

RESEARCH MANUAL FOR RESIDENTS

A guide to the path less traveled

Joy L. Palmer, D.O.
With contributions from
Cynthia Norton, M.S., OMS IV
Judith Viola, OMS III

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INTRODUCTION

Good day, Colleagues:

By no means am I an expert on designing, performing and/or publishing clinical research. In fact, before residency, I had never even participated in any research activity outside of being a subject in psychology studies as an undergrad! I have however, lived through, that's right, I

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I. Why conduct clinical research?

The Family Practice and Neuromusculoskeletal residency programs at UNE are three years long. Those 36 months are packed with clinic responsibilities, on-call shifts, didactics, educational programs to attend and lectures to give. Why would any resident even want to embark on such a daunting journey as clinical research? Beside the fact that there is a scholarship requirement that a research project fills nicely; conducting research also:

- Contributes to the greater good of medicine
- Expands personal and profession knowledge

Despite being wrought with challenges on many levels (time, academics, rules, scarcity of funding), participation in clinical research is crucial to the advancement of osteopathic medicine. This is an opinion shared by many osteopathic physicians and researchers¹⁻⁴.

In Dr. Still's writings, osteopathy is based on structure and function, on improving the current medical model and on working in harmony with natural laws⁵. For over a century, physicians and patients have seen the significant benefits of osteopathic manipulation. Osteopathic medical training consists of a standard didactic and clerkship curriculum as well as continuous instruction in technique and philosophy regarding osteopathic practices and principles throughout pre- and post-graduate training. However, compared to our allopathic and even chiropractic colleagues, we are doing very little in the realm of research to "scientifically" prove the benefit of osteopathic medicine.

Not to say there hasn't been improvement in this arena. Funding to osteopathic colleges has increased exponentially in the past fifteen years. While many of the awards have gone to PhD basic scientists, the number of osteopathic physicians receiving grants for research evaluating practices and principles has increased as well. In 2004, the number of osteopathic physicians receiving awards grew to 134 from a total of 84 in 1999⁶. Because of the way success and prosperity are rated in the academic world, the amount of research dollars secured by an institution plays an important part in its rating for quality. Insurance companies, colleagues and patients are all asking for the proof in the pudding. Therefore, research, both in basic sciences at colleges of osteopathic medicine and studies exploring osteopathic principles, is certainly one way to secure our future and improve upon osteopathic medicine – its delivery, its concepts, its practices.

To answer the original question of why to conduct clinical research: The bottom line is that clinical research is a tremendous learning process. Participating in, or conducting research as a

II. TYPES OF CLINICAL RESEARCH

Clinical research comes in two flavors: observational and experimental. An observational study is just as it sounds: passive observation of study participants. Participants can be followed over time, known as a **cohort**, or be examined at one-point in time, known as **cross-sectional**. Another type of observational study is the **case-controlled study**. This is typically a case report comparing those with and without a particular condition. Cohort and case-controlled studies can be retrospective or prospective. A retrospective study looks back in time at a defined sample and collects data about predictor variables after outcomes have occurred. A prospective study follows events into the future for a select period of time for a sample defined by the researcher with predictor variables measured before outcomes have occurred and outcome variables measured as they occur¹⁻³.

Observational studies are passive in that they do not involve manipulation of the variables. A variable can be what is being measured (outcome), or what helps to define the participants (predictor). Observational studies often provide data for larger experimental clinical trials. Cohort studies help provide incidence of a variable, whereas cross-sectional studies provide prevalence of a variable. Cohort studies can lead to more detailed research design, can provide data for hypothesis and insight into risk factors^{1,2}.

In experimental clinical research, we actively manipulate the independent variables and then measure the effects of this manipulation on the dependent variables². Experimental clinical research studies tend to assess the effectiveness of an intervention¹. A randomized, blinded trial is the gold standard for establishing the causality and effectiveness of an intervention. Many physicians and scientists will not read or consider a clinical trial unless it is blinded. Blinding describes a process by which information that could skew the results, or introduce bias, is withheld from either just the participants (“single-blinded”), or both the participants and experimenters (“double-blinded”).

