# Effective Research Strategies for Trainees in Internal Medicine Residency Programs

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## ABSTRACT

For most training programs, the development of research endeavors among trainees is an ongoing challenge. In this article, we review various considerations when attempting to undertake research activities within an internal medicine residency training program, including availability of institutional resources (eg, dedicated research time for trainees and faculty, available faculty mentors, accessible adjunctive personnel), engagement of residents into research, classic project quagmires in training programs, the institutional review board, publication options (eg, letters to the editor, case reports, literature reviews, original research reports), and journal submission strategies. Given that research entails multiple components and distinct skills, the overall program goal should be to make research an educationally understandable process for trainees. Research can be a rewarding activity when nurtured in a facilitating educational environment.

Research endeavors are an ever-present challenge in most training programs, including internal medicine residencies. According to the Accreditation Council for Graduate Medical Education (ACGME) research requirements for residents in general internal medicine, (1) the curriculum must advance residents' knowledge of the basic principles of research, including how research is conducted, evaluated, explained to patients, and applied to patient care, and (2) residents should participate in scholarly activities.[1] This mandate from the ACGME cogently indicates the need for resident training in research and indirectly implies project execution and publication. In addition, the ACGME requires that 50% of training program graduates must demonstrate at least 1 type of completed scholarly activity, which may include a formal research endeavor. In this article, we review our grass-roots approach to research training in an internal medicine residency, emphasizing the possible ways to nourish such endeavors in other programs. Given the backdrop of a highly demanding training environment, we eschew a theoretical perspective and anchor our approach to pragmatic tactics.

## ASSESSING INSTITUTIONAL RESOURCES FOR RESEARCH

### Dedicated Research Time for Trainees

At the outset, the research process requires a number of fundamental resources, many of which need to be facilitated by the sponsoring academic program/institution. First, residents require dedicated time to participate in original research endeavors (ie, available elective time). Based on our experience, research endeavors are difficult to execute over a span of time due to ever-changing resident schedules, indeterminable time commitments, and potential loss of trainee motivation—realities that may result in poor outcomes. In contrast, short-term projects that are adapted to a single elective month are generally more attractive to trainees, as these endeavors are clearly focused and time limited.

To address the need for short-term original research experiences, we have developed an approach that we refer to as "lobby research" (ie, survey research that takes place in the lobby of our internal medicine outpatient clinic). This clinic is the outpatient training ground for our resident physicians. Using the lobby method, we can accommodate a 4-week research elective (ie, maintain a tightly circumscribed timeframe for resident commitment) and simultaneously collect a sufficient number of respondents for legitimate statistical analyses (eg, typically 300–400 outpatients). As a caveat, this approach to original research requires careful planning. For example, research materials need to be submitted to the institutional review board (IRB) well ahead of the start date of the rotation in order to obtain a completed review and exemption/approval. Also, before the project begins, the statistician must review with the trainee the format for data collection and entry so that subsequent analyses can be conducted most efficiently. These strategies enable the rotation to be singularly utilized by the resident to recruit participants and to enter collected data.

### Available Faculty Mentors

Access to experienced research mentors, one common shortfall in most training programs, is absolutely necessary for trainees to have a rewarding experience with research. The research process requires multiple integrated steps

- Research demands in academic programs continue to increase for both trainees and faculty; however, several strategies can improve research productivity.

- Research strategies include assessing at the outset the institutional resources/support for such endeavors (eg, dedicated research time for trainees/faculty, availability of mentors, availability of adjunctive resources such as access to a statistician); developing projects that are simple, focused, and time-limited in duration; avoiding grant support, when possible; maintaining a well-defined and lean research team; considering projects that are most likely to be exempt from institutional review board review; and strategizing publication type and journal submissions.

