The roles and responsibilities of the principal investigator of a research project are described to allow the young researcher to make an intelligent decision regarding which role to take in a research project. Guidelines are given about which tasks may be delegated and how to do this. These tasks include formulation of the question, project design, obtaining funding, project startup and ongoing management, data analysis and publication. Particular attention is paid to design/analysis and publication, since these determine authorship on biomedical research articles.

THE PRINCIPAL INVESTIGATOR: TO BE OR NOT TO BE

This article concludes the first part of the series on Research in Physical Medicine and Rehabilitation. Its goal has been to stimulate interest in physiatry research. During the past year, articles have been published concerning formulation of the question, conceptual review of the literature, the retrospective chart review, issues in experimental design, data management and project management issues. If you have persevered and diligently read the previous research articles, by now you have a fairly good idea of the multiple components of a research project. The question you must ask at this point is, given all the inherent responsibilities, do you want to be a principal investigator? You may conclude that your other clinical and academic roles do not permit the time expenditure required to fulfill the additional tasks of a principal investigator. Alternately, you may have decided that your professional interests are prioritized in other endeavors, although you would still like to maintain some involvement in research. Fortunately, you may still contribute to, and learn from, research activities as a secondary author or by assisting in the collection of data, setting up/designing equipment, and screening subjects.

These articles should allow you to make an intelligent choice about potential involvement in research, or improving projects already underway. While we have not given you enough information to complete your project, you do have enough to get started. Two general references are recommended here for self study, if you do not have access to an experienced mentor or do not want to wait until the end of this series to get started in research.

By now, you have a general interest in research, or you would not have read this far. However you may be unsure whether you can make the commitment to be principal investigator on a project, since this involves more time and training than you may think you have. You have been exposed to a limited number of researchers in physiatry as role models. You are aware of the 'research giants' who seem to publish endlessly, but you might wonder if they ever have time for family and other interests. Fortunately, research is a collective endeavor and you do not have to be a "giant" to have a meaningful and productive experience in research. This article will guide you in deciding what role you would like to take, as principal investigator, collaborator, assistant, or educated consumer of research. It will highlight some of the differences between these roles, and point out some of the key issues (and potential stumbling blocks) that you must consider if you choose to be a principal investigator.

While we tend to think of researchers in terms of principal investigators, most papers have multiple authors and even more collaborators. The editors of the scientific journals have specified what makes a collaborator worthy of being listed as an author of a paper. It is helpful to decide first if you fit this role.9 While some editors are more restrictive regarding authorship, most agree that you must (1) participate in the design or data analysis of the project, (2) write a portion of the manuscript, and (3) read
To be a co-author, you have to do some writing _either_ project design _or_ analysis. If that is not for you, then you will want to take a different role. There is no disgrace in participating in a research project because you enjoy edging in the research article. Many articles have a very long list of acknowledgments. This is an lent and safe way to begin research if you have no experience. You can learn a great deal by apprenticing yourself writing, and the sooner the better. Return to article I of this series and write out your answers to those exercises! If you are having difficulties with the later ration until the second part of this series, consult texts research.

Write out your conceptual literature review and submit it as a submit it or distribute it to your will be ready to seek funding in earnest.

Having decided you will stick with the project to the end (publication), you also must decide whether you will take the orator and co-author, or principle investigator and primary author on the research project. If this is your first project, ideally you should work with an experienced investigator who will take the principal offer research fellowships where you can learn such skills. If you have a choice, don't be a principal investigator on your first project unless you have an experienced mentor who is willing to devote the time necessary to help you.

the appropriate specialists, you can be a principal investigator without knowing how to do every step of your project. You do have to know the steps are, and when they have been done correctly, specialists. As a matter of fact, as your project gets larger, it is impossible for you to do everything yourself and you will have to rely on others.

must perform, and what tasks he or she perform, but may designate to other research staff members when appropriate. Each task is discussed in detail after presentation in this

FORMULATION OF THE QUESTION

_Initiate Research Content Area_

During the course of clinical work or academic pursuits, numerous, questions arise that stimulate your curiosity and motivate you to find better ways

