality control.

Applying the principles of project management to the research plan elements (Figure 1) can lead to a more organized and effective research approach. It is critical that the project's scope is clearly defined to produce a high-quality product; otherwise, resources and effort will be wasted on poor results.

This article describes practical approaches to successful implementation of practice-based research by integrating the components of the research plan and the principles and practices of project management.

Project scope, research question, and specific aims

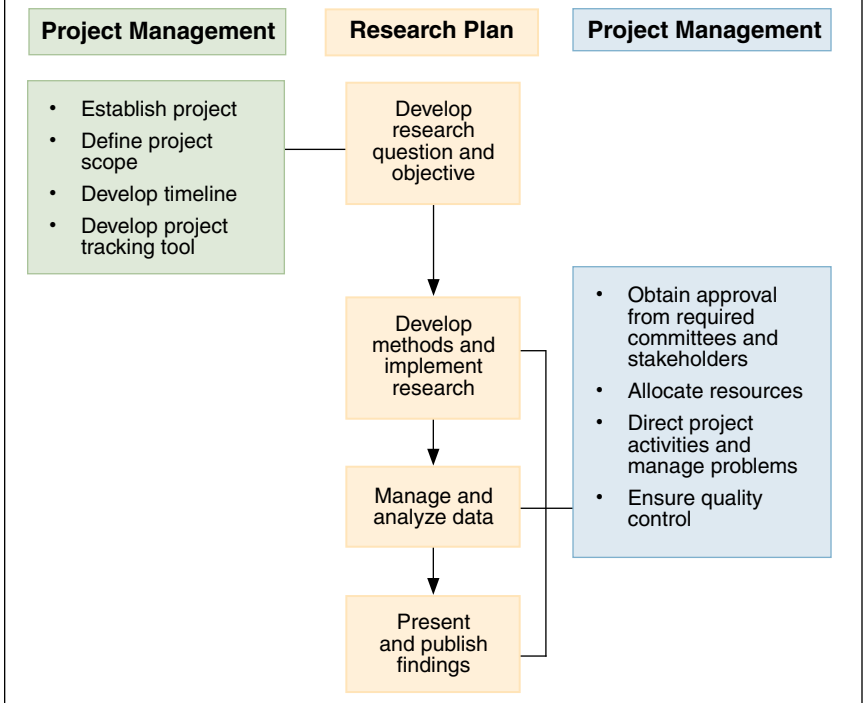
In order to successfully complete a research project, its scope must be clearly defined. The research question and the specific aims or objectives should guide the scope of the study. For practice-based research, the clinical setting is the most likely source to find important research questions. The research idea should be realistic and relevant to the interests of the investigators and organization and its patients. Establishing practice relevance is critical to developing a strong foundation for the project.

Once the lead investigator has developed a research idea, a comprehensive literature review should be performed in order to develop a thorough understanding of existing evidence related to the topic. Formulating the research question and specific aims is the most important and difficult part of the research plan.[11] A review of the literature will ensure that the investigators do not duplicate questions that have been effectively answered and will provide insights into important unanswered questions related to the focus area.

Specifically, the aims or objectives of the project should be new, relevant, concise, and feasible.[12] Focusing on objectives can be a difficult task but can be accomplished through a well-written research question. A common error in research design, especially among new investigators, is the inclusion of too many objectives. Limiting the number of objectives allows the researchers to devote adequate time to effective data collection and analysis.[11] The National Institute of Allergy and Infectious Diseases provides web-based guidance on writing specific research aims.[13]

The researchers must budget adequate time to carefully consider, develop, and seek input on the research question and objectives using the principles of project management. For a one- to two-year project, approximately two to three months should be devoted to synthesizing and defining the research question and the specific aims. As part of this process, the lead investigator should consider developing a formal presentation to present the literature review, research question, and objectives to experienced researchers and clinicians. Significant planning is necessary to coordinate these types of review sessions, but they can provide important insights and lead to higher-quality research questions and objectives. Leaders in departments of pharmacy, academic departments, and residency programs should consider establishing an organized forum through which new investigators can obtain feedback for every step of the research plan, from the development of the research question to the completion

