

# 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

UNECOM 2008

# *TABLE OF CONTENTS*

Introduction

Acknowledgement

I.	Why conduct clinical research?	3
II.	Types of clinical research	5
III.	Nitty-gritty terminology	8
IV.	Timeline	11
	a. PGY-1	
	b. PGY-2	
	c. PGY-3	
V.	Designing your project	16
	a. And the correct question is...	
	b. How and what to measure	
	c. Subject participation – who, where, how long?	
	d. Data analysis	
VI.	Institutional Review Board (IRB)	20
VII.	Funding your project	22
	a. Where to look	
	b. Networking	
	c. Grant writing	
VIII.	Manuscript Writing and Publication	26
IX.	Resources – people, places, publications	28
X.	Lessons learned	32
	a. Mentor selection	
	b. Proposal review, and review, and review	
	c. Recruiting	
	d. Size does matter	

Appendix A – Annotated bibliography of recommended readings

Appendix B – Table format of recommended timeline

Appendix C – Poster template

Appendix D - Hard Copy of Biosketch

# 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 have survived the experience of designing and implementing a clinical research project as a resident at the University of New England and want to pass on the lessons I've learned. At times it has felt like I was in a foreign country without an interpreter, without any knowledge of how to speak the language, AND without any money to bribe or shall we say compensate someone to provide me with directions.

My goal is to provide you with a useful resource – a travel guide of sorts to help you navigate and successfully complete a research study. This book contains basic clinical research terminology, timeline recommendation, list of resources, nitty-gritty instructions on how to set up a research project, an appendix of required forms for UNE's IRB and an annotated bibliography of recommended readings.

Stay the course and success will follow!!

Fondly,

- Joy

## ACKNOWLEDGEMENT

The author would like to thank Cynthia Norton, M.S., OMS IV for her contributions to the grant writing section and overall web-based design of the manual.

Thanks to Judith Viola, OMSIII for her editorial work and contributions to several areas of the manual.

Sincere appreciation to Holly Korda, PhD, Evelyn Schwalenberg, D.O., Marilyn Gugliucci, PhD., and William Papura, D.O. for their support throughout this project. Their time and commitment to the success of the residents and students at UNECOM is greatly appreciated.

## *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 researchers<sup>1-4</sup>.

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 laws<sup>5</sup>. 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 1999<sup>6</sup>. 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

resident may spark an interest that otherwise may not have been apparent. Going through the process may also lead to a greater appreciation for the work and effort involved in the studies evaluated and incorporated into one's practice throughout one's career.

## References

1. Guillory VJ, Sharp G. Research at US Colleges of Osteopathic Medicine: A Decade of Growth. *J Am Osteopath Assoc.* 2003; 103:176-181.
2. Clearfield MB, Smith-Barbaro P, Guillory VJ, Cavalieri TA, Wood DL, Hahn MB. How Can We Keep Research Growing at Colleges of Osteopathic Medicine? *J Am Osteopath Assoc.* 2007; 107:463-465.
3. Patterson MM. A research program for the osteopathic profession, our great and only hope. *J Am Osteopath Assoc.* 2001; 101:534.
4. Papa FJ. Research secures the future of osteopathic medicine: Part 1. Research – foundation for faculty, development, institutional recognition. *J Am Osteopath Assoc.* 1993; 93:606.
5. Still AT. *Research and Practice.*
6. Clearfield MB, Smith-Barbaro P, Guillory VJ, Cavalieri TA, Wood DL, Sharp GF, Hahn MB. Research Funding at Colleges of Osteopathic Medicine: 15 Years of Growth. *J Am Osteopath Assoc.* 2007; 107:469-478.

## *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 occur<sup>1-3</sup>.

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<sup>1,2</sup>.

In experimental clinical research, we actively manipulate the independent variables and then measure the effects of this manipulation on the dependent variables<sup>2</sup>. Experimental clinical research studies tend to assess the effectiveness of an intervention<sup>1</sup>. 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.