Including a control group is another way to decrease the bias of the end results. Having half the subjects receive a sham protocol, the other half actual OMT is an example of a controlled, single-blinded study. A randomized trial involves the random allocation of different interventions (or treatments) to subjects. Randomization ensures that known and unknown confounding factors are evenly distributed between treatment groups, or the treatment and control groups.

References

1. Hulley SB et al. *Designing Clinical Research, 2nd ed.* Philadelphia: Lippincott Williams & Wilkins, 2001.
2. Cruser dA. *Manual of Basic Tools for Osteopathic Manipulative Research, revised 2007.* University of North Texas Health Science Center, Texas College of Osteopathic Medicine. Accessed online at:
<http://www.hsc.unt.edu/>
<http://www.hsc.unt.edu/orc/documents/ResearchManual.pdf>
3. Glossary: study design. Accessed via <http://www.hsrmethods.org/>

III. NITTY-GRITTY TERMINOLOGY

Alternative hypothesis: The alternative hypothesis states that an association between predictor and outcome variables is present. It represents the possibility that the experientially-observed effect is genuine. It cannot be tested directly. The classical approach is to calculate the probability that the observed effect will occur if the null hypothesis (aka random chance) is true. If this value (the “p-value”) is small, then the the null hypothesis is rejected in favor of the alternative hypothesis.

Categorical variables: phenomena that cannot be quantified, thereby measured by classifying into categories. Example: blood type, gender.

Cluster sample: sampling technique where the entire population is divided into natural groupings, or clusters, and a random sample of these clusters is selected.

Continuous variable: rich in information; have quantified intervals on an infinite scale of values.

Confidence interval (CI): statistic calculated from the range

Independent variable: one that comes before the outcome variable. Does not change. May be a qualifier, or descriptor of study population. Also known as, predictor variable.

Intervention: special predictor variable that the investigator manipulates.

Measurement scales: describe phenomena that can be analyzed statistically; continuous or ordered discrete and categorical variables. Considered with methods.

Methods: detailed tasks, steps, stages and procedures you will use to conduct the study.

Null hypothesis: states that there is no association between the predictor and the outcome variable. It is the opposite of the alternative or research hypothesis. Ideally, you want the data to prove the null hypothesis is false, which makes your (“research”) hypothesis true.

Odds ratio: estimate of strength of association between each predictor variable and presence or

Sample size: number of subjects needed to observe the expected difference in outcome between study groups with a reasonable degree of probability or power.

Significance: in regards to the study question - why is the question important, how will it contribute to society, what benefit will it bring, any existing research around this topic that may have left unanswered questions, or questions you wish to challenge.

In regards to statistics - a result is considered (statistically) significant if it is unlikely to have occurred by chance. The significance level is usually represented by the Greek symbol α (alpha).

Simple random sample: give numbers to qualifying sample population, then randomly select participants.

Stratified random sample: dividing the population into subgroups based on specific criteria, then randomly selecting from each group, or “strata”.

Study sample: subset of target population available for study.

Target population: defined by clinical, demographic, geographic population; who the results will be generalized to.

Type I error: incorrectly concluding that the null hypothesis is false, when it is actually true. The probability of committing a Type I error is equivalent to ***alpha***, the significance level given to the study.

Type II error: occurs when the test fails to reject the null hypotheses as false when it is in fact false. Probability of this type of error decreases as the amount of data collected increases. The probability of committing this type of error is equivalent to ***beta***. The probability of not committing a Type II error is equivalent to ***power***.

Validity: how well the measurement represents the phenomenon of interest.

References

Hulley SB et al. *Designing Clinical Research, 2nd ed.* Philadelphia: Lippincott Williams & Wilkins, 2001.

