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Clinical Research During Internal Medicine Residency: A Practical Guide

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Clinical research opportunities attract physicians-in-training to internal medicine, and research remains a core mission of many residency programs. Curiosity, critical thinking, and humanitarianism define the medical profession and are the driving forces behind research. Although programs seek these attributes in applicants, nurturing research interest is often displaced by the primacy of patient care during residency.[1] In 1998, recognizing a decrease in clinical research grant submissions, the National Institutes of Health (NIH) recommended several policy changes to encourage research by young physician investigators.[2] The Accreditation Council for Graduate Medical Education (ACGME) stipulates that internal medicine residents must "participate actively in a scholarly activity," such as original research, writing of a review article, presentation at a scientific society meeting, or other activities that promote a spirit of inquiry and scholarship.[3] In a survey of internal medicine program directors, Levine and colleagues found that in both university and non-university programs, approximately 20% of physicians-in-training fulfill the scholarly activity requirement by conducting hypothesis-driven research.[4]

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Given the importance of resident scholarly activity, including research, this article describes a practical approach for program directors, faculty mentors, and residents to optimize the clinical research experience. The focus is on clinical research because the time required to conduct a basic science project is often prohibitive. This framework is most applicable to traditional internal medicine programs rather than specialized research tracks such as the American Board of Internal Medicine Clinical Investigator Pathway. Three phases of the resident research continuum are described: a *preparatory phase*, an *investigatory phase*, and a *synthesis phase*, as defined by tasks before, during, and after a traditional research elective block (Table 1).

WHY PERFORM RESEARCH DURING RESIDENCY?

Previous work demonstrates that a structured research curriculum can substantially enhance scholarly success for physicians-in-training and their mentors.[5-7] Hayward and Taweel surveyed alumni of an internal medicine residency program with a research requirement.[8] Most alumni felt their research projects were a valuable learning experience; in fact, no other residency program component was rated higher than that of the research project.[8] A similar survey of family medicine residents revealed a greater appreciation for evidence-based medicine among those who had themselves received research training.[9] Recently, a survey of residents who presented at the 2002 American College of Physicians (ACP) Annual Session revealed that a ma-

Table 1 The Three Phases of Resident Research

Time Line		
−12 months	1-2 month(s) (The research elective)	+12 months
Preparatory phase	**Investigatory Phase**	**Synthesis phase**
Selecting a topic and formulating a question	Creating a database	Statistical analysis
Finding a mentor	Data collection	Presentation and publication
Utilizing existing institutional resources	Storage and management of data	Reflection on research interest
Study design and statistical consultation		
Institutional review board submission		

jority of residents thought research should be required during residency.[10] The absence of a research curriculum was identified as a barrier to completion of a research project by 44% of those surveyed.[10] Although these data are limited, they suggest that residents do find the research experience rewarding. However, in a survey of internal medicine program directors in 1996, Alguire and colleagues demonstrated that only 37% of programs had an organized and comprehensive research curriculum.[11] A more recent survey indicated that nonuniversity programs are more likely than university programs to have a structured research curriculum and to require research as part of residency training.[4] In a systematic review of published resident research curricula, Herbert and colleagues concluded that a lack of detailed developmental information and few meaningful evaluation methods were barriers to effective implementation.[12]

WHO SHOULD DO RESEARCH DURING RESIDENCY?

Residency is an important time for exploration of personal and professional interests as well as self-discovery. Common reasons for residents to pursue research include intellectual curiosity, exploration of potential career options within academia or a subspecialty, completion of a program requirement, and development of credentials, especially while applying for competitive fellowships. In 2003, 66% of senior internal medicine residents applied to subspecialty fellowships.[13] In a survey of internal medicine residency alumni, 31% reported that their research projects influenced their career choices, such as pursuing a career in academia versus a career in private practice.[8]

Not every resident should be required to perform original research during residency. Scholarly activity, as defined by the ACGME, can take many forms including: a continuous quality improvement project, a literature review, a meta-analysis, or a case presentation at an academic society conference. If feasible, internship is the ideal time to start the preparatory phase of research. Benefits of intern involvement include early exploration of the academic career path and greater total time to complete the project. Because most residents apply to subspecialty fellowship during the second postgraduate year, starting a research project during internship can be crucial to a successful application. The biggest challenge is limited nonclinical time during internship. Other drawbacks include the potential for interns to feel overwhelmed or to rush into commitments before taking the time to explore time constraints and career preferences. Programs may wish to develop a standardized research curriculum by devoting 1 to 2 half-days per week of an intern ambulatory block to a supervised discussion of study design, human subjects' considerations, biostatistics, and other introductory topics. Alternatively, a 2-week research elective could be offered to interested, highly motivated interns. In most programs, second- and third-year residents have more elective time and are often better equipped to juggle the time commitment of research beyond the preparatory stage without violating ACGME duty hour limitations.