as well as diverse skills. For example, there is the initiation of the project idea, the translation of the research idea into a statistically viable format to address the hypothesis, the completion of research training for each investigator, drafting of the submission for IRB review, revision of the IRB submission if necessary, collection of data, analysis of data, and write up and submission of the manuscript. Each step requires vastly different types of knowledge and skills, from creative conception and statistical finesse to the completion of forms, professional writing expertise, and proficiency with journal strategies. Without experienced faculty guiding the research process, these multiple steps and their corresponding diverse skills can readily derail trainees—discouraging them from further research initiation in the future. Therefore, we have found it necessary to "roll up our sleeves," "get into the trenches," and actively participate in the process with the trainees. Because of this mentoring commitment, faculty need sanctioned research time as well to directly assist with trainee research projects (ie, draft study materials, participate in submissions to the IRB, draft and submit manuscripts to journals, handle revisions based on reviewer comments).

As an example of a unique experiential skill to be offered by experienced faculty, consider the publication strategy. Seasoned researchers are invaluable given their knowledge of (1) the importance of submitting to journals that are accessible through a recognized search engine such as PubMed, (2) journal requirements for manuscript formatting (eg, abstract structure, in-text and end-of-article referencing styles, word counts), and (3) journal preferences with regard to content (ie, Does a given journal approve of the methodologic approach of the article being drafted?).

### Adjunctive Personnel

At the outset, most if not all projects require the support and input of an experienced statistician—another important institutional resource. A talented statistician can assist in the translation of the research idea into empirical data that can be effectively statistically analyzed. In other words, the statistician translates response options into reliable and valid forms of measurement to accommodate the intended

statistical analyses. As an example, while a specific query may be valid, perhaps write-in response options allow for too many responses/variables to be effectively analyzed. As another example, the research query may not be worded explicitly enough, allowing for misinterpretation by respondents, and thereby introducing additional error variance.

Because research endeavors entail a wide variety of different formats, from case reports to original research, particular types of projects may require adjunctive or specialized personnel. For example, for projects entailing mailed surveys, the use of administrative assistants to fold, address, and mail questionnaires can greatly reduce the researchers' time investment. However, these personnel need to be accessible through the institution unless there is grant support to hire an external employee.

Some projects may entail multiple recruitment sites for obtaining participants, yet the nature of the research may not require a recruiter with medical training. So, the use of nonmedical research recruiters may be most feasible, if available. However, if existing administrative personnel are asked to add participant recruitment to their current roles, careful training and incentives are important to ensure a relatively high response rate and quality data as a result.

Other types of proposed projects may require funding. While research grants are typically not practical for most resident endeavors, some trainees may occasionally elect projects that require their pursuit. In these instances, experienced grant facilitators (ie, individuals who monitor grant opportunities and are able to draft successful grant applications) are helpful, if not absolutely necessary. The pursuit of funding takes time as well as additional skills, but time alone may prevent a project from being feasible given resident schedules as described earlier.

Importantly, all project resources need to be assessed at the outset of development for *feasibility*—Are these resources available? How long are the resources available for? Who will fund these resources? With a menu of available adjunctive personnel, a training program has the capability of undertaking diverse types of research endeavors (eg, interview projects, multisite projects).

### ENGAGING RESIDENTS IN RESEARCH

Compared to other types of trainees (eg, family practice, psychiatry), internal medicine residents tend to readily engage in research projects. First, the ACGME guidelines for research in internal medicine residencies are more explicit. Second, a significant proportion of internal medicine trainees eventually seek fellowships. Given that fellowships remain fairly competitive, candidates with research experience tend to have an entry edge. Still, to foster research involvement, the requirements for scholarly activity as defined by the ACGME as well as the potential advantages of research for fellowship application need to be advertised to residents, beginning with the first year of training. This type of resident education can be easily achieved by providing an annual 1-hour research seminar to trainees.