Cruser dA. *Manual of Basic Tools for Osteopathic Manipulative Research, revised 2007.* Univeristy of North Texas Health Science Center, Texas College of Osteopathic Medicine. Accessed online at: <http://www.hsc.unt.edu/orc/documents/ResearchManual.pdf>

IV. TIMELINE

PGY-1

TOPIC SELECTION

Most of your PGY-1 year is committed to learning how to effectively and efficiently care for the hospitalized patient. Certainly in the first six months, you are becoming accustomed to the responsibilities of being a house officer: rounds, call, pharmaceuticals, interventions. No need to embark on a literature search yet, just try to keep in the back of your mind events, cases, procedures that interested you most. Did you read an article that might have sparked your interest, did an attending speak about a topic you would like to learn more about? Begin thinking about what your research question

with. When you do decide on a mentor, approach them with your request in such a way that they do not feel obligated or trapped. If they have research experience, they will be familiar with the arduous task ahead. Be clear about your expectations and allow them to inform you of their expectations for you. Give them time to consider the idea, then follow-up with a phone call, email or personal visit.

IRB REQUIREMENTS

Get a jump start on UNE's IRB requirements in the last 2-3 months of this first year. There is an on-line course in the topic of human and animal protection during research trials. There are approximately 16 modules to be read, with questions to answer. If you do not sufficiently pass the quiz, the module must be redone. This course is actually quite labor-intensive – it takes anywhere from 16-20 hours to complete. You may log on and off so that it is not necessary to burn your eyes out in one sitting, but it is quite lengthy. This must be completed as part of your IRB application.

BOTTOM LINE

By the end of your PGY-1 year you want to have:

- a firm question in mind
- a preliminary literature review completed
- a mentor committed to working with you
- completion of UNE's IRB Research Compliance Course.

PGY-2

Just like the PGY-1 year, PGY-2 can be divided into an early half (first 6 months) and a late half (months 7-12). Having decided on the study question, you must now conduct a literature review. Initially, this will entail articles written on a similar topic and articles that support your hypothesis. As you concomitantly work on your study design, you will also be searching for articles that support any tools being utilized (surveys, equipment). Review articles that discuss study design and methods. There are several listed in the recommended reading section. It is better to design the study well early in the process, then to read about how it should have been done later.

STUDY DESIGN

Study design is one of the most challenging parts of this process. There are several "how to" texts available. Chapter V in this manual is dedicated to study design. Helpful articles to review at this time include:

- "Blinding Protocols, Treatment Credibility, and Expectancy: Methodologic Issues in Clinical Trials of Osteopathic Manipulative Medicine," by Licciardone and Russo (*J Am Osteopath Assoc.* 2006;106:457-463.)
- "Effectiveness of a Sham Protocol and Adverse Effects in a Clinical Trial of Osteopathic Manipulative Treatment in Nursing Home Patients," by Noll et al (*J Am Osteopath Assoc.* 2004;104:107-113.)

- Korr's "Osteopathic research: The needed paradigm shift" (*J Am Osteopath Assoc.* 1991;91:156-171.)
- "Evidence-Based Medicine, Part 2. An Introduction to Critical Appraisal of Articles on Therapy by Cardarelli, et al (*J Am Osteopath Assoc.* 2007;107:299)

REVIEW, REVIEW, REVIEW

Utilizing UNECOM's Research Club is an excellent resource as well. Many of the students involved have some form of research experience. Setting up a noon-time meeting to present your project for critique and feed-back is an easy

STUDY IMPLEMENTATION

Plan to begin implementing your project in the **latter half** of your PGY-2 year. Depending on the length of the study protocol, allow yourself 12 months for the active study (subject enrollment & study protocol). Aim for project completion by the time you graduate residency. Completion of your research project means your article is ready to be sent to journals for publication. Therefore, everything is complete: data collection, study analysis, graphs/figures and write-up/poster/article (including peer-review).

If your study is considered a clinical trial (see <http://www.icmje.org/faq.pdf> for the definition), it needs to be registered in a public trials registry before you start enrollment. Apart from contributing to a comprehensive, publicly available database of clinical trials by registering your trial, your final paper might not be published by reputable journals if you did not register your study. The U.S. National Institute of Health maintains a public trials registry: <http://www.clinicaltrials.gov/>

PGY-3

PGY-3 year can be looked at as a year for completion. Completing call, completing clinic, taking certification boards, completing your research project! Most of this year is dedicated to continuation of the active project, i.e. study protocol and data collection. Securing a data analyst should be completed in the first three months of PGY-3.

