NYCOMECE RESEARCH MANUAL

INTRODUCTION

The purpose of NYCOMECE’s Research Committee is to encourage and support research in all the NYCOMECE programs. To this end, NYCOMECE is pleased to provide this Research Manual. It is designed to provide basic information that will be useful to both the novice researcher and those with experience. Note that the focus is primarily on experimental research, although other types of research are discussed. Case studies are briefly addressed in the appendices.

Several excellent research resources exist on the Internet and as textbooks. Perhaps the best reference is Hulley, et.al.: Designing Clinical Research, 4th Ed. (full citations are in the References). In developing this manual we have drawn from several excellent sources (See Appendix A).

- Research Manual, prepared by the Louisa Burns Osteopathic Research Committee of the American Academy of Osteopathy, August 2001. This is no longer available on the Internet, but copies may still be available from the residency Directors and the DME. [LBORC] The funding program and an introduction to the Committee are in Appendix B.

- AOA Research Handbook. The Research Handbook of the American Osteopathic Association, 2010. Due to the change in the AOA funding process, this is no longer available. [AOA] This Handbook was primarily designed to assist with proposals for AOA funding and utilizes NIH style.

At several points in this Manual reference is made to information available in these resources. The reference is indicated by the codes (in brackets and bolded) associated with each resource.

Several sections of this Manual have been adapted from a powerpoint presentation on research prepared by the Ohio CORE and used by permission. These are indicated by CORE. The Ohio CORE website has been updated and can be accessed through https://www.ohio.edu/medicine/about/offices/core-research-office/getting-started.cfm

Finally, a recent series of 3 publications provide a good introduction to research:


Dumsha, I.Z, Yens, D.P., & Brannan, G.D. Funding and Other Resources for Beginning Researchers. Osteopathic Family Physician, July/August 2015

Two online resources may also be useful. NYCOMECE has archived a series of 9 webinars dealing with research that can be accesses through the NYCOMECE web site. Contact Alana Berg (aberg@nyit.edu) for access information.

The AAO has made access to a series of workshops called Scholar7. These are videotapes of the live workshops. A description of Scholar 7 is in the October 2007 issue of the JAOA (Vol. 117, #10, pp. 643-650, accessible through the JAOA website). They can be accessed through:

http://www.academyofosteopathy.org/announcements/scholar-7-a-guide-to-research-development-for-the-osteopathic-profession

Scholar 12, a more formal educational program, has just been released: https://scholar12.org.

Due to the availability of these other sources, this manual is largely written in outline form to provide the basic information without excessive verbiage. The Appendices provide extensive supplementation to this outline.

A bibliography of useful texts and resources is provided in the References. This Research Manual will be available online through the NYCOMECE web site.
OUTLINE OF THE RESEARCH PROCESS

WHAT IS RESEARCH?  Research is a process that combines formal, structured inquiry with acceptable scientific methodology with the intent to answer questions, solve problems, and to contribute to generalizable knowledge.

Conducting research is a lot like solving a puzzle. [CORE] It requires:
- A strategy or plan
- Critical thinking
- Motivation
- Diligence
- A good environment
- Organizational skills
- Permission
- Monetary support (maybe)
- Common sense!

WHAT KIND OF RESEARCH do you want to do?
- Experimental
- Clinical
  Clinical research drives evidence-based medicine, which in turn, impacts clinical practice.
- OMM/OMT
- Community/epidemiological
- Family – Epidemiological or case study research on families
- Many others
--- HOWEVER: Don’t bite off too much. Keep it simple (KISS: Keep It Simple, Stupid)

WHY?
- Requirement for residents and may be required for retention or promotion of Attendings (especially with the new Single Accreditation System)
- Research is required by all specialty colleges.
- Click: http://do-online.osteotech.org/index.cfm?PageID=acc_postdocstdspecialist to check the AOA requirements specific to your specialty college

- The AOA core competency on Practice-Based Learning and Improvement emphasizes that residents must demonstrate the ability to critically evaluate their methods of clinical practice, integrate evidence-based medicine into patient care, show an understanding of research methods, and improve patient care practices.

- AAFP (American Academy of Family Practice) identifies Basic Skills that are required:
  - Perform detailed literature searches (such as PUBMED, Google Scholar)
  - Critically evaluate research articles
  - Utilize evidence-based medical information resources
  - Interpret treatment and screening recommendations
  - Interpret and apply clinical decision rules
  - Appropriately apply evidence in clinical decision-making
  - Formulate a research question
  - Design a descriptive and/or explanatory study
• Collect and analyze data
  o Evaluate and discuss study findings
  o Be able to write a research paper
  o Apply rules of English usage, style, and composition for publication
  o Deliver effective presentations
  o Intellectual advancement

Professional development and growth depend on having adequate skills to:
Critically read and evaluate journal articles, and
Understand and engage in conference workshops and presentations.

By mastering basic research skills, physicians will be better prepared to critically assess the veracity and integrity of published medical literature.

  o Answer clinical questions
  o AOA (and nationwide) emphasis on outcomes research/Evidence-based medicine
  o Satisfaction/pride
    • The osteopathic voice needs to be present in the research arena.
  o Academic recognition/advancement
    • Faculty positions require evidence of competency in research methods. Tenure criteria usually include research productivity.

  o WHAT DO YOU WANT OUT OF IT?
    • An answer to a question?
    • A presentation, poster, or publication?
    • Fame and fortune?
    • Ideally, the first two

  o Note that office practice is different from hospital practice, and there are differences between specialties.

WHO?
  o YOU! If you are not interested and involved, it won’t happen
  o Collaboration with colleagues – the best way to start
  o Office staff support – they may be able to help with communication and clerical needs
  o Data collection/processing – by you and/or colleagues.
  o Consultants
    • Research design, statistician, technical (NYCOMEC support)
    • Writers, editors, etc.

WHERE?
  o Office
  o Clinic
  o Hospital
  o Medical School
  o Community
--- **Consider LOGISTICS.** Supply of subjects, facilities, space, etc.

**WHEN?**
- When questions arise or a topic interests you
- When required by your program director
- When you have the opportunity to participate in large a project or in someone else’s project
- Start during your first residency year

**When is the Best Time to Start a Research Project?**

Sample Timelines from Ohio COM - **CORE**

These are timelines for preparation for a poster contest (15 months for research, 10 months for a case report), but also provide a good indication of timing for a relatively simple research project. With concentrated work these times can be reduced.

**HOW?**
- Participate in a project managed by someone else (good way to start)
- Conduct research by yourself or with colleagues (recommended) using the research design and methods described below. Two common types of research
  - Prospective clinical study
  - Retrospective, chart review
- Participate in a research network (a network of clinical researchers that gather specific data and forward it to a central collecting site, usually using a computer network)
CRITERIA FOR A QUESTION

- Is it feasible?
- Can you recruit an adequate number of subjects?
- Is sufficient technical expertise (clinical, design, statistical) available?
- Is it affordable in time & money?
- Is it manageable in scope?
- Is it interesting to you?—absolutely essential
- Does it advance the field or answer new questions?
- Is it novel? (not been done before)
- Does it confirm or refute previous findings?
  - Extends previous findings?
  - Provides new findings?
  - In some cases you might want to replicate prior findings if the results are in question
- Is it ethical?
- Is it relevant?
  - To scientific knowledge
  - To clinical and health policy
  - To future research directions

(from: Hulley, et.al.)

* See Appendix D for suggestions about how to develop ideas for a research project.

IDENTIFY A PRELIMINARY PROBLEM

IDENTIFY AND DEFINE VARIABLES (to be described below)

- In what variable do you want to make a difference?
- What variables will you manipulate?
- Variables come in several varieties:
  - INDEPENDENT VARIABLE
  - What you are manipulating (e.g., drug dose)
  - DEPENDENT VARIABLE
  - The outcome; what you observe/measure (e.g., reduction of fever)
  - MODERATOR VARIABLE
  - Secondary Independent Variable (e.g., gender of subject)
  - CONTROL VARIABLE
  - To be controlled: eliminate its effect (e.g., race of subject)

SPECIFY HYPOTHESES

- What outcome do you expect?
  - Null Hypotheses
    - What is tested statistically (hypothesis of no difference)
  - Research/Alternative Hypothesis
  - What outcome do you expect?
LITERATURE REVIEW AND ANALYSIS
- Insure the study has not been done
- Validate your problem
- Assist with planning

INTERNET LITERATURE REVIEW
- Evidence-based resources
  - e.g., Cochrane Collection (http://www.cochranelibrary.com/)
- Direct search of the internet with keywords
Do not use Wikipedia or internet searches without fact-checking. The reliability of the results may be questionable because these sources are not vetted by experts.

Select design using above as a guide, select statistical analysis, obtain IRB approval, conduct the study, and publish – details follow.

HOW TO DESIGN A RESEARCH STUDY

Following is a more detailed description of the research process, courtesy of Ohio-CORE (with permission). See the overview of the research process on the following page.

The Ohio-CORE website contains other useful information and is provided below. Adapted from the OHIO-CORE Research Resources Guide (PowerPoint). They now have a new set of directions that are excellent:
https://www.ohio.edu/medicine/research/ORG/getting-started.cfm

Research comes in many flavors:
- Bench research, such as finding a chemical compound that will kill bacteria in a Petri dish
- Animal research, such as testing a drug to see if it reduces a cancer in rats
- Human research, in which that drug is used to assess its effectiveness in humans
- Human research, in which attitudes toward the change in the healthcare system are assessed by questionnaire in a group of people.

We assume that those using this research guide are doing research with humans.

These disparate research approaches are addressed with the DESIGN of the study. Several of these were briefly addressed above. Here we will discuss research methods in more detail.

Designing a research project requires a stepwise approach and usually requires the submission of a proposal (project description) to an IRB (Institutional Research Board), especially if humans are involved. (A similar review panel is required if animals are used.) The parts of this proposal include the following:
- Significance (background)
- Design
- Subjects
- Selection criteria
- Sampling procedures
- Variables - independent and dependent
- Hypotheses and analytical approach
- Procedures
OVERVIEW OF THE RESEARCH PROCESS

STUDY DESIGNS/KINDS OF RESEARCH
Many different kinds of research can be done, and different “designs” can be used? The following is an outline of different designs with examples.

<table>
<thead>
<tr>
<th>Table 2-1 Basic Study Designs</th>
<th>EXPLANATORY</th>
</tr>
</thead>
<tbody>
<tr>
<td>DESCRITVE</td>
<td>Examine etiology, cause, efficacy, using the strategy of comparisons</td>
</tr>
<tr>
<td>EXPERIMENTAL</td>
<td>OBSERVATIONAL</td>
</tr>
<tr>
<td>Case report or series</td>
<td>Investigator controls allocation</td>
</tr>
<tr>
<td>• Rash developing during drug treatment</td>
<td>Seek causes, etiologies, predictors, better diagnosis</td>
</tr>
<tr>
<td>• Cluster of cases of Kaposi’s sarcoma</td>
<td>Investigator observes nature</td>
</tr>
<tr>
<td>Clinical series</td>
<td></td>
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<tr>
<td>• Treatment of 50 snakebite victims</td>
<td></td>
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<tr>
<td>Population</td>
<td></td>
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<tr>
<td>• Prevalence of HIV in military recruits</td>
<td></td>
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<tr>
<td>Community survey of needs of elderly</td>
<td></td>
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<tr>
<td>Program or course</td>
<td></td>
</tr>
<tr>
<td>• Course on sexuality for medical students</td>
<td></td>
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<tr>
<td>Examples:</td>
<td></td>
</tr>
<tr>
<td>Clinical Trial</td>
<td></td>
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<tr>
<td>• Comparison of two antidepressant drugs</td>
<td></td>
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<tr>
<td>• Surgical vs. medical management of angina</td>
<td></td>
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<tr>
<td>Educational intervention</td>
<td></td>
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<tr>
<td>• Self-instruction vs. lecture on anemia</td>
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<tr>
<td>Health-care trial</td>
<td></td>
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<tr>
<td>• Nurse practitioner vs. physician care</td>
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<tr>
<td>Table 1 From Gelbach, S.H. Interpreting the Medical Literature, 3rd Ed. New York: McGraw-Hill, 1993</td>
<td></td>
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</tbody>
</table>

A DESCRIPTIVE study is just that, it provides descriptive information about a case, prevalence of a disease, etc. Basic statistics used would include means, medians, standard deviations, etc.

An EXPLANATORY study provides comparative information or attempts to identify causes.

OBSERVATIONAL studies are naturalistic – they use existing data or prospectively collected data to determine relationships. Surveys are a common example of observational research.

EXPERIMENTAL studies control variables to evaluate whether differences exist on one or more outcome variables.

A PROSPECTIVE study establishes the groups or parameters and then watches what happens in the future. A template for the design of a prospective study is in Appendix E.

A RETROSPECTIVE study uses data already obtained (such as charts) to determine whether different conditions led to different outcomes, for example. A template for the design of a retrospective study is in Appendix E.

Note that different kinds of studies may require different kinds of statistics.
OUTLINE OF COMPONENTS OF A RESEARCH PROPOSAL NARRATIVE
Also see Appendix F, Research Proposal Project Outline

Significance/Introductory Section/Background
In this section, you describe why you want to do the research and justify your proposal.

Where can you get ideas for research? You get your information and ideas from several different sources:

- Professional experience
  - Work with patients (Mrs. Jones had a very peculiar rash),
  - Discussions with colleagues (patients are having an unexpected response to a new drug),
  - Attendance at lecture, conferences, etc. (a research paper leads to additional questions)
- Published literature
- Proceedings from conferences (a presentation stimulates your curiosity about why a drug acts as it does)
- Journals
- Textbooks (2 textbooks have different explanations for a phenomena)

Background and context serve to establish it as a credible issue to explore or problem to address. Based on these ideas, you formulate a research question and the objective(s) of the study

SIMPLE EXAMPLE:
Current data suggest that increases in hemoglobin may decrease nitric oxide and adversely affect vascular function. In the preclinical setting, these changes could precipitate the development of heart failure (HF). We hypothesized that higher hematocrit (HCT) would be associated with an increased incidence of new-onset HF in the community.¹

DESIGN/METHODOLOGY
Once you have an idea about a research study, you need to determine how it will be done. Basic research designs fall into one of three categories, as noted on the previous page:

- Descriptive studies
- Observational studies
- Interventional trials

These designs provide guidelines about how a study can be planned, but many studies are hybrids or approximations of these designs.

* Note that a research program can be developed by using the above designs in sequence. For example, using a sequence provided by Hulley, et.al.²:

A descriptive study would ask, “What is the average number of servings of fish per week in the diet of Americans with a history of coronary heart disease (CHD)?” This would be followed by an analytic (observational) study to evaluate associations that would permit inferences about cause-and-effect relationships: “Is there an association between fish intake and risk of recurrent myocardial infarction in people with a history of CHD?” (p. 5). This would be followed by an interventional trial: “Does treatment with fish oil capsules reduced total mortality in people with CHD?” (p. 6).

¹ Examples adapted from Coglianese EE, Qureshi MM, Vasan RS, Wang TJ, Moore LL. Usefulness of the Blood Hematocrit Level to Predict Development of Heart Failure in a Community. Am J Cardiol. 2011 Oct 12. [Epub ahead of print]
DESCRIPTIVE STUDIES

- Case Reports
  - A comprehensive report on a specific case that you might have seen or in which you participated. E.g., the use of osteopathic manipulation of a patient with Kugelberg-Welander disease.
  - Case reports usually constitute the majority of posters at clinical poster competitions.
- Case Series
  - A report on several similar cases and their treatment.
- Determination of Frequencies
  - Such as in the descriptive study described above.

ANALYTIC (OBSERVATIONAL) STUDIES

- Cross-sectional studies
  - Used to determine the relationship between predictor and outcome variables, such as the presence or absence of a risk factor and disease; a sample is taken from a population and the measures are made during the same time period.
- Case-controlled studies
  - A sample is taken from a population that has a disease, another sample is taken from the population at risk of the disease that is free of the disease, and predictor variables are measured. An excellent example is a study of smoking: a sample of people with lung cancer is obtained, a second sample of smokers that do not have lung cancer is obtained, and the groups are compared.
- Cohort studies: characteristics are measured on a group of subjects that might be related to some outcome of interest. Cohort studies can be either prospective (start now and see what happens in the future) or retrospective (collect information from the past and see the status of the outcome now).
  - In a prospective cohort study, the group is observed over time to see whether the outcome occurs. A good example is the Framingham study in which many characteristics were measured and, in subsequent years, related to cardiovascular events.
  - A retrospective cohort study examines those characteristics that existed in the past as they relate to current outcomes. For example, a history of smoking could be related to present instance of lung cancer.

INTERVENTIONAL TRIALS

- REQUIREMENTS
  - These are studies where an experimental intervention is introduced to a group of subjects to determine the efficacy of certain procedures or treatments. This type of study is also called a clinical trial, and can be either controlled or uncontrolled. Due to the nature of this study design, trials are always prospective.
  - Intervventional trials require more steps than the other designs. At the outset, you are more concerned with the sources and number of subjects, with randomization, with stating hypotheses concerning the anticipated outcomes, and with the statistical analysis required to determine whether the results have adequate validity.
  - Source of subjects and randomization: Subjects for all arms of the study must be drawn from the same population. The subjects are then randomly assigned to the study groups. This is essential for this kind of study to assure that groups are equivalent (their equivalence is also evaluated at
the end of the study). The process of randomization is discussed below.

- A second concern is the number of subjects required to make the research statistically valid. This must be predetermined; formulas and computer programs are available to determine this; they are discussed below.
- For interventional research it is also necessary to state at least one hypothesis concerning the anticipated outcomes. This is required to permit an appropriate statistical analysis and to insure that the research is properly focused.

**TYPES OF INTERVENTIONAL TRIALS**

**Randomized controlled trials (RCT)**

This is the classic interventional trial, with an “experimental” group and a control group (or more than one of either). For example, to evaluate a new drug, two groups are formed; one to take the drug and a second “control” group to take a placebo. Potential subjects are randomly assigned to one group or the other. The trial continues for a predefined period of time and at the end the groups are compared on the outcome of interest (blood pressure, hematocrit, etc.).

- **EXAMPLE:** Relationship of hematocrit with heart failure from Framingham Heart Study
- Research hypothesis
  “Higher hematocrit (HCT) would be associated with an increased incidence of new-onset HF in the community.”
- Proposed sample size and composition - what would be appropriate for this study
- Inclusion and exclusion criteria PLUS rationale for such criteria
  “3,000 (~50% women) from the Framingham Heart Study who were 50 to 65 years old and free of HF.”
- Data source:
  Results from a physical examination, x-rays or other imaging reports, survey/questionnaires, focus groups, interviews, etc.
- Proposed analyses
  “Subdivide HCT into 4 gender-specific categories (women: HCT 36.0 to 40.0, 40.1 to 42.0, 42.1 to 45.0, >45.0; men: 39.0 to 44.0, 44.1 to 45.0, 45.1 to 49.0, >49.0).”
  Use gender-pooled multivariable Cox proportional hazards models to estimate the association of HCT with incident HF, adjusting for clinical risk factors
  Determine hazards ratios for HF in the low-normal, normal, and high HCT categories.
- Identify known possible risks and benefits
  - To the individuals involved in the study
  - To the scientific community
    “No known risks; benefits in obtaining an estimate of the Usefulness of the Blood Hematocrit Level to Predict Development of Heart Failure in a Community.”
- Bibliography

- **Historical Controlled Trials**
  Designed like a RCT but data are randomized and gathered from charts; a retrospective RCT

- **Cross-over trials**
  Also called an A-B-A-B design, typically used for comparison drug trials, where a subject is given:
  Drug A, its effectiveness noted,
Followed by a washout period,
Then given drug B, its effectiveness noted
Then drug A, its effectiveness noted, and then
Drug B, its effectiveness noted
The drugs are then statistically compared

- Factorial design trials
  Permits the addition of other factors, such as gender or race, to the RCT.

- Ecological studies
  Utilizes existing “aggregate data” (data that exist for groups of subjects) and compare group information on risk factors with the rate of and outcome. These data may exist in NIH databanks or clinical registries.

