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Scholarly Activity: What counts?

Each residency program has its own policies or guidelines on scholarly activity requirements. If your program has a graduation requirement, you must consult with your program staff to find out what constitutes scholarly activity worthy of meeting your graduation requirements. Some programs accept case reports, while others require original research. If you are not sure, discuss your requirements with your Program Director.

There is a variety of activities that may be considered scholarly activity. These include but are not limited to: case reports, literature reviews, quality improvement initiatives, and research studies.

A case report is a detailed report of the symptoms, signs, diagnosis, treatment, and follow-up of an individual patient, usually about an unusual or novel occurrence.

A literature review summarizes and synthesizes published information in a particular subject area from numerous publication sources.

The term “research” refers specifically to a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

By contrast, quality assurance or improvement initiatives are only undertaken to assess or improve internal operations within one’s own institution. These projects are systematic but NOT generalizable to other institutions.

Examples of these types of scholarly activity are available for your reference in the following locations:

- In the Library Reserves
- In the Examples section of the Scholarly Activity Blackboard Course

Purpose of this handbook

This handbook will specifically address how to design, write, and present research protocols. Quality assurance and quality improvement projects can be similarly written. However, you should be careful when addressing things like statistical analysis as this will be different for those types of projects. Case reports and scholarly literature reviews will not be covered in this handbook.

Recommended Reading

How long will it take?

Ideally, residents armed with the right information can pace themselves so that their research project does not conflict with their clinical duties.

**Pace Yourself!**
A reasonable timeline for presenting at the end of your third year

<table>
<thead>
<tr>
<th>PGY Year</th>
<th>Months</th>
<th>Task</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Jan</td>
<td>Consider topics</td>
</tr>
<tr>
<td></td>
<td>Mar</td>
<td>Choose mentor</td>
</tr>
<tr>
<td></td>
<td>Mar-Apr</td>
<td>Review literature</td>
</tr>
<tr>
<td></td>
<td>May-Jun</td>
<td>Write literature review/background/rationale</td>
</tr>
<tr>
<td>2</td>
<td>Aug</td>
<td>Write methods and stats</td>
</tr>
<tr>
<td></td>
<td>Sept</td>
<td>Take IRB Training</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Create data collection tools</td>
</tr>
<tr>
<td></td>
<td>Oct</td>
<td>Complete IRB Forms and submit to IRB</td>
</tr>
<tr>
<td></td>
<td>Dec</td>
<td>Respond to IRB requests for changes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Get IRB Approval</td>
</tr>
<tr>
<td></td>
<td>Jan-Jun</td>
<td>Collect data</td>
</tr>
<tr>
<td>3</td>
<td>Jul-Mar</td>
<td>Collect data</td>
</tr>
<tr>
<td></td>
<td>April</td>
<td>Clean and analyze data set</td>
</tr>
<tr>
<td></td>
<td>May</td>
<td>Draft presentation or poster</td>
</tr>
<tr>
<td></td>
<td>June</td>
<td>Present your research</td>
</tr>
</tbody>
</table>

Still, many of you will wait until your third year to begin your project. Be realistic and get started right away! You do not have time to waste. This timeline might also be helpful for residents wanting to complete projects early, prior to submitting applications for specialty fellowships.

<table>
<thead>
<tr>
<th>Month</th>
<th>Weeks</th>
<th>Task</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aug</td>
<td>3</td>
<td>Consider topics</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Review literature and</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Choose mentor</td>
</tr>
<tr>
<td>Sept</td>
<td>2</td>
<td>Write background/ rationale</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Write methods and stats</td>
</tr>
<tr>
<td>Oct</td>
<td>1</td>
<td>Create data collection tools</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>Complete IRB Forms and submit to IRB</td>
</tr>
<tr>
<td>Oct-Nov</td>
<td>4</td>
<td>Wait for IRB Review</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Take IRB Training</td>
</tr>
<tr>
<td>Dec</td>
<td>2</td>
<td>Respond to IRB requests for changes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Get IRB Approval</td>
</tr>
<tr>
<td>Jan-Apr</td>
<td>16</td>
<td>Collect data</td>
</tr>
<tr>
<td>May</td>
<td>1</td>
<td>Clean and analyze data set</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>Draft presentation or poster</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>Present your research</td>
</tr>
</tbody>
</table>

**Panic!**
A timeline for grads with no project (or for completing before fellowship applications)
Developing Your Research Question

Where do I start?
To get started, determine the area of medicine that most interests you.
• Are you hoping to apply for a fellowship?
• Do you have interest in a specific disease process or treatment?
• Is there a particular division within your discipline/specialty that piques your interest?

Next, think of specific questions within the area of medicine that you have chosen. It is okay to be vague at this stage. Review of the literature will help you refine your questions and hypotheses later on.
• Have you ever asked a question and heard your attending reply, “I’m not sure that’s been studied.” or “That’s a good question.”?
• Have you had a question that you could not answer by reading textbooks or reviewing the literature?

Example 1: Do primary care physicians know enough about a new technology to non-invasively screen for coronary artery disease? Is there an information gap between primary care and specialists?
Example 2: Do reminder letters and phone calls improve diabetic patients’ adherence to their regularly scheduled screening/check up visits?

State your question clearly and define important terms as specifically as possible.

Do hand lacerations require suturing? (Too vague)

Do simple (not involving joints, tendons, or fractures) hand lacerations that present to the ED for treatment have similar cosmetic outcomes when treated with and without sutures?

Refining Your Research Question
Work with your faculty mentor to refine your research question to create something that is, interesting, novel, ethical, and relevant.

The FINER Criteria
Feasible — Do you have the resources in time and expertise to complete the project? Can the investigation be done with measurable variables and endpoints?
Interesting — Are you passionate about the subject??
Novel — Does your idea add to or refute previous findings? Will it confirm previous studies which remain controversial?
Ethical — Can your idea be carried out within the bounds of professional guidelines for patient care and legal guidelines for human research?
Relevant — Would your research results impact current medical care? Could it inform policy makers or provide direction for future research?

Searching the Literature

It is important to be familiar with the pertinent literature as you develop a research protocol. By searching available literature you can summarize preliminary data, avoid duplicating another investigator’s work, find areas where further study is needed, and model your study in a way that will avoid pitfalls experienced by other research teams. It is important to distinguish between point-of-care searches and research related searches. These two tasks often require different resources and different search techniques.

Where do I look?

PubMed is often the first place clinical researchers go to search scholarly literature. This is because it comprises approximately 20 million citations for biomedical literature from MEDLINE, life science journals, and online books. Publishers of journals can submit their citations to NCBI and then provide access to the full-text of articles at journal Web sites using LinkOut.