POSTER PRESENTATION

Once you have secured and analyzed some data you can begin preparing a poster for your study. In the southern Maine area, there are two arenas in which you can present your poster: Maine Osteopathic Association's Mid-winter Conference in February and NEOMEN's Research Forum in April. For those attending the AAO Convocation in March, there is a research poster presentation held during Convocation, and you might win the "Ram of Reason". Another poster presentation opportunity is at the American College of Family Practice Conference in the spring (GME receives notices from them each fall/winter for applications).

There is a standardized format to follow for all posters. Important information to include in your poster is:

- Title
- Author(s), with institutional affiliations and addresses of these institutions
- Abstract
- Introduction/Background
- Methods
- Results
- Discussion
- References

- Other things that need to be included on your poster (if applicable) include the source of funding and grant number, IRB or IACUC approval, and the use of informed consent.

UNE's Basic Sciences department will print the poster for about \$30.00. Amy Davidoff, PhD, is the contact person for utilization of the printer. A poster template in electronic format is accessible in Appendix C.

PUBLISHING DATA

Along with poster presentations comes completion of your article and application for publication in various journals. Contacting the journal(s) of choice and requesting information on publication submission is important. It is essential to have your article peer-reviewed by your colleagues and editing it carefully for manuscript specifications. Chapter VIII is dedicated to article writing and publication.

References

Licciardone JC, Russo DP. Blinding Protocols, Treatment Credibility, and Expectancy: Methodologic Issues in Clinical Trials of Osteopathic Manipulative Treatment.

V. DESIGNING YOUR PROJECT

For those with limited to no research experience, designing a research project may seem like the most daunting of all the tasks involved. Seeking guidance from your mentor and people with research experience early in this process is paramount. Where to begin? How do you get to the end? What falls in between? Attacking the research design in a systematic fashion will help clarify the whole process.

What is the question? Why is it significant? What will you measure to support your hypothesis? Who will participate? How many participants will you need? How will the data be analyzed? The answers to these questions form an outline for your research project, and need to be included in your proposal. Once the proposal is written, the process that ensues will be much clearer.

Parts of a study design include:

- Hypothesis
- Background
- Methods

AND THE QUESTION IS...

First off, what interests you? This project will en

BACKGROUND

This is where performing a literature review at the end of the PGY-1 year starts to pay off. This section helps to support the theory behind the hypothesis. Include prior studies and relevant outcomes. Include pathophysiology or anatomical correlates. The BACKGROUND sets the stage

METHODS - SUBJECT PARTICIPATION – WHO, WHERE, HOW LONG?

This section will tackle sample size first. Sample size calculation is quite important, because too little and the data will lack power, and too large and your study is inefficient. There does come a point where after a certain sample size, the increase in the power to support the study is no longer significant and more work will be done than gains received. Contacting the Osteopathic Research Center (ORC) at the University of North Texas Health Sciences Center (refer to info under Resources chapter) is your best bet in obtaining help here. **DO THIS IN THE PRELIMINARY DESIGN PHASE.** It is too early in the game to expect to have any funding to consult with a biostatistician, so utilizing the ORC is most helpful.

Who?

Deciding how you will select or recruit for the study's sampling population is of great importance. Limiting bias is of course a major factor. Accessing data bases at hospitals, medical offices, public health agencies or relying on other physicians for referrals are all viable options. A captured audience, i.e. nursing home or hospitalized patients offer easy access, though may result in poor follow-up if the study is for an extended period of time and obtaining consent may be more difficult. Of course, a study that is blinded (single or double) has greater strength.

Exclusion/Inclusion criteria should be consistent with other published studies. This will allow for greater ease of comparing the studies for outcome efficacy at a later date. Also, keep in mind who you want to generalize the study to. This takes you back to the question phase, i.e. what is the significance of the study, who will be effected by the results, how will the results contribute to our medical understanding or public health policy? The more exclusion criteria involved, the less the study will be generalized.