- Meta-analyses – A technique that combines the results of many studies to determine a common outcome

The research question and available resources will drive the following design decisions:
- Number and composition of groups, inclusion of a control group
  - Number of groups
- Measures/Variables
  - Number of variables
  - Available indices of reliability (known kappa indices) and validity (appropriateness)
  - Grounded in the literature
  - Realistic, measurable, and relevant
- To blind or not to blind
  - Pre-determined criteria to break a blind
- Sampling plan
  - Adequate if not optimal sample size
  - Inclusion/exclusion criteria
  - Process for monitoring and/or controlling safety and confidentiality
  - Appropriate analyses for stated hypotheses

Potential Data Sources
- Questionnaires or surveys
  - Free, purchased, freshly developed
- Focus groups
- One-on-one interviews
- X-rays or other diagnostic imaging procedures
- Surgical records ○ Medical records ○ Public records
- Established data sets, such as those at the CDC or NIH

Data Collection and Management (see Appendix G, developing a data collection form)
- Have a plan. Use a data collection form to extract and record data in a systematic way.
- Only use ‘de-identified’ or ‘non-identifiable’ data (try not to use any type of tracking or coding, do not record names, social security #s, medical record #s, address, or phone #s, etc.).
- Store electronic data on a password-protected computer, housed in a locked, limited-access facility.
Research Protocol: Methodology - Reliability

- Reliability means consistency.
- Appropriate measures of reliability are specific to different situations, such as the reliability of a survey form, or a pre-post measure.
- Reliability is a precursor of validity. It is necessary but not sufficient to establish validity.
- Whenever possible, report known reliability indices (found in the literature) for standardized instruments, such as tests and questionnaires.

Research Protocol: Methodology – Validity (see Appendix H, Threats to Validity, for a more detailed discussion)

- Validity can be thought of as accuracy. It also can be thought of as appropriateness.
- Validity is not a state of being. Instead, it is a snapshot of a situation at a given moment in time.
- Validity is at the heart of every research study. Without valid measures, applied in a valid design to a valid sample, interpretation will be hindered and the study becomes a waste of human, temporal, and fiscal resources.

Some Common Uses of Statistics

- To describe a set of data
- To demonstrate differences between 2 or more groups
- To analyze a questionnaire or survey by computing the reliability and determining the factor structure of a survey
- To establish a linear association between two variables
- To predict an outcome from key pieces of information (or measures)

Measurement Scales

The type of statistic that you use depends on the scale used for measuring the dependent variables, thus, we need to review the 4 types of measurement scales that have been identified.

- **Nominal data** convey labeling only and cannot be used to indicate magnitude or order.
  - Example: males=1, females=2
- **Ordinal-level data** are used to indicate rank order, such as 1st, 2nd, or 3rd.
  - Note that this doesn’t mean that data points are equidistant. It only indicates order.
  - Ordinal-level data examples:
    - Prize winners are often identified as 1st, 2nd, or 3rd place winners. There is no way to know how close the race was, based on the outcome. It may be the case that the 1st place winner was significantly better than the other two winners and that those two were relatively equal.
    - Survey data collected on a Likert scale.
- **Interval-level data** indicate order as well as magnitude of difference. These require continuous data such as temperature. The distance between points is the same, for example, the distance between the temperature of one and 2 degrees is the same as between 500 and 501 degrees.
  - Examples: Results of an intelligence test (note that zero has no meaning!). Fahrenheit temperature
- **Ratio-level data** have all the characteristics of interval-level data plus the additional benefit of an absolute zero.
  - Examples: (1) The number of calories consumed in a day; (2) weight; (3) height; (4) distance, temperature with an absolute zero
Types of Variables
- Independent
  - This is the variable that is manipulated by the researcher. It is the variable that is believed to cause the change in the dependent variable.
  - Independent variables can be categorical or continuous.
    - Categorical variables can be used to define groups.
- Dependent
  - This is the variable that is measured/studied under each condition or level of the independent variable.

STATISTICS

Descriptive vs. Inferential Statistics (See Glanz, 7th Ed. Or other statistics books (references))
- Descriptive statistics are used to describe a given sample of data.
  - The purpose is to organize and communicate characteristics of a data set.
- Inferential statistics are used to extrapolate from a sample of data to a larger population.
  - The purpose is to make inferences about the population represented by the sample.

Descriptive Statistics
- Measures of Central Tendency
  - Mean (average)
  - Median (‘middle’)
  - Mode (most frequent)
- Measures of Dispersion
  - Variance
  - Standard Deviation
  - Range
- Measures of Association
  - Correlation

Inferential Statistics are used:
- To make group comparisons (analysis of variance)
- To estimate a pattern (cross-tabulation)
- To establish associations (correlation)
- To make predictions (regression)
- To sort into categories
- To place onto a continuum
- Parametric data
  - Interval- or ratio-level measures
- Nonparametric data
  - Nominal- or ordinal-level measures

The t-test:
The t-test is commonly used to determine whether the mean value of a continuous variable in one group differs significantly from that in another group.
- Underlying Assumptions:
  - Normal distributions of the two groups and reasonably equal sample sizes
- Alternative hypothesis can be either one or two tailed
  - HA: i1≠i2 or HA: i1<i2 or HA: i1>i2
Analysis of Variance: ANOVA - Used to compare the means (averages) of 3 or more groups
  o Assumptions:
    • Groups are relatively equal in size
    • Homogeneity of variance between groups
    • Distributions are normally distributed
  o May require follow-up (post hoc) tests to interpret practical significance (effect size)

Association
  o A correlation index can be computed between two variables.
    • A high positive (linear) correlation is said to be present when high values on one variable are
      associated with high values on a second variable AND low values on the first variable are
      associated with low values on the second variable.
  o Correlation indices indicate the degree of linear association between two measures. The greater
    the absolute value, the stronger the correlation. Depending on the type of correlation index
    computed, this value typically ranges between -1 and 1.
    • A procedure commonly used for two continuous variables is the Pearson correlation
      coefficient.
    • A point-biserial correlation is computed when a ratio (or interval) measure is being used
      with a dichotomous variable.
    • Spearman’s rank-order correlation is computed when pairs of ordinal (ranked) measures are
      involved.

Regression involves the prediction of a criterion by one or more predictors. Many different
  types of regressions are available; these are covered in statistics and advanced statistics texts.

UNDERLYING STATISTICAL PRINCIPLES

Significance of statistical tests
The statistical tests described below provide an indication of whether the results could be considered
valid at a certain confidence level or not. Typically, the level of confidence has been the 0.5 “ P ” level.
Essentially, this provides an indication of the quality of the evidence, whether the evidence is good
enough to support the hypothesis beyond a reasonable doubt with a certain probability. However,
more recently, research has been using confidence intervals that specify the boundaries within which the
“true” value (e.g., the mean) is likely to fall, also with a specified probability.

Tails - A one-tail test assumes a prediction that the test mean will be greater than or smaller than the
reference mean. A 2-tailed test says that the test mean will be either greater or smaller than the
reference mean, in other words, you are only predicting that one will be different from the other but not in
any direction.

Null hypothesis
  • Example: There is no difference in the frequency of mouth cancer between pipe smokers and
    non-pipe smokers.
  o Alternative hypothesis (2-tailed)
    • Example: There is a difference in the frequency of mouth cancer between pipe smokers and non-
pipe smokers.

ERRORS

- Statistical errors are usually categorized into one of two types:
  - Type I errors - otherwise known as false-positives.
    - They occur when a researcher rejects a null that is actually true in the population.
  - Type II errors - otherwise known as false-negatives.
    - They occur when a researcher fails to reject a false null hypothesis.

Statistical Power (Also see Glanz, 7th Ed. Or other statistics books (references))

- A useful analogy is to think of statistical power as the magnifying power of a microscope or telescope
  - The high the power, the better the ability to see things that are really there...and to have confidence to state that nothing is present, when, in fact, nothing is present
- Statistical power is influenced by three things:
  - Sample size
  - Sample variation
  - Effect size – the magnitude of the effect you aim to detect. It is often influenced by sampling unit used in the study

Types of Statistical Analyses

- Parametric Procedures (Ratio or Interval level data)
- Dependent samples t-test (2 dependent or related groups)
- Independent samples t-test (2 independent groups)
- ANOVA (>2 independent groups)
- Non-parametric Procedures (Ordinal or Nominal data)
- Wilcoxon test (2 dependent/related groups)
- Mann-Whitney U or 1-way Chi Square (2 independent groups)
- Kruskal-Wallis (> independent groups)

Qualitative” Research

(Qualitative research is appearing in medical literature more frequently and is a paradigm worth exploring for future research. Computer programs, such as NVIVO are available to help.)

- A different way of “knowing”
- Characterized by inductive reasoning: a type of logical reasoning based upon natural investigation from direct observation--often referred to as “phenomenological.” (Do not control variables.)

- Qualitative research does not assume an a priori stance
  - Begins with a broad general question and that seeks to make the researched phenomena accessible and tangible
  - Example: What is the patient’s experience using Email with their doctor?

- Researcher serves as “instrument” gathering data directly from observation, participation, documents, interviews, journals... multiples sources (at least 3 – triangulation)
- Findings “emerge” from data analysis
QUALITATIVE RESEARCH STEPS

Step 1: Research topic & problem statement
Step 2: Review of literature
Step 3: Design your study (IRB Approval)
Step 4: Collect data from natural setting
Step 5: Systematically analyze data
Step 6: Write up findings

Qualitative Research: STEP 1 – Research topic & problem statement
- An issue, uncertainty, dilemma, or paradox that intrigues you
- A statement of the intended contribution of your research—can relate to description, verification (of existing theories, hypotheses, generalizations, or practices), evaluation, prescription, as well as understanding (a remedy to ignorance)

Qualitative Research: STEP 2 – Review of literature
- Used to help find focus, justify, and warrant project topic
- Used to inform research design and interview questions
- Used to get your arms around different perspectives of the problem

Qualitative Research: STEP 3 – Design your study (IRB Approval)
- Qualitative research depends on a variety of methods for gathering data (direct observation, participation, field notes, program documents, rich descriptions, interviews, video analysis, journals...)
  - Multiple-data-collection (triangulation) = trustworthiness
  - The more sources tapped for understanding, the more believable the findings
- Other Design Considerations
  - Participants: how many, who, situation
  - Access to site
  - Time frame
  - Data storage and coding
  - A Pilot study: to test site, instruments, coding, logistics, interview questions, language, techniques, researcher role...

Qualitative Research: STEP 4 - Collect data from natural setting
- Researcher becomes a trusted participant-observer seeking to make the strange familiar
- Field notes, descriptive notes, quotes, analytic notes, document analysis, transcription, interviewing, journal instructions, conversations, questions, good listening
  - Nondirective but patiently probing for “what else”
  - Protect data and relationships

Qualitative Research: STEP 5 - Systematically analyze data
- Interpretation is born on the weight and diversity of data
  - Categorize, synthesize, and code data
  - Watch for emerging themes and patterns
  - Mine coded data for important concepts (to mine the data means to identify which codes seem
most important by the breadth [different instruments producing it] and depth [frequency of occurrence] and then study the “instances” of that code occurrence for patterns, ideas, and hidden items of interest)

**Qualitative Research: STEP 6 - Write up findings**
- Provide an introduction, brief review of literature, description of methods, description of context and setting, analysis and interpretation of data, and subsequent discussion and recommendations

**ETHICAL CONSIDERATIONS OF CONDUCTING RESEARCH ON HUMAN PARTICIPANTS**

**Institutional Review Boards (IRBs) - What, Why, When, and How?**

**What is an IRB?**
- **Institutional Review Boards** for research on human subjects monitor and review all research that involve human participants:
  - Beneficence - To do ‘good’
  - Justice - To be ‘fair’
  - Autonomy - To have control over one’s self

*NYIT-COM has two IRBs and Touro also has two IRBs; most large hospitals have their own IRB's and procedures for submitting research for IRB approval. Contact your IRB Chairman for information and forms. If your hospital does not have an IRB or access to an IRB, NYCOMEC can facilitate access to the NYIT-COM IRB. Additionally, there are commercial IRD agencies that can provide an IRB review. No subject/participant recruitment, nor data collection, can take place before final IRB approval is obtained.*

What kinds of studies are considered ‘research’ and are subject to IRB review?
- Just about every kind of study that uses human participants, in any way, needs to be reviewed by an IRB.
- Some studies, such as those using questionnaire, are “exempt,” which means they can be approved by one IRB member, but you should review your plans with your IRB Chairman prior to submission.

Points that need to be well described:
- What is the intent of the researcher?
  - Is this work being conducted with the INTENT to publish or present findings in the public domain?
- Does this work entail systematic methods?
- Does this work contribute to generalizable knowledge?
  - Any risks to subjects that might occur

**Typical FAQs and Answers**
1. What if the study is survey based?
   - As a rule, survey-based studies are required to undergo IRB review. Based upon the purpose of the survey and the nature of the questions contained in that instrument, the type and level of review will be determined. A consent form can be made a part of the survey
2. What if the data will be gathered via chart reviews?
   All retrospective studies are subject to IRB review, regardless of the clinical subject matter of the study. This includes medical records, lab or radiological reports, and/or surgical reports/records.

3. What if only one case will be used (a single-case report) but findings will be published or publicly presented? If a single, non-identifiable case will be reviewed and there is no intent to publish the resulting paper/report, then no IRB review is required. Some journals that publish case studies require that a consent form be completed by the subject. For most poster competitions where only an abstract is submitted, no IRB review is required. However, if the content of that poster is to be published, then the journal may require a consent form.

4. What if minors or other protected populations will be used in the study?
   Protected populations include minors, pregnant women, fetuses, students, mentally impaired/incompetent persons or anyone of compromised capacity. The purpose of providing an extra layer of protection for members of protected populations is because their circumstances put them at greater than minimal risk.

**Federal Law States...**

- Research involving human subjects is permitted to commence ONLY after a protocol has successfully cleared the IRB process, as evidenced by a signed approval document.
- Periodic reviews are required of all projects running for more than one year.
- Research is required to be suspended if, at any time during the study, it is deemed unsafe or unreasonable to proceed.

*For examples of forms for IRB submissions, see Appendix I.*

**Data Safety Monitoring Boards (DSMB) - Usually used for large-scale research or research that may pose a substantial safety hazard**

- This type of board (different than an IRB) consists of a panel of experts who are trained in the various aspects of a given study.
- If at any time in the life cycle of a research project the DSMB believes that research participants are at risk of serious injury or death resulting from their participation in that study, then the board has the authority and responsibility to suspend a study until an assessment can be conducted.

**What is “informed consent”?**

- Consent is a process, not a product.
- Consent is the vehicle by which a researcher addresses the fundamental concerns of any IRB:
  - Beneficence, Justice, and Autonomy
- Involvement/participation in research cannot be coerced:
  - Participants must have the freedom to withdraw at any time, without penalty or prejudice.
- Participants understand what is going to be expected of them in the course of the research study.
- Proposals submitted to an IRB must include the consent document to be used with subjects

**Note: Inclusion/exclusion of participants must be equitable across target groups and potential benefits must outweigh potential harm to subjects.**
Ingredients of a Consent Form (See Appendix F and I)

- Emphasize that your study is about RESEARCH and that participation is completely VOLUNTARY.
- Convey this point to potential participants through written form (i.e. your consent form).
- You must state that subjects can withdraw at ANY time, without recrimination, penalty or repercussion.
- In order to facilitate good communication, be sure to keep the text simple. Write between an 8th and 10th grade level.
- If you are offering compensation for participation, have a plan to pro-rate payments.
  - Payments or other form of compensation to participants cannot be coercive.
- Include a description of the study, a description of the procedures to be followed, and the expected duration of the subject’s participation.
- Clearly state any reasonably foreseeable risks or discomforts to the participants.
- State any benefits to the subject or to others (like the scientific community) which may reasonably be expected.
- Include a disclosure of appropriate alternatives, treatment, or options.

Offer an explanation as to whether any compensation or treatment will be available in the case of injury to the subject.
- Include contact information for questions about the research, subject’s rights, or possible injury.

Using Deception in Research

There are only a few defensible/acceptable reasons for using deception in research:

- To achieve stimulus control or random assignment of subjects;
- To study responses to low-frequency events;
- To obtain valid data without serious risk to subjects;
- To obtain information that would otherwise be unobtainable because of subjects’ defensiveness, embarrassment, shame, or fear of reprisal.
- Deception can ONLY be used when other, more reasonable means, cannot accomplish the research objectives.
- Debriefing is nearly always required when deception is employed.
  - Note that any type of deceptive research will be reviewed very carefully by the IRB committee.

OPPORTUNITIES TO DISSEMINATE RESEARCH FINDINGS

Disseminate Findings: Papers

- Components of a Protocol
  - Introduction
  - Methods
  - Bibliography
- Components of a Paper
  - Introduction
  - Methods
  - Results
• Discussion/Conclusion
• References
  o Developing a Protocol into a Paper
    • Change the verb tense from future to past
    • Add two new sections:
  o Results
  o Discussion/Conclusion
    • Turn the bibliography to references

Disseminate Findings: Posters and Presentations
  o Posters are a great way to disseminate research findings. Venues include the annual NYCOMEC Trainee Poster competition, the annual NYSOMS poster competition, AOA, AACOM, and specialty college meetings
  o Key elements to posters:
    • Poster Title
    • Authors’ Name(s) and Institutional Affiliation
    • Abstract
    • Method
    • Results
    • Conclusion
    • Visual component

Disseminate Findings: Posters and Presentations (continued)
  o Key elements to presentations:
    • Introduction - State goals and objectives of the presentation
    • Body - State key points with supporting data or examples
    • Conclusion
    • Presentation skills (verbal and non-verbal)
  o The application materials and brief instructions for writing an abstract for the annual NYCOMEC Research Poster competition are available in Appendix L.
  o A useful PowerPoint on preparing an abstract is Mohammad K. Ismail MD, How to Write an Abstract:
    Abstract Submission & Poster Presentation, available through the website address below (or Google search Mohammad K. Ismail MD Abstract)
    http://docslide.us/documents/how-to-write-an-abstract-abstract-submission-poster-presentation-
    how-to-write-an-abstract-abstract-submission-poster-presentation-mohammad-k-ismail.html

Disseminate Findings: Publications
A useful strategy is to present a poster prior to preparing the research or case study for publication. This permits you to obtain comments from observers that can improve the presentation. Many journals are available, or course; look for one that typically publishes the kind of study you did. Make sure you obtain and follow the instructions for submission that are published by the journal. A good publication opportunity available to our residents is the online journal published by the St. Barnabas Hospital: http://www.newyorkmedicaljournal.org/
Resources: Support and Funding
○ Methodological and statistical support
  • NYCOME Research Director and NYIT-COM statistician
  • Statistical software packages (SPSS) are available in the NYIT-COM library.
○ Outside statistical consultants

Funding Sources
○ External Funding (See Appendix K for some possibilities and resources)
  • Professional organizations, government agencies, private foundations.
  • See Appendix L for help in grant writing.
  • See the Osteopathic Family Medicine article by Jane Dumsha, et.al.

Final Reminder!
○ Make a note of your timeline. Do not wait until the last minute to get started!
RESEARCH OUTLINE FORM

BELOW IS AN OUTLINE FORM THAT CAN BE USED TO SKETCH OUT YOUR RESEARCH PLANS AND REQUIREMENTS. THIS IS DESIGNED TO BE COPIED AND USED FOR THE INITIAL RESEARCH PLAN.

QUESTIONS CONCERNING RESEARCH

a. WHAT DO YOU PROPOSE?

b. WHY IS THIS OF INTEREST?

c. WHAT DOES THE PUBLISHED RESEARCH SAY?

d. WHAT RESEARCH DESIGN WOULD YOU USE?

e. WHAT VARIABLES WOULD YOU USE OR MEASURE?

f. HOW WOULD THE VARIABLES BE DEFINED AND MEASURED?

g. WHAT OUTCOMES WOULD YOU PREDICT?
CLINICAL RESEARCH REFERENCES

David P. Yens, Ph.D.
Revised August 2019

A good, accessible, and reasonably comprehensive review of the research process.