## Types of Observational Research Studies

DESIGN DESCRIPTION	STRENGTHS	WEAKNESSES
<u>Prospective Cohort</u> <ol style="list-style-type: none"> <li>investigator defines and selects a sample from a population</li> <li>measures predictive variable(s)</li> <li>measures outcome variable(s) at follow-up some defined time later.</li> </ol>	<ol style="list-style-type: none"> <li>powerful for defining incidence and investigating potential causes of a condition</li> <li>allows measurement of predictive variable(s) in the moment, no reliance on reconstructing patient after outcome variable(s) occurs</li> </ol>	<ol style="list-style-type: none"> <li>often need to follow populations for long periods of time to achieve numbers sufficient for causal relationship power, therefore expensive and inefficient for general population questions – better for specific populations (ie, outcome of colon ca. surgery)</li> </ol>
<u>Retrospective Cohort</u> <ol style="list-style-type: none"> <li>identifies a population that has been assembled from past events</li> <li>collects data on predictive variable(s) as available from past records</li> <li>collects data on outcome variable(s) as collected from past or present events</li> </ol>	<ol style="list-style-type: none"> <li>can establish that predictor variable(s) precede outcomes</li> <li>less costly and time-consuming than prospective cohort</li> </ol>	<ol style="list-style-type: none"> <li>investigator has limited control over the sampling of population and what data was collected, thereby what data is available to serve as the predictive variable(s)</li> </ol>
<u>Cross - Sectional</u> <ol style="list-style-type: none"> <li>all measurements made at once with no follow-up</li> <li>investigator selects sample from population</li> <li>measures predictor and outcome variables</li> </ol>	<ol style="list-style-type: none"> <li>great at describing variables and their distribution patterns</li> <li>fast, inexpensive, no subjects lost to follow-up</li> <li>may generate questions for future studies</li> </ol>	<ol style="list-style-type: none"> <li>difficulty of establishing causal relationships</li> <li>limited in information they can produce on prognosis or natural history</li> </ol>
<u>Case - Controlled</u> <ol style="list-style-type: none"> <li>often retrospective</li> <li>sample group from a population of people with the disease (cases)</li> <li>sample group from a population at risk that is free of the disease (controls)</li> <li>measurement of predictor variable(s)</li> </ol>	<ol style="list-style-type: none"> <li>provides descriptive information on cases</li> <li>provides odds ratio</li> <li>high yield of information with small subject size makes for efficient results and ability to generate hypotheses</li> <li>good for rare conditions</li> </ol>	<ol style="list-style-type: none"> <li>increased susceptibility to bias: separate sampling of cases and controls, retrospective management of predictor values</li> <li>no direct way to estimate incidence or prevalence of disease or excess risk</li> </ol>

## References

1. Hulley SB et al. *Designing Clinical Research, 2<sup>nd</sup> 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 of the lower confidence limit and the upper confidence limit. A 95% CI indicates, that if the study were replicated several times, there is a 95% chance that the same results would be obtained.

**Correlation coefficient:** measures strength and direction of the linear relationship between 2 variables.

**Dependent variable:** variable often being measured as endpoint. Also known as the outcome variable.

**Design:** the way in which you conceptualize your research project.

**Exclusion criteria:** defines the subset of population not eligible for study participation; if too excessive, then ability to generalize becomes compromised.

**Hypothesis:** version of research question that summarizes all of its elements: sample, design, predictor variables, outcome variables. Establishes basis for tests of statistical significance.

**Incidence:** statistic obtained from a cohort study; proportion of variable over a period of time.

**Inclusion criteria:** define the main characteristics of the subject population.

**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 absence of disease.

**Ordered discrete:** scale with a finite number of intervals.

**Outcome variable:** variable often being measured as endpoint. Also known as the dependent variable.

**Power analysis:** procedures and formulas that allow the researcher to determine the likelihood of achieving statistical significance with a particular sample size. Contains four variables in its calculation:

1. level of significance set by the researcher (identified as alpha, typically alpha is given the value of .05)
2. probability of obtaining a significant result (power desired computed as 1-beta, typically beta is given the value of 0.8)
3. population effect size, or the hypothesized effect on the groups
4. sample size

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

**Prevalence:** statistic obtained from a cross-sectional study; proportion of variable at one point in time.

**P-value:** measures the strength of evidence in support of the null hypothesis. Since the null hypothesis is the opposite of the study hypothesis, naturally you would want your data to support your study hypothesis and not the null hypothesis. A p-value less than or equal to .01 is generally considered statistically significant. A p-value less than or equal to .005 or less than or equal to .001 is considered highly significant.