## POTENTIAL QUAGMIRES IN PROJECT CONSOLIDATION

Over the years, we have experienced a number of potential quagmires in undertaking research with trainees. Fortunately, with sufficient foresight, most of these pitfalls can be avoided. First and foremost, we advise keeping projects relatively simple and focused. A brilliant but complex project usually does not survive operationalization to active research. Second, we tend to discourage projects that require financial support/grants. The potential time lag in applying for, receiving, and administratively processing grants is generally not feasible given the 3-year training time in internal medicine. Third, we discourage multiple, unnecessary investigators. Each investigator should have a defined and legitimate role necessary to the completion of the project. We are particularly stringent about authorship in case reports (ie, was there any contribution by the individual other than having provided past medical care to the subject?). Fourth, unless the project entails paid institutional recruiters, we avoid relying on others in the community (investigators who are not directly affiliated with the research team) to collect data—they rarely have the same motivation and investment in the research, which ultimately affects sample size and quality.

Fifth, when applicable, we strive for the IRB submission status of *exempted*, rather than expedited or full review. Exempted projects do not require annual reports or closure reports to the IRB. To garner this status, one must collect and/or utilize unidentified (ie, anonymous) or deidentified data. Sixth, we avoid having the resident function as either the principle investigator or the corresponding author. As principle investigator, most residents are not available to complete the IRB closure paperwork (when necessary) after departing from residency. As corresponding author, trainees may relocate, which potentially complicates and delays completion of the publication process, such as the reviewing of galley proofs. Finally, we caution residents about the potential confusion in indiscriminately discussing their research ideas with other attending physicians, as we have found that some faculty assume that this discussion is an invitation to join the research team, despite having no role or contributable skills.

## THE INSTITUTIONAL REVIEW BOARD

First and foremost, the purpose of the IRB is to protect human research participants. Therefore, when reviewing research projects, the IRB is keen to ensure that participants are reasonably safe, given the potential benefits of the research versus the risks of that research. IRBs require evidence of research training for each investigator on the team. This training is usually undertaken through Internet training modules that take 2 to 3 hours to complete and provides accreditation for 2 to 3 years (ie, for longitudinal researchers, the training must be updated every so often). IRBs vary slightly in their required submission materials, so mastering the skill of the IRB submission process is not, in our opinion, a worthwhile training skill for the residents with whom we work—particularly given a 1-time endeavor. Of note, projects with investigators who have multiple academic and clinical affiliations will require project submission to all affiliated IRBs, which can not only be time-consuming, but may also result in a "ping-pong" style of revisions (ie, back and forth between IRBs). Interinstitutional agreements alleviate this problem by having the site IRB take the lead in endorsement. Fortunately, most of the requested revisions from our IRB have focused on the consent form and been grammatical in nature.[2]

Researchers in medical facilities may be interested in accessing patient medical records to conduct a project. However, patients who are treated in a health care organization that electronically transmits any health information in connection with the US Department of Health and Human Services will most likely be covered by the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule.[3] This rule protects individually identifiable health information. It does not apply to deidentified data (data with no names and no medical record identifiers, addresses, and telephone numbers). For projects entailing access to the private health information of patients, the researcher may require the written permission of the patient or alternatively may seek a waiver from the IRB, which under certain conditions will be granted. The IRB will offer guidance regarding HIPAA Privacy Rule requirements.

## PUBLICATION TYPES: ADVANTAGES AND DISADVANTAGES

At the outset, the explicit goal of each and every research project should be publication in a journal that is indexed in a major citation search engine, such as PubMed. This philosophy not only incentivizes trainees but also thrusts the research to a higher level of academic design. Otherwise, trainees tend to understandably think, "Why go through all of the rigorous and time-consuming steps of the research process without the benefit of publication?"

In terms of publication, there are a number of possible formats, including letters to the editor, case reports, literature reviews, and original research reports. Each format has its own advantages and disadvantages for both faculty and trainees, which we consider here.

### Letters to the Editor

Letters to the editor typically opine about a previously published journal article, although some journals will accept small research reports in this section as well. With this format, when it involves editorial opinion or commentary, there is one distinct advantage—no data collection and therefore no time-consuming IRB submission. However, there is a potential disadvantage—obtaining effective leadership for the authorship team. Letters to the editor are typically most effective when undertaken with the direct guidance and first-authorship status of an experienced faculty member, as this lends the necessary expertise to credibly clarify some fine clinical or academic point. Likewise, a key limitation

with letters to the editor is determining a realistic role for the trainee, which may be limited to gathering rebuttal articles for references.