Basic, simple, includes journal clubs and how to interpret research.


APPENDIX A
RESOURCES FOR PREPARING GRANT APPLICATIONS

Information about NIH grants
https://grants.nih.gov/grants/grants_process.htm

For a description of and access to an NIH-prepared manual for developing grant applications,
visit the site below; focus is on R01 grants.
http://grants.nih.gov/grants/writing_application.htm

The following may also be helpful:
https://www.nsf.gov/funding/azindex.jsp

Funding opportunities at NSF
  Guide to proposal writing for NSF

NYIT resource:
00000000000-----------------------------------------------8
APPENDIX B: LBORC TABLE OF CONTENTS
These 2 Appendices provide an additional overview of the research process

Section I  Louisa Burns Osteopathic Research Committee Manual Table of Contents

i. Overview of the Louisa Burns Osteopathic Research Committee (LBORC)
   • Purpose
   • Functions
   • Composition of the Committee
   • Processing of Research Proposals by the LBORC
   • Funding, Reports and Publication

ii. Research-Related Programs
   1. Research Funding Resources
   2. Assistance for Physicians to Develop Clinical Research

iii. The Role of LBORC in Osteopathic Clinical Research
   1. Research Considerations, Models, Methods & Philosophy

iv. Reviewing the Literature
   1. Purpose
   2. Sources and Relevance
   3. Getting Published – The Report

v. Getting Started
   1. Guidelines for Physicians as the Principle Investigator in Osteopathic Clinical Research
   2. Additional Guidelines for Research Designs
   3. Research Design Considerations

vi. Specific Guidelines for Designing Osteopathic Research Protocols
   1. Osteopathic Manipulative Treatment and the Somatic Dysfunction
   2. Standards
   3. Objectives
   4. Suggested Guidelines
   5. Controls used when OMT is the Treatment Variable

vii. Simple Clinical Research Designs: Procedures and Formats
   1. Retrospective Study / Descriptive Study
   2. Prospective Clinical Study
   3. Comparison Groups – Experimental and Control

viii. Criteria for Research Proposals Submitted to the Louisa Burns Osteopathic Research Committee
   1. Projects Requiring Full Committee Review
   2. Exemptions from Full Committee Review & Expedited Review

○ Louisa Burns Research Committee Applications for Support
   • Guidelines for LBORC Application
• Ethical Conduct
  o References for Clinical Research

• Fundamentals of Writing for Specific Journals (due to be completed by October)
  • Choosing Journals for Submission
  • Methods of Getting Published
  • Multiple Submission Rules

• LBORC Application Forms
  • Form A: Application for Grant from the Louisa Burns Osteopathic Research Committee of the American Academy of Osteopathy
  • Form B: Administrative Data Sheet
  • Form C: Certificate of Compliance: Protection of Research Subjects
  • Form D: Summary of Budget & Financial Statement
  • Form E: Researcher’s Personal Data Sheet
  • Form F: Project Management
  • Form G: LBORC Questionnaire
  • Form H: Quarterly Research Report

• Appendix I: Basic Study Design Flowchart

• Appendix II: Validity (definitions)
  • Internal Validity
  • Construct Validity
  • Statistical Conclusion Validity
  • External Validity

• Appendix III: Statistics Glossary
  (http://www.reading.ac.uk/ssc/resources/Docs/Statistical_Glossary.pdf)
  • Probability
  • Hypothesis Testing
  • Non-Parametric Methods
  • Presenting Data
  • Categorical Data

• Appendix IV: Outpatient Osteopathic SOAP Note
  • Instruction manual
  • Sample Form

• Appendix V: Hospital Osteopathic Inpatient SOAP Note
  • Instruction manual
  • Sample Form

• Appendix VI: Cranial Osteopathic SOAP Note
  • Instruction manual
• Sample Form

o Appendix VII: Single Organ System Osteopathic Musculoskeletal SOAP Note
  • Instruction manual
  • Sample Form
APPENDIX C:

2010 AOA RESEARCH HANDBOOK

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X. REQUIRED FORMS FOR RESEARCH GRANT APPLICATIONS

XI. RESEARCH FELLOWSHIP APPLICATIONS

XII. REQUIRED FORMS FOR RESEARCH FELLOWSHIP APPLICATIONS
a. Checklist - must be completed, signed and submitted with the application, with 1 copy attached to Cover Letter

XIII. EVALUATION WORKSHEETS

XIV. GRANT REVIEW WORKSHEETS

XV. FELLOWSHIP REVIEW WORKSHEETS
AOA Research Training Grants - 2017

AOA has identified five research priorities it believes have the greatest potential to impact patient care and evidence-based medicine and demonstrate the value DOs and their approach to care bring to the medical profession.

These programs are designed as a mechanism for supporting the research training of the applicant and will enable the applicant to conduct a basic science, clinical, or health services research project that will make a significant contribution to osteopathic medicine. Additionally, these programs seek to encourage physicians in training and medical students to contribute to osteopathic research throughout their career.

**RFA: Physicians in Training Research Program**

Projects must be designed to assess the osteopathic approach in one of the five priority areas.

Preference will be given to proposals that: (1) use novel approaches; and (2) lead to results/outcomes that could be translated to physician practices. Please note that while the AOA has a preference for novel projects it will also support supplemental projects of existing research studies. Supplemental projects must have research questions and specific aims distinct from the existing (parent) study. Applicants will be required to provide information regarding the parent study.

**RFA: Osteopathic Medical Students Research Program**

The AOA will support supplemental projects only of existing research studies. Supplemental projects must have research questions and specific aims distinct from the existing (parent) study. Applicants will be required to provide information regarding the parent study.

**Deadline for Application**

- The deadline to submit all Research Training RFAs is Jan. 31, 2018
- Project start date is Sept. 1, 2018

**Application Process**

- Download and review the Checklist for Completing the Physicians In Training Research Plan and Forms
- Download and review the Checklist for Completing the Medical Students Research Plan and Forms
- Download and review the How to Register via the AOA Grants Submission Portal
- Go to the AOA online application system, register and submit an application (see other forms located in the sidebar). The online applications system will open on Nov. 1, 2017.

**Technical Assistance/Questions**

Questions should be directed to the AOA Department of Research and Development at:

Gloria Dillard, MPH, Research Manager  Phone: (312) 202-8006
Fax: (312) 202-8306  Email: gdillard@osteopathic.org
APPENDIX D

HOW TO DEVELOP IDEAS FOR RESEARCH

This is from an email by Ronan Conroy on April 9, 1999 to edstat-l, an Internet list and to sci.stat.edu, a USENET group, which summarized a presentation he made about how to develop ideas for research. Provided by Dr. Ronald Dvorkin, formerly Emergency Medicine Physician at the Good Samaritan Hospital.

INTRODUCTION

This paper tackles one of the questions that statisticians dread most: the most basic one of all. How do you start formulating a research project?

It began life as a talk at a research seminar in the Rotunda Hospital, Dublin. Trying to write it up, I decided to mail the statistics lists that I subscribe to. This paper has been greatly enriched by the ideas and discussion generated on edstat-l, the statistics teaching list, as well as contributions from subscribers to the stata list and the UK statistics list allstat. Quotes are often attributed to the only person who made the point most memorably, but many of the ideas emerged repeatedly in different postings. I'd like to thank all those who took part in the discussion.

EXPLORING YOUR ENVIRONMENT

The first thing you need to do is identify your resources for research. This is often easier when you first arrive somewhere. After a while you begin seeing an environment as the place where you work or live or eat. You need to see it with a fresh eye to see it as a potential research environment.

Don't forget that your research environment includes not just your patients and your colleagues, but also includes any source of data, ideas or help that you have access to. Many of my own research projects have taken shape because my office is next door to the psychology department; a casual remark has often triggered a flurry of speculation, articles rooted out, contacts mentioned and so on.

The internet is also a valuable environment. Discussion lists abound, which can provide not just free advice but also an insight into current controversies and new directions in research. Simply subscribing to a list and reading the postings (the word for a person who does this is a lurker) without taking part in the discussions will often give you ideas.

GENERAL RESOURCES

How much time will you be able to devote to research? To what extent can you integrate it into your daily work?

Will colleagues help? For instance, if you need blood taken outside working hours, will the doctor on call oblige? Will nursing staff collaborate by collecting extra information?

Do you have access to a person, unit or department with a specific research interest? They can often be a useful source of ideas. Never underestimate the value of just going for coffee with someone who does a lot of research, or, better, a research team. The speed with which a bunch of researchers can take a vague idea and shape it into a research design is amazing. Most of these ideas go nowhere, but eavesdropping on the process can help you to do it yourself.

Giovanni Leonardi of the Environmental Epidemiology Unit at London School of Hygiene and Tropical Medicine put it like this: “There are many potential research ideas that never make it to becoming research projects, and the likelihood that a research idea will become a research project
is heavily influenced by this idea having being selected and refined in an environment where potential ideas are routinely tested for their viability. Think of this as 'natural selection' of research ideas within the research environment."

Do you have access to a statistician, or someone who can advise you on study design and sample size? What library facilities do you have access to? Skimming journals is a good ideas generator, which I will deal with in more detail later; but access to a good library, including literature searching and reprint ordering facilities, is a must. Add extra points for library staff who are willing to do literature searching with you looking over their shoulder to refine the search.

What computer facilities are available?
  o Ideally you should be able to write your own research papers and reports.
  o This is helped greatly by being able to create tables and graphs, so if you can't do this, learn.
  o The next real bonus is having a dedicated bibliographic package which you can use to store, organize and annotate your references, and to generate bibliographies for papers -- well worth investing in.
  o Finally, have you a statistical package, or access to someone who will do your statistics for you? Ideally, you should be able to examine your data using graphs and tables, rather than handing the whole analysis over to a number crunccher. Professional statisticians are best used to answer complex questions, but you should be able to do the simple statistics yourself, perhaps guided by a statistician. Not being able to do any statistics means that you lost contact with your data at the vital point when it is being investigated for patterns, anticipated and unanticipated.

What are they funding this year? This sounds like a cynical point, but if there are funds available for research in specific areas, make use of them. What charities are there who might be interested in your research area? Talk to colleagues; there is often no single listing of available research sponsors, and you have to rely on the grapevine.

**SPECIFIC RESOURCES**

Do you have access to information already collected which could be the basis for a research project? This information could have been collected as routine clinical information. Although you probably cannot do a research project solely on the contents of patients' charts, routinely collected information may allow you to
  o Identify patient groups that are interesting to study (and figure out if there are enough of them to be worth studying!)
  o Identify controls
  o Add already-collected clinical information to the data that you will collect in the course of your project.
    • Information may also be available as an offshoot of another research project. You may liaise with another research project and
  o Study a subgroup of their patients in more detail
  o Follow up a previously-studied group
  o Add a sub-study of your own to a study that is being planned or, not so easy, ongoing.
    • It is a good idea to talk to people who are doing research in the setting in which you work. They will be able to spot potential difficulties in proposals, and may also
have useful ideas as to what they would do if they had access to your facilities.

POTENTIAL PROJECTS

Now all you need to do is to get an idea for a project which will be realistic, given the resources available to you. This is often a stumbling block. I had one person come into the office to discuss a research project with me. 'I have 24 patients with rapid cycling mood disorder' he said. And stopped, waiting for me to say something. The trouble is that 24 patients with rapid cycling mood disorder is no more a research project than 24 trout in a shoebox. What you need to ask yourself is 'what do we not know about rapid cycling mood disorder?'

One very important piece of advice that recurred frequently in the edstat-l discussion was the need to develop many ideas simultaneously. Christie Brown, Assistant Professor of Marketing at University of Michigan Business School tells her students to imagine that inside them they have a large basket of research ideas, some better than others:

'I point students toward Donald Campbell's work on creativity. Campbell suggests one secret to generating better ideas lies in the QUANTITY of ideas generated. In other words you stand the best chance of pulling an idea from the "high" end of your good-idea basket if you make a lot of draws.' (Campbell, Donald T. "Blind variation and selective retainments in creative thought as in other knowledge processes." Psychological Review. 1960;67:380-400.)

Don't focus prematurely on a single idea. Develop a few together. It's like the process of conception: the chances of a child resulting from a single act of sexual intercourse are small. But the chances of a child not resulting from regular sexual intercourse are likewise small. Carry a notebook and write down every idea that you get, good or bad. You will learn from thinking about why the bad ones are bad as well as from why the good ones are good.

Christie Brown again: 'Write down everything. Do not self-censor. Keep a log of your baby-ideas in case they end up being worth pursuing. Get in the habit of generating at least one idea based on everything you read in your domain and even out of it.

Bob Frick, a cognitive scientist, actually forces students to develop a number of research ideas as a learning exercise. 'The assignment was to come up with three "kernels", and the students had about a month to do it. The notion was that they were supposed to find some original idea they had. It usually ended up being an original observation. Original to them -- it didn't have to be original to the field of psychology. Their original idea would then be a kernel that could be developed into an experiment. Most people have these, but they don't pay attention.'

EXTENDING THE IDEAS OF OTHERS

Much of the discussion on edstat-l centers on where ideas for research projects come from. The sources of ideas divide into two:

- Replicating/extending the work of others
- Doing something original.

I'll take the easy one first! Repeating research that has been done by others doesn't sound like task, but there are several important reasons why it needs to be done, and there are some other benefits too. The reasons why research needs to be replicated include:

- Local research is needed to make sure that findings from other countries apply locally.

Indeed, basic research is constantly needed to monitor local health needs and to evaluate
the services being delivered.

- **Is the problem the same here?** For instance, research has shown that liaison psychiatry in Ireland sees a very different spectrum of morbidity than its counterpart in the US. Planning services using US models is inappropriate. If you suspect that the service in which you work sees a spectrum of patients or problems that is different to what you would expect, research this. It can lead to a better understanding of the health service needs in your service.

- **Do the strategies worked out elsewhere apply?** Many treatments and interventions have been researched in settings that may be quite different to your own. You might well ask if they are best for your setting.

**All research needs extension to new contexts** and development along an obvious line - Clinical trials are often done on homogeneous, idealized patient groups; they need extension to realistic groups such as those with comorbidity, or beyond the age range of the original research. Think of

- **Treatment of hypertension in the elderly.** This is a classic case where treatment was wrong for many years because it was based on the results of studies of younger patients.

- **Use of treatments in neonates that have only been studied in older children or adults.** This example has become topical recently, as pediatricians have realized that very young children are often excluded from treatment trials, yet the treatments end up being used to treat them,

- **Many treatments are evaluated on patients who have 'pure' diagnoses, while they are frequently applied to people who have more than one disorder.**

**Factors which have been identified in a disease may be present in other similar diseases.** Since its role in peptic ulcer disease was uncovered, *H pylori* has been investigated for many other unsolved crimes.

- **Is it responsible for the digestive symptoms some pregnant women experience?**

- **Is it linked to cancers?**

Yes, there is a feeling of a bandwagon rolling along, but someone has to check out these questions.

You may spot an explanation which the original study failed to identify and test. This is, of course, classic 'stroke-of-genius' research. Just remember, though, that the explanations that are most often overlooked are the commonest, most familiar things.

**You may not believe a piece of research.** Not all research is good research. I have, several times, replicated and extended research because I didn’t believe it. Incredible research deserves to be replicated. If you confirm the original findings, you have helped to overcome the resistance that they will find in being accepted. If you fail to confirm the findings, this in itself is interesting. Though try to make sure that the original author isn’t asked to review your paper!

Even doing a **straightforward replication of a previous study** can be a very worthwhile exercise. As a first project, it means that you already have a 'canned' methodology, and you will learn a lot about running, analyzing and presenting research, But there are often surprises too.

Chris Zorn of Emory University wrote, “As a social scientist responsible for training grad students in statistics, one thing that I’ve always found useful is replications. While the main reason I use replications is to teach students statistics and/or software, these exercises often prompt them to extend the work they are replicating. These can range from the simple (e.g. testing for relationships in the data that the original investigators didn’t look for) to the very involved. The result is often interesting, if a bit derivative, research projects, some of which have led to PhD
theses, etc.”

Andersson Roland puts it simply: *Dig where you stand.* That is, make use of all the data that is already at hand and that nobody had time to analyze. Almost always there will be unexpected or unknown patterns in these data that can be detected if you analyze them with an open mind. You do not always need to have a research idea ready when you start. They will come up when you try to formulate an explanation for the patterns that you find in your data.

Alex Heath, an economist from Australia, wrote, “A good way to get started thinking about research questions for me is to find things which have been done overseas (usually the US or the UK) and adapt them to Australian data. I find that once you start replicating things you find interesting twists and turns which allow you to say something completely new.”

Although I have replicated several studies because I did not believe them, this probably is not the best spirit in which to replicate. But neither should you simply accept the original research as scripture.

Paul Velleman, the person responsible for the DataDesk statistical package and ActivStats, a statistical teaching package, wrote in praise of an attitude of well-informed skepticism: *This misses the most important part of the process -- an abiding skepticism. You must know your science before you can be intelligently skeptical about it, but just because you know what is common wisdom doesn’t mean you should believe it. Indeed, if science is to progress, you must maintain a willingness to disbelieve. You don’t do research by replicating previous results but by doubting them.*

Dennis Roberts, responding to this, said, “A good replication study does not have to be done BECAUSE one doubts them, but rather to bolster the case that the research findings made ...”

I think that he and Paul really just differ in emphasis, with Dennis arguing that 'replication is very valuable ... we don't do enough of it ...' while Paul cautions against literal-minded repetition. I think everyone would agree that the scientific idea of replication is doing something more intelligent than just looking for what the other guys already saw.

Paul makes the point, too, that it is hard to sit down and work carefully through a set of data without coming up with at least one pattern that needs further investigation. You may start by replicating a study, but this is almost guaranteed to act as a springboard to innovative questions of your own.

**GETTING A RESEARCH IDEA BY READING PAPERS**

You can simply bury yourself in the library with a whole year’s worth of your favorite journal and, starting from the most recent issue, use a series of filters to identify studies that you would be interested in and capable of extending. Even when I'm not in need of a research project, I often graze my way through a small stack of journals, picking up an interesting methodological approach here, or a useful measurement technique there. Many of my more prolific colleagues do this a lot. One, in particular, seems able to rummage out a half-a-dozen relevant journal articles from her shelves on any topic in about five minutes.

If I am looking for a potential project, I look at each article in turn and ask:

- Does the title sound interesting? If so, look at the abstract. There is little point in taking on a research project that doesn’t sound interesting. It will be a lot of work, so it will have to hold your attention.
Can I extend this study to a relevant patient group? Think about the sorts of patients you have access to--would it be interesting to try this on them?

Can I extend the methods by assessing something not assessed in the original paper, or increasing quality of assessment? Remember that you are one of your own best research resources. Can you refine the study design by substituting a personal interview or a medical examination for a self-administered questionnaire?

Read the end of the discussion to see if the authors identify areas for future research.

Usually the researchers will make a big play to inflate the importance of their area of interest, and do a paragraph of ‘we-simply-must-know’ stuff. They are usually either working on this themselves or they have applied for a grant already, so if you decide to follow up their suggestion, move fast.

If you find that an article catches your attention as a possible project, do a literature search to get a feel for the area (and look carefully through the references in the original article, of course; aside from identifying useful articles to read, you will get an idea of the sorts of journals that might take your paper, and you can target it accordingly).

Contact the authors. Authors love to hear from people who think that what they are researching is interesting. They often provide advice, access to unpublished manuscripts, free consultation time simply because that’s the way research works. Be prepared to do the same in your turn! The easiest way to contact the authors is get an email address. Search the website of their institution if the article doesn’t have an email address, or try using an email search engine on the internet to find them. People reply faster to email, and you can bombard them with small queries which would be irritating in letters. And, of course, keep them in touch with your work. They may be a great help when it comes to analyzing and writing up.

Finally, you should also think about plundering the abstracts from conferences.

There may well be something there, and the work will be newer than published articles. If you are actually at a conference, seek out the people who are doing research that would interest you. Over coffee you can usually get ideas for several projects from them. One favorite ploy I use is to ask them how they would do their research if they could start all over again, knowing what they know now.