**Research question:** what the outcomes of the study address.

**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  $\alpha$  (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, 2<sup>nd</sup> 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>

<http://stattrek.com>

## ***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 might be. The article by Dr. Irving Korr, “Osteopathic research: The needed paradigm shift” (JAOA; 91(2): 156-171) and exploring the following link <http://www.health.usyd.edu.au/currentresearch/designingastudy.pdf> would offer a backdrop on study direction and design as you begin to think about formulating a question.

By the middle of the second half of the year you should perform a few preliminary literature reviews on your topic. Electronic databases, yearbooks and specialty journals are all great resources. This preliminary search does not entail reading every article you find, or even printing off the abstracts, it simply serves to make you aware of what is out there, what has been done around your particular topic of interest, and how many years have elapsed since the last publication. You may want to replicate a study, perform a retrospective review, or design a prospective trial all your own.

#### **MENTOR SELECTION**

Finding a mentor begins in this year as well. You will be working with numerous attendings, some more directly than others. Was there anyone you clicked particularly well with? Anyone currently doing research, or who was involved in research in the past? Picking a mentor is an integral piece of a successful project, so it is a great idea to keep your eyes open.

Be sure to do a little research on your potential “mentors”. Look to see if they have any publications (how recent? what topics?). Speak with their co-workers or research partners in an attempt to assess them as a researcher – reliability and predictability come into play here as well. Fellows who worked under the clinician, former residents or medical students are all good resources for you to utilize when investigating your mentor.

This project will require a big commitment from both of you – time, energy, thought. Be sure your mentor is someone with a dependable track record as well as someone you could spend time

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 task, especially if you are on campus for Tuesday OPP, and could certainly be well worth the effort. This will also serve as an opportunity to attract students to help you with data entry, chart review, database design, or any other piece of your project that you could use a hand with. If necessary, compensation for their time could be monetary or authorship.

Present your idea to other researchers and clinicians as well. The more feedback you receive, the better your project will become. Every discussion will lead to sharing of evidence for your hypothesis' support, defending it, as well as helpful tips and suggestions on how to improve the project. Get as much review as possible before applying for IRB approval or funding applications.

### **INSTITUTIONAL REVIEW BOARD**

Applying to UNE's Institutional Review Board (IRB) is certainly something you need to get done in the first 6 months of PGY-2. Often, it may take several attempts to receive their approval. The website has everything necessary to successfully complete an application: checklist and copies of needed forms, proposal requirements, sample proposals, sample consent forms, link to the research compliance course, and the email address it gets sent to. The homepage is quite thorough and easy to navigate. Obtain access at <http://faculty.une.edu/irb/> . Because most funding applications are due within the first 6 months of the academic year, it is best to apply for IRB approval early. Be prepared for the request of revisions to your proposal, or the need to answer particular questions posed by the Board. As mentioned earlier, completion of an on-line compliance course (course in the protection of human research subjects) is a must. The IRB meets monthly. See chapter VI for more details. Carrie Bogue is the contact person if you have any questions about the logistics (administrative assistant to Nicholas Gere, Director of Sponsored Programs). She may be helpful in finding funding as well.