## Case Reports

Case reports represent an attractive publication venue for trainees. Unfortunately, trainees often erroneously believe that unusual case reports are only encountered in well-known tertiary care facilities. In reality, unusual clinical cases regularly materialize in medical centers across the country every day. As for potential advantages, case reports are excellent initial forays for a first-authorship endeavor by a resident. They are typically limited by word count, easy to draft because of their simplistic format, and require no formal IRB submission as required with original research. With this publication option, the trainee's role is fairly defined: (1) cull through the existing literature, (2) screen for previously published articles of similar cases (an explicitly constructed comparison grid is extremely helpful, particularly if there are similar but not identical cases), and (3) collect adjunctive articles for the didactic portion of the case report. While some institutions require a form to be submitted to the IRB to confirm that the project is not official research, the overall paperwork is minimal. In terms of enhancing publication probability, photographs and/or x-rays are particularly appealing, but may require patient permission and may not be applicable to many cases.

As for the potential disadvantages of case reports, it is essential that faculty develop the habit of pointing out the atypical features of a clinical case based on experience (trainees generally lack this expertise). Moreover, faculty members have the responsibility to dissuade trainees from considering overt malpractice cases for publication. Finally, faculty must actively guide the content in the didactic discussion (the major selling point of the manuscript), which is essential in promoting the case report. On a side note, fewer and fewer journals are publishing case reports, so finding outlets for these types of manuscripts may be challenging.

## Literature Reviews

Literature reviews tend to be risky undertakings, particularly when initiated by a trainee. The potential advantage of a literature review is the circumvention of data collection and the associated IRB paperwork. However, the potential disadvantages are numerous. First, a great deal of experience is required to successfully present a literature review that is clinically well integrated (ie, adept synthesis of the existing data accompanied by meaningful and relevant conclusions). Second, certain topics may have seemingly endless articles to review; therefore, the selection of a very narrow topic is highly advised (eg, one might avoid the topic of "selective serotonin reuptake inhibitors" and narrow down the focus to "bone effects of selective serotonin reuptake inhibitors"). Third, literature reviews are often requested of and written by leaders in the field; therefore, finding accessible publication outlets for trainee authors is a realistic problem.

## The Original Research Endeavor

We now come to the original research endeavor. The distinct advantage of conducting original research is, simply put, academic prestige. Given this preamble, there are a number of challenges to consider at the outset, including the determination of a viable study population, assemblage of a tightly defined research team, defining the research query and translating it into data that can be collected and analyzed, gathering assessment tools, and submitting the project proposal to the IRB.

Given that we are focusing on the trainees, a useful research mantra in this context is the following: first, determine what clinical population the trainee has direct access to and then develop the research query. In other words, it is essential to initially identify population access. While developing a research query about fibromyalgia may be of keen interest to a particular resident, without robust access to such a population, what is the point? Simply put, a small sample substantially reduces publication probability.

After the identification of an accessible population, the faculty mentor and trainee may then realistically develop a viable research query. For example, we have traditionally maintained a strong research interest in borderline personality disorder and its manifestations in primary care populations. Given the high number of indigent patients in our clinic, and known relationships between socioeconomics and psychopathology, there have been sufficient numbers of patients to adequately meet our research needs. On occasion, there may be trainees who have access to unusual populations (eg, a fibromyalgia or pain clinic cohort), which enables a practical research endeavor in a unique sample.

The research query for trainees needs to be simple and, most importantly, feasible. A great idea that is not practical or feasible in a given clinical setting is just a great idea. So, it is necessary to guide the trainee toward a project that is genuinely doable. After the development of the research query, the research team then needs to undertake a thorough literature search to clarify whether the idea has been previously studied and published—this material subsequently provides the grist for the introduction to the manuscript. In our opinion, this is best undertaken in conjunction with faculty members, who have the experience and knowledge to know how to cull through articles as well as to envision the eventual introduction to the manuscript.