GETTING YOUR OWN IDEAS

This is an even harder subject to write about than extending and developing the ideas of others. (Did I say plagiarizing? Never!). The secret seems to be keeping your eyes and ears open all the time. The observation doesn’t have to be complicated. On the contrary, spotting an obvious question in an everyday event often has greater potential.

Jack Schnell of Department of Economics at the University of Alabama in Huntsville remembers simple advice he got as a student: ‘look out of the window’, meaning ‘pay attention to what is happening out there in the world, look for issues that are ripe for investigation’. And since that time I have tried to do just that. For me, this has been more intellectually sustaining than, say, combing through some literature in the hopes of seeing a useful extension.

A simple observation can spark off a whole train of ideas. Roland Andersson, of the Department of Surgery in Joenkoeping, Sweden, said For me it started like this: I observed that we had had 12
patients with appendicitis during one week. The following weeks we had only one or two. I wondered: 'Had we had an epidemic of appendicitis?'. I happened to know about Knox space-time analysis and I started off from there and finally have written a thesis about 'Appendicitis - epidemiology and diagnosis'. Lots of new questions arise and I am now involved in a (as it seems) never ending project about aspects of appendicitis. (And please, don't worry if you have no idea what Knox space-time analysis is; the important point is that Roland brought together a specialized theoretical framework which he already knew and a common everyday observation. In other words, he applied the theory he knew to the world outside the window.)

**But what frame of mind, what view of the world do you need in order to have productive research ideas?** A lot of discussion focused on this question. At one extreme was Robert Hamer, who very much doubted whether you could teach anyone how to look at the world in a questioning manner. I don't think that this is true, though. **We are brought up in a way that does not encourage us to question the explanations we are given for things.** Don't forget that all children are hungry to find things out, to know why things are so. This voice of hunger for knowledge and delight in figuring things out is much smaller and more timid by the time we have grown up, but with patience it can be called back. **It takes time to rid ourselves of this learned incuriosity.**

The trick is doing what children do: **asking lots of questions and teasing out the logical consequences of the answers.** Paul Velleman said, 'Dennis is right that the problem is nudging the mind. We need to start that process in childhood. We must cultivate in our children and our students a broad-based skepticism coupled with a sense that there *is* order in the universe.'

These are the sorts of questions that scientists and other children ask.

- **How does this work?**
- What is the proposed biological explanation for the thing I am looking at?
- **How do we know?**
- Is there another possible explanation?

One must maintain an active and abiding skepticism about the explanations and models that have been proposed in science. Skepticism, which Paul Velleman identifies as a key attitude, doesn't involve simple disbelief, but rather **being able to entertain a number of different explanations at once.**

This struck a chord with Robert Knott: **After being involved with masters and doctoral students for over thirty-years and looking back for an answer to the original post, I find that the statement above applied to over 90% of those I helped... The first person I worked with was bothered by a statement in a 10th grade Biology book which said that trees were pruned in the fall in order to make them fill out areas and become more symmetrical. This still bothered him eight years later. He finally did is work on 'wound' hormones in plants.**

**Says who?** Many pieces of medical knowledge are folkloric, and the evidence is slender. In particular

- **Clinical signs and diagnostic tests--are they really reliable and valid?** The apex beat, for instance, is taught as a religion in some cardiology departments. Research into the repeatability of this clinical sign shows that it is hard for two observers to locate it in the same patient, much less in the same place.

- **Factors are supposed to be associated with prognosis or diagnosis: where's the evidence?** Women with small feet, for instance, are supposed to be at higher risk of caesarian section because of the baby's head being too big for the pelvis. But this assertion rests on a couple of small and doubtful studies. Better research (already done--sorry!) has shown that this is just a medical myth.
- **Rituals of patient management** (surgical masks, changing wound dressings) may have no evidence to support their usefulness.

**I don't believe that!** Always trust your disbelief. Often a trip to the library will put your mind at rest, but think about:
  - Alternative explanations for things you have been told
  - Your feeling that *what you see in your own practice is not what you have been told you will see*

**Why are we doing this?** At every point in clinical practice there are decision forks. Some may be invisible (we always do X when Y happens) but these are the most interesting! For example:
  - What is the *most informative sequence* of diagnostic tests?
  - What are the treatment options at a given moment?
  - How do we decide between them?

**Why are they both right?** Some disagreements in the literature are because no-one has yet spotted the reason why two different sets of investigators should have observed data that were seemingly contradictory.

Can we learn from the abnormal? We learn once from describing the normal--normal course of disease, normal range of variation etc. We learn a second time by examining cases that do not fit the general picture. Rare, pathological conditions can give us an insight into how more subtle, commonplace processes work.

  - Congenital homocysteinemia and CHD led to the investigation of homocysteine in CHD in 'normal' people
  - Research into doctor-patient interactions in hypochondriasis gave leads for investigating health anxiety as a dynamic in these interactions in normal patients.

**FINAL THOUGHTS**

I don't know where ideas come from, but I do know that you get more ideas if you *try to remember everything that happens that doesn't have a good explanation*. I carry a little black notebook which can simply be used to note phone numbers and things I have to buy next time I go shopping, but it also means that I have a way of writing down an idea the instant I spot something interesting.

The last thing I want to say is based on my experiences teaching music to adolescents, as much as teaching research methods to medical students. **The biggest obstacle you encounter is a feeling that you can't do this;** that you aren't the sort of person who can sing, or make interesting observations or pose original questions. **Just remember: this is what you did as a child, before you were taught any different. So you already know how to do this; just think of yourself as a little rusty.**
APPENDIX E
OSU TEMPLATES FOR RESEARCH PROTOCOLS

OSU TEMPLATES

Prospective Research Protocol Template
Prospective Research Protocol Template

*(Title of Study)*

I. INTRODUCTION
   a. Existing studies in your research area
   b. Gaps from the literature
   c. Fill gaps
   d. Research questions
   e. Direct observation, a survey, questionnaire, a critical analysis of the existing medical literature, or clinical experiments?

II. METHODS
   a. Study Population
      i. Population you are studying
      ii. Number of subjects from the population (sample size)
      iii. Assumptions
      iv. Exclusion or inclusion criteria
   b. Hypothesis
      i. Statements, assertions, or propositions about your target population
      ii. Null and Alternative Hypotheses
      iii. Making comparisons or exploring associations
   c. Study Variables
      i. Key variables of interest to you
      ii. Define variables that are not commonly used
      iii. Commonly used variables are, but not limited to age, race, gender, height, weight, and medical records
      iv. Negative outcomes should be clearly spelled out
      v. Operational definition of variables
      vi. Measurement of variables
   d. Study Design
      i. Obtain information: Sampling? Type?
      ii. Simple, random, systematic, stratified, and cluster sampling?
      iii. Direct observation, a survey, questionnaire, critical analysis of the existing medical literature, or clinical experiments?
      iv. Recruitment of subjects
      v. Data collection and storage
   e. Statistical Analysis
      i. Screening and cleaning data
      ii. Statistics to be generated
      iii. Methods of analysis: Parametric vs. Non-Parametric
      iv. Assumptions underlying data
      v. Test assumptions?
      vi. Cater to violations of assumptions, if they exist
      vii. Level of significance
f. Institutional Review Board (IRB)
   i. Consent process *(see an attached sample Consent Form)*
   ii. Recruitment of subjects
   iii. Compensation
   iv. Risks and discomforts
   v. Benefits and costs
   vi. Coercion
   vii. Deception
   viii. Data handling and storage
   ix. Data safety monitoring board
   x. Health Insurance Portability and Accountability Act (HIPAA) compliance

III. REFERENCES
   a. List all references
   b. Choose relevant citation
   c. Consult specialty area guidelines, your program director, and journals for publication
   d. Common styles are the AMA, APA, MLA, and Chicago
CONSENT TO PARTICIPATE (GENERIC SAMPLE)

You have been invited to participate in a research study that will investigate the effectiveness of a (procedure). (Hospital) and (Ohio University) have approved this study, and it will be conducted under their supervision. Your participation in this study is completely voluntary, and you have the right to refuse to take part. Your acceptance or refusal to participate will not affect your future care or relationship with us in any way.

EXPLANATION OF THE STUDY
This research study will be limited to patients that have __________________________. The researchers will assess (1) ____________________________ and (2) ____________________________ regarding this procedure.

RESEARCH METHODS
With your permission, a review of your medical chart will be performed in the office of Dr. _______________, the attending physician at ____________________________. The specific information that will be accessed is the following: (variables/medical information).

Secondly, you will be asked to complete a brief written survey. Questions will specifically address two dimensions of your treatment: the effectiveness of the procedure and your satisfaction with the results. The information obtained from your medical record and your answers to the survey questions will be combined together and added to a list containing other patients’ records. Information such as name, medical record number, social security number will NOT be included. There will be no way to identify you from the data collected.

BENEFITS AND RISKS
There are no known risks associated with participating in this research study. While there will be no direct benefits to you, there will be contribution to the medical/scientific community by increasing understanding of ____________________________. The alternative to participating in this study is to not participate. You can elect to abstain from any part of this research.

CONFIDENTIALITY
No identifiable information (i.e. social security number, medical record number, name etc.) will be recorded. All information collected will be kept in password-protected computer.

CONTACT INFORMATION
To obtain additional information regarding this study, you may contact the principal investigator, Dr. ________ at (phone number, email, etc.).

To obtain information or report concerns regarding this study, you may contact Dr. _______________ IRB Chair, at (phone number, email, etc.).

Yes ______ I would like to participate in the above-described study.

No ______ I would prefer not to participate in the above-described study.

Patient’s Signature ____________________________ Date ____________________________
OSU TEMPLATE

Retrospective Research Protocol Template
Retrospective Research Protocol Template

*(Title of Study)*

I. INTRODUCTION
   a. Existing studies in your research area
   b. Gaps from the literature
   c. Fill gaps
   d. Research questions
   e. Direct observation, a survey, questionnaire, a critical analysis of the existing medical literature or clinical experiments?

II. Methods
   a. Study Population
      i. Population you are studying
      ii. Number of subjects from the population (sample size)
      iii. Assumptions
      iv. Exclusions of inclusion criteria
   b. Hypothesis
      i. Statements, assertions, or propositions about your target population
      ii. Null and Alternative Hypothesis
      iii. Making comparisons or exploring associations
   c. Study Variables
      i. Key variables of interest to you
      ii. Define variables that are not commonly used
      iii. Commonly used variables are, but not limited to, age, race, gender, height, weight, and medical record number
      iv. Negative outcomes should be clearly spelled out
      v. Operational definition of variables
      vi. Measurement of variables
   d. Study Design
      i. Obtaining information: Sampling? Type?
      ii. Simple random, systematic, stratified, and cluster sampling?
      iii. Direct observation, a survey, questionnaire, a critical analysis of the existing medical literature or clinical experiments?
      iv. Recruitment of subjects
      v. Data collection, recording, and storage: Data Collection Plan and Data Collection Chart
   e. Statistical Analysis
      i. Screening and cleaning data
      ii. Statistics to be generated
      iii. Methods of analysis: Parametric vs. Non-Parametric
      iv. Assumptions underlying data
      v. Test assumptions?
      vi. Cater to violations of assumptions?
      vii. Level of significance?
   f. Institutional Review Board (IRB)
      i. Remember that all protocols have to be reviewed by the IRB. It is only the IRB that can confer exempt status on research
III. REFERENCES
a. List all references
b. Choose relevant citation
c. Consult specialty area guidelines, your program director, and journals for publication
d. Common styles are the AMA, APA, MLA, and Chicago
APPENDIX F: RESEARCH PROPOSAL OUTLINE - LUTHERAN

Research Project Proposal Outline for Lutheran HealthCare
provided by Kell Julliard, M.A., Lutheran Hospital

When submitting a research proposal to the Institutional Review Board (IRB), please make sure you include as much of the following information as is needed, preferably in the order given below. Depending on the kind of study, you may need to modify this outline.

The numbered points below usually should be major headings, while the lettered points usually should be minor headings or describe the contents of paragraphs. Submit your proposal with an IRB application form, which can be obtained on the Lutheran HealthCare Intranet. To obtain the application, go to “Clinical Research and Grants,” and click on “Institutional Review Board.”

* Please write your proposal in paragraph form, NOT in outline form. Outline form is used here only to clarify the points to be included in your proposal.

I. TITLE PAGE
   a. Title (similar to your research question)
      i. Include the main elements of your study in the title
         1. WHAT – the name of the disease, syndrome or clinical state, or target the intervention is intended to improve
         2. WHO – the population who will be sampled
         3. HOW – the intervention (drug, supportive treatment, training, interviewing)
      ii. Example:
          1. NO – “A New Treatment for Mild Hypertension in Elderly Persons”
          2. YES – “Hypotensol, a New Drug, Controls Mild Hypertension in Elderly Patients as Effectively as Oligotensin: A Randomized Controlled Trial”
   b. All coauthors (listed in order of who will do the most work, including mentor)
   c. Department
   d. Institution, location of institution

II. SYNOPSIS
   a. For most studies, the synopsis consists of the following (not to exceed 200 words):
      i. One sentence describing the background/need for the study
      ii. One sentence giving the goal of the study
      iii. Two sentences describing the methods, including any risks involved
      iv. One sentence describing the most important outcomes to be measured

III. INTRODUCTION (This section describes the problem that is motivating the research. Each letter in this section should be at least one paragraph)
   a. Background – give information necessary to your readers for them to understand the context and background of the problem your research question addresses. This may include general information, as well as findings of research studies that have already been done. Cite these previous research studies and include each study in list of references
   b. Survey of published research that is directly relevant to the project – This should include recent research studies that are directly related to your research goal. Cite each study and include it in your references
c. Need for this particular project – for instance, what is lacking in published research studies to justify doing your study, or a problem with the patients at Lutheran Medical Center that justifies the study. Include here why the study is plausible. Cite other research studies as needed and include each study you cite in your list of references.

IV. RESEARCH GOAL AND OBJECTIVES (THE SPECIFIC AIMS OF YOUR STUDY)

a. Goal (research question)
   i. A concise statement of the specific question that the research seeks to answer. This is usually one sentence with a question mark at the end that includes the following information:
      1. The setting for the research
      2. The specific population to be studied
      3. The treatments or risk factors under consideration
      4. The measurements to be made of outcomes
      5. The duration of the project for each subject

b. Objectives
   i. Use bullet points to list the specific aims of the study that will enable you to answer the research question (goal)

V. METHODS

a. Design
   i. Briefly state which methodology you will use to answer the research question. Some examples are below or see “Overview of Research Methodologies” in the LMC research manual in the Clinical Research and Grants section of Lutheran HealthCare Intranet:
      1. Descriptive or analytic cohort study
      2. Pre-test post-test control group design
      3. Survey

b. If the study is a clinical trial: trial organization and procedure
   i. Who will conduct the trial and where?
   ii. Who will review the protocol to make sure it is adequate and ethical; who will approve it and when?
   iii. If applicable, what will be the procedures for randomization, stratification and masking?
   iv. What procedure will be selected for decisions on altering conduct of the trial and/or stopping it? Who will be responsible?

c. Subjects
   i. How and where will you find subjects
      1. (How) Chart review, computer database, logbooks of specific units or clinics
      2. (Where) Specific ambulatory clinics, inpatients from particular services, ICU, ED
   ii. Inclusion criteria (including essential characteristics of subjects
      1. List specific ICD-9 diagnoses, CPT procedure codes (the codes for medical procedures and therapies), along with their clinical definitions. Cite a reference for any specific criterion used for a diagnosis or procedure
      2. Objectively define each characteristic of the subjects and way of measuring that characteristic; cite the reference that describes this way of measuring.
3. If applicable, list other specific inclusion criteria, such as capacities for participation, age, gender or ethnic group

iii. Exclusion criteria (characteristics that will cause you to exclude subjects from study)
   1. List specific ICD-9 diagnoses, CPT procedure codes (the codes for medical procedures and therapies), and clinical definitions with references for the specific details of these diagnoses and procedures to be excluded.
   2. Objectively define each characteristic and way of measuring that characteristic and cite the reference that describes this way of measuring.
   3. If applicable, list other specific exclusion criteria, such as capacities for participation, age, gender, or ethnic exclusion.

iv. Nature of any compensation or incentives for subjects

v. Nature of an expenses to subjects
   1. Describe any out-of-pocket costs for participating in the research. These can include transportation, laboratory tests, and supplies

vi. If applicable, procedures and criteria for dropping participants from the study

d. Interventions
   i. If applicable, how will participants be assigned to the study, and what will be the randomization method?
   ii. Description of interventions, such as treatments, interviews or surveys that are part of the research question. Include specific definitions of these interventions and associated risks, and cite these definitions with references (books, articles) that describe them.
   iii. Describe each step needed to carry out your research in chronological order, especially any interventions that will occur with subjects. Include when, how, where, and by whom data will be collected. Document how often and at what time intervals you will collect data on each subject.

e. Tests and Measurements for research purposes
   i. Clearly identify which tests and measurements are not part of Lutheran HealthCare’s standard of care
   ii. Describe tests and measurements that help to answer the research question, such as specific laboratory tests, x-rays, or cultures. List the technical characteristics of any lab test to be done, including how samples will be collected and the name of the technique used. Include specific definitions of these tests and measurements, and cite these definitions with references (books, articles) that describe them.
   iii. Describe all of the sources of your data, such as patient logbooks, computer databases, patient charts, or the Physician Portal.
   iv. Specify and reference any assessment instruments such as the Mini-Mental Status Exam or the SPF-36 (quality of life measure)
   v. Describe any other measurements to be made, such as how risk factors will be assessed. Make sure you include a definition for each risk factor, and cite an article or book that supports that definition.
   vi. Attach copies of any formal measurement instruments used, such as surveys or scales.

f. Risks and Benefits
   i. Describe the potential risks to subjects from participating in the research (you do not need to include risks associated with procedures or tests that are standard of care).
      1. Include applicable physical, psychological, social, legal, and ethical risks and risks to confidentiality that may occur because of research interventions or tests
      2. Assess the likelihood and seriousness of such risks (none, low, moderate, high)
      3. Included the incidence of complications, if known
4. Describe procedures for protecting against or minimizing potential risks

ii. Describe the potential benefits of the research
   1. To subjects of the research (often there is none)
   2. To those who are like the subjects of the research (i.e., benefits of future patients)
   3. To society

\[ \text{g. Implementation}\]

i. Mandatory: List which resident or faculty will do each step of the project
   1. If the project’s data collection will go on for more than one rotation, list which resident or co-author will be responsible for the project during each rotation

ii. Work plan and timetable: give appropriate times needed to do major steps of the project
   1. Use Grantt Chart if this would be helpful (see Example 1 below)

iii. If applicable, describe how subjects will be recruited for the study. Copies of any advertisements, notices, letters, and emails used to recruit subjects must be submitted with the proposal to the IRB.

\[ \text{h. Plan for analyzing and displaying results}\]

i. Name the software that will be used for statistical analysis (LMC uses SPSS or Excel)

ii. List the statistical tests you will use and what kinds of data you will use them on. Make an appointment with the Clinical Research Office to get help with this.

iii. Explain the basis for the anticipated sample size (i.e., give results of a statistical power analysis)

iv. Show how you will display your results:
   1. List the demographic characteristics of subjects that will be reported
   2. Create dummy tables showing how you will display study outcomes.

   \[ \text{Dummy tables have column headings containing the names of the groups that you want to compare and row headings showing the variables and outcomes that are being compared. The dummy tables contain no actual data.}\]

\[ \text{i. Resources and Budget}\]

i. List the resources needed from staff members outside the research team

ii. List lab tests, clinic visits, or supplied that are not a part of standard clinical care

iii. List and total the costs for all these extra items

iv. Describe any gains you might receive from taking part in this study, other than the normally scholarly gains.

\[ \text{v. Your time and organizational resources, such as pulling charts and using computers are items that should be addressed in the budget. Here are sample sentences to add regarding these kinds of expenses:}\]

\[ \text{1. The time spent annually by each of the researchers is not expected to exceed 5% of their total hours employed by Lutheran Medical Center. Thus, the cost for time will be minimal}\]

\[ \text{2. The number of charts to be reviewed for this study is considered small enough by administration [specify the person verifying this, such as Kell Julliard, Department Chair, or the Director of Health Information] that Lutheran Medical Center will donate this to the study.}\]

\[ \text{3. The equipment needed by the study (specify, for example, computers, medical devices, imaging equipment) will be used outside of clinical time or is}\]
designated for this purpose, so the cost of this equipment will be minimal.