TABLE 1

The tasks of the principal investigator

<table>
<thead>
<tr>
<th>Must</th>
<th>Should</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formulation of the question</td>
<td></td>
</tr>
<tr>
<td>Initiate research content area</td>
<td>X</td>
</tr>
<tr>
<td>Formulate hypotheses</td>
<td>X</td>
</tr>
<tr>
<td>Review the literature</td>
<td>X²</td>
</tr>
<tr>
<td>Contact outside experts</td>
<td>X</td>
</tr>
</tbody>
</table>

| Project design | |
| Outline project proposal and seek critique | X² |
| Select collaborators, consultants, and equipment | X² |

| Obtain funding | |
| Make inquiries to potential | X² |
funding sources
Calculate budget (salaries, equipment, supplies) X
Write project proposal in format of funding agency X

Project startup
Initiate formal institutional review X
Design data forms X
Obtain equipment X
Designate or hire clinical and support staff X

Ongoing project management
Recruit subjects X
Examine rate of recruitment X
Enforce recruitment of subjects X
Conduct/perform pilot studies X
Collect/enter/reduce data X
Conduct staff meetings at regular intervals X

Project analysis
Choose statistical tests X
Review data X
Analyze data X
Interpret data X

Publication
Prepare manuscript X
Edit manuscript X
Present research results at conferences X

Portions of these tasks may be delegated to other members of your research team, provided that you make certain that they are done correctly.

... of dealing with patient problems. You therefore should stir things up and initiate research in the appropriate area. Often, other members of the rehabilitation team are the ones to define a question/problem and initiate potential ways of examining it. Indeed, it may even be the patient who initiates the actual inquiry.

Formulate Hypotheses

Although any of the individuals noted above may initiate the research content area, the principal investigator must formulate the hypotheses. Having read article 2, “How to Ask the Question,” you are well aware that this is more difficult than it seems at first glance. If the research question has been initiated by other individuals, the principal investigator should confer with these initiators, to establish all the components of the research question in detail. Remember that establishing the question is the most important part of the study and dictates the approach of the entire project.

Review of Literature

Particularly in a large project, you may want to have other staff members who are experts in a particular area select the most pertinent articles and put them in a conceptual framework (see article 2). But you must read each and every article you cite. It is especially dangerous to cite an author who has been cited in another publication, because the citation might be to the wrong page (a minor embarrassment) or the article may not in fact say what it was purported to have said (a major embarrassment).

Contact Outside Experts for Academic and
Clinical Information

One of the most valuable ways of benefiting from other professionals’ knowledge and experience is through direct contact with them. The principal investigator therefore, must establish this contact. A conceptual literature review helps to put your project in the context of the published literature, and personal contacts put your project in the framework of unpublished literature and the clinical experiences of others.

PROJECT DESIGN

The project design is determined by your question, your available resources and your analysis techniques, but always involves compromises to generate relevant conclusions with existing resources. While you should try to get professional assistance in the statistical aspects of design, the ultimate decisions are yours and you must understand why you selected a particular design. Seek help from anyone who wants to be a co-author with you, since he/she must help you here or in the analysis phase to earn the credit of authorship. Presentation of the proposed design to members of the research group, as well as to the clinical staff within the facility, will allow for valuable feedback to optimize the final project design.

Outline Project Proposal and Seek Critique

This step is often omitted, but making an outline is particularly important. By first viewing the project in its skeletal form, you can more quickly identify the most important issues and weaknesses, which then can be remedied before too much writing has been done. The outline also facilitates communication with collaborators, consultants and peers who can quickly get to the point of your work and critique it.

Select Collaborators, Consultants, and Equipment

By the time you complete your outline, and begin the first major draft of your grant, you should have a good idea of who your collaborators and consultants will be. Collaborators must be strongly committed to the project and contribute to it in major ways usually becoming authors on the final paper. Consultants are paid experts who contribute in well-defined areas, such as statistics or data analysis. They may or may not be authors, depending on the breadth of their contributions. You may want to select the professionals you contacted for clinical and academic information in the formulation phase of your project. Were any expert and enthusiastic enough to serve as collaborators or consultants? The equipment you use will influence the level of expertise needed so it should be selected early. When the principal investigator is planning a study similar to one she/he has already conducted or participated in, she/he should choose the equipment. If you delegate choice of equipment, be certain that you get an outline of the available equipment and features, calibration procedures and accuracy, and reasons for choosing each piece. The principal investigator is ultimately responsible for the performance of the equipment, so choose carefully. The actual obtaining, testing and calibration of equipment may be delegated to appropriate members of the research team.