Where?

Where will your project take place? How easy is it to get to? If at a hospital or nursing home, you will need to obtain permission from that particular facility. Obtaining permission in writing is necessary for your IRB application. If you utilize University Health Care facilities, obtain permission from the site managers (Barbara Schuman at UHC-Peds and Anne Gionest at UHC-Saco.)

How long?

You need to figure out how long participants will be committed to the project. The longer a project extends, the more likely it is that participants will drop out. Also, because the residency program has a finite time-line, you need to keep in mind the goal of completing this project in approximately 12 months, start to finish. If you are conducting an experimental trial, that translates to 12 months to recruit or obtain participants, conduct study protocol, collect data, have the data analyzed and complete your paper. If you are performing a prospective study measuring outcomes yet to occur, keeping the 12-month time crunch is important as well.

METHODS - DATA ANALYSIS

This is where all your hard work pays off. Unless you have experience in this arena, finding someone to assist you will be so very helpful. The Osteopathic Research Center (ORC) at the University of North Texas (contact info under Chapter IX: Resources) is a fantastic resource. Contact them early in your design phase to obtain sample size calculation and to discuss the best way to analyze your prospective data. You will need this information when applying for funding or IRB approval. Perhaps Gail Tudor, PhD could be of assistance as well, simply to discuss analysis options in the early phase. You can find her contact info under Chapter IX. Plan to utilize a biostatistician for the end-result. This saves time and ensures accuracy (yes, they will most likely require monetary compensation).

You also need to have a plan as to how or where you will keep the collected data. It is important to ensure patient confidentiality. Their intake info should be kept in a locked cabinet. You will want to design some sort of computerized data base for electronic storage of the collected information. This is where medical students could be helpful. Many of them have experience in this area – try to find them via mass email or visiting with the New

VI. Institutional Review Board (IRB)

To ensure compliance with federal regulations in the protection of research participants, both human and other animals, each research institution – be it a University, hospital or private group - must have a review board. All research proposals must be presented to this board for evaluation. The project will either be deemed exempt, approved, approved with revisions or denied. As eluded to in the Timeline chapter, this must be thought of as a process. Expect questions or revision requests from the Board – seldom are projects approved on first pass.

The IRB wants to ensure that the study is safe, ethical and purposeful. Portraying a well-thought-out design for the study protocol, detailing privacy of patient personal information and a thorough consent form written in lay-man's terms are of utmost importance. The Board is composed of basic scientists, liberal arts faculty and at least one clinician. Do not assume that the reader is familiar with the physiology of the gastrointestinal system. If it is important to the safety and efficacy of the study, be sure to utilize definitions and terms that are clear and concise.

At the University of New England, the IRB has a very detailed website, accessible at <http://faculty.une.edu/irb/>. A checklist of necessary proposal components is provided, all required forms are available as electronic and pdf files, as well as a link to the research protection and compliance course that is mandated by the IRB (Course in the Protection of Human Research Subjects).

The IRB proposal packet consists of:

1. face sheet (signatures required)
2. research proposal including literature cited, consent form, recruiting propaganda and outcome measurement tools such as surveys
3. supportive documents, such as host site approval for space utilization, letters of support from research mentors, certificat

An electronic copy of the IRB application must be sent to irb@une.edu by the first of the month with paper-copy to follow within 4 days. Hard copy should be sent to IRB, attn: Carrie Bogue, Office of Sponsored Programs, UNE-Biddeford Campus, 11 Hills Beach Road, Biddeford, ME 04005.

Beginning this process early in your PGY-2 year is essential. Funding applications will inquire as to the IRB approval status of the study. Certainly, no funds will be dispersed until approval is granted. The IRB only meets once a month, so it is best to get your proposal in early.

<http://www.mehaf.org/>

charge of the review board will help shape your proposal to satisfy their interests. It may also be helpful to inquire about pre-procurement workshops that you can attend.