VI. If using a consent form is not possible or advisable AND the study collects patients’ protected health information, request a waiver of HIPAA informed consent:
   a. A HIPAA waiver of informed consent is needed for retrospective studies or any research where it is problematic to obtain consent from the patients to have their information used for research purposes.
   b. The template for requesting this waiver can be found on the Institutional Review Board link of the Clinical Research and Grants section of the Lutheran HealthCare Intranet.

VII. List all references, including those cited in introduction:
   a. Standard journal articles
   b. Chapter in an edited book
   c. Website

VIII. Consent Form
APPENDIX G: DATA COLLECTION FORM

Developing a Data Collection Form, provided by Kell Julliard, M.A., Lutheran Hospital

The data collection form is critical to the success of your research project. A poorly designed form can cost you extra time and energy, while a well-designed form can decrease frustration and even prevent mistakes in computer data entry. This sheet will help you develop a form that increases your chance of success. Note: A survey (questionnaire) is a type of data collection form, but the guidelines for creating surveys are different from the ones listed here. If you want to design a survey, see the clinical research office for help.

General guidelines for creating the first draft of your form

1. Consult experts in the field to decide exactly what data you need to describe your study population and answer your research question. Include in the form only the data you truly need to answer your question – why do extra work if it’s not necessary?
2. Find studies similar to yours in the medical literature. They will give you good ideas about the kinds of data you should collect, including both patient characteristics and outcomes.
3. Put all the essential information that you need to know on the form. This may include diagnosis codes, laboratory values, results of diagnostic tests, and patient characteristics such as age, gender, and ethnicity. Place the pieces of information in the sequence that they appear in the chart, Physician Portal, or E-Clinical Works. This way, those collecting data do not have to go back and forth in the patient charts or computer screens.
4. Group large and complex items such as “past medical history” or “medications taken” into a small number of categories directly related to your research question. See the attached form for examples.
5. Once you have a first draft of your form, come to the clinical research office for help.

SPECIFIC TIPS FOR DESIGNING YOUR FORM

1. See the sample data collection form at the end of this handout for examples of each tip.
2. Give the data collection form an appropriate title – one that relates to your project.
3. Each patient’s form should have a space for a patient research ID number (see top right of sample), to identify that unique patient in the spreadsheet.
4. Because of HIPAA, the patient’s name and medical record number should be on a separate list with the research ID number, not on this form unless absolutely necessary. (Quality control studies are sometimes an exception to this rule.)
5. If the answers to a particular question are mutually exclusive (such as gender), list them so that the data collector can simply circle the appropriate answer. Number each possible answer – the number (not the words) will be keyed into a spreadsheet for data analysis.
   a. For example, if patients are going to be grouped by chief complaint on admission, the possible answers could be as follows: 1. cardiac conditions; 2. neurological conditions; 3. Pulmonary conditions. Only one of these would be listed as chief complaint.
6. If the answers to a question are not mutually exclusive, list each one followed by yes or a no.
   a. For instance, for past medical history, a patient can have both diabetes and hypertension, so those categories are not mutually exclusive. Thus, the entry on the form would be as follows: Past medical history. Diabetes: 1. Yes 2. No.  HTN: 1. Yes 2. No
7. Race, culture, and ethnicity are particularly difficult data to collect accurately. Refer to the Research Involving Patient Race and Ethnicity handout if this kind of data is important to your study.
8. If appropriate, include “not applicable” or “unknown” for a given data point. This shows that
the data collector didn’t skip the question.

9. Specify the units for each type of data and write them after each blank on the form.
   a. For example, diastolic blood pressure:
      ________________ mm Hg, or age:
      ________________ years.
   b. In addition, after any space for a date, type (mo/day/year) so that everyone collecting
      the data will be consistent. (See attached form for an example).

10. If more than one person will collect the data, clearly assign who collects what information, so
    that no information is duplicated or missed. The bottom of the form can identify who collected the
    data on the form (see example).

Kell Julliard, MA, Asst. VP for Research, Lutheran Medical Center
6/1/09, t:\research guide\2008 templates in progress\developing a data collection form 1-05-09.doc

SAMPLE DATA COLLECTION FORM:

Thyroid function in the elderly – Form number: __________

Age: ________ years (must be >64)

Sex: 1. Female 2. Male

      5. Other 6. Unknown


Date of admission: __/____/______ (month/day/year)

PAST MEDICAL HISTORY:
   A. HTN: 1. yes 2. no 3. unknown
   B. DM: 1. yes 2. no 3. unknown
   C. Pregnancy (can change the level of
      thyroid hormones): 1. yes 2. no 3. unknown
   D. H/o radiation to the neck: 1. yes 2. no 3. unknown
   E. Hyperlipidemia (can be a result of
      hypothyroidism): 1. yes 2. no 3. unknown

MEDICATIONS:
   A. NSAIDS: 1. yes 2. no 3. unknown
   B. Iodide: 1. yes 2. no (can lead to hypothyroidism) 3. unknown
   C. Lithium: 1. yes 2. no 3. unknown
   D. PTU: 1. yes 2. no 3. unknown
   E. Methimazole: 1. yes 2. no 3. unknown
   F. Levothyroxin: 1. yes 2. no 3. unknown

T3: _______ nmol/L
T4: _______ nmol/L
FT4: __________
TSH: _______ mU/L

Test date: __/____/______ (month/day/year)

Team member filling out form: ______________________________________________________
APPENDIX H: THREATS TO VALIDITY

THREATS TO THE VALIDITY OF A STUDY

Internal Validity

Design problems that may affect the internal validity of results; violation may threaten the accuracy of the results.

The initial set is from the classic list described by Campbell and Stanley that are elaborated in the following table:

**History:** External events that may affect the experimental and control groups differently, especially if they are evaluated at different times. Experimental and control groups must participate simultaneously to control for history.

**Maturation:** Differential changes that take place in subjects during the study that are not related to the treatment, e.g., children (or the elderly) change rapidly in many ways. If this is a concern, ages of the groups must be equated.

**Testing:** Potential effect of a pre-measure or pretest on subsequent evaluations; potential sensitization of the control group to the goals of the study.

**Instrumentation:** Changes or instabilities in measurement instruments or research methods during the study; e.g., lack of instrument calibration, taking blood pressures at different sites of the body or at different times.

**Statistical Regression:** The tendency for extreme values, outliers from the mean, to move (regress) toward the mean when measured again. This is one reason why outliers must be evaluated carefully.

**Selection:** If groups are not equivalent by age, gender, race, and other variables, any differences in the dependent variable are not valid. This is why randomization is required for a valid study.

**Experimental mortality:** If different percentages or numbers of subjects in the groups being compared are lost, the resulting groups may not be comparable. Reasons for this differential loss should be determined.

**Stability:** If the findings of the study are unreliable due to variations in the way measures are taken or unreliable instruments, the study results are not valid.

**Expectancy:** The expectations of the experimenter or the subjects may subtly influence the results of the study. To overcome this problem, double blind studies are preferred. Interactive Combinations: Combinations of the above problems may lead to severe validity problems.

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ADDITIONAL SOURCES OF INTERNAL VALIDITY PROBLEMS

Compensatory equalization: Administration of some treatment to a control group to compensate for its lack of the beneficial treatment being received by the experimental group. If something special is provided to the control group to compensate for lack of the treatment, it may affect the outcome by reducing the difference between the groups on the outcome measure.

Compensatory rivalry: Behavior of a control group such that participants attempt to exceed performance of the experimental group because they are not receiving equal treatment.

Resentful demoralization: Lowered performance level by the control group because participants resent the lack of experimental treatment.

- Diffusion of treatment: Unintentional administration of treatment to a control group that reduces the post-treatment differences.

CONSTRUCT VALIDITY

Inadequate preoperational definitions: If the initial definitions of the variables, treatments, and methods are not adequate, flexibility in the conduct of the study will reduce its validity.

Hypothesis guessing: Subjects may guess the experimental hypothesis or how the experimenters expect them to behave, and their behavior may reflect the result of their guess. This is related to Expectancy.

Interaction of different treatments: If more than one treatment is being given, they may interact in unexpected ways to affect the outcome. This is a special concern if subjects are self-medicating with over-the-counter drugs.

Interaction of testing & treatment: In A-B-A-B designs the testing or evaluation component may interact with the treatments in unexpected ways. Also, pretest sensitization to the treatment will limit generalizability of results.

STATISTICAL CONCLUSION VALIDITY

Low statistical power: If the power of the statistical analysis is low; a nonparametric test typically has lower power than a parametric test. If the assumptions of a parametric test are violated, the power would be low.

Violated assumptions of statistical tests: The assumptions of a parametric test are violated, such as unequal variances or non-normal distributions.

Fishing & error rate: Performing multiple analyses without adjusting the significance level, or using sequential designs to try to find something significant.

Reliability of measures: Amount of error in the outcome or dependent measures.

Reliability of treatment implementation: Amount of error in the treatment, for example, different physicians use a specific osteopathic manipulation differently.
Random irrelevancies in the experimental setting: Amount of error in the experimental setting other than treatment, for example, subjects are treated differently by staff, specific protocols are not followed exactly, etc.

Random heterogeneity of subjects: Variation in subjects can affect results. Even random assignment can result in differences between the groups, requiring an analysis of group equivalence after the study.

EXTERNAL VALIDITY: HOW GENERALIZABLE ARE THE RESULTS TO OTHER SETTINGS?

Interaction of selection and treatment: The subjects in the study may not be the same as other locations and may have an idiosyncratic response to the treatments. Example: if only males are used, the results may not be applicable to females.

Interaction of setting and treatment: Studies conducted in a unique setting, such as a pressure-packed inner-city emergency room, may yield results that are not generalizable to other settings.

Interaction of history and treatment: Some external event that impacts the study, such as a new treatment with demonstrated effectiveness or a change in personnel, may interact with the treatment so that it is not generalizable to other time periods.
APPENDIX I: NYIT IRB PROTOCOLS

NEW YORK INSTITUTE OF TECHNOLOGY
Institutional Review Board for the Protection of Human Participants
Modified from a guide by Dr. John McDonald, Chair, Institutional Review Board, Lehman College/CUNY

DESCRIBING YOUR RESEARCH TO THE IRB

The principal component of your application for approval from the IRB is your description of the research that you plan to conduct. The application form includes a set of 8 specific requests for information that require investigators to describe:

1. The goals of their research;
2. The source of subjects and the selection criteria;
3. The procedure;
4. The potential risks and benefits for subjects;
5. The methods by which confidentiality and anonymity will be protected;
6. The debriefing process and the actions that will be taken in adverse situations;
7. The consent form;
8. And any other information that might be relevant to the approval decision.

This format is a simple, clear, concise way to describe your research to the IRB members. What follows is a brief discussion of each of the 8 requests for information delineated on the application form. Common mistakes, misconceptions, and omissions are described for each one in turn.

1. State the purpose of the research. Include major hypotheses and research design. If the study is part of a larger study, briefly describe that larger study and indicate whether it has received IRB approval from another institution. Please keep in mind that the IRB is composed of individuals from many disciplines and thus the description of your research should be written in terms readily comprehensible by non-experts. What are the major research questions that you are trying to answer? Are you trying to assess the effectiveness of a particular software program, technological device, pedagogical method, etc. on subject’s performance on a certain task? Are you merely trying to collect opinions about an existing program or treatment method? Are you using a case study to illustrate a particular strength or weakness of some program or treatment? Whatever the goals of your research, state them as clearly and precisely as possible. When you are describing your hypothesis, try not to describe it in a biased manner (e.g., “I intend to show that this new method is clearly more effective than the old method.”), but describe it as a something to be tested (e.g., “I intend to statistically test the hypothesis that the new method is significantly better than the old method.”).

The main problem that occurs in response to this request is already bolded in the request itself. Applicants frequently employ highly technical terms as if everyone on the IRB, which consists of people from very diverse disciplines, will be familiar with these terms. Don’t just say things like, “I intend to use the Sontein Technique of Audio Interference Assessment”, without previously, or immediately thereafter, explaining exactly what this assessment technique is.
2. Describe the source(s) of subjects and the selection criteria. Selection of subjects must be equitable and, in the case of protected populations such as children, prisoners, pregnant women, the mentally disabled, etc. should address their special needs. The text of any advertisement, letter, flyer, oral script or brochure used to solicit potential subjects must be attached. Your subjects must be described in detail to the IRB. Don’t just say things like, “Participants will be Hispanic women residing in the Bronx”, when you should be saying, “Participants will be 20 Hispanic women currently enrolled in an Introduction to Psychology class at Bronx Community College.” Just as importantly, include not only a description of your subjects, but also a separate description of the selection criteria. How are the 20 students described above going to be selected? Is the total number of Hispanic women in this class 20, or will they be selected randomly from a larger class? Will an announcement be made at the end of class, and will everyone who signs up be included as subjects? Is this a class that the investigator herself teaches? If not, has the instructor given permission to announce the experiment during or at the end of class time? Keep in mind that the goal of the IRB is to ensure that subjects are treated fairly and adequately protected from research risks. This includes the right to a fair and equitable opportunity to be a participant in research studies. You cannot just say that you are going to select 8 of your own students to serve as subjects in your research. This allows for the possibility that you are selecting only students of one gender or ethnic group because you are more comfortable working with people from these groups. The selection process must not be biased in any way. Unless gender or ethnicity is a focus of the research, as it would be in a study on women’s attitudes toward child-care, the method of selection should be nonbiased. Random selection of subjects from a larger available sample, for example, is a good nonbiased selection method.

3. Provide a description of the procedures to be followed. If available, include copies of questionnaires and/or interview protocol, or a sufficiently detailed description of the measures to allow the IRB to understand the nature of subjects’ involvement. The goal here is to make the procedure that you intend to follow clear to the members of the IRB. When a subject shows up for this study, exactly what are they asked to do? Whenever possible, provide a complete list of the questions you will be asking or the tasks you will be asking subjects to perform. Make it clear where the study will take place and how long it will take. Will subjects be run individually or in groups? Also, keep in mind that the primary job of the IRB is to weigh the risks and benefits of your research for participants, and this means that in some cases the validity of your design can become an issue for the IRB to address. If a study has no validity, then even minimal risks are not justified. Try not to design a study in which you are virtually guaranteed to get whatever results you are looking for. For example, if you are testing the effectiveness of a particular workshop in reducing classroom violence, don’t construct a questionnaire in which every question asks respondents to describe positive ways in which the workshop helped to reduce violence. Also, try to control for obvious confounds in the design. For example, of course a large group of students who performed at the bottom 10% on some test will perform better upon retesting after being given your remedial lecture. Regression to the mean would ensure that this group will show improvement even if your technique is completely worthless.

4. Describe any potential harms or benefits to be derived by subjects, with a discussion of the risk/benefit ratio. For approval of any study with more than minimal risk, the benefits must clearly be shown to outweigh the risk. Describe how the study may expose participants to
stress, physical, psychological or interpersonal hazard, including the possibility of pain, injury, disease, discomfort, embarrassment, worry or anxiety. The most important point to make here is that you should be honest about any risks your study poses and not try to mislead the IRB. Studies with limited risks are frequently approved, as long as adequate precautions are taken and the benefits outweigh the risks. Thus, instead of trying to say that your study, which asks subjects to describe traumatic autobiographical experiences, has no risks, indicate that there is some potential for this study to upset some subjects. Then go on to say that the signup sheet will describe the procedure ahead of time to prospective subjects, the consent form will do the same, and you will have a referral source at the counseling center available just in case any subjects need someone to talk to after the study.

5. Describe the specific methods by which confidentiality and anonymity will be protected, including the use of data coding systems, how and where data will be stored and who will have access to it, and what will happen to data after the study has been completed. Keep in mind that confidentiality and anonymity are two different things. Confidentiality refers to the fact that personal information will never be revealed by the researchers. Anonymity refers to the fact that even the researchers themselves will have no way of identifying any of the participants in the study from their data. Make it clear whether your study provides confidentiality or anonymity and describe the procedure by which these are achieved. Also, as indicated in the question itself, provide a clear detailed description of how the data will be stored and who will have access to it.

6. If applicable, provide the following: 1) a description of the debriefing procedures to be used in cases where deception has occurred; 2) a statement describing what actions you will take should the research reveal the possibility of a medical or other potentially troubling condition. In cases in which a debriefing seems warranted, indicate what it is that the subjects will be told and whether the debriefing be verbal or written. Also, describe what will happen if a subject’s data indicate that he or she might have a serious health problem or might be the victim of abuse etc. Of course, most procedures will probably not produce data that could reveal such information.

7. Before submitting this application, all investigators should familiarize themselves with the discussion of informed consent. Describe the oral and written consent processes and attach all consent documents, including scripts for oral consent and assent form for research involving minors under the age of 12. When the consent form to be used will be in a language other than English, an English translation must be provided. Unless one or more of the required elements described below is explicitly waived by the IRB, informed consent documents should contain: A. A fair explanation of the procedures to be followed and their purposes, including any procedures that are experimental. B. A description of any possible attendant discomforts and risks reasonably expected. This includes any potential financial risks that could ensue. C. A description of any benefits reasonably expected. D. A disclosure of any appropriate alternative procedures. E. An offer to answer any inquiries concerning the goals of the research or the research procedures and to provide a summary of results upon request. A contact person and phone number should be provided. F. An instruction that the subject is free to withdraw or discontinue participation at any time without prejudice. G. A statement that the data are confidential and that the subject will not be identified by name in writing or orally. H. Provisions for parent or guardian approval for participation of minors or for subjects from vulnerable populations when appropriate. This
request for consent forms is especially important. The federal agencies that oversee the IRB insist that all subjects be adequately informed about the exact nature of the procedure they are volunteering to participate in, including any potential risks or discomforts the procedure might create. In composing your consent form, pay attention to all of the required elements listed in the request itself (lettered A through H). 8. Please provide any other information that might be pertinent to the IRB’s decision. Most research designs will not require any further elaboration given that all of the prior requests were appropriately answered. However, if your design requires additional explanation include it here. Provide information about your qualifications to conduct the proposed study. If you will be working with subjects from a vulnerable population, please describe your background and experience working with this population. You should also attach a resume or CV.
IRB FORMS FOR NYIT
Check the website for the latest versions
Application Checklist for Expedited or Full Review

The following checklist must be completed by the Principal Investigator with the submission of any expedited or full review protocol to the Institutional Review Board for the Protection of Human Participants.

Principal Investigator: 

Department: 

Protocol Title: 

Attached N/A

Application Form (with all required signatures) .................................................................

Attachment A .................................................................................................................
Attachment B .................................................................................................................
Attachment C .................................................................................................................
Attachment D .................................................................................................................
Abstract (limit 400 words) .........................................................................................
Protocol Description ....................................................................................................
Purpose .........................................................................................................................
Source(s) of Subjects and the Selection Criteria ....................................................
Procedures ...................................................................................................................
Assessment of Risks & Benefits .............................................................................
Protection of Data/Privacy .........................................................................................
Debriefing Process ......................................................................................................
Consent Procedures ....................................................................................................
Investigator Background and other Relevant Information .....................................
Draft Consent Form ....................................................................................................
Draft Assent Form ........................................................................................................
Fliers/Advertisements/Announcements ....................................................................
Surveys/Questionnaires ............................................................................................
Interview Questions ....................................................................................................
Vitas of all Investigators ............................................................................................
Copy of Certificate of Completion of Online Training Module for all key personnel...
Authorization from Performance Sites ......................................................................