Figure 1. Relationship between the research plan and the principles of project management.



of a manuscript. For example, at the University of Pittsburgh's residency research training program, regular research conferences are held that involve residents and faculty and ensure the development of a relevant and clear research idea to improve the probability of project completion and peer-review publication.[14]

Project team establishment

High-quality research is most often the result of team, not individual, efforts.[15] Identifying a group of individuals that can work together to ensure successful completion of the proposed research should be one of the first steps in developing the research plan. It is important to identify and engage individuals who have the skills and expertise needed to complete the research. Practice-based research usually involves several types of professionals and is well served by the involvement of a multidisciplinary research team. The involvement of coinvestigators has several other advantages as well. Diverse perspectives are considered throughout the study, and individuals with limited research training can learn through participation on a research team. Also, working as a coinvestigator on a project enhances professional development for new investigators, particularly if the work results in a peer-reviewed publication. Dividing work tasks can also alleviate workload for individual members of the research team, which can increase the odds of successful completion of the research.

During development of the research team, new investigators should identify a mentor who can guide them through each of the steps of the research process from idea generation to final submission of a manuscript for publication. The mentor should share an interest in the area of research. It is important that the new investigator and the mentor have a collegial and collaborative relationship.

A biostatistician or an individual with knowledge and experience in biostatistics is a critically important member of the team.[16-18] The biostatistician should be consulted regarding sample size calculations and selection of appropriate statistical tests for studies that use inferential statistics to compare groups. The biostatistician should be involved in the data analysis to ensure that the data are analyzed and interpreted correctly. The more experienced biostatistician should also be able to contribute to the design of a rigorous study. It is important to determine early in the planning process how many hours of biostatistics support will be needed to complete the study and to garner the financial resources required to support the biostatistician. Good statisticians are often in very high demand in research institutions; therefore, it is important to mutually agree on delivery of research data and completion of work.

One of the biggest frustrations for new investigators is engaging in technical dialogue with the statistician. When preparing for the first meeting with the biostatistician, new investigators, especially those with limited biostatistics skills, should consider reviewing a primer such as *Statistics at Square One*.[19]

The roles and responsibilities of research team members should be defined early in the process. There should also be early agreement on the process that will be used to develop an author structure for the abstract and manuscript that emanate from the proposed research.

Research timeline and progress tracking

The development of a timeline to help guide the execution of the research project plan is critical in the effective coordination of the necessary steps in the research process.[20] The ASHP Research and Education Foundation offers a sample research timeline.[21] Once a comprehensive timeline has been established, the research team should develop a mechanism to track the completion of the steps included in the research process.

The establishment of a comprehensive timeline provides the researchers with an opportunity to identify all of the major tasks that will be required to successfully complete the proposed research. The timeline often may further develop when the research question, specific aims, and methods are generated. It is critical to break the research plan into steps that can be easily accomplished when planning the timeline. The plan is usually divided into a cluster of tasks that include

- Identifying the investigator team,
- Completing a thorough review of the existing evidence regarding the research idea,
- Generating the research question and specific aims,
- Developing the methods,
- Developing the data management plan,
- Identifying the resources required to complete the research,
- Considering the logistics necessary for execution of the methods,
- Educating stakeholders and garnering support from the involved departments or organizations,
- Pursuing institutional review board (IRB) review,
- Ordering equipment and supplies,
- Training individuals to conduct the research,
- Conducting the study,
- Entering and analyzing data, and
- Developing a plan for presentation and publication of the results.