OBTAIN FUNDING

The principal investigator should seek funding for the project. If she/he already has a track record in successful and meaningful research, the principal investigator is in an excellent position to obtain funds since credibility is already established (“in my experience…”). If, however, another individual has greater powers of salesmanship, this task can be delegated to that person. If the project is worth doing, it is worth trying to get someone else to pay for it, if only for the reason that preparing a proposal and getting it formally reviewed will make the project that much better.

Make Inquiries to Potential Funding Sources

Finding the right funding source for the project is half the battle. Most physiatrists know about the important federal sources, e.g., the National Institute on Disability and Rehabilitation Research (NIDRR) or the National Institutes of Health (NIH), but many smaller agencies are also rich sources of potential support. If you are affiliated with a university, contact their research development or grants office. They often keep lists of potential funding agencies, foundations, intra-university “seed” grants, and for-profit industries that might be interested in contracting your research. When working with industry, however, it is critical to avoid situations that may compromise your scientific objectivity.

Once you have found some potential agencies, the principal investigator should call the program officer and discuss the project or send a letter of inquiry. This serves many functions: (1) You can determine if the agency would be
interested in the project, allowing you to avoid the wasted effort of inappropriate application. (2) Some project officers will give you an excellent and educational critique. (3) Grantors may look more kindly on your proposal if they have a sense of you as a person. (4) Early contact assures the agency that you are willing to work with them. The bottom line is that you need to prove to the granting agency that your work will ultimately have the kind of scientific impact that they will be proud to have supported.

**Calculate Budget**

Most of the planning stages and costs must be anticipated even before funding is sought. You need to anticipate everything: staff requirements, how long it will take to enroll the necessary number of patients, the cost of equipment and the expenses of running the office. If research is your livelihood and you depend on grants, in essence you are trying to "win" fixed periods of time and resources to investigate problems whose solutions are not known. One of the greatest challenges in grant-supported research is that you must put the cart before the horse, and only then figure out how to get there.

All grant applications have a section with itemized costs. Get help from your university business office or colleagues if this is your first grant. It is common to underestimate costs, or to forget some key element (such as the salaries of nurse researchers to abstract records). Think of broad categories of items: salaries and benefits of collaborators, consultants and support staff (don't forget yearly cost-of-living increases if the project is to go beyond a single fiscal year), equipment, statistical and other consultants, office maintenance and supplies (copying, paper, telephone), travel, computer access, software and publication costs. Remember, making nice posters for the professional meetings can be expensive!

**Write Proposal in Agency Specific Format**

The principal investigator *must* perform this most important function, since it requires familiarity with every nuance of the project to write convincingly about the importance, safety and efficacy of the study. Remember, however, that all your co-authors *must* do some writing for publication. Now is your chance to enlist their help in writing selected sections. You need to check everything for accuracy, but you should have someone else who is not familiar with your project read your proposal to be certain that it is understandable.

**BEGINNING THE PROJECT**

*Initiate Formal Local Institutional Review (IRB)*

If you are submitting a grant to a federal agency, it must, be signed by many university officers before submission. Watch out for deadlines! Any study even remotely involving human (or animal) subjects must be approved by your Institutional Review Board (IRB). You usually must also get signed informed consent from human subjects. Most grantors want to see informed consent forms in the appendices of the grant.

**Design Data Collection Forms**

You should include a copy of the preliminary form you plan to use in the appendix of your grant application. In some studies it is possible to use secondary data sources. A secondary data source is one which was initially collected for some purpose other than your research. Often these data sets are already on computer tape. If you use a secondary data source, you should test the quality of the data ahead of time (and document its quality) in your formal proposal.