Another valuable resource for searching scholarly literature is actually your good friend, Google! Search for articles at www.scholar.google.com and you may find things available for free that you can not find in PubMed. Search for a specific article by putting the article’s title in quotation marks.

Often used as a clinical database, the Cochrane Library is also a useful reference resource for research. Their well-known reviews provide systematic summaries of current research efforts in a particular disease state or treatment modality. These reviews can lead you to the literature that resulted from these investigations.

Helpful Q&A

Q. What is LinkOut?
By using the PubMed LinkOut service through the Library’s webpage, you can gain access to online full text articles from publishers and from PubMed Central. If EVMS has an electronic subscription to a journal you will see an “EVMS ONLINE” icon appear in PubMed’s Abstract and Citation displays.

Q. What is a meta-analysis?
Meta-analysis articles, like those included in the Cochrane Reviews, are analyses that look at several studies and provide new information/analysis using the combined results of several studies. They can helpful because, unlike literature reviews, they provide quantitative analysis of the existing studies rather than simply describing the current state of research.

Q. How do I find an article referenced in another paper?
The fastest way to do this is by using the Single Citation Matcher in PubMed (right). This tool is listed on the PubMed Homepage under PubMed Tools. Complete as many fields as you can and search for the article you need.

Q. When should I use the Advanced Search tool instead of a simple search?
If your simple search returns more than 50 results, consider using the Advanced Search Limits tool to set limits on your results. For example, you may only be interested in research publications from studies in humans, or a specific gender or age range. Setting limits this way will tailor your search results for your needs. It may also be helpful to build a search using Boolean operators. This can be done with the Advanced Search Builder.
EVMS Library Resources for Research Related Activities

What can they do for you?
Reference librarians are trained to analyze complex questions and formulate search strategies.

Reference librarians can help you:
- find quick factual information
- conduct subject research
- compile bibliographies
- learn how to use Library resources
- learn your way around the Library

When the Information Desk is not staffed, the circulation staff is available for basic reference assistance.

The Library subscribes to a variety of bibliographic and full-text databases. For a list of the resources available visit http://evms.edu/evmslib/resources.html

Computer searches are provided without charge to EVMS faculty, staff, and students.

You should also contact the clinical librarians to discuss options like Inter-Library Loan (ILLiad) for obtaining materials that EVMS does not have available. For more information about using ILLiad, visit http://157.21.75.250/tutorial-illiad/main.htm

What can you do?

- **Call them!**
  (757) 446-5851
- **Email them!**
  library@evms.edu
- **Visit them!**
  The Information Desk is on the 2nd floor Aug. 9 through January due to construction. Thereafter, it will be located in its usual area on the first floor. The desk is staffed by librarians Monday through Friday, 8 a.m. - 5 p.m.

Helpful Resources

PubMed Basics:
http://nnlm.gov/training/resources/pmtri.pdf

PubMed: Ten Tips
http://www.hsl.unc.edu/Services/guides/pubmed10.cfm

August 2010
Critically Analyzing the Literature

While it may be true that “studies show evidence” of a particular phenomenon, it is the responsibility of the good investigator to critically review pertinent literature before embarking on a new investigation. Knowledge of basic research methodology will increase your research literacy and critical evaluation skills. Be sure to review the Research Methodology section of this handbook for more information.

“The best evidence for a cause and effect relationship stems from well-conducted experimental studies with a large number of patients, randomly allocated comparison groups, blinded caregivers, patients, and analysts, few patients lost to follow up, and in which methods of high quality have been used for measurements of effects and for analyzing gathered data. The study design that carries the most weight is a randomized controlled trial (RCT)”

More in-depth discussion on questions to ask about specific study designs is included in “How to critically appraise an article” by Jane Young.

Questions for Critical Appraisal

1. Is the study question relevant?
2. Does the study add anything new?
3. What type of research question is being asked?
4. Was the study design appropriate for the research question?
5. Did the study methods address the most important potential sources of bias?
6. Was the study performed according to the original protocol?
7. Does the study test a stated hypothesis?
8. Were the statistical analyses the correct ones for the study and were they performed correctly?
9. Do the data justify the conclusions?
10. Are there any conflicts of interest?

Writing your Background Section

Once you have gathered your literature resources, it is time to write a thorough literature review. This is the foundation of good clinical research. Your literature review is the source of your background and rationale section when writing your protocol. A good literature review is both a summary and a synthesis of the information available. It will recap of the important information from each source and organize information in an efficient way. After reading your literature review, your reader should know what the problem is, what research has been done to date, and where more research needs to be done.

The 5 Cs of literature review

Cite — Do not stray too far on personal experience. Stick to the information in your resources.
Compare — Where do the authors of your resources agree? What seems to be consistent across the literature?
Contrast — Where do the authors of your resources disagree? Is there inconsistency that calls for more investigation?
Critique — Based on your knowledge of research methodology, which resources seem the most reliable? How does the author’s approach to the problem affect his/her conclusions?
Connect — Synthesize what you have learned to show the relationships between the resources and how the information has led you to your new research question.

References:
Helpful resources

How to write a mini literature review

Works-cited style guides (AMA, APA, and MLA)
http://www2.liu.edu/cwis/cwp/library/workshop/citation.htm

End Notes Web: use your EVMS username and password to access:
https://www.myendnoteweb.com/chekov.evms.edu/EndNoteWeb.html?SID=2FabEEpOK5BgFPnnj4h&returnCode=ROUTER.Success&Init=Yes&SrApp=CR&
Designing Your Study

Establishing a testable hypothesis

Once you have established a good research question using the FINER criteria and have done your preliminary literature review, you need to put your hypothesis in writing. Your hypothesis should be “simple, specific, and stated in advance”.\(^5\)

Proper statistical analysis is dependent on establishing null and alternative hypotheses. What many people call “the” hypothesis is actually called an “alternative hypothesis”. This is an assertion that there is an association between a predictor and an outcome. One-sided and two-sided hypotheses are types of alternative hypotheses. The null hypothesis states that there will be no association between a predictor and outcome in a population.

Choosing a study design\(^6\)

Research design is a collection of techniques and processes that formalize your project into a study that is: empirical, completely defined in operational terms, replicable, and valid.