### **FUNDING**

It is important to take a look at potential funding resources early on. This will also be expounded on in further detail in Chapter VII. Many foundations have deadlines by early December or early January, so it's best to find out deadlines, application requirements, application qualifications and so on EARLY!! Networking is also an important part of securing funding, so finding out who the contact person is and speaking with them prior to applying for the award is definitely beneficial. Many folks may not chat with you unless funding is secured, so this will be a huge part of your research project. Not all funding sources require IRB approval prior to applying, but they will certainly not administer any funds until the project is approved, and certainly, approval gives further credit to the project. With any funding application, the Department of Sponsored Programs needs to be notified since most funding applications will be submitted by this office.

## **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. *J Am Osteopath Assoc.* 2006;106:457-463.

Noll DR, Degenhardt BF, Stuart M, McGovern R, Matteson M. Effectiveness of a Sham Protocol and Adverse Effects in a Clinical Trial of Osteopathic Manipulative Treatment in Nursing Home Patients. *J Am Osteopath Assoc.* 2004;104:107-113.

Korr I. Osteopathic research: The needed paradigm shift. *J Am Osteopath Assoc.* 1991;91:156-171.

Cardarelli R, Virgilio RF, Taylor L. Evidence-Based Medicine, Part 2. An Introduction to Critical Appraisal of Articles on Therapy. *J Am Osteopath Assoc.* 2007;107:299.

International Committee of Medical Journal Editors. *Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication.* 2007.

Accessed online at: <http://www.icmje.org/>

## ***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 encompass many hours over the next two to three years, so you don't want to become sick of it. Rather, try to find something you are passionate about.

The objective of the study is encompassed by the hypothesis <sup>1</sup>. The hypothesis is based on a theory you are trying to prove or disprove. Brainstorm questions that need to be answered to support the study hypothesis. How feasible is it to measure or obtain data about these questions? What is the significance of your hypothesis? How will society benefit from your research? Will it act as a stepping stone for other projects? Will your question be able to be reproduced or replicated? What is the relevance to medical society, pathophysiology and current treatment regimens?

Have other studies been done that had a hypotheses similar to yours? If so, what were their strengths and weaknesses? Did they leave questions unanswered, or do you want to challenge the outcomes? This information may be included in the introduction or background section of the proposal write-up, but it also plays an important role in helping to form the question you will be investigating.

## 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 and will help illicit support for the hypothesis.

## METHODS - WHAT/HOW TO MEASURE

Now that a question exists, outcomes and how they will be measured need to be selected. If your question is, “What effect does osteopathic manipulation have on the management of knee osteoarthritis?” you need to establish some outcome to measure – daily pain scale, quality of life, amount of medication taken. All are examples of outcome variables. How you measure outcome variables depends on whether you are assessing a dichotomous or a continuous relationship. A dichotomous variable is one for which there are only two possible outcomes. Dichotomous would mean, yes, there was less daily pain on visual analogue scale, or no, there was not less pain on visual analogue scale, OR less amount of medication taken over a seven-day period versus no decrease in medication over a seven-day period. A dichotomous variable does not address the amount of decrease on pain scale or amount of medication taken, just whether there was a change. Dichotomous variables (absolutes such as “Was daily pain decreased? Yes/No”) provide less information and require a larger sample sizes. Data will be analyzed by a chi- squared test.

Continuous outcome variables are measured via a t-test. They can achieve a greater power with a smaller sample size when compared to dichotomous data.

Predictor and outcome variables can be classified into quantitative or categorical variables (1). A quantifiable variable is: 1) continuous, quantified on an infinite scale or 2) ordered discrete, quantified on a finite scale. Categorical variables are classified into categories. If there are only two categories, such as: dead or alive, then this is termed “dichotomous” category. If there are more than two categories this is termed “polychotomous” and is further divided into nominal, such as blood type, and ordinal, such as degree of pain. **When designing your study, variable types help determine how much power your results will have and the efficiency in obtaining those results.** Continuous variables typically give you more “bang for your buck” – more power with a smaller sample size because they offer more information.

Further information on designing measurement scales for your study is beyond the scope of this guidebook. It is strongly recommended however, that regardless of measurement tool used, be it a survey, pain scale, or event frequency, you ensure that the tool has been well studied for precision, accuracy and validity. Utilizing instruments or measurements that have been used in similar studies is one way to assume consistency, but researching your measurement tool offers greater reliability.