There are a number of steps in the research process that can be especially time-consuming, challenging, and sometimes frustrating to the research team as it works to implement the research plan. Examples include obtaining financial support, garnering support from key stakeholders, and

IRB review. Determining financial resources needed to support the proposed research is important. If external grant support is required, this can slow, and in some cases prevent, execution of the research. Getting the involved departments and individuals to participate is also key to successful practice-based research. For practice-based research, along with obtaining IRB approval, investigators will need to obtain approval and financial support from several institutional departments and groups. Securing departmental and institutional support for a potential research project is critical to the project's success. For example, if a study will involve patients in the emergency department (ED), investigators need to obtain approval from ED leadership and participation from the emergency physicians and nurses. Most practice-based research is interdisciplinary; therefore, the support of other health care professionals who are affected by the research is necessary.

New investigators should plan to invest significant amounts of time to educating key stakeholders about the proposed research project and seeking support from those departments and individuals. Adequate time should also be allocated for the IRB process. Given the nature of practice-based research, it is often necessary to determine whether the proposed work is research or quality improvement, which could be exempt from IRB review. This determination should be made by the IRB because several biomedical journals now require evidence of IRB approval as part of the publication process.

If the study design involves recruitment of research subjects, this process will have a major impact on the timeline. In the initial planning, the investigators need to carefully consider the amount of time required for recruitment based on the availability of potential subjects. The research team should also be prepared to modify the timeline if recruitment does not proceed as expected.

One of the primary goals of conducting research is to share the knowledge that has been gained through presentations at national and international conferences and publications in peer-reviewed biomedical journals.[22-24] Identification of appropriate meetings and journals should be included in the research timeline. Abstract submission deadlines and timing of conferences should be integrated into the plan. The research team should plan to set aside significant resources to prepare and submit the abstract and manuscript. It is highly recommended that the development of the manuscript be done while conducting the proposed research. If the background and methods can be shaped into the format of a manuscript, the research team will have completed a significant portion of the manuscript in advance. This can speed up the manuscript preparation process. Once data collection and analysis have been completed, results, discussion, and conclusions can be inserted into the manuscript that is already in progress. If the research plan proceeds as expected, the manuscript should be submitted within two to three months after completing the data collection and analysis.

An effective research plan tracking system can be maintained in a simple word processing table or spreadsheet. Key elements of the tracking form include all steps of the research process, projected completion dates for each step, status information for each step, and documentation of actions required for completion of the research tasks and protocol modifications. Designing a format that enables the investigators to identify areas in which the plan is not progressing is critical. For example, inclusion of a status column will enable the investigators to easily determine if a research task is progressing, lagging, or completed. Detailed documentation of actions related to completion of each step in the research plan is also important. It is especially important to keep documentation of changes in methods and reasons for those modifications. Placing the plan on a shared data drive on a computer network can help the research team stay updated on the progress of the research activities. The tracking tool should be used to guide discussions at regular research meetings.

Methods and instrument development

Similar to the development of the research question and specific aims, adequate time should be allocated to the selection of a research design and the development and review of the methods. Learning the advantages and disadvantages of different study designs could be helpful to new investigators as they make decisions about their study.[25]

When developing the methods, the investigator should list each step required to undertake the proposed research. This list will provide a strong framework for the methods section. The literature is an excellent source of guidance for methods. Studies that addressed similar research questions or research in the same area can provide critical information about past successes and failures as the study methods are designed. The research team and uninvolved experienced researchers should review the methods draft to address flaws, feasibility issues, and missteps. When conducting practice-based research, it is helpful to obtain a methods review from experienced clinicians who work in the practice area where the research will occur. These individuals can provide valuable insights into logistics issues that might impact the feasibility of completing the proposed research. Formal presentation of the methods to a group that includes the research team and other experienced researchers and clinicians can lead to valuable insights that can ultimately

strengthen the methods. Review of data collection tools and study instruments by these individuals can also be beneficial. Existing literature is an excellent source of validated study instruments.