<table>
<thead>
<tr>
<th>Experimental Studies</th>
<th>Quasi-Experimental</th>
<th>Observational Studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evaluate causal propositions through manipulating a participant’s experience</td>
<td>Examine how different groups respond to an experimental manipulation</td>
<td>Evaluate associations between predictors and outcomes to develop a predictive or explanatory model</td>
</tr>
<tr>
<td><strong>Characteristics</strong></td>
<td><strong>Design Types</strong></td>
<td><strong>Example</strong></td>
</tr>
<tr>
<td>Greatest concern: internal validity and control</td>
<td>Randomized Controlled Trial (RCT)</td>
<td>Randomized study of vitamin D deficiency treatment options.</td>
</tr>
<tr>
<td>Manipulation of at least one variable (2 levels)</td>
<td>Non-randomized study with contemporary or historic controls</td>
<td></td>
</tr>
<tr>
<td>Presence of:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Independent Variable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dependent Variable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Randomization</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blinding</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Characteristics</strong></td>
<td><strong>Design Types</strong></td>
<td><strong>Example</strong></td>
</tr>
<tr>
<td>Looks like an experimental design, but at least one variable is pre-existing (e.g., sex)</td>
<td>Time Series</td>
<td>Does gender affect the efficacy of different vitamin D deficiency treatments?</td>
</tr>
<tr>
<td>Sometimes crossed with an actual experimental manipulation</td>
<td>Equivalent Time Sample</td>
<td></td>
</tr>
<tr>
<td>Basis for causal assertions is weaker</td>
<td>Nonequivalent Control Group</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Characteristics</strong></td>
<td><strong>Design Types</strong></td>
<td><strong>Example</strong></td>
</tr>
<tr>
<td>No manipulation</td>
<td>Cohort study (follow subjects over time)</td>
<td>Medical record review of patients treated for vitamin D deficiency.</td>
</tr>
<tr>
<td>Often paired with a causal hypothesis, but cannot provide strong support due to lack of controls</td>
<td>Case-Control Study (compare subjects with and without a disease, look for predictors)</td>
<td></td>
</tr>
<tr>
<td>Focus is placed on developing and testing a “model” of the problem of interest</td>
<td>Cross-Sectional Study (make observations about groups at the same time point)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Case Report (review of a single unique clinical case)</td>
<td></td>
</tr>
</tbody>
</table>


\(^6\) Adapted from: “Fundamentals of Research Design” Presented by James Paulson, PhD
Design Characteristics to Consider

Retrospective vs. Prospective
In a prospective study design, the investigator defines the sample and measures predictor variables before outcomes have occurred. In a retrospective study design the investigator collects data about predictor variables after the outcomes have occurred. 7

Blinding
In a multi-arm study, blinding is used to limit possible bias that might occur while conducting the study and interpreting results. In a single-blind trial, the research subjects do not know to which study arm they have been assigned. In a double-blind trial, investigators are also in the dark. This keeps subjects and investigators from letting their expectations influence their assessments.

Randomizing
Random assignment is used in multi-arm studies to limit bias that might occur during subject selection and study arm assignment. This prevents errors like assigning the healthier subjects to the experimental arm.

Controls
Controls are needed as a comparator group to show evidence of a causal relationship.

Choosing variables

Predictor variables vs. Outcome variables
A predictor variable (or independent variable) is a study variable that exists prior to the experiment. In experimental designs, this is the study intervention (i.e. study drug). Outcome variables are those that will be affected by the predictor variables and then measured.

Types of Variables

Qualitative data
- Nominal:
  - Categorical data
  - No ranking
  - No incorrect choice
  - Ex: Gender, blood type, dead/alive
- Ordinal:
  - Categorical data
  - Can be ranked
  - Cannot be used in mathematical operations
  - Ex: Staging in breast cancer, rating on a scale

Quantitative data
- Continuous:
  - Numeric data
  - Can be used in addition and subtraction but not useful in multiplication and division
  - Can have fractions or decimals
  - Ex: Temperature, weight, height, blood pressure, salary
- Discrete:
  - Numeric data
  - Can be used in all mathematical operations
  - Integers only, cannot have fractions or decimals
  - Ex: Number of children, frequency of visits

**Choosing the study subjects**

Proper selection of study subjects is a vital component when designing your study. The sample should be representative of the total population being studied. An improper selection of study subjects influence the results and interpretation of them. Sampling procedures should be explained so that the generalizability of the findings can be determined.

**Finding Sample Size**

**Sample vs. Population**

A population is the entire group that is affected by the problem being studied (ex., all pediatric asthmatics). The sample is the group of subjects that is available to study (ex., pediatric asthmatics seen by CHKD in January 2010). Ideally, the sample will be representative of the population. Using a representative sample increases the validity of the findings of a study.

**Sample Size and Effect Size**

The number of subjects needed to detect the smallest worthwhile effect. Effect size is the size of association you would like to be able to detect in the sample.

**Alpha, Beta, and Power**

Alpha is the maximum probability of making a type I error. It is usually set at 0.05. Beta is the probability of making a type II error (usually 0.2). Power is the probability of rejecting your null hypothesis. When interpreting the results of an experiment that found no significant difference, you need to ask yourself how much power the study had to find various hypothetical differences (had they existed).

**One-Tailed vs. Two-Tailed Tests**

A one-tailed test is used if you are interested only in the direction of the association between the predictor and outcome variables. For example, you want to know if treatment A is better than treatment B. A two-tailed test is used if you want to know whether an association exists. For example, you want to know if treatment A is better or worse.

**Bias and Errors**

**Statistical Errors**

A Type I error (false-positives) occurs when you conclude that there is a statistically significant effect when, in fact, there is not. A Type II error (false-negatives) occurs when you conclude that there is no statistically significant effect, but the treatment was really effective.

**Bias**

Bias is a flaw in the design, conduct, or analysis of a study.

**Confounding**

Confounding is a type of bias that occurs when the researcher fails to take into account for variables other than the predictor variable leading to an incorrect or biased estimate of the measure of effect. For example, an investigator concludes the percentage of gray hairs is associated with the risk of heart attack. The investigator did not take into account age, leading to biased results.

**Selection Bias**

A type of bias introduced into your study by the way in which participants are selected from the population. For example, the treatment being studied might be given to most severely ill patients, with poor results. The results from this study are not generalizable to patients who are not sick.

**Information Bias**

A type of bias introduced into your study whenever there are errors in obtaining information on your subjects.
**Things to Consider When Designing Your Study**

- Will the study design address the study questions?
- What population(s) will be used to obtain your sample?
- What is the impact on your study if you make the eligibility criteria more or less stringent (e.g. cancer stage, co-morbidities)?
- Will changing the eligibility criteria increase or decrease subjects from certain groups (e.g. race)?
- What kind of bias is likely?
- Are all potential confounding factors accounted for?
- How easy will it be to collect the data?
- Has the outcome, including how and when it is to be measured, been specified?
- How likely are the results from your study to lead to changes in clinical practice?
- Are there less time consuming ways to obtain the same knowledge?