After confirming the viability of the research query, the research team may then be fully assembled. In doing so, each and every team member must have an explicit and well-defined role (eg, project developer, statistician, participant recruiter). Because trainee projects tend to be fairly basic, a large number of authors may justifiably create suspicions among journal editors, who understandably question the legitimacy of each author's respective contribution. Therefore, senior "advisors" are rarely practical for these types of endeavors. We generally recommend no more than 3 or 4 investigators per trainee project.

Next, we recommend searching for standardized measures, if available, that are hopefully brief and free of

charge. If suitable measures are not available, we work closely with our statistician to develop a pragmatic and focused author-developed assessment. The risk with an author-developed assessment is the lack of established validity and reliability and resulting concerns from journal editors and reviewers.

The next major step in this process is the submission of required materials to the IRB. We, as faculty, tend to complete the IRB submission materials for trainee projects, as formats and processes may vary from IRB to IRB, thereby limiting the educational usefulness of this type of experience (ie, it may not generalize well to future facilities in which residents may find themselves). As faculty, we are keenly familiar with the submission process for our institution, and if difficulties arise, we are familiar with the staff who may be contacted to help us promptly resolve them.

At the time of submission, the team needs to determine the submission status of the research packet: exempt, partial review, or full review. For anonymous survey projects with unidentified (anonymous) subject data, we recommend a request for an exempt review. An exempt review eliminates the need for either an annual report or a closure report to the IRB. In addition, the collected data can be used in the future without IRB oversight (ie, the alternative submission types require that the project be active to work on data from that particular project unless the team deidentifies the data at some point).

The original research project tends to be considerably more work than the other types of submissions, with the possible exception of a literature review article. However, the rewards are more plentiful and may include publication, posters, and presentation at professional meetings.

## WRITING THE MANUSCRIPT

In drafting the manuscript, keep in mind that the text must maintain focus and tell a story. The story has a beginning (introduction), broaches controversy (past limitations of previous research, conflicting past results), builds tension (the current investigation), and delivers a resolution (results and conclusion). Importantly, the manuscript needs to close with an effective ending. While this seems fairly straight-forward, it is surprising how many manuscripts lack organization/structure, focus, an effective storyline, and/or a satisfying closing.

## JOURNAL SUBMISSION STRATEGIES FOR TRAINEE MANUSCRIPTS

Trainee projects are typically less sophisticated than studies initiated by teams of experienced and well-funded investigators. Therefore, the submission strategy needs to be well executed and generally geared toward journals that welcome the type of research that has been undertaken.

The first step is identifying potential journals for submission possibilities. At the outset, trainees may query various faculty members with similar areas of interest about outlets for manuscripts. As a caveat to these types of faculty recommendations, submissions should be directed to journals with a clear presence in a popular citation index, such as PubMed (one of the ACGME criteria).

Beyond asking faculty, another practical strategy is to enter the topic of the manuscript into the PubMed search engine, note relevant journals that populate the results, and then review the "information for authors" for each journal (available at each journal's website). After excluding poor journal candidates, the resulting journal possibilities may then be placed into a ranked list, based on their content, requirements, and overall fit with the manuscript.

After the election of a journal for the first submission effort, the finished manuscript needs to strictly adhere to formatting guidelines, particularly word counts, font and margin requirements (mostly Times New Roman with 1-inch margins), heading and subheading styles, and citation and referencing formats, of that journal. The writing needs to be scientific in style, not colloquial. While some trainees are able to execute this type of writing style, more often than not, faculty will be required to undertake the basic writing (or be willing to work extensively with the resident to edit the manuscript successfully) to secure journal acceptance.