Data management and analysis plans

The data management and analysis plans are critical components of the research plan.[26] The data management plan should address the selections of database platforms, data elements to be collected, data entry, processes for ensuring data quality, and data security. The data elements that are collected should be limited to those necessary to answer the proposed research question. In this era of health information privacy, collecting more data than needed is not appropriate and may violate a patient's privacy rights.

The investigator team must determine how the data will be analyzed and whether descriptive statistics, inferential statistics, or both will be used. A biostatistician should be consulted early in the design phase. Many new investigators make the fatal error of consulting with the biostatistician when data collection is complete and analysis is required. This can result in method flaws or inadequate data collection and can prevent useful analysis of the data.

Endorsement by the required institutional committees and stakeholders

Review by and approval of the IRB are imperative to ethical research conduct, to protection of human subjects, and to ensure compliance with federal regulations that govern research. In the early stages of project planning, the investigators should incorporate IRB processes into the research timeline. This provides a good opportunity for new investigators to become acquainted with the IRB's procedures and review requirements.[27] A list of useful web-based resources for information related to IRB review and protection of human subjects is provided in the appendix.

One of the most important steps that a new investigator can take regarding the IRB process is to schedule a meeting with an IRB representative to learn about the institution's IRB processes. This can result in the development of long-term collegial relationships that enable investigators to facilitate IRB review and approval.

As the methods for the proposed study are being developed, the research team should assess the impact on different departments within the institution. After this assessment has been completed, an organized plan for obtaining support from each of the involved departments should be developed and integrated into the timeline and tracking process. This plan should also address logistical issues that are critical to the execution of the study. For example, will the pharmacists need education regarding the research protocol? Should certain departmental research committees review the study protocol before IRB submission? If a medical records review is involved, have all patient privacy implications (as outlined in the Health Insurance Portability and Accountability Act) been addressed with the medical records department before IRB submission?

The study methods should be revised as required to reflect the logistics discussions that occur. Efforts to engage other departments will positively impact execution of the study and will be beneficial as the study is being reviewed by the IRB and by the institution's office of grants administration should a grant submission occur. In cases in which the research is not funded by a grant organization, approvals may be necessary from other funding sources (e.g., hospital, university) for staff and faculty time and supplies related to a specific research project. Obtaining approval and participation can take considerable time and effort and must be considered when developing the research timeline and tracking document. Research projects that do not obtain the required institutional approvals and participation are at risk for not being completed.

Resource allocation

As each step of the research plan is formulated, resources needed to accomplish these specific steps must be determined and allocated. Resources include the necessary materials and personnel to conduct rigorous research. Required resources can be somewhat controlled during establishment of the research question and specific aims. A common mistake that new investigators make is developing research questions that can be only answered with large trials that demand significant financial resources. It is unlikely that a new investigator will be able to secure the financial resources required to undertake research of this magnitude. This is a major threat to the feasibility of completion of the proposed research. The methods, as well as the research question, are key to determining the resources required to successfully undertake the proposed study. Investigators should carefully review each step in their methods to determine the associated costs. This should include an analysis of the human resources required to complete the study.

Pilot testing of the proposed methods to get a "real-life" view of necessary resources is an important step in determining the actual costs of the study. For example, if a research project involves review of patient medical records, a series of records should be reviewed to determine the time necessary to collect the required information. Survey research is another example of the importance of pilot testing a study to adequately project resource needs. The survey can be conducted in a pilot group to determine the amount

of staff time required for completion. This pilot test can also provide helpful insights into the usefulness of the survey instrument.

Grant submissions

For most new investigators, the grant submission process can be overwhelming. However, the quality of the grant application will have a major impact on funding decisions. Organization is critical to the research process. New investigators who are interested in pursuing grant funding should read the application and make a list of each step required for completing the application. This should be followed by a discussion between the new investigator and the mentor that focuses on a timeline for developing the application. Although the tutorial on grant writing provided by the National Institute of Allergy and Infectious Diseases is geared toward developing a National Institutes of Health grant submission, it still provides valuable information for any grant writer.[28] The quality of the application can be greatly enhanced by seeking review from experienced researchers who are not involved with the study.