THE RESEARCH CONTINUUM

Without a research curriculum, programs may miss an opportunity to develop future clinician investigators. An informal survey of program directors from the 406 internal medicine training programs in the United States and Canada through the Association of Program Directors in Internal Medicine (APDIM) web-based listserver was conducted. Of the 143 programs that replied, 121 (85%) reported offering at least one 4-week research elective. Although a 4-week research block is helpful, a resident research project usually requires a much greater commitment of time, interest, and resources, averaging 12 to 24 months to complete. Resident research should be conceptualized as a longitudinal process rather than an isolated elective experience. The *preparatory phase* consists of generation of a topic, acquisition of mentorship, development of study design, and submission of appropriate institutional review board (IRB) paperwork. This process often takes 6 to 12 months to complete and should start as soon as possible during residency. The *investigatory phase*, typically a 1- or 2-month research elective block, should be an opportunity to complete tasks otherwise

Table 2 Resident Checklist for Clinical Research

Preparatory Tasks	Choose a topic
	Draw from your own questions encountered during patient care.
	Discuss your ideas with as many people as possible.
	Formulate a specific question
	Define the population, intervention, and outcome.
	Find a mentor (or two)
	Discuss research, personal, and professional interests with your mentor(s).
	If you don't "click" with someone, look for another mentor.
	Identify existing institutional resources
	Consult with experts in your area of interest.
	Look for existing databases to help answer the question.
	Detail the study design
	Think through each and every step of data collection.
	Anticipate what problems may arise.
	Create a database.
	Complete the institutional review board (IRB) paperwork
	Call the IRB directly for questions related to category of review.
	Make sure your study is HIPAA compliant.
	Determine whether informed consent is necessary (ask the IRB).
	Consult with a statistician
	Clarify what a clinically significant finding would be.
	Perform a power calculation.
	Determine the statistical tools you will need after data collection.
Investigatory Tasks	Set goals for the research project
	Make goals related to the project and to personal career plans.
	Collect the data
	Securely store the data.
	Keep a log of problems encountered and solutions.
	Perform a periodic quality check of data collection.
Synthesis Tasks	Statistical analysis
	Develop additional specific questions for a statistician to answer.
	Submit an abstract to a regional or national societal meeting
	ACP deadline for abstracts is early October.
	Consider SGIM or subspecialty organization meetings.
	Get feedback from others about your work.
	Write a manuscript
	Discuss criteria for authorship with your mentor.
	Determine an appropriate journal for submission.
	Reflect on your research experience
	Review whether your goals were achieved.
	Review what you've learned about yourself and your interests.
	Consider the role of research in your future career.

not practical during clinical rotations, such as data collection. The *synthesis phase* includes statistical analysis, presentation at scientific meetings, publication, and self-reflection with renewal of research and career goals. This last phase takes another 6 to 12 months, making the second year or early third year of residency ideal times for the research elective block. Table 2 is a suggested resident checklist for completion of the continuum of clinical research during residency.

THE PREPARATORY PHASE

Selecting A Topic and Formulating A Question

Residents frequently ask important clinical questions. Applying evidence-based medicine principles to patient care experiences engenders an appreciation for gaps in the current literature. Residents often draw from these experiences to select a research question, but maintaining realistic expectations for completion can be challenging. The best resident research questions are quite focused. Given the myriad of time constraints during training, a resident should choose a project that maximizes learning and minimizes data collection. Frequently, the most workable, meaningful resident research projects initially feel "too small."