## **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 England Research Club (contact info in Chapter IX: Resources.)

## **References**

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

## *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, certificate of IRB research compliance training

The IRB homepage offers an outline of what a research proposal should entail. This format will closely resemble the format utilized by funding agencies. It also offers a template for a consent form and a sample consent form for review.

Certificate of IRB research compliance is necessary for study approval. The course touches upon the history necessitating human subjects protection (Belmont Report, Declaration of Helsinki and The Nuremburg Code) and also highlights important aspects of the consent form and study design that, if incorporated into the proposal, will ensure easier passage through the IRB. The site hosting this training can be accessed via the UNE IRB webpage or at <https://www.citiprogram.org/default.asp>.

An electronic copy of the IRB application must be sent to [irb@une.edu](mailto: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.

## VII. FUNDING

Securing funding is one of the most challenging aspects of research. It is a piece you have to jump on early because of its competitiveness, the arduous paperwork requirement, as well as researching the potential funding source as each have their own application requirements to complete. All this being said, funding is essential. It will give you the resources needed to pay for study tools such as surveys, a data base, folders, photocopying, recruiting material, data analysis, poster presentation...the list goes on and on. So, where and when to begin? ONLINE AND EARLY.

It is true that in order to apply for funding, there must be a study to fund. Having completed the study design in the first part of PGY-2, begin obtaining information on funding in the early half of this year as well. It is important to make contact with some foundations at least 6 months prior to their application deadline, so you want to get on this part of your project as soon as your study has been designed.

### *Where to look for funding?*

**Amy Davidoff, PhD:** has a web page with links to various fellowship opportunities. Access via [www.une.edu](http://www.une.edu), click: faculty directory, faculty web page, Davidoff, amy.

**The American Osteopathic Association (AOA):** Administers grants and fellowships through the Osteopathic Heritage fund. They look primarily for studies investigating:

- a. Mechanisms of Action of OMM/OMT
- b. Clinical Efficacy of OMM/OMT
- c. Inter- and Intra-rater reliability of palpatory assessment
- d. Cost effectiveness of osteopathic health care
- e. Osteopathic physician and patient interactions
- f. Methods of teaching palpation and OMM/OMT

Grant applications are due December 1<sup>st</sup>, while fellowship applications, open to residents and students, are due around the second Monday in January. [www.do-online.org](http://www.do-online.org) is the website that allows access to more information on the application process including the AOA Research Handbook.

<http://www.grants.gov/>

Online resource sponsored by federal government. Assists with grant searches, application, tracking of an application.

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

**Maine Health Access Foundation (MeHAF)**

Maine's largest health care foundation. MeHAF was founded in 2000 and each year provides approximately \$5 million in grants and program funding to expand access to health care (particularly for people who are uninsured and medically underserved) and improve the health of all Maine residents.

**Maine Osteopathic Heritage Fund** is a board of physicians who may be a resource for study funding (smaller amounts). Contact person is Chase Rand, D.O. Board members include Lesley Ingraham (Director of CME programming at UNECOM), Stephanie Waecker, D.O.

<http://www.nih.gov/>

**National Institute of Health** has increased the amount of their grants to COM researchers – PhD and physicians alike. While this is a great resource, most of these grant applications require pilot studies in support of your proposal. If you are performing a pilot study, then you would most likely not qualify for this type of grant.

<http://rf.osu.edu/>

**Ohio State University** has a list of national funding opportunities linked from their research website.

<http://www.hsc.unt.edu/orc/>

**Osteopathic Research Center:** The Osteopathic Research Center in North Texas is in the process of developing opportunities for residents and students to complete research projects at or in affiliation with the ORC. The organization was founded in 2001 and serves to foster nationwide collaborative research on the efficacy of osteopathic manipulative medicine. The ORC's mission is to demonstrate the efficacy of OMM through research.

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

**University of New England: Research** Almost countless links to various funding opportunities and access to Community of Science Funding Alert system. Based on individually selected criteria, Funding Alert sends you information weekly on new funding opportunities.