**Helpful Resources**


Grimes D, Schulz K. An overview of clinical research: the lay of the land. Lancet 2002; 359: 57-61. [http://www.sciencedirect.com/science?_ob=MImg&_imagekey=B6T1B-44XVR4B-14-1&_cdi=4866&_user=960061&_pii=S0140673602072835&_origin=search&_coverDate=01/05/2002&_sk=996400699&view=c&wchp=dGLzVlz-zSkWA&md5=ef291d501002d9d11389aa58c8f0da5c&ie=/sdarticle.pdf]
Common data collection methods for students

These characteristics can be mixed and are not exclusive of each other.

<table>
<thead>
<tr>
<th>Methods</th>
<th>Description</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Quantitative</strong></td>
<td>Involves analysis of numeric data (survey)</td>
<td>Fixed nature produces results that enable hypothesis testing and are more generalizable</td>
<td>Limited scope of investigation, may miss important variables especially confounders</td>
</tr>
<tr>
<td><strong>Qualitative</strong></td>
<td>Involves analysis of words, pictures, objects, etc. (focus groups, art therapy analysis)</td>
<td>Flexibility provides opportunity for a more in-depth investigation</td>
<td>Absence of numeric data makes analysis difficult and time consuming</td>
</tr>
<tr>
<td><strong>Primary</strong></td>
<td>Collection of original data (original surveys, case study, observation, experiments, etc.)</td>
<td>More control for the investigator over the environment and data collected</td>
<td>More time consuming for the investigator</td>
</tr>
<tr>
<td><strong>Secondary</strong></td>
<td>Analysis of existing data (review of medical records, existing literature, etc.)</td>
<td>With less time, an investigator can get a preliminary look at a problem</td>
<td>Investigator must rely on the accuracy of the original data recorded, necessary data may not be available</td>
</tr>
</tbody>
</table>

**Surveys**

Surveys are often favored for their simplicity but there are some tips and common pitfalls you should keep in mind. As much as possible, use standard answer sets like multiple choice, true/false, or Likert scales. Open-ended text cannot be analyzed without extensive knowledge of qualitative methods.

If available, previously designed and validated tools are better than designing your own. If you are developing your own survey tools, have a statistician review it to ensure that your data will be useful for analysis. Also test any new tool on colleagues first to find inconsistencies. In either case, you should critically review your questions and responses to ensure that your tool will actually give you the information you need to assess your formulated aims and hypothesis.

**Online surveys**

Websites like Survey Monkey and Zoomerang have become very popular in recent years. They can be the best resource if your subjects will all certainly have internet access and your study only requires one questionnaire per subject. These websites provide descriptive statistics for your data, can export your data in Excel format. They also offer extended subscriptions that provide access to inferential statistical analysis of your data. If you are using one of these services, be upfront with the IRB about your recruitment methods and survey settings like identification of IP addresses, if applicable.

**Phone Surveys**

If you do not have in-person access to your subject population, you might consider a phone survey. However, these surveys require a great deal of time on your part in comparison to surveys left in a waiting room. Do not embark on a phone survey without being sure you have the time to complete the study.

**Interviews and focus groups**

Interviews and focus groups are used to gather detailed, qualitative information (e.g. person’s attitudes, preferences or behavior). Interviews and focus groups are usually conducted with the target population. Questions are generally open-ended and responses are documented.

**Interviews**

Interviews are conducted face-to-face or by telephone. Interviews involve trained interviewers visiting people to collect questionnaire data. It is a good approach for ensuring a high response
rate, and trained interviewers gather better quality data. Disadvantages to this approach are that it is often expensive, time consuming, and includes respondent bias. Telephone interviews are quicker and less expensive than face-to-face interviewing. However, only people with telephones can be interviewed and respondents can become irritated.

**Focus Groups**
A focus group is a guided group discussion with a group of seven to twelve individuals from similar backgrounds. Skilled moderators guide the group into increasing levels of focus and depth on key issues of the research topic. The sessions can generate new research ideas, identify possible issues in research projects, and provide valuable information in the population being studied.

**Tests and assessments**
Many times, research data is gathered on tests and/or assessments (e.g., Mini-mental status exam). They can include those that are standardized and those that are non-standardized.

**Standardized tests**
Standardized tests are valid (measure what they claim to measure) and reliable (produce the same answers each time). Use standardized tests only on the type of subject it is intended for (e.g., Geriatric Depression scale is not for college students). Standardized tests are usually accompanied by a manual which you should review any appropriate manuals before administering the test. A thorough literature search will help you find standardized tests, if available, for your research project.

**Non-standardized tests**
Non-standardized tests are not valid or reliable when they are administered. If an investigator changes a standardized test in any way, the test is no longer a standardized. The changes made should be discussed in the protocol or manuscript.

**Observations**
Observational research is used for selecting, watching and recording behaviors and characteristics of living beings and phenomena. Observation of human behavior can be classified as participant observation and non-participant observation.

**Participant Observation**
The observer takes part in the situation she observes. For example, a nurse hospitalized with a broken, now observes hospital procedures from within.

**Non-participant Observation**
The observer watches the situation, openly (e.g., shadowing a nurse with her permission during routine activities) or concealed (e.g., patient trying to obtain antibiotics without medical prescription), but does not participate.

**Document reviews**
Whether limited by time, cost, or information availability, document review may be the only option for your research project. Document review is also an excellent place to start gathering pilot data when developing a larger project. However, when you gather secondary sources, ask yourself:
- Where has the data come from? Who recorded it?
- Is it current? Is it complete?
- Is the source reliable?

**Paper-based sources:**
Patient’s medical chart, minutes from meetings, books, journals, periodicals, abstracts, directories, research reports, conference papers, annual reports, and internal records of organizations.

**Electronic sources:**
CD-ROMs, on-line databases, Internet, and videos.
Writing Your Protocol

What is it?
A protocol is a document that explicitly states the reasoning behind a research project and describes in detail the plan, or structure, of a research project. The preparation of a protocol is the most important stage in the research process because:

• It clearly establishes the question you want to answer.
• It encourages you to plan the project in detail, before you start.
• It allows you to see the total process of your project.
• It acts as a map to keep you and your team on task as you conduct your study.
• It is necessary if you need to apply for funding or ethical approval.