The application checklist, application form and protocol description, and additional materials should be
submitted to the Education, Social Science and Behavioral Research (ESB) IRB or the Biomedical and Health Sciences (BHS) IRB at the Office of Sponsored Programs and Research, North House, Second Floor.
NYIT Institutional Review Board for the Protection of Human Participants

APPLICATION FOR EXPEDITED OR FULL REVIEW

- This form must be completed for all protocols that do not qualify for exemption. (To request an exemption, review the exempt categories carefully and submit the Request for Exemption form.)
- The Principal Investigator (PI) assumes responsibility for the conduct of the study. Students and non-NYIT personnel may not serve as principal investigators. The PI should complete sections I through IV of this form and attachments A, B, C or D as applicable.
- Submit the application checklist, application form and attachments and other materials as needed to the Education, Social Science and Behavioral Research (ESB) IRB or the Biomedical and Health Sciences (BHS) IRB at North House, Second Floor.

PROTOCOL TITLE: ________________

I. PERSONNEL

Principal Investigator: ____________________________________________

(Last)(First) ________________

☐ ☐ ☐ Check One: Faculty Staff Other: ________________

Department: ______________________________________________________

Address (where you want notification sent): ______________________________

____________________________________________________________________

Telephone (Home): ___________________________ Campus: _________________

Email: _____________________________________________________________

If the project has additional investigators, including students, complete ATTACHMENT A

II. PROTOCOL

1. Assessment of Risk

- D Minimal risk (the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests)
- D Moderate risk (minor increase over minimal risk)
- D Considerable risk (greater than minor increase over minimal risk)

Comments Regarding Risks: ___________________________________________
2. Type of Review

D I am requesting an EXPEDITED REVIEW under category:

D 1
D 2
D 3
D 4
D 5
D 6
D 7
D 8
D 9

Submit the original and three (3) copies of your application to the IRB.

D I am requesting a FULL REVIEW because my research does not fit precisely into any of the expedited review categories

Submit the original and fifteen (15) copies of your application to the IRB

PLEASE NOTE: Applications that qualify for Expedited Review are reviewed on a rolling basis. Check the IRB web site for a listing of IRB meeting dates and application receipt deadlines for full review protocols.

3. Participant Information: Will data be collected from any of the following populations?

D

Minors (Under 18 years of age; specify age range) 

D Prisoners
D Fetuses
D Pregnant Woman
D Cognitively impaired
D Staff/Employees
D Students
D Non-English Speakers
D Poor/Uninsured

4. Research Support: Do you plan to or have you applied for funding for this project? Please review the sponsor’s guidelines carefully and allow sufficient time for IRB Review.

D Yes

Please provide the funding source: 

Program/Grant Number (if known): 

Please provide one (1) copy of the complete grant proposal or contract

D No

Please check the following as appropriate:

D The above-referenced sponsor intends to fund 100% of the costs associated with participant participation in the research protocol.
D The above-referenced sponsor intends to fund 100% of the costs associated with participant care that is beyond regularly required care. Regular care will be billed to the participant or the participants’ insurance.
D The above-referenced sponsor intends to fund only a portion of the total costs associated with participant care. Explain fully in the protocol description.
5. Financial Conflict of Interest: Does the principal investigator, any co-investigator or study coordinator involved in the study (or in aggregate with his/her spouse, dependents, or members of his/her household):

A. Have an equity interest in the entity that sponsors this research or the technology being evaluated that exceeds 5% ownership interest or a current value of $10,000?
   D  Yes
   D  No
B. Receive salary, royalty, licensing fees, or other payments from the entity that sponsors this research or the technology being evaluated that is expected to exceed $10,000 per year?
   D  Yes
   D  No
C. Have a license agreement with the University or an external entity that would entitle sharing the current or future commercial proceeds of the technology being evaluated?
   D  Yes
   D  No

If yes to any of the above, please submit detailed information on a separate sheet.

2. Study Site(s):
   D  NYIT – Old Westbury
   D  NYIT – Central Islip
   D  NYIT – Manhattan
   D  Other (please specify): _______

Please provide letters of agreement and/or complete ATTACHMENT B

2. If this proposal has been submitted to another Institutional Review Board, give the name of the institution and date of review. Supply copies of approval letters and recommendations of that committee.

Institution: __________________________________________ Date of review: ___/___/___

3. Timetable: What is the estimated duration of the entire study?

Begin: ___/___/___ End: ___/___/___

4. Participant time commitment: What is the time commitment for each participant participating in the study? Indicate the number of visits/sessions and the time involved per visit/session

Visits/Sessions: __________________________ Time per visit/session_________________

5. Compensation: If compensation to participants is intended, indicate how much and in what form (cash, taxi fare, meals, etc.). The amount of compensation is subject to IRB approval.
Is any form of compensation being provided?

☐ Yes

Describe: _

☐ No

PROTOCOL DESCRIPTION - Please respond to the following requests on a separate sheet.

1. State the purpose of the research. Include major hypotheses and research design. If the study is part of a larger study, briefly describe that larger study. Briefly discuss the background and rationale for the study. Is the study design appropriate to prove the hypothesis? Provide references for the background information. Please keep in mind that the IRB is composed of individuals from many disciplines and thus the description of your research should be written in terms readily comprehensible by non-experts.

2. Describe the source(s) of participants, the selection criteria and the recruitment methods. Provide a detailed description of the procedures to be followed. If applicable, include a detailed description of all drugs to be used including dosages, dosage changes varying from manufacturers’ recommendations, frequency of use, FDA status of a formerly approved drug being used for new therapies, IND# of all new drugs and all other drug information necessary. Include copies of questionnaires and/or interview protocols, or a sufficiently detailed description of the measures to allow the IRB to understand the nature of participants’ involvement. Include a time line for the study.

3. Describe any potential harms or benefits to be derived by participants, with a discussion of the risk/benefit ratio. For approval of any study with more than minimal risk, the benefits must clearly be shown to outweigh the risk. Describe how the study may expose participants to stress, physical, psychological or interpersonal hazard, including the possibility of pain, injury, disease, discomfort, embarrassment, worry or anxiety. Discuss how risks will be minimized and additional safeguards for vulnerable subjects. Describe the procedures that will be followed in the event of a study-related emergency, either at NYIT clinical performance site(s) or at off-campus location(s).

4. Describe the specific methods by which confidentiality or anonymity will be protected, including the use of data coding systems, how and where data will be stored and who will have access to it, and what will happen to data after the study has been completed.

5. If applicable, provide the following: 1) a description of the debriefing procedures to be used in cases where deception has occurred; 2) a statement describing what actions you will take should the research reveal the possibility of a medical or other potentially troubling condition.

6. Before submitting this application, all investigators should familiarize themselves with the discussion of informed consent. Describe the oral and written consent processes and attach all consent documents, including scripts for oral consent and assent forms. When the consent form to be used will be in a language other than English, an English translation must be provided. Use the Informed Consent Checklist (ATTACHMENT D) as a guide in drafting your consent form.

7. Please provide information about your background. You may attach a CV or resume for all investigators.
III. CERTIFICATION AND APPROVAL

By signing this document, I certify that in my opinion the protocol and safeguards described in this application meet the standards of the New York Institute of Technology (NYIT) and all Federal regulatory requirements concerning experiments that use human participants. I accept responsibility for assuring adherence to Federal and NYIT policies relative to the protection of the rights and welfare of participants in this study. I certify that my participation and the participation of any co-investigators does not violate the NYIT policy on conflicts of interest.

By signing below, I certify that I have undergone training in basic human participants protections and will ensure that all key personnel complete this training before working on this protocol.

PI Signature: _______________________________ Date: ____/____/____

Department Chair: ___________________________ Date: ____/____/____

*If students will be involved in the project, complete ATTACHMENT C.*
ATTACHMENT A:

ADDITIONAL INVESTIGATORS AND KEY PERSONNEL - Fill out this section if additional investigators will work on this project. Attach additional pages as necessary.

1. ADDITIONAL INVESTIGATOR/KEY PERSONNEL

Check one:

☐ Student  Faculty  Staff  Other

______________________________
Name: ________________________________ (F ________________________________
(Last) ________________________________
(First) ________________________________

Department: ________________________________

Telephone #: ________________________________  E-mail: ________________________________

By signing below, I certify that I have undergone training in basic human participants’ protections and will conduct my work on this project according to established ethical principles and the protocol contained in this application.

Signature: ________________________________  Date: _____/_____/_____

Department Chair: ________________________________  Date: _____/_____/_____

2. ADDITIONAL INVESTIGATOR/KEY PERSONNEL

Check one:

☐ Student  Faculty  Staff  Other

______________________________
Name: ________________________________ (F ________________________________
(Last) ________________________________
(First) ________________________________

Department: ________________________________

Telephone #: ________________________________  E-mail: ________________________________
By signing below, I certify that I have undergone training in basic human participants’ protections and will conduct my work on this project according to established ethical principles and the protocol contained in this application.

Signature:__________________________________________ Date:____/____/_____  

Department Chair:________________________________ Date:____/____/_____
ATTACHMENT B:

RESOURCES

The following consultants and service departments (e.g., NYIT/NYIT-COM Academic Health Care Center [AHCC], Old Westbury; NYIT/ Family Health Care Center [FHCC], Central Islip; Hospital Department or Clinic; School Principal or Superintendent; Counseling Center Supervisor, etc.), affected by elements of this protocol, have been consulted and agree to participate to the extent required by the protocol. Any protocol involving the NYIT/NYIT-COM AHCC and/or the NYIT/NYIT-COM FHCC must be reviewed by the Medical Director of the AHCC/FHCC. The investigator is responsible for submitting the protocol to the AHCC/FHCC Medical Director for his/her signature.

This project does not involve the NYIT/NYIT-COM Academic Health Care Center (AHCC).

This project does not involve the NYIT/NYIT-COM Family Health Care Center (FHCC).

Service or Consultant (Please print)

Department/Organization: NYIT/NYIT-COM AHCC Name: ________________________________

Signature: ____________________________ / / 

Department/Organization: NYIT/NYIT-COM FHCC Name: ________________________________

Signature: ____________________________ / / 

Department/Organization: __________________ Name: ________________________________

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Department/Organization: __________________ Name: ________________________________

Signature: ____________________________ / / 

Department/Organization: __________________ Name: ________________________________

Signature: ____________________________ / / 

Letters of agreement may be substituted for signatures here.

HIPAA Certification

On April 14th, 2003, privacy regulations went into effect that regulate the access and handling of medical information. The investigator, not the IRB, is responsible for understanding and ensuring that the regulations are followed. If the protocol involves any unit of the Academic Health Care Center at NYIT/NYCOM, you must discuss the protocol with the compliance officer of NYIT/NYCOM, currently Nancy Bono, DO, in the Old Westbury Academic Health Care Center. If there is any doubt whether this applies, please discuss it with the HIPAA compliance officer. If the project involves medical records at any other institution, you must discuss your proposal with the compliance officer of that institution. I certify that I have discussed my proposal involving medical records of any kind with the appropriate compliance officer, and understand and will comply with the requirements of HIPAA regulations.
ATTACHMENT C:

STUDENT PARTICIPATION IN RESEARCH

Principal Investigator

I certify that I have instructed the student(s) listed below in research techniques and human protections standards; I have reviewed the entire research proposal, including any components composed by the student(s); any student role will be consistent with the description I provide in this proposal and in compliance with NYIT Human Protections Policies, to the best of my knowledge.

PI Signature: ___________________________ Date / / 

Students

I certify I am at least 18 years of age and that to the best of my understanding I will comply with the NYIT policies regarding Human Research Protections and will participate in research consistent with the descriptions in the submitted protocol.

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ATTACHMENT D:

INFORMED CONSENT CHECKLIST

Please use this checklist to develop your informed consent form(s). Sample consent forms are available at
http://www.nyi.edu/ospar
Submit ONE copy with your copies of the proposal and other forms.

Unless waived by the IRB, informed consent shall be documented by the use of a written consent form approved by the IRB, and signed by the participant or the participant’s legally authorized representative.

The consent form may be either of the following:

1. A written consent document that embodies the elements of informed consent required by Federal regulations (45CFR46.116). This form may be read to the participant or the participant's legally authorized representative. The investigator should give either the participant or the representative adequate opportunity to read it and ask questions before it is signed. Copies of the consent form should be given to the participant(s).

2. A short form written consent document, stating that the elements of informed consent required by 45CFR46.116 have been presented orally to the participant or the participant's legally authorized representative. When this method is used, there should be a witness to the oral presentation. The IRB must approve a written summary of what is to be said to the participant or the representative. Only the short form itself is to be signed by the participant or the representative. However, the witness should sign both the short form and a copy of the summary, and the person obtaining consent should sign a copy of the summary. A copy of the summary should be given to the participant or the representative, in addition to a copy of the short form.

Please check one:

☐ I am requesting a waiver for documentation of informed consent.
   Complete Section 1 below

☐ I have enclosed a draft informed consent form and assent form (if applicable).
   Complete Section 2 below.

Section 1:

An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all participants, if it finds either:

1. That the only record linking the participant and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern; or

2. That the research presents no more than minimal risk of harm to participants, and involves no procedures, for which written consent is normally required outside of the research context.
In cases in which the documentation requirement is waived, the IRB may require the investigator to provide participants with a written statement regarding the research.

A. Does the research present more than minimal risk to
   □ the participants? Yes
   □ No
B. Will a waiver adversely affect the rights and welfare of
   the participants? Yes
   □ No
C. Can this research be practicably carried out without the waiver? Yes
   □ No
D. Will participants be provided with additional pertinent information after
   □ participation? Yes
   □ No

Section 2:
Consent documents must be written in lay language at the 6th grade reading level and include the following required elements:

Included

□ A statement that the study involves research and an explanation of the purposes of the research, the expected duration of the participant's participation, and a description of the procedures to be followed and identification of any procedures which are experimental

□ A description of any reasonably foreseeable risks or discomforts to the participant

□ A description of any benefits to the participant or to others, which may reasonably be expected from the research

□ A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant

□ A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained

□ For research involving more than minimal risk, an explanation as to whether any compensation will be offered, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained

□ An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the participant

□ A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits, to which the participant is otherwise entitled
Additional elements, as appropriate:

**Included N/A**
A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant), which are currently unforeseeable

Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent

Any additional costs to the participant that may result from participation in the research

The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant

A statement that significant new findings developed during the course of the research, which may relate to the participant's willingness to continue participation, will be provided to the participant

If minors are involved, an **assent** form
APPENDIX J: NYCOMECE POSTER COMPETITION

NYCOMECE RESEARCH POSTER COMPETITION
ABSTRACT APPLICATION FORM (Both experimental research & case study)
This form is available as fillable pdf online at <www.nycomec.org/resources>

Please complete this form and email with a Word version of your abstract to
<NYCOMECE Meetings & Events Coordinator> or fax to 516.686.3767 by <DESIGNATED DATE>.

Poster Title: ____________________________

First Author: ________________________________

Presenting Author (if different from First Author): ________________________________

Intern, Year of Residency or Fellowship (check one):  
☐ OGME 1  ☐ OGME 2  ☐ OGME 3  ☐ OGME 4

Institution AND Department: ________________________________

Institution Address: ____________________________________________

City, State, Zip Code ____________________________________________

Telephone: ________________________________

Best email address: ____________________________________________

List other authors with TITLE, DEPARTMENT & INSTITUTION: 1:

Was this research funded by some agency? If so, please list:

2: IRB approval has been:  
☐ Received  ☐ Not applicable. Why? ____________________________________________

3: Check the primary category into which your research would fall:  
☐ Experimental Research  ☐ Clinical: Case study

4: Anticipated poster size (Length x Width): ________________________________

5: Signed proprietary statement/disclosure:
I certify that I have no affiliation or financial involvement in any organization or entity with a direct financial interest in the
subject matter or materials discussed in the abstract or presentation, except as disclosed in an attachment. I further verify that I
had significantly participated in this research project.

_________________________________________________________  ____________________________
Author(s) signature(s)                                      Date Signed

6: Hospital’s Osteopathic Director of Medical Education or Program Director Signature and date signed:

_________________________________________________________  ____________________________
Signature                                      Date signed
New York Colleges of Osteopathic Medicine Educational Consortium
(NYCOMECE)

TRAINEE RESEARCH POSTER COMPETITION POLICIES

1. NYCOMECE’s Annual Poster Competition is open to Interns, Residents, & Fellows who are training in a NYCOMECE-sponsored program.

2. NYCOMECE will produce a "book" of abstracts that will be provided to the judges and distributed at the Competition (8.5" x 11").

3. Multiple entries are allowed, but only one abstract will be accepted for each competition. Only one prize is awarded per Intern/Resident/Fellow.
   a. Confirmation of receipt of the abstract will be sent within one week of receipt.
   b. Notification of acceptance of the abstract will be sent within 3 weeks of receipt
   c. All abstracts that meet the criteria specified in the Procedures section will be accepted and placed in the Abstract book.
      1) Abstracts that do not meet the criteria will receive an explanation of why it was not accepted within 3 weeks
   d. Accepted abstracts will be judged using criteria specified in the Procedures and ranked. In the event that more abstracts are accepted than can be accommodated by the display space, finalists will be selected; those not selected as a finalist will not be displayed but the abstracts will still be published.
   e. NYCOMECE reserves the right to limit the number of accepted posters based on space availability.

4. The sequence of authors should be the same on the abstract and on the poster. The first author must be an Intern, Resident, or Fellow who is training in a NYCOMECE-sponsored program.

5. The NYCOMECE application form must be completed and sent at the same time as each abstract, with signatures verifying that the work is that of the person submitting it. The application form may be faxed, but the abstract must be submitted as a Microsoft WORD document. All entrants are required to complete the box on the application form that the research project received IRB approval or state why IRB approval was not necessary (e.g., case study). The signature of the hospital’s Osteopathic DME or Program Director will be required on each applicant’s form.

6. Posters must be prepared following the NYCOMECE Poster Competition Application and Presentation guidelines. For uniformity, they should be oriented horizontally in a landscape format.

7. The competition will be open to research of the type acceptable to the AOA Scientific Conference. The work presented must be the work of the Intern, Resident, or Fellow submitting it. Explanatory clinical research, health policy, educational, and other research subjects will be accepted. Pure literature review will not be accepted. The final posters must contain the results of the study or clinical case.

8. Entrants are encouraged to submit research that is original to this competition; however, entries that have been shown at local hospitals, or regional and national conferences, will be accepted.

9. All entrants will receive a Certificate of Participation. A copy of the book, Designing Clinical Research, most recent Edition, will be given to each entry. One copy will be given per poster entrant. (For those persons who have multiple posters, one copy per entrant.)

10. NYCOMECE cannot be responsible for unclaimed posters following the presentation.
New York Colleges of Osteopathic Medicine Educational Consortium (NYCOMEC)

TRAINEE EXPERIMENTAL RESEARCH POSTER COMPETITION

APPLICATION AND PRESENTATION PROCEDURES

ABSTRACT AND POSTER

1. An abstract must be received ELECTRONICALLY using Microsoft WORD by the NYCOMEC office no later than 11:59 pm April 7, 2017. The application form, available from DMEs, Program Directors and on-line at the NYCOMEC website (http://iris.nyit.edu/~nycomec), must be used and may be faxed. Abstracts are to be sent to: aberg@nyit.edu.

2. The abstract must have no more than 500 words in minimum 11-point type size, single spaced, typed, and fits on one page. The margins should be one inch wide.

3. The abstract format should include title and authors followed by hypothesis, research design, methods and materials, results and conclusions. Please refer to the recommended format for the abstract.

4. The abstract must contain sufficient preliminary results to permit adequate assessment of the research, although final results are expected on the poster itself. Judgement of the poster will be based upon the appropriateness of the abstract.

5. The poster itself must be two-dimensional. It should use a horizontal format, not to be larger than 4 ft by 6 ft. The preferred size is 3’ x 4’ (35” x 48”). Text must be large enough to be read from a distance of three feet. The text for the title, institution, and authors must be no less than one inch high. Although not mandatory, it is strongly encouraged to have the NYCOMEC logo or name printed next to the hospital name on the poster. The anticipated poster size should be entered on the application form.