## *Networking*

Foundations, organizations and national groups have funds available for various, yet also specific research areas. Prior to developing a research proposal, it can be very advantageous to establish contact with these types of funding sources. It is crucial to inquire about what research areas they may have available funds “ear-marked” for and also begin facilitating relationships with the various funding sources. It can also be useful to obtain information about what projects and what researchers were funded for the previous year or two. Also, be sure to determine who will be evaluating your grant for funding and what their backgrounds are. All this information will begin developing your research foundation and help you gain a better understanding of the current research dynamics and politics. In addition, establishing contact with the person in

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](http://grants.nih.gov/grants/grant_tips.htm)

[www.thegrantinstitute.com](http://www.thegrantinstitute.com)

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

[http://www.hopkinsmedicine.org/fac\\_development/research/grant\\_writing/#item1](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](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 to include employee taxes, state fees, insurance coverage. Figuring out direct and indirect costs, matched and unmatched funds can be a bit daunting. Nicholas Gere, Director of Sponsored Programs can be very helpful with this part of the process. Numbers for this budget will then be used to complete the “pink sheet” (a form required by UNE). Ohio State University has a nice web site with a link that walks you through designing your budget. The forms are specific to their school, but generalities can be ascertained.

### **BIOSKETCH**

The biosketch (biographical sketch) is another important piece to the grant proposal. It is very similar to a CV, just in a different form and more succinct. Most funding agencies have their own format. Complete the information requested, and run your copy by other researchers for

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

## VIII. Manuscript Writing & Publication

The first step is consideration of the target audience. The best way to determine this is by looking at the study outcomes. What was measured? Who will benefit from the study? Will it impact practice management? Does the specialty college have a journal that may be interested in publishing Resident research?

Potential sources from a Family Practice and Neuromusculoskeletal Medicine perspective include:

1. American College of Osteopathic Family Physicians (ACOFP), <http://www.acofp.org/>
2. American Academy of Osteopathy (AAO), <http://www.academyofosteopathy.org/>
3. American Osteopathic Association (AOA), <http://www.osteopathic.org/>
4. American Osteopathic Association (AOA) Publication, <http://do-online.org>
5. Journal of the American Osteopathic Association, <http://www.osteopathic.org/>
6. Journal of the American Medical Association, <http://jama.ama-assn.org/>

Generally, there is no fee for the publication application. It is simply a matter of inquiring with the journal their publication requirements: manuscript style, electronic submission, cd or hard-copy form. Each will have particular specifications to follow. Once the article has been submitted, it will be sent to reviewers. Questions, comments, revision requests will be returned or article may be denied. Author(s) have the opportunity to respond to the initial review. The revised version is then resubmitted. The author does not necessarily have to abide by the reviewer's suggestions. The editor of journal then decides; yeh or nay.

When accepted, the author will be sent "galley proofs" from the copy editor. The author is responsible for reviewing style, flow and typographical errors. Upon completion, the article is then sent back to the journal.

Keep in mind that there is a defined format according to which research papers are written. The acronym "IMRAD" stands for Introduction, Methods, Results, and Discussion, and is the format expected of most observational and experimental articles. A great resource to consult when writing and publishing your article is:

International Committee of Medical Journal Editors. *Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication*. 2007. Accessed online at: <http://www.icmje.org/>

This site really covers everything you might need to consider regarding your article: publication ethics (such as authorship, sponsorship and accountability), copyright issues, format, manuscript

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](mailto:jforce@mail.une.edu) and [dhoffman@mail.une.edu](mailto:dhoffman@mail.une.edu).

#### **MARILYN R. GUGLIUCCI, PHD**

#### **DIRECTOR, GERIATRIC EDUCATION AND RESEARCH**

#### **DEPT OF FAMILY MEDICINE, UNECOM**

Phone: 207-602-2453

E-mail: [mgugliucci@une.edu](mailto:mgugliucci@une.edu)

**Research expertise:** Qualitative research design and analysis, IRB preparation, combined methods research design.

**Research interests:** Gerontology - health related quality of life, death and dying, late onset stress, functional fitness, successful aging.