What should it say?
All protocols contain two types of information: (i) information about the problem to be investigated and (ii) information about the method of investigation.

The problem to be investigated:
- Background and rationale (with references)
- Preliminary data from literature
- Specific Aims/Objectives of the study

The method of investigation:
Research Design and Methods
- Subject population
- Study design
- Procedures
- Statistical Analysis Plan
Consent procedures (if applicable)
Risks to subjects/Minimization of Risks

Can you write a five-page protocol?
Keep to the point and try to say what needs to be said in five pages or less.

Page 1-2: Study Title
Investigators/Affiliations
Aims/Objectives
Background/Significance
Page 3-4: Design, Subject
Population
Methods
Statistical Analysis Plan
Page 5: Ethical Considerations
References

Helpful Websites
Rochester Subjects Review Board, Guidance for Investigators p. 29-36
http://www.rochester.edu/rsrb/documents/pdf/invguidance.pdf#pagemode=bookmarks&page=1

Western IRB Suggestions for Writing a Research Protocol
http://www.wirb.com/content/spo_guidelines.aspx
Writing a research protocol for the IRB

Instructions for using this guidance tool
When writing your research protocol for the IRB you need to include sufficient information to permit the IRB to assess the rationale, scientific merit, the potential risks to subjects, benefits to subjects, what the subject is being asked to do, how the data will be analyzed, and alternatives available to the subject.

A good protocol should be readable and detailed enough for a stranger to follow. It is a clear, well-written narrative of the study. It should be written so that an intelligent, non-expert reader can understand it. The reader should be able to identify:
1. Why your study is being done,
2. What your primary aims are, and
3. How your aims are addressed in the study plan.

Use bullets or numbering only for lists. The template below only uses bullets to show the different issues that should be addressed in each section. It is not intended to imply that you should respond to each bullet, nor should you only include the information from each bullet prompt.
Background and rationale
- Provide information regarding particular techniques/conditions that may be unfamiliar.
- Describe previous studies and their findings. How does this relate to your proposal?
- How does your proposed study add new information to the current body of literature?
- INCLUDE IN-TEXT CITATIONS FOR YOUR LITERATURE SEARCH!

Specific Aims/Objectives of the study
- What is your research question? What do you hope to learn?
- What is your hypothesis? What do you think the outcome will be?

Research Design and Methods

Subject population
- Where will you recruit your subjects?
- Who is eligible? List your inclusion/exclusion criteria.
- What are some important demographics of your subject population (age, gender, etc.)?
- If using vulnerable subject groups (under 18 or over 89, prisoners, etc.), provide justification.

Study design
- Is your study prospective or retrospective?
- Are you using a randomization scheme?
- Does your study include a control group or blinding?

Measurement
- What variables are you going to look at? How are you going to measure them?
- On what scale is each variable measured?
- Where applicable, have you defined values that represent “normal” or “abnormal” values?

Procedures
- What study tests/procedures will be performed? Differentiate from standard of care.
- Provide a step-by-step account of each stage of your study.
- What tools will you use to collect your data (forms, surveys, etc.)? Provide data collection sheets to support your protocol.

Statistical Analysis Plan
- At minimum, include a justification of the proposed sample size (power analysis).
- How will you analyze your data to answer your proposed research question?
- What outcomes will be measured?

Consent procedures (if applicable)
- Is consent required for this study?
- If so, how will you obtain consent from your subjects?
- Who will obtain consent?
- Can/will all subject consent be obtained in person?

Risks to subjects/Minimization of Risks
- What risks are present for subjects that participate in your study?
- Include risks such as breach of personally identifying information.
- How will you minimize these risks?

References
- What resources have you used to develop your research protocol?
- At minimum, you should consider using as many references as you have pages.
### Data Collection Variables Appendix

<table>
<thead>
<tr>
<th>Field name</th>
<th>Description of variable</th>
<th>Type of Data</th>
<th>Possible entries/ units of measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td>Gender of patient</td>
<td>Nominal</td>
<td>1=Male 2=Female</td>
</tr>
<tr>
<td>Pain</td>
<td>Pain score on 10 point scale</td>
<td>Ordinal</td>
<td>0=No pain 1=Slight pain 2=Moderate pain 3=Extreme pain</td>
</tr>
<tr>
<td>Age</td>
<td>Age of patient at time of admission</td>
<td>Continuous</td>
<td>18-89 (years)</td>
</tr>
<tr>
<td># of visits</td>
<td>Number of visits to ER in 2010 calendar year</td>
<td>Discrete</td>
<td>0-infinity</td>
</tr>
</tbody>
</table>

**Field name** should be limited to 8 alphanumeric characters (no spaces, commas, asterisks, etc.). If needed, you may use underscores.

**Description of variable** should be as descriptive as possible about when the value is measured if this is important.

**Type of Data** should be one of the following:
- Nominal (categorical)
- Ordinal (categorical)
- Continuous (numeric)
- Discrete (numeric)
- Open-ended text*

*Be careful when collecting data as text. This kind of information cannot be easily analyzed.

**Possible Entries/ Units of measure** varies depending on data type:
- For nominal and ordinal: assign numbers to possible responses (1=Tylenol, 2=Motrin, 3=Aleve, etc.)
- For continuous and discrete: list units of measure and range, if applicable, provide the format of the entry (mm/dd/yyyy, hh:ss, etc.)
- For open ended: use “text”
About the IRB

What is the IRB?
The Institutional Review Board, or I.R.B., is a committee housed within the EVMS Office of Human Subjects’ Protections. The committee has the fundamental charge of protecting the rights and welfare of human subjects recruited to participate in research activities. They are bound by the regulations developed and maintained by federal agencies that direct the ethical review and conduct of human subjects research in the United States.

Who is on the IRB?
The IRB is comprised of scientific, clinical, and non-scientific laymembers. Each IRB has a Chair, Vice-Chair, voting, and non-voting members.

When do I need IRB approval?
The EVMS IRB provides review of all human subjects research AND requests for “not human subjects research” determinations. In general, as clinicians, you will need to submit to the IRB when you are doing a systematic review that is not for clinical purposes.

Research is....
a systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Human subjects are....
living individuals about whom an investigator (whether professional or student) conducting research obtains:
(1) Data through intervention or interaction with the individual, or
(2) Identifiable private information

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

Always make sure any research you are asked to conduct has the appropriate approvals and that you are added as an approved research team member!