**Designate Staff**

This task *must* be performed by the principal investigator. It involves multiple considerations of who is best suited to particular duties as well as realistic availability within the framework of the entire facility (see article VI-Project Management). In addition, budgeting factors may play a role in who can actually be hired. When projects are large it is often necessary to hire additional staff. If you are planning a moderate or larger-sized study, expecting clinical staff to do both their usual work and the additional research tasks can compromise both their clinical and research contributions. It is possible to do research as a clinician, but this takes careful planning and sensitivity to staff and patients.

**ONGOING PROJECT MANAGEMENT**
Subject Recruitment

The principal investigator (PI) must determine inclusion and exclusion criteria of subjects as part of the study design (see above) and should recruit the subjects as a personal explanation by the PI often encourages the potential subject to participate. Even if the PI delegates this task to other research staff members, she/he still must enforce the recruitment of subjects. The PI must scrutinize the rate of subject recruitment, since this may be crucial in the successful and timely completion of the originally proposed study.

Investigators commonly overestimate the availability of subjects and ease of recruitment. In the case of experimental designs meant to show clinically and statistically significant outcome differences between control and treatment populations, recruitment is particularly important. The smaller the benefit of treatment, the larger the number of cases you will need. Ask a statistician to calculate how many subjects you need (in the control and experimental population) to show the expected differences (the power of the study). If you think it would be too difficult to obtain this number of patients, then it would not be wise to start such an ambitious study.

Conduct Pilot Studies

Experience gained via pilot studies provides the groundwork for subsequent planning, design and conduct of the definitive research project. The PI, therefore, must perform any pilot studies serving as a prelude to further investigative attempts. Based on the results of these preliminary studies, many research tasks can then be delegated to other members of the team. Funding agencies look kindly on proposals supported by pilot projects. Initial forms designed for the study are often modified and improved following the pilot phase.

Collect l Enter l Reduce Data

The PI should perform these tasks for the first few subjects, although later they may be delegated. Their actual execution may provide valuable information or any potential ambiguities in data collection. Sometimes a vague finding or mild discrepancy in the data can point the way to a revolutionary discovery!

Whether or not data collection/entry/reduction was delegated to other research team members, the PI must review the data, including "spot checking" for accuracy as well as examining the completed data in detail. When there are discrepancies and/or questionable results, the PI must serve as the primary detective in solving these mysteries.

Conduct Research Staff Meetings at Regular Intervals

Regular staff meetings must be conducted by the PI. This serves to provide an ongoing update of research activities and allows early troubleshooting or problem solving, avoiding more serious problems. For instance, if you review data collection forms as they are completed, often you can reconcile discrepancies or missing data elements while your experimental subject is still fresh in your mind. If you delegate data collection, have formal instructional sessions. Keep a dated logbook of 1) any important decisions and changes in the protocol, 2) anything that is irregular about particular cases or which might be confusing later.

PROJECT ANALYSIS

Choose Statistical Tests

Choice of appropriate statistical tests for study data must be made by the PI unless the research team is well trained and experienced in this area. While a statistician may guide you as to which tests to use, you must choose them and know why they were chosen. Certainly, if the PI is not adequately trained or experienced in statistics, she/he must seek the assistance of a qualified individual. Again, the statistical approach should be worked out early in the design phase. It is just as important to work with your statistician in the planning as in the analysis phases of your project.

Analyze Data

As you become more skilled at research and familiar with the simple statistical approaches, you will want to do more and more complex analyses so a statistical consultant is invaluable regardless of your sophistication in research methodology. You must fully educate yourself about any statistics test you decide to use. Don't report any statistical analysis unless you are prepared to explain why you selected that particular methodology. The same goes for actually doing the analysis: while you do not have to be an expert in writing the statistical analysis computer code, you should
personally look at the programs that your consultant has written. Ask her/him to send you a copy of the program along with the results. Any persons who want to be co-authors and who join your research team after it starts must help with analysis since they were not around to assist with the design.