One of the most common mistakes made by grant applicants is underestimating the time needed to complete each institutional step required for a successful grant application. Investigators often underestimate the time needed for review by the investigator team, submission of the protocol and consent to the IRB, requests for letters of support, and submission of the entire grant application to the institution's grants management office. Many new investigators are often unaware that a grants administration process exists in their institution, but this is an important process and should not be overlooked. All grant applications should be submitted to the grants administration office before submission to the funding agency. The research team should allow adequate time for the grants administration process to be completed. If this process is overlooked, it can delay or prevent submission of the grant. If the research team determines that a grant will be pursued, the new investigator and research mentor should meet with a grants officer early in the process to learn about the institution's policies and procedures related to grants administration.

Research implementation

Directing activities. The principal investigator (PI) is responsible for directing the activities required for completing the research. In the case of new investigators, this is an example of an activity that should be shared with the research mentor who is acting as the senior investigator for the proposed study. The key to effectively directing activities in research is based on the ability of the PI to clearly define and communicate the research tasks and establish expectations for completion. Oversight of the research activities begins with establishment of the research team and continues through publication of the manuscript. The research timeline is an important tool that is available to the PI to track and direct the research activities. Overall, it is the responsibility of the PI to ensure that all activities associated with the research are completed in accordance with the timeline established by the research team. The PI has responsibility for ensuring that research instruments are developed and tested and the research is conducted in accordance with IRB-approved methods. Clear communication with the research team and all stakeholders who are involved in the research is key to the PI's ability to direct the study activities. The PI should also be the point of contact for all communication related to the research (e.g., communication with the research team, the IRB, and other institutional departments). The PI is also responsible for all documentation associated with the study including maintaining a clear record of decisions regarding study execution, reporting human subject events, renewing IRB approvals, and reporting to grantors.

Managing problems. Most research projects do not go as planned. There will be issues and problems that need to be rectified in order to complete the study. The best defense against problems is proper planning. If a problem occurs, the best way to address it is through a proactive transparent approach and effective communication. An example of problem management is working with the IRB when there are questions as to whether a project qualifies as research or as a quality-improvement study because the approval process for these types of studies is different in most institutions. The researcher needs to seek input from the IRB and others (e.g., risk management department) to decide the most appropriate course of action. After a decision is made, the researcher then needs to communicate the reasons for the decision to provide full disclosure on the conduct of the research.

Ensuring quality control

In order to protect human subjects and ensure collection of quality data, the research methods need to be followed with precision. Precise execution is critical to the integrity of the research results. As research is published, the authors of the paper assume responsibility for its entire contents. The lead author assumes a majority of the responsibility, but the entire research team is culpable for any research ethics violations. An effective way to ensure adherence with the study methods and the collection of quality data is to implement quality control in the research plan.[26] The quality-control process may be ongoing or episodic. An example of an ongoing quality-control activity is duplicate data entry in order to prevent data entry errors. For episodic

quality control, if a study employs a direct observation technique to identify occurrence of medication errors, for example, the lead investigator should randomly shadow the observer to ensure that the research methods are properly employed.

Presentation and publication of findings

Plans for presentation and publication of the research findings should be considered as the research plan and timeline are being developed. For example, the investigators will probably have a sense of what scientific meeting would be most appropriate for presenting the findings. A projected abstract submission deadline should be incorporated into the timeline in order to ensure that there is coordination between the time frames for data analysis and abstract submission.

Presentation of research findings in a public forum is often intimidating for new investigators.[22-24] New investigators need to develop the ability to concisely present study findings in as little as 10–15 minutes. The presenter may choose to present only the most important objectives and research results in order to accomplish this. A short platform presentation does not allow for a lengthy discussion of the background for the research. In preparing the background slides, there may be time to present only one or two points along with the study objectives. All additional data should be included in a separate slide set and provided to the audience upon request.