#### **INDIA BROYLES, EDD, ASSOCIATE PROFESSOR FOR MEDICAL EDUCATION, DEPARTMENT OF PEDIATRICS, UNECOM**

Phone: 207-602-2694

E-mail: [ibroyles@une.edu](mailto:ibroyles@une.edu)

**Research interest:** Curriculum development and instructional design; learner assessment; faculty development; program evaluation; qualitative research; educational technology and distance learning.

#### **OMM/ANATOMY FELLOWS**

Phone: 602-2533

Located in Alford and closely associated with the students and COM faculty. From July to December they are super-busy with anatomy, clinic and OPP. From January to June, they are more available to help with research projects and most are eager to jump on with someone. You

can obtain email addresses and contact information through Mary Spang, administrative assistant in the OMM department at UNECOM, [mspang@une.edu](mailto:mspang@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](mailto: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](mailto:cbogue@une.edu).

### **JACK GINTY, EXECUTIVE DIRECTOR OF MAINE OSTEOPATHIC ASSOCIATION**

**Phone:** 207 623-1101

[jginty@mainedo.org](mailto: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](mailto: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](http://www.hsc.unt.edu/research/orc)

Contact here is Cathleen Kearns, Administrative Director.

Phone: 817 735-0515

E-mail: [ckearns@hsc.unt.edu](mailto: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](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>

Research site for Ohio State University. Great links, great instruction on proposal writing.

<http://www.cos.com>

Community of Science grant database as a source for possible research fund. Ability to set up an account under “Funding Alert”, where you will be notified of opportunities that match selection criteria.

## **PUBLICATIONS**

<http://www.health.usyd.edu.au/current/research/designingasstudy.pdf>

Manuscript on designing a study.

Cardarelli R, Virgilio RF, Taylor L. Evidence-Based Medicine, Part 2. An Introduction to Critical Appraisal of Articles on Therapy. *J Am Osteopath Assoc.* 2007;107:299.

Korr I. Osteopathic research: The needed paradigm shift. *J Am Osteopath Assoc.* 1991;91:156-171.

Noll DR, Degenhardt BF, Stuart M, McGovern R, Matteson M. Effectiveness of a Sham Protocol and Adverse Effects in a Clinical Trial of Osteopathic Manipulative Treatment in Nursing Home Patients. *J Am Osteopath Assoc.* 2004;104:107-113.

Licciardone JC, Russo DP. Blinding Protocols, Treatment Credibility, and Expectancy: Methodologic Issues in Clinical Trials of Osteopathic Manipulative Treatment. *J Am Osteopath Assoc.* 2006;106:457-463.

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

Stone J. *Conducting Clinical Research: A Practical Guide for Physicians, Nurses, Study Coordinators, and Investigators.*

International Committee of Medical Journal Editors. *Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication.* 2007.

Accessed online at: <http://www.icmje.org/>

## *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 groups can surely make the recruiting process shorter and less difficult.

It is a gross understatement to say that relying on referrals from outside physicians is quite challenging. As one can imagine, there are many reasons for this: priorities, presence, time to name a few.

1. **Priorities** - The study is simply not as important to them as it is to you. The day is overbooked. They have numerous responsibilities in their own practice. If you acquire funding, incentives such as gift cards or lunches can be helpful, as long as this is included in the recruiting protocol accepted by the IRB. Asking physicians to recruit for a study they have no investment in is almost futile – but success is always a possibility.

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 A – ANNOTATED BIBLIOGRAPHY**

**Cardarelli R, Virgilio RF, Taylor L. Evidence-Based Medicine, Part 2. An Introduction to Critical Appraisal of Articles on Therapy. *J Am Osteopath Assoc.* 2007;107:299.**

Contains steps for reading and appraising clinical articles. Contains definitions for relative risk reduction, absolute risk reduction, confidence intervals. Discusses practicality of study results.