Grant Writing

<http://www.hsc.unt.edu/orc/documents/ResearchManual.pdf> - Osteopathic Research Center Manual

http://grants.nih.gov/grants/grant_tips.htm

www.thegrantinstitute.com

<http://healthlinks.washington.edu/rfs/gw/>

http://www.hopkinsmedicine.org/fac_development/research/grant_writing/#item1

<http://www.medicine.wisc.edu/mainweb/DOMPAGESText.php?section=cipp&page=trainingseminars>

http://www.grantforms.com/bookstore/authors_consultants/liane_page.html

Resources to educate you on grant writing are numerous and at times overwhelming. They include, but are not limited to, seminars, workshops, books and online resources. In addition, previous grants accepted and experienced researchers can prove to be invaluable. Depending on the organization and researcher, this may or may not be a group effort. With clinical researchers attempting to secure funding on limited time and resources, a team effort is an awesome idea, but one not easily attained. If you are able, assigning team members to complete the various parts of the application is most helpful. There are face sheets to complete, abstracts to submit, signatures needed (sometimes from third party entities), networking to do, meetings to attend, research to perform, and copy editing to complete. Include a timeline for expected delivery of product, be it templates, progress updates, or results.

BUDGET

Grant proposals include a budgeting of funds section. Be sure to allocate sufficient time for staffing, funds for recruiting tools, study materials, space utilization (this may include photocopier rental/use, electricity, internet access). Depending on staff size, it may be necessary

critique. Appendix C has a hard copy of the biosketch form used by the National Institute of Health and a link to their site.

preparation and submission, overlapping publications, reference citation, editorship, etc., etc., etc. Everybody publishing an article should make sure it meets these uniform requirements set by top scientific journals, such as *JAMA*, *The New England Journal of Medicine*, *The Lancet*, *Annals of Internal Medicine*. Think about it this way: if your article meets the requirements set by the top medical/scientific journals in the world, any and every journal with less strict guidelines will accept it as well. If you have any interest in future research, it is best to adopt good habits early. You will probably include your article in your CV, fellowship, or employment application, so you want it to be a “gold star”.

IX. RESOURCES

PEOPLE

<http://www.une.edu/research/directory/>

Fantastic directory detailing who is doing what for research on campus. A must see.

NEW ENGLAND RESEARCH CLUB

Composed of MS-I's and MS-II's this group meets every second Wednesday of the month. Research experience of those involved varies greatly, from lots to not so much. Presenting to them would be a great way to obtain feedback regarding study design, measurement tools, inclusion/exclusion criteria. Additionally, they can promote research endeavors throughout the 1st and 2nd year medical student body and recruit assistants if needed. They are in the process of designing their own website. Current contact is Jeremy Force and Despina Hoffman, co-presidents. Respective email address are: jforce@mail.une.edu and dhoffman@mail.une.edu.

MARILYN R. GUGLIUCCI, PHD
DIRECTOR, GERIATRIC EDUCATION AND RESEARCH

can obtain email addresses and contact information through Mary Spang, administrative assistant in the OMM department at UNECOM, mospang@une.edu.

TUDOR, GAIL, PHD ASSOCIATE PROFESSOR

Research expertise: Study design, questionnaire design, data analysis - particularly categorical data, PhD in Biostatistics.

Research interests: 20+ years experience as a statistical consultant in many areas of medicine and has helped to write 25+ grant proposals for mainly medical faculty.

NICHOLAS GERE, MBA

E-mail: ngere@une.edu

Expertise: Joining UNE in February, 2005, Nick is UNE's founding director of Sponsored Programs. Holding a B.A. from Boston College and an M.B.A. from Boston University's Public Management Program, Nick has extensive experience in the administration of sponsored research at organizations such as Boston Children's Hospital, Boston University School of Medicine, Whitehead Institute for Biomedical Research, and New England Research Institutes, Inc.

Director of Sponsored Programs, Mr. Gere is a great resource if you need help finding funding sources, logistics of the "pink sheet," and proper submission. He needs to review all proposals for external funding, so try to get the information to him early. Many applications are submitted electronically by the Office of Sponsored Programs or at the very least require a signature from Mr. Gere, some sort of qualifying number, or some other obscure technicality. You can set up appointments with him through Carrie Bogue, his secretary. Her email is cbogue@une.edu.