Another challenge is incorporating complex study methods into a few slides. Diagrams are very effective in providing the audience with an overview of the study methods. Graphic presentation of results is most effective. When presenting results, busy tables that the audience will not be able to read or fully grasp in a short period of time should be avoided. During a brief platform presentation, there will not be sufficient time for an extensive discussion of the findings. Investigators should remember to take time to discuss the limitations of their study; otherwise, the audience will point these limitations out during the question and answer session. One of the most important steps that a new investigator can take in preparing for the first platform presentation is to schedule a practice session in which colleagues can provide constructive feedback. In addition, sending the presentation for peer review to other colleagues may also provide useful and productive changes.

There may be specific biomedical journals that are being considered, but the final decision regarding submission of a manuscript may be delayed until the investigators have an understanding of the strength of their findings. It is important to establish a timeline for the manuscript submission process so that this phase of the research plan does not languish. Many new investigators, and even seasoned researchers, become overwhelmed by the process of submitting a manuscript to a biomedical journal. Successful manuscript development requires an organized approach and an understanding of the various sections of the paper (i.e., introduction, methods, results, discussion, conclusions).[29] A key first step is reviewing the desired journal's author instructions in order to understand submission requirements. Also, as mentioned, starting early will allow for a more manageable process. The background and methods sections can be written even before the study results are available. The investigator team should make an early determination regarding the order of authors for any manuscripts that emanate from the research. While the order may change as the research progresses and the degree of each individual's contributions become more apparent, early determination of the first, second, and last or senior author positions can help avoid misunderstandings.

Conclusion

Practice-based research presents numerous challenges, especially for new investigators. Integration of the principles of project management into research planning can lead to more efficient study execution and higher-quality results.

References

1. Kaboli PJ, Hoth AB, McClimon BJ et al. Clinical pharmacists and inpatient medical care: a systematic review. *Arch Intern Med.* 2006; 166:955-64.
2. Sanghera N, Chan PY, Khaki ZF et al. Interventions of hospital pharmacists in improving drug therapy in children: a systematic literature review. *Drug Saf.* 2006; 29:1031-47.
3. Guchelaar HJ, Colen HB, Kalmeijer MD et al. Medication errors: hospital pharmacist perspective. *Drugs.* 2005; 65: 1735-46.
4. Murray MD, Callahan CM. Improving medication use for older adults: an integrated research agenda. *Ann Intern Med.* 2003; 139:425-9.
5. Wade K, Neuman K. Practice-based research: changing the professional culture and language of social work. *Soc Work Health Care.* 2007; 44:49-64.
6. Chen DT, Worrall BB. Practice-based clinical research and ethical decision making—part II: deciding whether to host a particular research study in your practice. *Semin Neurol.* 2006; 26:140-7.
7. Chen DT, Worrall BB. Practice-based clinical research and ethical decision making—part I: deciding whether to incorporate practice-based research into your clinical practice. *Semin Neurol.* 2006; 26:131-9.
8. Wolf LE, Walden JF, Lo B. Human subjects issues and IRB review in practice-based research. *Ann Fam Med.* 2005; 3(suppl 1):S30-7.
9. Cobaugh DJ, Spillane LL, Schneider SM. Research subject enroller program: a key to successful emergency medicine research. *Acad Emerg Med.* 1997; 4:231-3.
10. Berkun S. The art of project management (theory in practice). Cambridge: O'Reilly Media; 2005:1-23.
11. Kwiatkowski T, Silverman R. Research fundamentals: II. Choosing and defining a research question. *Acad Emerg Med.* 1998; 5:1114-7.
12. Cummings SR, Browner SW, Hulley SB et al. Conceiving the research question. In: Hulley SB, Cummings SR, eds. Designing clinical research. 1st ed. Baltimore: Williams & Wilkins; 1988:12-7.
13. National Institute of Allergy and Infectious Diseases. National Institutes of