The elements of an ideal research question are teachable (Table 3). Residents may generate relevant, interesting ideas but need to validate them through discussions with peers, mentors, and educators. A common mistake is trying to "save the world" with a single project that would require many years and significant grant funding to accomplish. Focusing, paring down,

Table 3 Elements of an Appropriate Clinical Research Question

Relevant to clinical practice.
Focused.
Utilizes available institutional resources.
Involves a well defined study population.
Includes a well defined outcome.
Takes career strategy and interests into account.
Invokes curiosity in others.

Table 5 Elements of a Research Proposal

Background (1-2 paragraphs)
Hypothesis (1 sentence)
Specific aim (1-3 sentences)
Methods (2-4 paragraphs)
Anticipated results (1 paragraph)
Timeline (1-2 sentences)
Mentor signature of approval

and utilizing already-established resources such as databases, research tools, and data gathered from prior studies are essential to a successful project. Typical resident projects are retrospective or cross-sectional analyses such as surveys and chart reviews. However, small prospective studies are also possible (Table 4) (Yu A, Meyers FJ, unpublished observation).[14-18]

Research Mentorship

Steiner and colleagues described three important domains of mentorship: the relationship between mentor and mentee (guidance and support), professional attributes of the mentor (reputation), and personal attributes of the mentor (availability and caring).[19] Although all of these attributes are ideally embodied within one person, a second mentor may complement the primary mentor. One mentor may provide methodological expertise, whereas the other offers clinical content guidance.

The best mentor-mentee relationships embody mutual respect and are cultivated over time. Due to limited interactions, residents often need help identifying and accessing potential mentors. Some programs assign mentors to interested residents, but this approach does not guarantee that an ideal mentor-mentee relationship will develop. During semi-annual reviews of resident performance, residents and program directors should discuss possible mentors for career, research, or personal counsel. Program directors serve as the "matchmaker" by recognizing similar interests among physicians-in-training and faculty and bringing compatible pairs together. Because the best mentors are often in high demand, it is imperative that departments recognize mentoring efforts in the promotion and tenure process. If a local mentor is unavailable, occasionally a suitable mentor can be found at an outside institution. The widespread use of e-mail allows effective mentoring at a distance. ACP and the Society of General Internal Medicine (SGIM) also offer mentoring opportunities during their annual meetings.

Study Design

Designing clinical research is a course unto itself. Resident journal clubs serve as a good introduction and, if well done, can entice residents to try their hand at clinical research. Unfortunately, journal clubs often lack the depth required to truly understand study design. *The Journal of the American Medical Association's Users' Guides to the Medical Literature*[20] is an effective tool for teaching study design during journal club. Experienced research mentors are a rich source of practical information, and there are many other easy-to-use references (see Appendix). As study design is developed, residents should generate a structured research proposal together with their mentor(s). The proposal should include the following essential elements (Table 5): background, hypothesis, specific aims, methods, anticipated results, timeline, and a mentor's signature of approval and commitment.

Residents need to incorporate biostatistics into study design. Many mentors have biostatisticians involved in other projects who may be available for brief consultation. There are several free web-based statistics cal-

Table 4 Examples of Resident Research Projects

Resident Research Project Title	Research Project Type
Attitudes and perceptions of end stage renal disease patients on stopping dialysis.*	Cross-sectional survey
A comparison of measured hemoglobin A1c and expected hemoglobin A1c from patient reported home blood glucose monitoring.[14]	Cross-sectional survey
Increased incidence of symptomatic venous thrombosis in patients with cervical carcinoma treated with concurrent chemotherapy, radiation, and erythropoietin.[15]	Retrospective cohort
Do physicians examine patients in contact isolation less frequently?[16]	Prospective cohort
"We're jinxed"–are residents' fears of being jinxed during an on-call day founded?[17]	Randomized clinical trial
Acetaminophen and diphenhydramine as premedication for platelet transfusions.[18]	Randomized clinical trial

*Yu A, Meyers FJ. Attitudes and perceptions of end stage renal disease patients on stopping dialysis. (unpublished observation).

culators and data management programs, such as The Center for Disease Control and Prevention's *Epi Info* (Appendix). Local graduate programs in statistics may offer free or low-cost consultation for residents. Program directors may want to consider sponsoring periodic office hours with a knowledgeable statistician who is an effective teacher. A brief consultation with a statistician during the planning stages has the potential to substantially influence the ultimate utility of data gathered by residents. Defining a clinically relevant finding, performing a power calculation, and determining the statistical tools necessary to interpret the data are essential tasks that sometimes require the expertise of a statistician.