August 2010
Levels of Review

<table>
<thead>
<tr>
<th>Not Research/Not Human Subjects Research</th>
<th>Exempt</th>
<th>Expedited</th>
<th>Full Board</th>
</tr>
</thead>
<tbody>
<tr>
<td>Some examples are:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Studies of deidentified data/tissue</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Studies of cadaveric tissues</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Research on decedents</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Most surveys (except in children)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Most retrospective reviews</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Some studies of identifiable tissue/data</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Clinical trials</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Studies with risks to vulnerable populations</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

What do I submit to the IRB?

| • Description of study procedures and data/tissue sources | • Application Form (includes Abstract) |
| • Cover letter requesting this level of review | • Complete Protocol |
| • Research Tools (data collection sheet, questionnaire, etc.) | • PHI Waiver (if accessing PHI without patient authorization) |
| • Other supporting documentation | • Consent Form |
| | • Waiver of Consent, if requesting |

How long does IRB approval take?

The actual amount of time approval will take, depends on several factors:

- The timing of your submission in the review cycle
- The complexity of your study design
- The effort put into writing a concise, clear research plan
- Your knowledge of the requirements for IRB submission
- Your timely response to any requests for revision or clarification
- Verification that all members on your study team have completed Human Subjects Research Training

You should expect the IRB process to take 4-6 weeks from the time you initially submit to the IRB. This does NOT include the time that you have worked preparing for submission.

How do I know when I am approved to begin my project?

You are approved if...

- You receive a signed, original letter with the phrase “you may initiate your study”, AND
- You receive a stamped copy of your IRB Application form, AND
- You receive stamped copies of your consent forms (if you have them).

Be sure to review your approval letter VERY carefully as it may include specific stipulations for conducting your study. It will also contain an expiration date by which you must update the IRB on the progress of your study and either request a continuance or a closure of your study.
Other IRBs and committee reviews

If the project will be carried out in full at another institution, ALWAYS start with their IRB process first. Once you receive that approval, you should submit those documents to the EVMS IRB along with our Application Form. If subjects will be enrolled at EVMS but you also require approval of another institution, you should contact the IRB office to discuss which approval process should occur first.

If you have affiliations with entities other than EVMS, those entities may also require IRB approval or other research approvals for your project. (Example: CHKD, Navy, etc.)

When doing research at Sentara Hospitals or CHKD, be sure to find out about any hospital committees that review research in that hospital. Sentara Norfolk General Hospital, for example, has its own Medical Affairs Committee (MAC) and a Medical Executive Committee.

Be sure to account for these additional reviews when planning your study!!

How do I contact the EVMS IRB?

The Office of Human Subjects’ Protections is located on the first floor of Andrews Hall in Suite 128. The main phone number for the office is (757) 446-8423. You can also email questions to IRB-INFO@evms.edu.
IRB Forms

The IRB has many forms that you may or may not need for your submission. Here is a helpful guide for understanding which forms you might need. If you are unsure, always contact the IRB for guidance.

<table>
<thead>
<tr>
<th>Forms used before initial review</th>
<th>Purpose</th>
<th>When do I use it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use of PHI Application</td>
<td>Request to use PHI for research development purposes</td>
<td>Used when an investigator needs to access PHI to determine whether a study is feasible, such as determining the number of eligible subjects</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Forms used at initial review</th>
<th>Purpose</th>
<th>When do I use it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application for Approval of Research Involving Human Subjects</td>
<td>Request to conduct research involving human subjects.</td>
<td>All requests except requests for “not human subject” or “not research” requests</td>
</tr>
<tr>
<td>Investigator Assurance</td>
<td>Agreement of the investigator to abide by applicable rules and regulations.</td>
<td>The first time you are a research team member. Expires after three years.</td>
</tr>
<tr>
<td>IRB Fee Waiver</td>
<td>$1,500 IRB fee waiver request</td>
<td>May be used for unfunded studies requiring Full Board Review</td>
</tr>
<tr>
<td>Waiver of Authorization for PHI</td>
<td>Requests waiving authorization requirements when accessing PHI for research purposes.</td>
<td>When conducting medical record review for research purposes without subject authorization</td>
</tr>
<tr>
<td>Waiver of Consent Request</td>
<td>Requests waiver of consent requirements for non-exempt studies when subject consent may not be obtained</td>
<td>When conducting non-exempt research in which the investigator believes consent is not possible or will affect study outcomes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Forms used after a study is approved</th>
<th>Purpose</th>
<th>When do I use it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amendment Form</td>
<td>Requests a change to any IRB-approved document</td>
<td>Required when submitting any changes for approval</td>
</tr>
<tr>
<td>Continuing Review Form</td>
<td>Request for continued approval of an IRB-approved study</td>
<td>Required at least annually for non-exempt protocols</td>
</tr>
<tr>
<td>Close Out Form</td>
<td>Notification to the IRB that an IRB-approved study is closed</td>
<td>Submitted at the completion of the study. No data collection or analysis may occur once this form has been submitted.</td>
</tr>
<tr>
<td>LOCAL - Serious Adverse Event*</td>
<td>Notification to the IRB a serious adverse event that occurred within the EVMS local study population</td>
<td>Submitted when a serious adverse event occurs in an EVMS subject</td>
</tr>
<tr>
<td>NON-LOCAL - Serious Adverse Event*</td>
<td>Notification to the IRB a serious adverse event that occurred at another site</td>
<td>Used in a multi-site trial when an SAE occurs at a non-EVMS site, but is related to the same study being conducted at EVMS</td>
</tr>
</tbody>
</table>

*see EVMS IRB SOPS for definition of SAE, Local and Non-Local
What is IRB Training?

All investigators and their research team members who engage in human subjects research must complete human subjects protections training.

A research team member is anyone working on any part of a research project that required IRB review. All persons, including residents, students, coordinators, and data management, are considered team members if their effort contributes to a study.

EVMS uses a web training website offered through the Collaborative Institutional Training Initiative (CITI).

Why is it so important?

Research design — You will learn about study designs commonly used in clinical and social-behavioral research. This is especially helpful for junior investigators with little to no research experience.

Ethics — You will be introduced to some of the historical cases that influenced the development of research ethics as a field of study. Learning this history is critical for understanding the need for federal regulation of human subjects research.

Regulations — You will read about the many federal regulations that create the framework for ethical research. You will learn what an IRB is and why you need their approval for your project. Gaining an understanding of the scope of these regulations will limit your “culture shock” as you enter the world of federally regulated research.

How do I complete Human Subjects Research Training?


If you have never completed training using the CITI system, follow the instructions below for creating a new account.