**Greenhalgh T. How to read a paper: Assessing the methodological quality of published papers. *BMJ.* 1997;315:305-08.**

Guide to assessing methods portion of study. Easy to follow. Good examples. Succint.

**Blinding Protocols, Treatment Credibility, and Expectancy: Methodologic Issues in Clinical Trials of Osteopathic Manipulative Treatment. *J Am Osteopath Assoc.* 2006;106:457-463.**

Reviews sources of bias in clinical trials; assesses patient perspective of credibility of OMT versus Sham versus No intervention utilizing subjective self-reporting scales.

**Makela M, Witt K. How to read a paper: critical appraisal of studies for applicataion in healthcare. *Singapore Med J.* 2005; 46(3):108.**

Critical systematic analysis of journal articles involving intervention style study. Good to read before getting into study design. Good to have in mind during study design phase.

**Noll DR, Degenhardt BF, Stuart M, McGovern R, Matteson M. Effectiveness of a Sham Protocol and Adverse Effects in a Clinical Trial of Osteopathic Manipulative Treatment in Nursing Home Patients. *J Am Osteopath Assoc.* 2004;104:107-113.**

Looks at effectiveness of sham protocol. Small N.

**Virgilio RF, Chiapa AL, Palmarozzi EA. Evidence-Based Medicine, Part 1. Introduction to Creating an Answerable Question and Searching the Evidence. *J Am Osteopath Assoc.* 2007;107:295-297.**

Introduces approach to asking a general medical question and how it pertains to care of patients, not necessarily a research question. Provides evidence-based medicine search engines.

## Appendix B - Table of Project Timeline

<b><u>PGY-1</u></b>	<ul style="list-style-type: none"><li>• Start thinking of your question –what interests you, what would you like to investigate further?</li><li>• Preliminary lit review on potential topics</li><li>• Find a mentor</li><li>• Complete UNE’s on-line course for protection of human and animal research participants</li></ul>
<b><u>PGY-2</u></b>	<ul style="list-style-type: none"><li>• Decide on a topic/question</li><li>• Literature review on selected topic</li><li>• Study design – at start of year 2</li><li>• Have study reviewed by colleagues, other scientists, New England Research Club</li><li>• Funding resources – at start of year 2</li><li>• Apply for IRB approval – may take several attempts</li><li>• Begin study implementation, i.e. recruiting, data collection (allow at least 12 months from start of recruiting to article completion)</li></ul>
<b><u>PGY-3</u></b>	<ul style="list-style-type: none"><li>• Continue study protocol/data collection</li><li>• Data analyzing</li><li>• Poster presentations</li><li>• Article completion</li><li>• Apply for publication</li></ul>

## **APPENDIX C - POSTER TEMPLATE**

TO ACCESS POSTER TEMPLATE, PLEASE GO TO:

<http://www.une.edu/com/residency/pdf/postertemplate.ppt>

# APPENDIX D – HARD COPY OF BIOSKETCH

For review only. For access please go to:

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

---

## BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form  
Page 2.

Follow this format for each person **DO NOT EXCEED FOUR PAGES.**

NAME		POSITION TITLE	
eRA COMMONS USER NAME (credential, e.g., agency login)			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY

**NOTE: The Biographical Sketch may not exceed four pages. Follow the formats and instructions on the attached sample.**

- A. Positions and Honors.** List in chronological order previous positions, concluding with your present position. List any honors. Include present membership on any Federal Government public advisory committee.
  
- B. Selected peer-reviewed publications (in chronological order).** Do not include publications submitted or in preparation. For publicly available citations, URLs or PMC submission identification numbers may accompany the full reference; copies of publicly available publications are not accepted as appendix material.
  
- C. Research Support.** List selected ongoing or completed (during the last three years) research projects (federal and non-federal support). Begin with the projects that are most relevant to the research proposed in this application. Briefly indicate the overall goals of the projects and your role (e.g. PI, Co-Investigator, Consultant) in the research project. Do not list award amounts or percent effort in projects.