Utilizing Institutional Resources

A program director familiar with local research programs can readily link residents with key research faculty. The University of California, Davis, School of Medicine internal medicine residency program has piloted a research chief resident who serves as an additional resident mentor and aide. Appointment of a faculty research director to assist residents with their research increases research productivity (defined as the number of resident presentations at national meetings and resident publications).[6] In general, residents should utilize pre-existing research tools rather than start from scratch. Other important resources include existing clinical databases, general clinical research centers, and other externally sponsored research units. Residents often conduct medical record reviews, cross-sectional surveys, or systematic reviews. They need access to experienced researchers with relevant content or methodological expertise. Ideally, program directors should identify local experts in survey design and systematic reviews.

Easy access to the local IRB early on in the preparatory phase is essential. Bad habits, outdated rules, and false rumors are often passed on to novice researchers, and the IRB should be the first stop for questions involving human subjects. Novice researchers seldom appreciate the time required for IRB submission, review, and revision. The United States Department of Health and Human Services Office for Human Research Protections and the National Cancer Institute have excellent web-based resources (Appendix) that detail the IRB process, categories of review, and informed consent. Before submitting a proposal, the IRB may require that the researcher complete a brief NIH web-based tutorial on the rights and welfare of human participants in research.

The Health Information Portability and Accountability Act (HIPAA) Privacy Rule is the first comprehensive federal protection for the privacy of personal health information. It is fundamentally important that novice researchers do not confuse the need to access patient charts for provision of medical care with the privilege of accessing charts for research purposes. HIPAA may challenge the researcher in terms of data management, and institutions should provide residents with a secure web-based account for data storage and management to facilitate HIPAA compliance.

THE INVESTIGATORY PHASE

The research elective should ideally be a 1- or 2-month block during which residents are free from most other residency duties. Attendance at continuity clinic and educational conferences should continue, leaving the remaining time to complete the research tasks that a typical rotation does not allow. Research is time-consuming and must be methodical. For instance, a resident who wants to survey hemodialysis patients about end-of-life care will not have adequate time to do so during a nephrology elective because of required clinic duties, consults, and educational conferences. Only with the ability to attend hemodialysis for an entire uninterrupted week can the resident access and survey a representative sample of patients. Tasks requiring protected time include: accessing medical records, reviewing patient databases, traveling to community providers to access patient charts, or working closely with colleagues who are otherwise not easily accessible over an extended period of time. Of course, optimal use of this time requires successful completion of the preparatory phase.

Many residents have difficulty achieving research goals because of insufficient time, low priority relative to patient care, use of "leftover" rather than "prime" time for research, poor availability of mentors, and lack of direction from residency programs. Furthermore, research goals themselves may be unrealistic, inflexible, or naive. These hurdles can be avoided by deliberate guidance during the preparatory phase of resident research. The research elective should not be used to accomplish the preparative tasks outlined above. Many programs require that residents submit a standardized research proposal (Table 5) that must be approved by a program director, chief resident, or designated faculty member before granting a research elective.

Residents should meet with a program director, faculty research director, or a research chief resident at the beginning and end of each research block. Residents appreciate the opportunity to ask questions about institutional resources, review goals, and confirm that their goals are realistic. These meetings also encourage self-reflection on the research process as it relates to career planning. Goals should range from specific tasks, such as collecting a prespecified number of data sets, to learning more about research interests and career plans. Lastly, opportunities for presentation or publication should be reviewed. Some programs invite residents to present their work as part of an educational lecture series or at grand rounds.

Data collection is inevitably fraught with unforeseen challenges: lost charts, missing data from existing charts, and, in the case of a survey or questionnaire, language barriers or other challenges related to human subject participation. Mentors may help troubleshoot these obstacles. Residents should keep a record of problems and their respective solutions during data collection. Developing a database early in the process of study design can be quite helpful. Available database programs include Microsoft Excel, which is relatively simple to use, and Microsoft Access, for residents with more advanced computer skills. Lastly, residents may need guidance in keeping data secure. Mentors may need to offer a locked drawer in their office or other secure mechanism for data storage. Alternatively, password protected and encrypted computer accounts can provide a safe and convenient means for both data collection and storage.