If you have used the CITI system to complete training at another institution, contact Thomas Abbott in the Office of Research to find out about changing your institution and learning group.
Informed Consent

In 1947, the Nuremburg Code was written in the wake of egregious war crimes committed by Nazi physician researchers. This code sets forth ten elements of ethically conducted research and remains one of the most important documents that guide ethical research today. Of primary concern following the Nazi trials was the concept of “informed consent”, the idea that one must not be coerced or forced to participate in any research against his or her own will.

Informed consent in observational studies

It is imperative that new investigators understand the importance of informed consent as it relates to research. Regulations guiding research differ from laws that govern clinical care. It is critical to be aware that even standard of care treatment information is protected by human subjects research regulations when that information is being accessed for research purposes. In observational studies, such as chart reviews, IRB review is required and only the IRB can waive any applicable requirements for obtaining subject informed consent.

The process of informed consent

The process of informed consent is one of the most important parts of planning a research study. It is important that human subjects exercise their right of free will in making the decision to participate. It is equally important that subjects be given the correct information, comprehend what is being said, and read and have the time to make their own decision about participation.

The following should take place during the consent process:

1. Review of recruitment materials
2. Verbal instructions
3. Provision of written material
4. Questions/answer sessions
5. Adequate time for the potential subject to consider participation
6. Agreement by documented signature

Prospective participants may elect to not sign the consent form at the initial time of the consent discussion. It is their option to take the consent form home and discuss it with family and friends. However, prospective subjects may not participate in the study until they have signed the consent form.

Subjects must be informed that it is their right to withdraw from a study at any time. The consent form must be read to any subjects who cannot read. Likewise, for subjects who do not read English, the consent form must be read and signed by an interpreter in a language the subject comprehends. In cases where the potential subject cannot read the consent form, it must be read to the individual and a witness signature is required on the form. This signature indicates that a witness was present during the reading/interpreting of the consent form and that it was presented in a manner that was comprehensible to the subject.

Children and other vulnerable subjects may need information presented as simply and straightforwardly as possible.

One or more (as appropriate) of the Subject Consent Form templates in the EVMS IRB SOPs must be customized with details of the study, approved by the IRB, and used during the consenting process. These forms are available at: http://www.evms.edu/research-home/standard-operating-procedures-sops.html
Analyzing Your Data

**Descriptive Statistics**

This type of analysis only DESCRIBES your sample by summarizing and displaying an overview of your data.

<table>
<thead>
<tr>
<th>Measures of Central Tendency:</th>
<th>Measures of Dispersion:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean: the average of all the scores in a dataset</td>
<td>Range: the difference between the highest and lowest</td>
</tr>
<tr>
<td>Median: the value separating the upper and lower</td>
<td>value in a dataset</td>
</tr>
<tr>
<td>halves of the dataset (aka the 50th percentile)</td>
<td>Variation: the relative difference between the data</td>
</tr>
<tr>
<td>Mode: the most frequently occurring value in a dataset</td>
<td>points in a set and the mean of the data set</td>
</tr>
<tr>
<td></td>
<td>Deviation: this tells us how widely distributed scores are from the mean</td>
</tr>
</tbody>
</table>

**Inferential Statistics**

Analysis of your sample actually enables you to INFER something, or draw conclusions, about the general population. Below is a list and table of commonly used inferential statistical tests.

- **t-Test**: The t-test is used to compare two means.
- **Mann-Whitney**: the non-parametric equivalent to the t-test
- **Analysis of Variance (ANOVA)**: used to compare the means of three or more groups simultaneously
- **Kruskal-Wallis**: the non-parametric equivalent to ANOVA
- **Chi-square**: used to compare proportions between groups (pass vs. fail)
- **Friedman**: used to compare observations repeated on the same subjects (non-parametric)

**Pearson Correlation**: used to find out the degree to which two variables are related.

**Spearman’s Rank Correlation**: the non-parametric equivalent to the Pearson test.

**Regression Analysis**: The main purpose is to make predictions. Linear regression is used to predict a continuous outcome variable from a continuous predictor variable. Logistic regression is used to test the effect of the predictor on a binary outcome variable (pass vs. fail).

**Survival Analysis**: used to describe, explain, or predict the occurrence and timing of events

<table>
<thead>
<tr>
<th>Summary of Common Statistical Tests</th>
<th>Type of experiment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Two treatment groups consisting of different individuals</td>
</tr>
<tr>
<td>Interval (and drawn from normally distributed populations*)</td>
<td>Unpaired t test</td>
</tr>
<tr>
<td>Nominal</td>
<td>Chi-square analysis of contingency table</td>
</tr>
<tr>
<td>Ordinal†</td>
<td>Mann-Whitney rank-sum test</td>
</tr>
<tr>
<td>Survival time</td>
<td>Log-rank test or Gehan’s test</td>
</tr>
</tbody>
</table>

* If the assumption of normally distributed populations is not met, rank the observations and use the methods for data measured on an ordinal scale.

† Or interval data that are not necessarily normally distributed.
**Important Concepts**

*Parametric vs. Nonparametric:*
Parametric statistics make certain assumptions about the population from which your sample was drawn. Parametric statistics are used for normally distributed samples. Nonparametric statistics make no assumptions about the distribution from which your sample was drawn. Nonparametric statistics are used when your sample does not meet parametric test assumptions.

*Confidence Interval:*
A range of values within which the true population value can likely be found. Confidence intervals are also analogous to p-values.

*Statistical Significance:*
A p-value of <.05 is often accepted as “statistically significant” in the medical literature; but this is an arbitrary cut-off. A cut-off of p<.05 means that in about 5 of 100 experiments, a result would appear significant just by chance (“Type I error”).

*Statistically significant does not mean that it is important or interesting.*
Surprisingly, a result that is not statistically significant may turn out to be very important.

*Statistical vs. Practical Significance:*
If a result is statistically significant, there are two possible explanations: (1) The populations are identical, so there really is no difference (Type I error) or (2) The populations really are different, so your conclusion is correct.

While a finding may be statistically significant it may not be practically significant. You should examine the usefulness of the results to determine its practical significance. When determining practical significance you should consider the following:
- The quality of the research questions
- The relative size of the effect
- Sample size
- The importance of the finding
- Confidence intervals
- The link to previous research

*Statistical vs. Clinical Significance:*
While a finding may be statistically significant it may not be clinically significant. Clinical significance refers to the practical or applied value or importance of the effect of the findings—that is, whether the findings make a real difference to the population being studied.