In terms of managing manuscripts, the filename for the article should include at the end of the manuscript title a journal identifier such as initials (eg, *Road rage among patients in a primary care setting, PCC* where PCC represents *Primary Care Companion*). If rejected and resubmitted, subsequent versions of the manuscript will most likely require different formats; filenames may be modified with new journal initials. Until acceptance, each manuscript version should be kept on file in the event that a future submission has similar formatting requirements.

Nearly all manuscripts are submitted via the Internet. At the outset, the website for the journal typically requires the corresponding author to initially register (ie, name, institution, contact information). After registration, the corresponding author may then begin the formal submission process. Submissions generally take 30–45 minutes for completion, depending on the degree of familiarity with the website. Required information may include coauthors' contact information, such as addresses, telephone and fax numbers, and e-mail addresses.

A number of journals will request *suggested reviewers*. Reviewers may not be close colleagues or recent coauthors, but may be known colleagues who share your area of interest. An alternative is to consider authors in the reference list of the manuscript. Their contact information can be accessed through PubMed (ie, locate the selected author in a publication where she/he is listed as the first author, access the abstract, and then click on the author's contact information to obtain the e-mail address).

Various journal websites may require the submission of permissions for the use of copyrighted scales or measures, a letter from the IRB confirming review, and/or signed copyright transfer forms at the time of submission. Unfortunately, copyright forms may require each author's signature, which can be bothersome if authors do not work in the same location. On occasion, copyright forms will be

required only after the manuscript has been accepted, which is a more appealing policy for authors.

When working with multiple projects, the corresponding author on the research team needs to keep track of each submission to each journal, one at a time (ie, log the manuscript title, journal title, submission date, and outcome). In addition, journals need to be contacted if there is no manuscript response/decision within 4 to 6 months of submission. On occasion, a manuscript may fall through the bureaucratic cracks. All decision letters need to be reviewed by the research team. If the manuscript is accepted without revision, hurrah! If a revision is offered by the editor, the team needs to carefully consider each concern and requested revision, point-by-point, and to address each in the manuscript as well as in a cover letter detailing how each concern was addressed by the authors. With revised manuscripts, journals may specify indicating changes with either bolding or the track-changes mode within the word processing program. When reviewer recommendations are unclear, the corresponding author may contact the editor for further clarification. For reviewer recommendations that the authors deem unacceptable, the authors need to outline in the cover letter their rationale for not undertaking a specific revision request. For rejected manuscripts, the team needs to cull through the commentary to see which points merit consideration, and then revise the manuscript accordingly before resubmitting to a new journal.

On a side note, some hospital systems have extremely conservative e-mail filters to block perceived spam. Unfortunately, perceived spam may include e-mail correspondence from other countries (ie, correspondence from journals located outside of the United States, such as Australia, the United Kingdom, or Sweden). Be aware of this possibility if you do not receive a response from a journal and contact information systems at your institution.

## INCENTIVES FOR FACULTY

Using the preceding approaches, the faculty member can not only augment the curriculum vita of trainees, but also build a significant body of work in an area under his/her leadership. Thus, these approaches offer economical, efficient, and voluminous research, while enabling the senior faculty to academically advance. Moreover, by incrementally adding to an existing line of research, the supervising faculty member becomes increasingly expert in that topic.

## CONCLUSIONS

Research is a vast vessel to steer. For trainees, completing 1 project reveals only a hint of the research process. It takes several projects over many years to master the art of research. So, in the teaching process, it is important for faculty to emphasize that this experience will enhance the trainee's *understanding* of the research process, but not truly develop proficient research skills in most cases. From our read of the present academic climate, research requirements in training programs are continuing to gain momentum. In order to develop viable research opportunities for trainees, programs need to create and maintain an educational environment that is genuinely conducive to research. One of the major obstacles facing many training programs is the lack of faculty who are actively engaged in research. This state of affairs is in part due to a lack of trained faculty as well as economics (ie, the need to generate monies through clinical practice). Hopefully, some of the tools outlined in this article will facilitate a more realistic approach to developing and maintaining a healthy research environment in training programs. After all, if the trainees of today have a satisfying research experience, they may be the researchers and research teachers of tomorrow.

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