PRESENTATION

6. Poster presenters must arrive no later than 7:00 AM for poster setup.

7. Each poster presenter must show their confirmation e-mail at registration to verify acceptance of the poster.

8. Authors must mount their posters one hour prior to the time of the competition at the designated site.

9. The posters will be mounted in a designated exhibit area.

10. Each entrant will have four minutes to present their research information to the judges. Only one author will be permitted to present, presumably the entrant author. In the event the entrant author cannot be present, the presentation may be made by another Osteopathic Intern, Resident, or Fellow listed as an author; however, points may be lost for presentation.

11. A panel of judges appointed by the NYCOMEC Research Committee using predetermined objective criteria and scoring forms will do judging. The judges’ decision will be final.

12. The posters will be displayed throughout the duration of the Research Day.

13. Prizes will be awarded to the top 3 posters determined by numerical ranking.
New York Colleges of Osteopathic Medicine Educational Consortium  
(NYCOMEC)  
TRAINEE RESEARCH POSTER COMPETITION CASE PRESENTATION  
May 25, 2017  
New York LaGuardia Airport Marriott

B. APPLICATION AND PRESENTATION PROCEDURES

ABSTRACT AND POSTER

1. An abstract must be received ELECTRONICALLY using Microsoft WORD by the NYCOMEC office no later than 11:59 pm April 7, 2017. The application form, available from DMEs, Program Directors and online at the NYCOMEC website (http://iris.nyu.edu/~nycomec), must be used and may be faxed. Abstracts are to be sent to: aberg@nyu.edu.

2. The abstract must have no more than 500 words in minimum 12-point type size single spaced, typed, and fits on one page. The margins should be one inch wide.

3. The abstract should answer the following questions: What? Why? How? What makes it unique? Include the review of prior literature, presentation, case description and results. Typically a case study does not require IRB approval unless the patient can be identified in some way. A case presentation describes the diagnosis and treatment of a single individual only. A case series may include multiple individuals.

4. The abstract must contain sufficient preliminary results to permit adequate assessment of the case, although final results are expected on the poster itself. Judgement of the poster will be based upon the appropriateness of the abstract.

5. The poster itself must be two-dimensional. It should use a horizontal format, not to be larger than 4 ft by 6 ft. The preferred size is 3’ x 4’ (35” x 48”). Text must be large enough to be read from a distance of three feet. The text for the title, institution, and authors must be no less than one inch high. Although not mandatory, it is strongly encouraged to have the NYCOMEC logo or name printed next to the hospital name on the poster. **The anticipated poster size should be entered on the application form.**

PRESENTATION

6. Poster presenters must arrive no later than 7:00 AM for poster setup.

7. Each poster presenter must show their confirmation e-mail at registration to verify acceptance of the poster.

8. Authors must mount their posters one hour prior to the time of the competition at the designated site.

9. The posters will be mounted in a designated exhibit area.

10. Each poster will be mounted in a numbered location that is predetermined.

11. Each entrant will have four minutes to present their research information to the judges. Only one author will be permitted to present, presumably the entrant author. In the event the entrant author cannot be present, the presentation may be made by another Osteopathic Intern, Resident, or Fellow listed as an author; however, points may be lost for presentation.

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13. The posters will be displayed throughout the duration of the Research Day.

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APPENDIX K: LBORC Research Grants Program

Research Grants Program Introduction
The AAO through the Louisa Burns Osteopathic Research Committee (LBORC) has funded pilot research within the profession for many years. The major purposes of research programs funded by the AAO are to:

- Generate and support research that develops and promotes an understanding of the philosophy, concepts and efficacy of Osteopathic Manipulative Medicine (OMM);
- and to
- Develop and maintain the research capacity of the profession through support and training for researchers including all aspects of uniquely Osteopathic research. This is to include but is not limited to bench top physiological models research, educational standards development, practice guidelines research, normative data collection, and clinical research. **LBORC will not fund machine or equipment engineering R&D.** Equipment development and engineering design research is explicitly excluded from this venue though assistance in obtaining funding from other sources may be obtained through the LBORC.

Research Grants
The AAO recognizes the value of all areas of biomedical and educational research. However the resources and facilities of the profession are limited and direct research funding must focus on those areas of research that investigate the unique aspects of osteopathic medicine. The breadth of this research focus may include but is not limited to:

1. Mechanisms of Action of Neuromusculoskeletal Medicine/Osteopathic Manipulative Medicine treatment
2. Clinical Efficacy of Neuromusculoskeletal Medicine/Osteopathic Manipulative Medicine treatment
3. Inter- and Intra-rater reliability of palpatory/sensory assessment
4. Cost effectiveness of osteopathic health care
5. Osteopathic physician - patient interactions
6. Methods of teaching palpation, sensing, diagnosis and Neuromusculoskeletal Medicine/Osteopathic Manipulative Medicine treatment
7. Collection of normative data in Osteopathic Manipulative Techniques
8. Validation of Osteopathic Manipulative Techniques specific research methodology

The LBORC will be using the [American Osteopathic Association research applications](https://osteopathic.org/cor/), guidelines and manuals as recommended by the American Osteopathic Association Council on Research (COR). The COR was charged with developing a professional standard set of research tools that would serve as a highly discriminating set and serve to educate our professions applicants as to the type and quality of
applications required at a national level of performance.
Additional funding is occasionally made available for unique circumstances in sponsoring osteopathically significant professional projects and/or interactions that are otherwise not fundable through professional resources. This may include but is not limited to travel for American Academy of Osteopathy representation at high profile events, historical preservation of rare artifacts or libraries, and other uniquely osteopathic functions that may not be directly research related. These are decided upon on a case by case basis, though there will be a uniform method of submission for review using application materials from the American Osteopathic Association research manual and a modified review process. For a complete description of the priorities of the AAO Research Grants programs, please consult the AOA Research Handbook and/or consult with the officers of the LBORC.

**Grant Funding**

Grant applications are accepted on an annual basis and have a submission deadline of 2 months prior to the American Academy Osteopathy Convocation or 2 months prior to the American Osteopathic Association Annual National Scientific Seminar. Funding decisions are approved or declined by the AAO Board of Trustees at their meeting following LBORC recommendation. All funding opportunities must clear funding capacity with the Finance committee and the respective research endowment funds of the American Academy Osteopathy prior to disbursement.

The LBORC will recommend funding for research proposals with budgets up to $10,000 per year; investigators should not expect to be funded for more than two years on a single project and must provide a budget plan at the time of submission explaining the need for a 2 year time frame and defining the budgetary needs as clearly as possible. At the discretion of the committee, a recommendation of a lower amount for funding may be offered and/or the American Academy Osteopathy Board of Trustees may elect to reduce the amount of funding recommended by the committee. Either case will be explained in writing to the grant recipient.

The AAO provides monies for research projects which satisfy the specific purposes of established investment funds.

1. The *William L. Johnston, DO, FAAO Research Fund* was established with the express purpose of supporting clinical research. The LBOR Committee recommends the following uses for the fund: to pilot research proposals that investigate (a) inter-examiner reliability studies; (b) use of validation instruments; and (c) defining somatic dysfunction in terms of basic science physiology and biochemistry.
2. The *Samuel V. Robuck Fund* was established to provide for osteopathic care in the pediatric service of the Academy, underwriting educational programs and research projects dedicated to pediatric health care.
3. The *Floyd J. Swift Osteopathic Education Fund* provides expenditures to
perpetuate and improve upon the study of and therapeutic use of, osteopathic manipulative therapy.

4. The *Foundation for Osteopathic Research and Continuous Education (FORCE)* was established to: promote research and education, emphasizing the integration of osteopathic principles, practice and manipulative treatment in patient care; and the raising of funds in support of these research and education objectives. (see below)

**Louisa Burns Osteopathic Research Committee**

The **Louisa Burns Osteopathic Research Committee (LBORC)** was named for an early prominent researcher, Louisa Burns, DO. As the director of the **A.T. Still Research Institute** for many years, Dr. Burns studied the physiology of viscerosomatic reflexes. Her work continues to inspire osteopathic research.

LBORC is the primary committee dedicated to clinical research in the American Academy of Osteopathy. The committee strives to develop and support standards for the collection of data related to osteopathic manipulative medicine and its effect on health and disease.

Committee members assist in developing and performing clinical research studies. They may provide a consultation service to help the investigator on various aspects of the research project, including formation of the hypothesis, data gathering and analysis and publication of study results. The committee also reviews clinical research applications, and if the research project is approved, it submits a recommendation for funding to the AAO Board of Trustees.

Committee members are leaders in expanding research within the osteopathic medical profession who encourage collaboration between clinicians and basic scientists. The group serves as the AAO’s liaison to the American Osteopathic Association’s Council on Research. Committee members have participated in the Osteopathic Collaborative Clinical Trials Initiative Conferences, and they have helped to create the **Osteopathic Research Center (ORC)** at the University Of North Texas Health Science Center Texas College Of Osteopathic Medicine. They collaborate with Foundation for Osteopathic Research and Continuous Education (FORCE). They create and deliver research workshops at the AOA’s Annual Osteopathic Medical Conference and Exposition and at the AAO’s annual Convocation. The group has created and validated the **Outpatient Osteopathic SOAP (subjective objective assessment plan) Note** as well as the new Single Organ System Osteopathic Musculoskeletal Form Series. They have also worked closely with the Student American Academy of Osteopathy to increase involvement in osteopathic research among students and residents. Through these efforts, LBORC strives to develop training for physicians who wish to participate in osteopathic manual medicine research.
The committee members work in subcommittees and task forces to accomplish the research goals of the Academy. Task forces are developed to accomplish specific, short-term goals while subcommittees develop and maintain long-term projects.

- LBORC Networking, Consultation, Mentoring Subcommittee
- LBORC Research Grant Review Subcommittee
- LBORC Research Poster Competition Subcommittee
- LBORC Research Training Conference Subcommittee
- LBORC SOAP Note Subcommittee
- LBORC Website Subcommittee
- Students for Osteopathic Academic Research (SOAR)
Foundation for Osteopathic Research and Continuous Education (FORCE)
http://www.forcedo.org/research

RESEARCH

FORCE has supported research to develop an evidence-base for the use of the Osteopathic Approach to health. To ensure its research meets rigorous scientific standards, FORCE populates its protocol, design, project management, and publication teams with experts in the design, implementation, and publication phase of each study. All research projects sponsored through FORCE must demonstrate:

1. Clinical significance
2. Osteopathic relevance
3. Translation to patient care

As of 2017 it appears that FORCE is not receiving applications for external funding, although that might change. Their research initiatives will pursue collaborations with major research institutions, colleges of Osteopathic medicine, and individual researchers whose work meets the standards set by the Foundation.

OUR PROCESS

FORCE designed its research process with two outcomes in mind:

1. Bring the best research talent to the design and management of projects, removing the burden from the principal investigators
2. Remain engaged in each phase of the research process from:
   a. Idea compilation
   b. Protocol design
   c. Project management
   d. Publication
   e. Education and translation to patient care

Our process first and foremost begins with the question, “What should be researched?” Research ideas originate from researchers, practitioners, and the Foundation itself. FORCE will review research ideas offered in the following four ways:

1. Submit a concept paper that describes the benefit your research brings to patients. The idea must demonstrate how it meets the criteria FORCE has developed to ensure the research it funds has the highest impact on patient care.
2. An existing project that is seeking collaboration with the Osteopathic Approach through FORCE and meets the Foundation’s requirements for approval. We define existing project as one that provides an opportunity for collaboration in the Osteopathic Approach to health.
   a. As a stand-alone clinical intervention comparative to the current standard of care
   b. As a clinical intervention adjunctive to conventional care
   c. As preventative care
3. A project submitted by LBORC to FORCE. To ensure any LBORC research project seeking collaboration with FORCE meets the Foundation’s requirements for approval, any idea proposed for collaboration must be submitted to FORCE with the concept paper and will go through the Foundation’s review process. If approved, FORCE will collaborate with LBORC on the next steps to develop a research protocol that meets FORCE standards.

4. Any project identified by action of the FORCE board that meets the Foundation's requirements for approval

**PROTOCOL DESIGN**

Protocol design is one of the most complex processes in research and impacts the way data is collected and analyzed, the management of the project, and the outcomes it can produce. To ensure thorough and proper design of its research protocols, FORCE will contract with expertise in the fields of epidemiology, statistics, data collection and management, subject matter experts both in the topic of study and the Osteopathic Approach, and the insurers and payers that reimburse for service provided. FORCE has executed master agreements with two major Contract Research Organizations (CRO’s) to bring these services to our research initiatives.

**PROJECT MANAGEMENT**

FORCE will find an Executive Management Team for each project. Larger multi-faceted projects, like the PBRN, with each have a Project Team to manage the operations of the individual cohorts in the PBRN.

FORCE projects have timelines that can extend for several years. Thus, the operational management to keep the research on target, compliant with the protocol, and relevant is critical to the success of the research and to provide the return on investment that the donors who support the projects expect.

What makes the FORCE approach unique is the assumption of the responsibility for this continuous management by the Foundation working in partnership with the PI and the carious research sites. The funding for the management infrastructure is embedded in the project budget itself. This means the entire donor funds are being used to support the project.

This allows the Foundation to maintain only a minimal administrative infrastructure to organize and manage the project development cycle at the Foundation, do fund development, and provide participation on and guidance to the Executive Management teams and the Project teams.

**PUBLICATION AND TRANSLATION TO PATIENT CARE**

Findings from research supported by FORCE that show Osteopathic relevance in the maintenance of health and treatment of disease are then published and translated into training and educational programs that teach the physician and clinical community the best practice to improve clinical outcomes and the delivery of patient care. Programs will be offered to clinicians by the American Academy of Osteopathy and made available by FORCE to the colleges of Osteopathic medicine to educate the student community.
AOA Research Development Toolkit: Grant Writing

Research Development Toolkit: Grant Writing
Grant Writing | Resident Resources | Developing a Research Project | Developing a Peer-Reviewed Article | Other Resources

Writing Research Proposals
Grant Writing for Research – Unfolding the Mystery - Cynthia D. Lamon, Director of Research Services, Oklahoma State University College of Osteopathic Medicine

Presentation Summary: Participants will learn the key strategies for locating funding sources for their respective research areas, including private, state, and federal sources. Participants will learn tips on appropriate search engines, governmental, university, and funder based websites. Additionally, participants will learn about collaborative processes, basic grant writing techniques, and timeless foundational rules to follow. Finally, workshop participants will better understand the resources available for pre- and post-award assistance to ensure successful grant submission, re-submissions, and/or guidelines for research project implementation, as well as sustainability planning.

Learning Objectives:
1. Identify key strategies for finding appropriate funding sources;
2. Identify steps for effective grant writing;
3. Identify critical resources for pre- and post-award assistance.

References:
1. “Grant Writing Tips Sheet,” NIH.gov
3. “Proposal Preparation and Submission,” University of Michigan


This takes you to the AOA sign-in page.
APPENDIX L: GRANT WRITING SHORT COURSE

Grant Writing - Short Course

Introduction

The subject of this short course is proposal writing. But the proposal does not stand alone. It must be part of a process of planning and of research on, outreach to, and cultivation of potential foundation and corporate donors.

This process is grounded in the conviction that a partnership should develop between the nonprofit and the donor. When you spend a great deal of your time seeking money, it is hard to remember that it can also be difficult to give money away. In fact, the dollars contributed by a foundation or corporation have no value until they are attached to solid programs in the nonprofit sector.

This truly is an ideal partnership. The nonprofits have the ideas and the capacity to solve problems, but no dollars with which to implement them. The foundations and corporations have the financial resources but not the other resources needed to create programs. Bring the two together effectively, and the result is a dynamic collaboration.

You need to follow a step-by-step process in the search for private dollars. It takes time and persistence to succeed. After you have written a proposal, it could take as long as a year to obtain the funds needed to carry it out. And even a perfectly written proposal submitted to the right prospect might be rejected for any number of reasons.

Raising funds is an investment in the future. Your aim should be to build a network of foundation and corporate funders, many of which give small gifts on a fairly steady basis and a few of which give large, periodic grants. By doggedly pursuing the various steps of the process, each year you can retain most of your regular supporters and strike a balance with the comings and goings of larger donors.

The recommended process is not a formula to be rigidly adhered to. It is a suggested approach that can be adapted to fit the needs of any nonprofit and the peculiarities of each situation. Fundraising is an art as well as a science. You must bring your own creativity to it and remain flexible.

Gathering Background Information

The first thing you will need to do in writing your proposal is to gather the documentation for it. You will require background documentation in three areas: concept, program, and expenses.

If all of this information is not readily available to you, determine who will help you gather each type of information. If you are part of a small nonprofit with no staff, a knowledgeable board member will be the logical choice. If you are in a larger agency, there should be program and financial support staff who can help you. Once you know with whom to talk, identify the questions to ask.

This data-gathering process makes the actual writing much easier. And by involving other stakeholders in the process, it also helps key people within your agency seriously consider the project’s value to the organization.
Concept

It is important that you have a good sense of how the project fits with the philosophy and mission of your agency. The need that the proposal is addressing must also be documented. These concepts must be well-articulated in the proposal. Funders want to know that a project reinforces the overall direction of an organization, and they may need to be convinced that the case for the project is compelling. You should collect background data on your organization and on the need to be addressed so that your arguments are well-documented.

Program

Here is a check list of the program information you require:

- D The nature of the project and how it will be conducted;
- D The timetable for the project;
- D The anticipated outcomes and how best to evaluate the results; and
- D Staffing and volunteer needs, including deployment of existing staff and new hires.

Expenses

You will not be able to pin down all the expenses associated with the project until the program details and timing have been worked out. Thus, the main financial data gathering takes place after the narrative part of the master proposal has been written. However, at this stage you do need to sketch out the broad outlines of the budget to be sure that the costs are in reasonable proportion to the outcomes you anticipate. If it appears that the costs will be prohibitive, even with a foundation grant, you should then scale back your plans or adjust them to remove the least cost-effective expenditures.

Components of a Proposal

I. Executive Summary:
   - a. Umbrella statement of your case and summary of the entire proposal 1 page

II. Statement of Need:
   - a. Why this project is necessary 2 pages

III. Project Description:
   - a. Nuts and bolts of how the project will be implemented and evaluated 3 pages

IV. Budget:
   - a. Financial description of the project plus explanatory notes 1 page

V. Organization Information:
   - a. History and governing structure of the nonprofit; its primary activities, audiences, and services 1 page

VI. Conclusion:

   Summary of the proposal's main points 2 paragraphs
The Executive Summary

This first page of the proposal is the most important section of the entire document. Here you will provide the reader with a snapshot of what is to follow. Specifically, it summarizes all of the key information and is a sales document designed to convince the reader that this project should be considered for support. Be certain to include:

D Problem — a brief statement of the problem or need your agency has recognized and is prepared to address (one or two paragraphs);

D Solution — a short description of the project, including what will take place and how many people will benefit from the program, how and where it will operate, for how long, and who will staff it (one or two paragraphs);

D Funding requirements — an explanation of the amount of grant money required for the project and what your plans are for funding it in the future (one paragraph); and

D Organization and its expertise — a brief statement of the history, purpose, and activities of your agency, emphasizing its capacity to carry out this proposal (one paragraph).

The Statement of Need

If the grants decision-maker reads beyond the executive summary, you have successfully piqued his or her interest. Your next task is to build on this initial interest in your project by enabling the funder to understand the problem that the project will remedy.

The statement of need will enable the reader to learn more about the issues. It presents the facts and evidence that support the need for the project and establishes that your nonprofit understands the problems and therefore can reasonably address them. The information used to support the case can come from authorities in the field, as well as from your agency’s own experience.

You want the need section to be succinct, yet persuasive. Like a good debater, you must assemble all the arguments. Then present them in a logical sequence that will readily convince the reader of their importance. As you marshal your arguments, consider the following six points.

First, decide which facts or statistics best support the project. Be sure the data you present are accurate. There are few things more embarrassing than to have the funder tell you that your information is out of date or incorrect. Information that is too generic or broad will not help you develop a winning argument for your project. Information that does not relate to your organization or the project you are presenting will cause the funder to question the entire proposal. There also should be a balance between the information presented and the scale of the program.