JACK GINTY, EXECUTIVE DIRECTOR OF MAINE OSTEOPATHIC ASSOCIATION

Phone: 207 623-1101

jginty@mainedo.org

Contact person for utilizing MOA for research advertising/networking purposes. Very willing to work with residents on various levels.

AMY DAVIDOFF, PHD, PROFESSOR, DEPARTMENT OF PHARMACOLOGY, UNECOM

Phone: 207-602-2824

E-mail: adavidoff@une.edu

Research interests: Cardiovascular physiology and pharmacology, with particular emphasis on diabetes and heart failure.

Expertise: Basic Science research design, evaluation, publication, and grant development.

<http://www.une.edu/research/directory/>

Excellent search engine that grants you access to research and expertise here are UNE. Very user friendly; simply type in the person's last name, or even the department of interest. This site highlights past research, current research, credentials and contact information.

SOUTHERN MAINE OSTEOPATHIC GROUP (S.M.O.G)

Ira Stockwell, D.O., President

Phone: 207 856-6010

Monthly meetings offer great venue for advertising research project. Membership is free as an intern/resident. Dr. Stockwell is very approachable and wonderful to work with.

PLACES

UNIVERSITY OF NORTH TEXAS BIOMEDICAL RESEARCH INSTITUTE – Osteopathic Research Center

www.hsc.unt.edu/research/orc

Contact here is Cathleen Kearns, Administrative Director.

Phone: 817 735-0515

E-mail: ckearns@hsc.unt.edu

The Institute offers services in regards to statistical analysis, both preliminary and after all the data has been obtained. The preliminary number crunching comes as a complimentary service to help get researchers on their way. Fee for service if you decide to use them as your biostatistician or for other services.

<http://www.cpb.org/grants/grantwriting.html>

Offers access to *Grant Proposal Writing Tips*, a manuscript dedicated to step-wise instruction on how to submit a grant.

<http://www.hsrmethods.org/>

Website about research providing glossary, data sources, ethics info, links to statistic tutorials and research guidelines, as well as bibliographic resources. Easy to use. Wealth of information!

<http://stattrek.com/>

Fantastic site offering tutorials on statistics and nitty-gritty definitions. Quite helpful.

<http://research.mlanet.org/resbib.html>

Website offering annotated bibliography on publications related to various research topics, encompassing statistics, types of research, grant writing and much more. No direct links to articles or books, but very thorough.

<http://www.research.umich.edu/proposals/pwg/pwgcontents/html>

Home of Don Thachrey's, Proposal Writer's Guide, copyright 2007, The Regents of the University of Michigan. Manuscript details steps to follow when writing a grant proposal.

<http://www.umass.edu/research/ogca/proceeds/dev.htm>

Grant writing guide put together by the University of Massachusetts. Covers grant writing and funding proposals for both the private and public sectors.

http://www.umdj.edu/idsweb/gsc/research_design.htm

Provides summary of publications helpful to planning, designing and conducting quality research.

<http://rf.osu.edu>

X. LESSONS LEARNED

FINDING A MENTOR

I simply cannot say enough about how important it is to find a good mentor. Depending on past experience brought by the resident researcher, the efficiency of the research project can be affected by the mentor. The style, design and implementation of the study may also all be affected in some manner by the mentor. Do not hesitate to “research” their qualifications.

Qualities to consider:

1. **Research experience** – current, 5 years ago, 15 years ago? What kind of studies did they perform? Have they published anything?
2. **Work ethic** – speak with their colleagues, research partners, fellows they have supervised in the past, students or other residents that may have worked with them. Are they punctual, sincerely interested in teaching someone how to conduct research, reliable, knowledgeable?
3. **Time** – most projects will require more mentorship in the beginning phases i.e., study design, IRB approval, funding applications. Be confident that they are willing to commit at least 1 hour per month for face-to-face discussions. Pay attention to how busy they are – are they already over-capacitated?