*Helpful Resources*
- The Little Handbook of Statistical Practice: [http://www.tufts.edu/~gdallal/LHSP.HTM](http://www.tufts.edu/~gdallal/LHSP.HTM)

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9 *ibid*
Poster Presentation Tips

Drafting your poster

- Use a layout that can be easily followed when you are not standing with your poster. It is helpful to use Background, Methods, Results, and Discussion sections in column format. Follow conference guidelines for the inclusion of an abstract (if applicable).
- Use a template similar to the case study template available at: http://www.evms.edu/evms-office-of-marketing-communications/logo-posters.html
- Include overviews of the background that led you to do your study and the methods used in your study.
- Make sure you have clear guidelines from the conference venue on poster size requirements.
- Letters when enlarged should be at least ½ inch tall. Tables and figures should be clear and easily seen from a distance of 3-4 feet.
- Have at least two colleagues proofread your poster.

Preparing for your presentation

- Practice your presentation in advance for flow and timing. Get feedback from colleagues.
- Anticipate questions and rehearse answers, especially “How does this work differ from the other research in this area?” or “What makes this case so unique?”

Presenting the poster

- Have a one-sentence “hook” that captures the attention of a viewer that stops at your poster.
- If they stay, give an overview of your work in 3-4 minutes.
- Ask the viewer if they have any questions.
- Listen carefully and wait for the person to finish the question.
- Rephrase the question, answer it and then ask if you have answered the question
- Thank your viewer for visiting.

Tips for presenting

- Talk to the viewer, not the poster! Make eye contact.
- Avoid jargon and acronyms when possible.
- Speak clearly and slowly; do not go into too much detail unless asked.
- Give people time to look at the poster; stand to one side but stay in the picture.
- Keep your hands out of your pockets. Point to specific parts of your poster to show the progression of your presentation.
- If more viewers arrive halfway through your presentation, finish for the earlier group first.
Oral Presentations of Research

When asked to give a presentation, you will almost always have the option of giving a projected PowerPoint presentation. This is an excellent option for new clinicians. Projected slides keep you on point and provide you the tools to highlight important items with visual aids.

Designing Your Presentation

How a presentation is designed has a significant effect on how the information it contains is conveyed, perceived and retained. These tips are intended to help you make the most effective use of presentation technology.

A Presentation is Not a Paper

Pick out the most important and interesting findings in your research, and present that in an entertaining way. Do not overload your presentation with too much information. It is better to leave topics out and present what you do have in a calm and understandable way, than it is to pack in as much as you can and lose your audience along the way.

Slides Should Be Sparse

Slides should support what you are saying, not be the whole story. Include images, animations, and text on slides that emphasize the point you are making, but are not complete in themselves. Try to stick with the 666 Rule.

Number of slides to use

A helpful rule of thumb is one content slide per minute of presentation. Here is a helpful guide for a 15 minute presentation. Use the information in your research protocol to create these slides:

<table>
<thead>
<tr>
<th>Study title, authors, presentation venue, and date</th>
<th>Background and Rationale</th>
<th>Aims and objectives of the project</th>
<th>Population Studied and Study Design</th>
<th>Measurements</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2-3</td>
<td>4-5</td>
<td>6-7</td>
<td>8</td>
</tr>
<tr>
<td>Procedures</td>
<td>Results and Data Analysis</td>
<td>Discussion/Implications for Care</td>
<td>References</td>
<td>Acknowledgements</td>
</tr>
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<td>10-13</td>
<td>14-15</td>
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</tr>
</tbody>
</table>

Images

If you can say it with a picture, do!
Images may appear grainy when projected on a large screen. Zoom in on the image as much as your presentation software will allow (400% in MS PowerPoint). If it looks okay, it should be fine. If it looks grainy at all, choose a new picture. Sometimes it is better to recreate tables, graphs, and flowcharts, rather than using images from the original source. This is time consuming but worth it. Cite or acknowledge any images that are copied from the web or other source.

Slide transitions and animations

Keeping an audience awake is a tough job with some topics! Most presentation software enables you to add eye-catching motion to your slides. Be careful, though, not too overdo these. Too many of these take additional work on your part in the presentation. Clicking through each transition is awkward. It also makes your audience more likely to pay attention to the moving slides instead of the speaker.

The 6-6-6 Rule

No more than:
6 bullets per slide
6 words per bullet
6 text slides in a row
Practicing and Giving Your Presentation

Practice Makes Perfect
Do not just write down your presentation, and wait for the big day; get up in front of a wall and deliver that sucker, over and over until it flows. If after practicing a presentation you find that you are not finishing on time, cut something out. If you do not, the time shortage will make you nervous, and — if you do go overtime — the whole room will be annoyed at you.

Do Not Be a Comedian
Unless you are a naturally funny person, and are confident telling a joke, don’t do it. At least, don’t plan to do it. You might be lucky and say something funny during your presentation, but if you plan a big joke, and it falls flat, your confidence could be completely shot. And what’s more, before you deliver the joke, you will probably be very nervous about it. Leave the jokes to Dave Letterman.

Tell a Story
If you can convey at least some of what you have to say in a story format, people will be much more likely to listen. Say things like, “We were interested in this topic because…. We decided to investigate further by looking at…. We found that....”

Engage the Audience
Make a conscious effort to look into the audience whenever you get the opportunity. In a small room, make eye contact with at least one person in each section of your audience. Your audience should feel that you are talking to them rather than talking to yourself.

If you do not have Microsoft PowerPoint
Most often, your presentation venue will be using Microsoft PowerPoint to project your slides. If you do not have Microsoft PowerPoint on your computer, you may wish to use one of the following options to save your file in a compatible format.

OpenOffice Impress
OpenOffice is a downloadable suite of office software containing tools for creating word processed documents, presentations, spreadsheets, databases, and other file types. IMPORTANT: When saving a presentation created in Impress you must save as a PowerPoint 97-2000 file type. You can download OpenOffice for free at OpenOffice.org.

Google Docs Presentation
Another no-cost option for creating presentation, if you have a Google account, is the Google Docs Presentation tool. Presentations created in Google Docs are no frills presentations. You only have access to basic tools for adding font and pictures. The benefit of this type of file is that if you have internet access to GoogleDocs, you will have access to your presentation.

Macintosh Keynote
For Mac users, remember to save your file in the file type that will be available when you present, usually Microsoft PowerPoint.

Information adapted from:
“Tips for Presenting Like a Prince” by Drew McCormack
http://www.macresearch.org/tips-presenting-prince

“EVMS Logo & Branding: PowerPoint Tips”,
http://www.evms.edu/evms-office-of-marketing-communications/powerpoint-tips.html