THE SYNTHESIS PHASE

Obtaining statistical expertise to interpret data is a common stumbling block because resident research is rarely sponsored by grants or other funding sources. It is unrealistic to expect resident researchers to acquire their own grant support to compensate a statistician. Program directors and mentors must be prepared to contribute intellectually and financially to resident research projects. Programs should develop a budget for resident scholarship that includes discretionary funds for travel, poster production, and statistical support. However, not all resident research projects require a biostatistician. Ideally, programs should designate a research associate program director to assist with straightforward statistical issues such as analysis of cross-sectional data and chi-squared calculations. For more complex projects, a few hours of a statistician's time can often be purchased for 50 to 70 dollars an hour. An unprepared resident may hand spreadsheets of raw data to a statistician hoping he or she can "figure out what it shows." Instead, residents must clearly articulate their needs to the statistician by reviewing the specific research aim, intervention, and outcomes of the study in advance.

Presenting the research findings at a local or national academic meeting is the next and most important step. Aside from the experience of preparing an abstract and presenting a poster, this gives residents the opportunity to network with experts in the field and to bolster their curriculum vitae. It is also the first step toward writing a manuscript. Here, the importance of mentors again comes into play. Most residents have little experience with scientific writing, poster design, and criteria for authorship, and will therefore rely heavily on a mentor for guidance. This person does not necessarily have to be the research mentor. The process of abstract writing and poster development can be streamlined by having a dedicated chief resident or a few experienced researchers coordinate the program's efforts. Encouraging participation in the regional meetings of the ACP and providing guidance on abstract writing and poster production is strongly recommended. Many residency programs subsidize travel expenses for residents, emphasizing the institutional commitment to achievement in research. Presentation at local and regional meetings where subsidized travel costs are offered to residents, such as ACP Associates meetings, can help defray costs. Programs can avoid excessive financial expenditures by capping the amount subsidized, providing funds for a maximum of one presentation per resident or providing a predetermined amount of discretionary educational funds (for books, board review materials, travel, and other expenses). Faculty mentors also may subsidize travel expenses for residents. Finally, an institution may host a local research fair to recognize and showcase resident research.

Publication should be the eventual goal for every resident research project after presentation at a society meeting. The best predictor of future behavior is past behavior; thus, academic institutions are more likely to hire a resident who has been able to successfully publish his or her work despite heavy clinical demands. Residents should be encouraged to look for opportunities to publish their work. Although additional mentorship is required for editing, journal selection, and submission, most well-done projects can be published.

CONCLUSION

Performing clinical research is an integral part of the internal medicine residency experience. Although not required, research during residency is valuable and may influence a resident's ultimate career path. The research experience is far broader than simply research elective time. Unfortunately, many residents and educators think of research as an isolated month during which a project can be carried out from start to finish. Such a paradigm often creates unrealistic expectations for residents and faculty mentors. Clinical research programs should model a longitudinal experience, emphasizing adequate preparation, protected time for investigation, and synthesis of the information gathered. When this process is integrated into the 3-year residency continuum, resident successes multiply.

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APPENDIX

Resources for Resident Research Study Design

Study design and methodology resources:

Hulley SB, Cummings SR, Browner WS, et al. *Designing Clinical Research.* 2nd ed. Philidelphia, Pennsylvania: Lippincott Williams and Wilkins; 2001.[21]

Dillman DA. *Mail and Internet Surveys: The Tailored Design Method*. Mississauga, Ontario, Canada: John Wiley & Sons; 1999.

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National Cancer Institute Human Participant Protections Education for Research Teams. Available at: cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp. Accessed December 5, 2005.

Institutional Review Board:

United States Department of Health and Human Services Office for Human Research Protections (OHRP) for information on the IRB. Available at: www.hhs.gov/ohrp. Accessed December 5, 2005.

Health Information Portability and Accountability Act:

National Institute of Health. Available at: privacyruleandresearch.nih.gov. Accessed December 5, 2005.

Statistics:

Centers for Disease Control and Prevention *Epi Info*. Available at: www.cdc.gov/epiinfo. Accessed December 5, 2005.

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