RECRUITING SUBJECTS

This is much more difficult than expected. Working with captured audiences, i.e., nursing home patients, hospitalized patients is certainly easier, though has its cons as well. Nursing home patients are accessible, but require travel to the facility, and may require consent from a power of attorney. Hospitalized patients can be convenient from an accessibility aspect, but also require you going to them. Hospitalized patients may also require approval of the study through the hospital’s Institutional Review Board in addition to UNE’s, and in-patient stay seems to be getting shorter and shorter. If you are willing to travel and jump through a few extra hoops, these grou but5Der 5-s cansuerelyemakre tho rcrqui

cent on

2. **Presence** – As you can imagine, the more folks are reminded about the study, the greater chance you have of obtaining referrals. Frequent calls, e-mails, reminder visits to participating offices, if done politely, should not be thought of as hounding– it is simply *reminding*.

Face time is always good. Offer to bring lunch or a morning snack in exchange for 15 minutes of explanation time. Be sure to speak with the medical assistants and office manager. The more people aware of the study, the increased chance that someone will think of it.

Request permission to hang fliers in their waiting room or encounter rooms. Making the patients aware of the opportunity is obviously a great way to get the participation conversation started.

3. **Time** - The less you require, the easier it will be for physicians to participate. Provide recruiting scripts and do not ask the referring practitioner to consent. Keep their involvement simple.

Be sure to think outside the box as well. Perhaps there are other groups that could offer a referral base, such as:

1. Physical or Occupational therapy groups
2. Occupational health practices
3. Free clinics
4. Assisted living facilities
5. Counseling services
6. Support groups

Advertise your study through S.M.O.G. (Southern Maine Osteopathic Group) meetings and the Maine Osteopathic Association. Utilize your attendings and administrative staff for access to their colleagues and network of resources. Get the word out and keep reminding, reminding, and reminding.

Flexibility – Enthusiasm – Persistence will pay off.

MULTIPLE (YES, MULTIPLE) PROJECT REVIEWS

The more people you discuss the study with, the better it will be. Each person will come from a background, slightly or grossly different from yours, altering their perspective and thought process. The more critique you receive, the stronger your study will become. REALLY.

Begin this early in your PGY-2 year – before you apply for IRB approval, before you apply for funding. Utilize the basic scientists at the local college or university (UNECOM), clinicians at area hospitals (Mercy, Maine Medical Center and Southern Maine Medical Center), and any affiliated research clubs (the New England Research Club at UNECOM). Talking with folks who are not involved with research is valuable as well. Listen with an open mind to the comments and questions received. These discussions enforce your convictions regarding the purpose of the study and will offer new insights. You need not incorporate all the new ideas that ensue, but many will certainly be noteworthy. It is recommended that 5-7 people critique the

study before it is finalized for IRB review. (This number is based purely on personal experience, but this shared critiquing is just so very beneficial.)

START SMALL

Remember that this project, from start to finish (literature review to article publication), needs to be completed in the 2 years of your residency training- concurrently with clinic and call and didactics and teaching. Best bet, start small.

Experimental pilot studies may be small in the number of participants, but they are a ton of work. Beginning with an observational study, retrospective cohort comparison or cross-sectional would certainly be easier, as well as provide data to support a larger, more complex study later on. Replicating a study that was completed in a different geographical location can be fairly easy – the design and methods are already laid out. Conducting a smaller study will still provide the invaluable experience of coming up with a question, study design and methods, IRB proposal writing, funding procurement and study implementation.

Appendix B - Table of Project Timeline

<u>PGY-1</u>	<ul style="list-style-type: none">• Start thinking of your question –what interests you, what would you like to investigate further?• Preliminary lit review on potential topics• Find a mentor• Complete UNE’s on-line course for protection of human and animal research participants
<u>PGY-2</u>	<ul style="list-style-type: none">•

APPENDIX C - POSTER TEMPLATE

APPENDIX D – HARD COPY OF BIOSKETCH

For review only. For access please go to:

<http://grants.nih.gov/grants/funding/phs398/biosketchsample.doc>