Health. Research plan. www.niaid.nih.gov/ncn/grants/cycle/part05.htm (accessed 2008 Aug 4).
14. University of Pittsburgh School of Medicine. The Department of Psychiatry. Residency training. www.wpic.pitt.edu/education/residency_training/default.htm (accessed 2008 Aug 7).
15. Choi BC, Pak AW. Multidisciplinarity, interdisciplinarity, and transdisciplinarity in health research, services, education and policy: 1. Definitions, objectives, and evidence of effectiveness. *Clin Invest Med.* 2006; 29:351-64.
16. Deutsch R, Hurwitz S, Janosky J et al. The role of education in biostatistical consulting. *Stat Med.* 2007; 26:709-20.
17. Clive J. Biostatistical consultation for dental research. *Dent Clin North Am.* 2002; 46:137-55.
18. Lesser ML, Parker RA. The biostatistician in medical research: allocating time and effort. *Stat Med.* 1995; 14:1683-92.
19. British Medical Journal. Statistics at square one. www.bmj.com/collections/statsbk/2.html (accessed 2008 Aug 4).
20. Lewis LM, Lewis RJ, Younger JG et al. Research fundamentals: I. Getting from hypothesis to manuscript: an overview of the skills required for success in research. *Acad Emerg Med.* 1998; 5:924-9.
21. ASHP Foundation. Research resources: establishing timelines. www.ashpfoundation.org/MainMenuCategories/ResearchResourceCenter/ResearchResources/TabularTimeline.aspx (accessed 2008 Aug 7).
22. Estrada CA, Patel SR, Talente G et al. The 10-minute oral presentation: what should I focus on? *Am J Med Sci.* 2005; 329:306-9.
23. Mayer K. Fundamentals of surgical research course: research presentations. *J Surg Res.* 2005; 128:174-7.
24. Cina SJ, DiMaio V, Smialek JE. Suggested guidelines for platform presentations. *Am J Forensic Med Pathol.* 1998; 19:54-6.
25. Centre for Evidence Based Medicine. EBM tools: study designs. www.cebm.net/index.aspx?o=1039 (accessed 2008 Aug 7).
26. Hulley SB, Cummings SR. Implementing the study: pretesting, quality control, and protocol revisions. In: Hulley SB, Cummings SR, Browner WS, eds. Designing clinical research. 2nd ed. Baltimore: Williams & Wilkins; 2001:259-70.
27. Office for Human Research Protections. Department of Health and Human Services. Guidance on written IRB procedures. www.hhs.gov/ohrp/humansubjects/guidance/irbgd107.htm (accessed 2008 Aug 7).
28. National Institute of Allergy and Infectious Diseases. National Institutes of Health grant cycle: "all about grants" tutorials. www.niaid.nih.gov/ncn/grants (accessed 2008 Aug 7).
29. Welch HG. Preparing manuscripts for submission to medical journals: the paper trail. *Eff Clin Pract.* 1999; 2:131-7.

Appendix—Suggested web-based resources for information about institutional review board requirements and protection of human subjects

Department of Health and Human Services. Code of Federal Regulations. Title 45, public welfare.; part 46, protection of human subjects. http://www.hhs.gov/ohrp/documents/OHRPRegulations.pdf

- Section 46.101 contains information on the types of studies that are exempted from review.
- Section 46.110 contains a list of research categories that the Secretary of the Department of Health and Human Services has determined may be reviewed through an expedited review procedure.

Department of Health and Human Services Office for Human Research Protections. Categories of research that may be reviewed by the institutional review board (IRB) through an expedited review procedure. http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm

U.S. Department of Health and Human Services Public Health Service Grant Application (PHS 398). http://grants.nih.gov/grants/funding/phs398/phs398.pdf

- Part II contains supplemental instructions for preparing the protection of human subjects section of the research plan.