Second, give the reader hope. The picture you paint should not be so grim that the solution appears hopeless. The funder will wonder whether an investment in your solution would be worthwhile. Here's an example of a solid statement of need: "Breast cancer kills. But statistics prove that regular check-ups catch most breast cancer in the early stages, reducing the likelihood of death. Hence, a program to encourage preventive check-ups will reduce the risk of death due to breast cancer." Avoid
overstatement and overly emotional appeals.

Third, decide if you want to put your project forward as a model. This approach could expand the base of potential funders. But serving as a model works only for certain types of projects. Don't try to make this argument if it doesn't really fit. Funders may well expect your agency to follow through with a replication plan if you present your project as a model.

If the decision about a model is affirmative, you should document how the problem you are addressing occurs in other communities. Be sure to explain how your solution could be a solution for others as well.

Fourth, determine whether it is reasonable to portray the need as acute. You are asking the funder to pay more attention to your proposal because either the problem you address is worse than others or the solution you propose makes more sense than others. Here is an example of a balanced but weighty statement: "Drug abuse is a national problem. Each day, children all over the country die from drug overdose. In the South Bronx the problem is worse. More children die here than any place else. It is an epidemic. Hence, our drug prevention program is needed more in the South Bronx than in any other part of the city."

Fifth, decide whether you can demonstrate that your program addresses the need differently or better than other projects that preceded it. It is often difficult to describe the need for your project without being critical of the competition. But you must be careful to do so. Being critical of other nonprofits will not be well received by the funder. It may cause the funder to look more carefully at your own project to see why you felt you had to build your case by demeaning others. The funder may have invested in these other projects or may begin to consider them, now that you have brought them to the funder's attention.

If possible, you should make it clear that you are cognizant of, and on good terms with, others doing work in your field. Keep in mind that today's funders are very interested in collaboration. They may even ask why you are not collaborating with those you view as key competitors. So at the least you need to describe how your work complements, but does not duplicate, the work of others.

Sixth, avoid circular reasoning. In circular reasoning, you present the absence of your solution as the actual problem. Then your solution is offered as the way to solve the problem. For example, the circular reasoning for building a community swimming pool might go like this: "The problem is that we have no pool in our community. Building a pool will solve the problem." A more persuasive case would cite what a pool has meant to a neighboring community, permitting it to offer recreation, exercise, and physical therapy programs. The statement might refer to a survey that underscores the target audience's planned usage of the facility and conclude with the connection between the proposed usage and potential benefits to enhance life in the community community for audiences the funder cares about.

The statement of need does not have to be long and involved. Short, concise information captures the reader's attention.
The Project Description

This section of your proposal should have five subsections: objectives, methods, staffing/administration, evaluation, and sustainability. Together, objectives and methods dictate staffing and administrative requirements. They then become the focus of the evaluation to assess the results of the project. The project's sustainability flows directly from its success, hence its ability to attract other support. Taken together, the five subsections present an interlocking picture of the total project.

Objectives

Objectives are the measurable outcomes of the program. They define your methods. Your objectives must be tangible, specific, concrete, measurable, and achievable in a specified time period. Grant seekers often confuse objectives with goals, which are conceptual and more abstract. For the purpose of illustration, here is the goal of a project with a subsidiary objective:

Goal: Our after-school program will help children read better.

Objective: Our after-school remedial education program will assist 50 children in improving their reading scores by one grade level as demonstrated by standardized reading tests administered after participating in the program for six months.

The goal in this case is abstract: improving reading, while the objective is much more specific. It is achievable in the short term (six months) and measurable (improving 50 children's reading scores by one grade level).

With competition for dollars so great, well-articulated objectives are increasingly critical to a proposal's success.

Using a different example, there are at least four types of objectives:

1. Behavioral — a human action is anticipated
   a. Example: Fifty of the 70 children participating will learn to swim.

2. Performance — a specific time frame within which a behavior will occur, at an expected proficiency level, is expected.
   a. Example: Fifty of the 70 children will learn to swim within six months and will pass a basic swimming proficiency test administered by a Red Cross-certified lifeguard.

3. Process — the manner in which something occurs is an end in itself
   a. Example: We will document the teaching methods utilized, identifying those with the greatest success.

4. Product — a tangible item results
   a. Example: A manual will be created to be used in teaching swimming to this age and proficiency group in the future.
In any given proposal, you will find yourself setting forth one or more of these types of objectives, depending on the nature of your project. Be certain to present the objectives very clearly. Make sure that they do not become lost in verbiage and that they stand out on the page. You might, for example, use numbers, bullets, or indentations to denote the objectives in the text. Above all, be realistic in setting objectives. Don't promise what you can't deliver. Remember, the funder will want to be told in the final report that the project actually accomplished these objectives.

**Methods**

By means of the objectives, you have explained to the funder what will be achieved by the project. The methods section describes the specific activities that will take place to achieve the objectives. It might be helpful to divide our discussion of methods into the following: how, when, and why.

How: This is the detailed description of what will occur from the time the project begins until it is completed. Your methods should match the previously stated objectives.

When: The methods section should present the order and timing for the tasks. It might make sense to provide a timetable so that the grants decision-maker does not have to map out the sequencing on his or her own. The timetable tells the reader "when" and provides another summary of the project that supports the rest of the methods section.

Why: You may need to defend your chosen methods, especially if they are new or unorthodox. Why will the planned work most effectively lead to the outcomes you anticipate? You can answer this question in a number of ways, including using expert testimony and examples of other projects that work.

The methods section enables the reader to visualize the implementation of the project. It should convince the reader that your agency knows what it is doing, thereby establishing its credibility.

**Staffing/Administration**

In describing the methods, you will have mentioned staffing for the project. You now need to devote a few sentences to discussing the number of staff, their qualifications, and specific assignments. Details about individual staff members involved in the project can be included either as part of this section or in the appendix, depending on the length and importance of this information.

"Staffing" may refer to volunteers or to consultants, as well as to paid staff. Most proposal writers do not develop staffing sections for projects that are primarily volunteer run. Describing tasks that volunteers will undertake, however, can be most helpful to the proposal reader. Such information underscores the value added by the volunteers as well as the cost-effectiveness of the project.

For a project with paid staff, be certain to describe which staff will work full time and which will work part time on the project. Identify staff already employed by your nonprofit and those to be recruited specifically for the project. How will you free up the time of an already fully deployed individual?

Salary and project costs are affected by the qualifications of the staff. Delineate the practical experience you require for key staff, as well as level of expertise and educational background. If an individual has already been selected to direct the program, summarize his or her credentials and
include a brief biographical sketch in the appendix. A strong project director can help influence a grant decision.

Describe for the reader your plans for administering the project. This is especially important in a large operation, if more than one agency is collaborating on the project, or if you are using a fiscal agent. It needs to be crystal clear who is responsible for financial management, project outcomes, and reporting.

Evaluation

An evaluation plan should not be considered only after the project is over; it should be built into the project. Including an evaluation plan in your proposal indicates that you take your objectives seriously and want to know how well you have achieved them. Evaluation is also a sound management tool. Like strategic planning, it helps a nonprofit refine and improve its program. An evaluation can often be the best means for others to learn from your experience in conducting the project.

There are several types of formal evaluation. One measures the product; others analyze the process and/or strategies you've adopted. Most seek to determine the impact on the audiences you serve and the measurable outcomes of your grant project. Either or both might be appropriate to your project. The approach you choose will depend on the nature of the project and its objectives. Whatever form your evaluation takes, you will need to describe the manner in which evaluation information will be collected and how the data will be analyzed.

Most sound evaluation plans include both qualitative and quantitative data. You should present your plan for how the evaluation and its results will be reported and the audience to which it will be directed. For example, it might be used internally or be shared with the funder, or it might deserve a wider audience. A funder might even have an opinion about the scope of this dissemination. Many funders also have suggestions about who should conduct the evaluation, whether it be your own program staff or outside consultants. Some funders allow for the inclusion of the cost of evaluation as part of the project budget.

Sustainability

A clear message from grantmakers today is that grantseekers will be expected to demonstrate in very concrete ways the long-term financial viability of the project to be funded and of the nonprofit organization itself.

It stands to reason that most grantmakers will not want to take on a permanent funding commitment to a particular agency. Rather, funders will want you to prove either that your project is finite (with start-up and ending dates); or that it is capacity-building (that it will contribute to the future self-sufficiency of your agency and/or enable it to expand services that might generate revenue); or that it will make your organization attractive to other funders in the future. Evidence of fiscal sustainability is a highly sought-after characteristic of the successful grant proposal.

It behooves you to be very specific about current and projected funding streams, both earned income and fundraised, and about the base of financial support for your nonprofit. Here is an area where it is important to have backup figures and prognostications at the ready, in case a prospective funder asks for these, even though you are unlikely to include this information in the actual grant proposal. Some
grantmakers, of course, will want to know who else will be receiving a copy of this same proposal. You should not be shy about sharing this information with the funder.

The Budget

The budget for your proposal may be as simple as a one-page statement of projected revenue and expenses. Or your proposal may require a more complex presentation, perhaps including a page on projected support and notes explaining various items of expense or of revenue.

Expense Budget

As you prepare to assemble the budget, go back through the proposal narrative and make a list of all personnel and non-personnel items related to the operation of the project. Be sure that you list not only new costs that will be incurred if the project is funded but also any ongoing expenses for items that will be allocated to the project. Then get the relevant costs from the person in your agency who is responsible for keeping the books. You may need to estimate the proportions of your agency’s ongoing expenses that should be charged to the project and any new costs, such as salaries for project personnel not yet hired. Put the costs you have identified next to each item on your list.

Your list of budget items and the calculations you have done to arrive at a dollar figure for each item should be summarized on worksheets. You should keep these to remind yourself how the numbers were derived. These worksheets can be useful as you continue to develop the proposal and discuss it with funders; they are also a valuable tool for monitoring the project once it is under way and for reporting after completion of the grant.

A portion of a worksheet for a year-long project might look like this:

<table>
<thead>
<tr>
<th>Item Description</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Executive director Supervision</td>
<td>$10,000</td>
</tr>
<tr>
<td>10% of salary = $10,000</td>
<td></td>
</tr>
<tr>
<td>25% benefits = $ 2,500</td>
<td></td>
</tr>
<tr>
<td>Project director hired in month one</td>
<td>$32,083</td>
</tr>
<tr>
<td>11 months at $35,000 = $32,083</td>
<td></td>
</tr>
<tr>
<td>25% benefits = $ 8,025</td>
<td></td>
</tr>
<tr>
<td>Tutors</td>
<td>$7,020</td>
</tr>
<tr>
<td>12 working 10 hours per week for three months</td>
<td></td>
</tr>
<tr>
<td>12 x 10 x 13 x $ 4.50 = $ 7,020</td>
<td></td>
</tr>
<tr>
<td>Office space</td>
<td>$5,000</td>
</tr>
<tr>
<td>Requires 25% of current space</td>
<td></td>
</tr>
<tr>
<td>25% x $20,000 = $ 5,000</td>
<td></td>
</tr>
<tr>
<td>Overhead</td>
<td>$12,926</td>
</tr>
<tr>
<td>20% of project cost</td>
<td></td>
</tr>
<tr>
<td>20% x $64,628 = $12,926</td>
<td></td>
</tr>
</tbody>
</table>
With your worksheets in hand, you are ready to prepare the expense budget. For most projects, costs should be grouped into subcategories, selected to reflect the critical areas of expense. All significant costs should be broken out within the subcategories, but small ones can be combined on one line. You might divide your expense budget into personnel and non-personnel costs; your personnel subcategories might include salaries, benefits, and consultants. Subcategories under non-personnel costs might include travel, equipment, and printing, for example, with a dollar figure attached to each line. Overhead, or indirect costs, is important to include because projects do not exist in isolation. Funders may have policies regarding the percentage of overhead they will allow in a project budget, if they allow it at all.

Support and Revenue and Statement

For the typical project, no support and revenue statement is necessary. The expense budget represents the amount of grant support required. But if grant support has already been awarded to the project, or if you expect project activities to generate income, a support and revenue statement is the place to provide this information.

In itemizing grant support, make note of any earmarked grants; this will suggest how new grants may be allocated. The total grant support already committed should then be deducted from the “Total Expenses” line on the expense budget to give you the “Amount to be Raised” or the “Balance Requested.”

Any earned income anticipated should be estimated on the support and revenue statement. For instance, if you expect 50 people to attend your performance on each of the four nights, it is given at $10 a ticket, and if you hope that 20 of them will buy the $5 souvenir book each night, you would show two lines of income, “Ticket Sales” at $2,000 and “Souvenir Book Sales” at $400. As with the expense budget, you should keep backup worksheets for the support and revenue statement to remind yourself of the assumptions you have made.

Budget Narrative

A narrative portion of the budget is used to explain any unusual line items in the budget and is not always needed. If costs are straightforward and the numbers tell the story clearly, explanations are redundant.

If you decide a budget narrative is needed, you can structure it in one of two ways. You can create “Notes to the Budget,” with footnote-style numbers on the line items in the budget keyed to numbered explanations. If an extensive or more general explanation is required, you can structure the budget narrative as straight text. Remember though, the basic narrative about the project and your organization belongs elsewhere in the proposal, not in the budget narrative.
Organizational Information and Conclusion

Organizational Information

Normally a resume of your nonprofit organization should come at the end of your proposal. Your natural inclination may be to put this information up front in the document. But it is usually better to sell the need for your project and then your agency’s ability to carry it out.

It is not necessary to overwhelm the reader with facts about your organization. This information can be conveyed easily by attaching a brochure or other prepared statement. In two pages or less, tell the reader when your nonprofit came into existence; state its mission, being certain to demonstrate how the subject of the proposal fits within or extends that mission; and describe the organization’s structure, programs, leadership, and special expertise.

Discuss the size of the board, how board members are recruited, and their level of participation. Give the reader a feel for the makeup of the board. (You should include the full board list in an appendix.) If your agency is composed of volunteers or has an active volunteer group, describe the function that the volunteers perform. Provide details on the staff, including the numbers of full and part-time staff, and their levels of expertise.

Describe the kinds of activities in which your staff engage. Explain briefly the assistance you provide. Describe the audience you serve, any special or unusual needs they face, and why they rely on your agency. Cite the number of people who are reached through your programs.

Tying all of the information about your nonprofit together, cite your agency’s expertise, especially as it relates to the subject of your proposal.

Letter Proposal

Sometimes the scale of the project might suggest a small-scale letter format proposal, or the type of request might not require all of the proposal components or the components in the sequence recommended here. The guidelines and policies of individual funders will be your ultimate guide. Many funders today state that they prefer a brief letter proposal; others require that you complete an application form. In any case, you will want to refer to the basic proposal components as provided here to be sure that you have not omitted an element that will support your case.

As noted, the scale of the project will often determine whether it requires a letter or the longer proposal format. For example, a request to purchase a $1,000 fax machine for your agency simply does not lend itself to a lengthy narrative. A small contribution to your agency’s annual operating budget, particularly if it is a renewal of past support, might also warrant a letter rather than a full-scale proposal.

What are the elements of a letter request? For the most part, they should follow the format of a full proposal, except with regard to length. The letter should be no more than three pages. You will need to call upon your writing skills because it can be very hard to get all of the necessary details into a concise, well-articulated letter.
As to the flow of information, follow these steps while keeping in mind that you are writing a letter to another person. It should not be as formal in style as a longer proposal would be. It may be necessary to change the sequence of the text to achieve the correct tone and the right flow of information.

Here are the components of a good letter proposal:

D Ask for the gift: The letter should begin with a reference to your prior contact with the funder, if any. State why you are writing and how much funding is required from the particular foundation.
D Describe the need: In a very abbreviated manner, tell the funder why there is a need for this project, piece of equipment, etc.
D Explain what you will do: Just as you would in a fuller proposal, provide enough detail to pique the funder's interest. Describe precisely what will take place as a result of the grant.
D Provide agency data: Help the funder know a bit more about your organization by including your mission statement, brief description of programs offered, number of people served, and staff, volunteer, and board data, if appropriate.
D Include appropriate budget data: Even a letter request may have a budget that is a half-page long. Decide if this information should be incorporated into the letter or in a separate attachment. Whichever course you choose, be sure to indicate the total cost of the project. Discuss future funding only if the absence of this information will raise questions.
D Close: As with the longer proposal, a letter proposal needs a strong concluding statement. Offer to provide more details or meet with the funder.
D Attach any additional information required: The funder may need much of the same information to back up a small request as a large one: a board list, a copy of your IRS determination letter, financial documentation, and brief resumes of key staff.

It may take as much thought and data gathering to write a good letter request as it does to prepare a full proposal (and sometimes even more). Don't assume that because it is only a letter, it isn't a time-consuming and challenging task. Every document you put in front of a funder says something about your agency. Each step you take with a funder should build a relationship for the future.

**Conclusion**

Every proposal should have a concluding paragraph or two. This is a good place to call attention to the future, after the grant is completed. If appropriate, you should outline some of the follow-up activities that might be undertaken to begin to prepare your funder for your next request. Alternatively, you should state how the project might carry on without further grant support.

This section is also the place to make a final appeal for your project. Briefly reiterate what your nonprofit wants to do and why it is important. Underscore why your agency needs funding to accomplish it. Don't be afraid at this stage to use a bit of emotion to solidify your case.

**What Happens Next?**

Submitting your proposal is nowhere near the end of your involvement in the grantseeking process. Grant review procedures vary widely, and the decision-making process can take anywhere from a few weeks to six months or more. During the review process, the funder may ask for additional information either directly from you or from outside consultants or professional references. Invariably, this is a
difficult time for the grantseeker. You need to be patient but persistent. Some grantmakers outline their review procedures in annual reports or application guidelines. If you are unclear about the process, don't hesitate to ask.

If your hard work results in a grant, take a few moments to acknowledge the funder's support with a letter of thanks. You also need to find out whether the funder has specific forms, procedures, and deadlines for reporting on the progress of your project. Clarifying your responsibilities as a grantee at the outset, particularly with respect to financial reporting, will prevent misunderstandings and more serious problems later.

Nor is rejection necessarily the end of the process. If you're unsure why your proposal was turned down, ask. Did the funder need additional information? Would they be interested in considering the proposal at a future date? Now might also be the time to begin cultivation of a prospective funder. Put them on your mailing list so that they can become further acquainted with your organization. Remember, there's always next year.

This short course in proposal writing was adapted from The Foundation Center's Guide to Proposal Writing, 5th ed. (New York: The Foundation Center, 2007), by Jane C. Geever, chairman of the development consulting firm, J. C. Geever, Inc.

The Foundation Center's Guide to Proposal Writing and other resources on the subject are available for free use in Foundation Center libraries and Cooperating Collections.

See also in the FAQs "Proposal Writing" and among the User Aids "Web Sites for Proposal Writers." The Foundation Center offers full-day Proposal Writing Seminars at various locations throughout the country and free one-hour introductions to the process, entitled Proposal Writing Basics, at all of its library locations.

The Foundation Center also offers a number of online training courses to help you learn to write grant proposals:

- Proposal Writing: The Comprehensive Course
- Proposal Writing: The Statement of Need
- Proposal Writing: The Project Description
- Proposal Writing: The Budget
WEBSITES

National Institutes of Health (NIH)  www.nih.gov

Medical Research Council (MRC)  www.mrc.ac.uk

Centers for Disease Control and Prevention (CDC)  www.cdc.gov

MDLinks  www.mdlinx.com

AOA Specialty Research Requirements
You need to check with each specialty college

AOA Research and Grants

http://www.osteopathic.org/inside-aoa/development/research-and-development/Pages/fellowship-applications.aspx

STATISTICAL PROGRAM WEBSITES

http://statpages.info/javasta2.html


http://www.predictiveanalyticstoday.com/top-free-statistical-software/

Phone Numbers

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Cell phone: 516-633-3731

Kurt Amsler, Ph.D.
Associate Dean of Research, NYIT COM  516-686-3716
**NYCOMEC Member Institutions:**

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<th>Institution</th>
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<td>Catskill Regional Medical Center</td>
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<td>Eastern Long Island Hospital</td>
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<td>Ellis Medicine</td>
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<td>MediSys Health Network – Flushing Hospital Medical Center</td>
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<td>New York Institute of Technology College of Osteopathic Medicine</td>
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