**Interpret Data**

Upon completion of data collection/entry/reduction/analysis, the PI must interpret all the results. It is advisable to distribute copies of all analyzed data to the entire research team and collect input from them about the interpretation and implications of the results. Again, you can expect help here from all those people who want to be co-authors. This interactive and dynamic process is one of the most exciting aspects of research. A group of people who can work well together can grasp a better understanding of the results.

**PUBLICATION**

*Preparation and Editing of Manuscript*

You have to delegate some tasks here to your co-authors, in order that they qualify for authorship under the uniform requirements for authorship in biomedical journals (see above). Let them know early what you expect, and the time deadlines, so you can focus your efforts on those aspects you cannot delegate. If there are people whose help was crucial in the conduct of your project, now is the time to enlist their help yet again in the writing so that they qualify as authors. If they were helpful earlier, they will have important contributions to make at this point.

*Presentation of Research Results at Professional Conferences*

The audiovisual presentation of research work to an audience is a valuable learning experience. The PI usually performs this function, but you may delegate this to another individual for their learning provided you are closely involved in the preparation of the presentation. Creating a "13 minute talk" about a project that might have taken a year to do forces you to distill your comments to highlight the most important conclusions. Colleagues listening to your presentation who are not so intimately involved in the project can often point out problems and even new approaches.

If by now you still want to be the principal investigator on your research project, congratulations! If you feel that you want to get more training, start with the suggested texts by Hulley' and Polit.' But if you are getting cold feet, and think that being an investigator is too much for you, please reconsider the field of physical medicine and rehabilitation needs more Pls.

**SUMMARY**

OK - you're hooked on research. Wouldn't you like to know what other scientists are like? Here is a selected list of personality traits which have been found to be associated with scientists (Garfield, 1989); we are sure you will recognize yourself in some of these areas.

- High level of general curiosity
- Skepticism
- Facility for precise, critical thinking
- Assertiveness
- Tendency toward taking risks
- Tendency toward preoccupation
- Reliability
- Independence
- Nonconformity
- Indifference to close personal relationships, group activities, politics
- Loneliness

While some of these characteristics are very helpful in accomplishing your research objectives, others such as loneliness are not necessary. Establishing collegial contacts is fun, and the camaraderie of a research group can be very stimulating. Take the time to establish human relationships - you will be well rewarded. Like all the other skills suggested here, the sooner you start the better.
If after reading this article you decide that being a PI is not for you, and you cannot find an experienced researcher with whom you can work, you can still get started with small scale clinical research. Although outside funding helps, it is not necessary. If your research question was inspired by your patients, you might be able to collect pilot data as you care for them. One of your patients might even want to help with your research. If your hunches pan out, you will then be in an even better position to seek funding for a more definitive study. But if you take this route, particularly if you are doing anything out of the ordinary clinical routine, be sure to get approval from your hospital Institutional Review Board and a signed informed consent from each patient before you start.

Regardless of how you start, remember that you are setting a lifelong pattern of work, and that you are also establishing a 'track record' that is very important in getting grants. It is common when starting out to try to do something that is too ambitious or complex for your level of experience. Start slow and small with a project that has a good chance for success, and clearly defined goals. If you can't decide where to start, how about that small project you did 4 years ago but never wrote up?

EXERCISES

You have now completed this first series of articles 'Research in Physical Medicine and Rehabilitation.' If you have done all the exercises up to this point (articles I-VI), congratulations! This last exercise set will show you just how far you have come. But remember this is only the beginning!

1. Return to the exercises for the first article! Select the strongest question you created, and modify it based on any new knowledge or ideas.
2. Get the forms you designed for the exercises in article 111’ and the information from the pre-test of the three charts.
3. If you have not already done a literature review’ on the topic, do it now.
4. Look at the experimental designs you listed for the exercises in article IV. Select the ones you feel are strongest and most practical.
5. Turn to lists of tasks of the PI and begin to write down each outlined step. This will give you a sense of what actually would be involved in developing, and submitting a proposal, and in functioning as a PI.
6. Start writing. Write up the literature review you did in step 3. Write up any old data you have lying around. Go to your colleagues with unpublished masters theses and offer to help with data reanalysis and writing. That is the write way to become a principal investigator.

REFERENCES