Introduction to Research
Statewide Campus System—OB/GYN Orientation Bootcamp
College of Osteopathic Medicine
Michigan State University
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Disclosures

Financial:
Presently Professor Emeritus, Dr. Jarski was a salaried Full Professor in the Oakland University School of Health Sciences with a Secondary Appointment in the School of Medicine.

He receives payments as a Consultant in Medical Research and Statistics from Beaumont Health and the Henry Ford Health System.

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Committee Member and former Chair of the National Wellness Institute Council on Wellness Accreditation and Education (CWAE).

Objectives

• Plan the steps needed for completing your program’s research requirement

• Explain how the number of patients needed and statistical power relate to your study

• Identify sources of research ideas and support
You Are Here

Getting started
↓
Identify your area of special interest
↓
Develop your project idea
↓
Exploratory lit review
↓
Study idea/objective/hypothesis
↓
Methods (number of subjects, instruments, procedures, statistical analysis)
↓
IRB application
↓
IRB approval
↓
Data collection
↓
Analysis
↓
Add results, conclusion and discussion and write up as poster/paper/publication

How to Begin

1. Know the requirements of your residency program and start planning now

2. Decide your general topic (area of special interest) and be alert for clinical questions that pop up

3. Write down questions or ideas immediately and do a brief lit review (eg, a phone Google)

4. Refine and rewrite a promising idea, question or hypothesis . . . as you write, you’re getting a jump start on your proposal!
The curriculum must advance residents’ knowledge of the basic principles of research, including how research is conducted, evaluated, explained to patients, and applied to patient care. (Core) IV.B.2.

Residents should participate in scholarly activity. (Core) IV.B.3. The sponsoring institution and program should allocate adequate educational resources to facilitate resident involvement in scholarly activities. (Detail) Gynecologic Oncology IV.B. Fellows’ Scholarly Activities

Resident/Fellow Scholarly Activity Updated 3/2017 ©2017 Accreditation Council for Graduate Medical Education (ACGME)
1) **Journal Publications** (case report or research project completed in the last academic year or in progress that will be submitted to a peer-reviewed journal recognized by the NLM);

2) **Conference Presentations** (abstracts, posters and presentations given at international, national or regional meetings);

3) **Other Presentations** (grand rounds and invited professorships, materials developed, or other work presented in non-peer reviewed publications, including peer-reviewed but not recognized by NLM);

4) **Textbook/Chapters** (chapters or textbooks published);

5) **Grant Leadership** (grants for which faculty member had a leadership role (principal investigator, co-principal investigator or site director);

6) **Leadership or Peer-Review Role** (active leadership role such as serving on committees or governing boards in national medical organizations, or served as reviewer or editorial board member for a peer-reviewed journal);

7) **Education Leadership/Materials** (teaching responsibility for seminar, conference series, or course coordination, such as arrangement of materials, assessment of participants' performance for any didactic training within the sponsoring institution or program (not a single presentation or lecture).
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To Get Started, Here Are Some Sources of Project Ideas

Keep an eye on clinical practice situations
Keep an eye on medical literature and medicine “in the news”
Join an on-going or TBC project
Ask preceptors/mentors
QA
OMT
Issues in practice or professional role
Medical education
Patient education
Attitudes/perceptions of patients and professionals
Community hospital practice
New technology, procedures or drugs
Off-label drug use
Economics and cost-effectiveness
Differences in practice by specialty
Doctor-patient, preceptor-resident interactions
“Suggestions for future studies” in journal articles
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Reviewing the Lit -- Selecting the Best Search Engine

**Google Scholar**: to find only scholarly resources on Google.

**PubMed**: from the U.S. National Library of Medicine, find full-text medical journal articles, >19,000,000 million available.

**MedlinePlus**: a service of the U.S. National Library of Medicine, a powerful search tool, dictionary for finding authoritative health information.

**Academic Index**: a scholarly search engine and web directory made for college students, websites in this index selected by librarians, teachers and educational consortia.

**Others…**

Reliable organizations, e.g., NIH, ACS, AHA
Preference for file extensions like .nih, .edu

(Meza and Passerman, 2011)

“You’re on your own…”

Wiki anything
Other open access sources
Articles with few, no or questionable references
Most commercial sources
Sites with an obvious agenda
e.g., [www.quackwatch.com/](http://www.quackwatch.com/)
[www.thinktwice.com/](http://www.thinktwice.com/)
A Librarian Is an Incredible Resource!

Getting started

↓

Identify your area of special interest

↓

Develop your project idea

↓

Exploratory lit review(s)

↓

Study idea/objective/hypothesis

↓

Methods (including number of subjects, instruments, procedures, statistical analysis)

↓

IRB application

↓

IRB approval

↓

Data collection

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Analysis

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Formulating Your Question

- Is it important to patients? (POEM—Patient-Oriented Evidence that Matters)
- or is it important for furthering the field (e.g., answering a research question, determining the mechanism of action)? (DOE—Disease-Oriented Evidence)
- A DOE may be OK
- It should be clear and concise
- It should be answerable
- “Most important clinical questions are initially thought of in the examining room or at the bedside.”
The Null Hypothesis ($H_0$) and the Alternative Hypothesis ($H_a$):

The “Ho” and the “Ha”

Null hypothesis ($H_0$) = a statement of no effect... there is NO difference (or relationship) between the variables being studied.

Alternative hypothesis ($H_a$) = there IS a difference (or relationship) between the variables being studied.

In Most Studies, We Use the Null Hypothesis ($H_0$)... as the “straw person”

that is, we disprove the null statement
How to Begin

5. Now you can start dealing with the technical details:
   - How many patients?
   - Define the control or reference group as necessary
   - Statistical analysis methods

You’re almost ready to complete your online IRB application.

Your IRB Application

Up to this point, the following is mostly achieved by the resident using preceptors and colleagues as mentors:
   - your name, co-investigators
   - project title
   - the problem
   - purpose (study objective, question or null hypothesis)
   - how you will obtain data and keep it secure

This is where most residents consult with a statistician:
   - methods (subjects, instruments, procedures and statistical analysis)
   - estimated number of patients needed ( = power analysis)
   - planned control or reference group
   - statistical methods

. . . basically, the IRB application is a brief project proposal, so you’re well on your way to completing your write-up!
Anatomy of a Study—They All Have the Same Overall Features

Introduction
- literature review
- problem
- purpose
  - study objective, question or
  - (null) hypothesis

Methods
- subjects, instruments,
  - procedures, statistical analysis

Results

Conclusions

Discussion

The problem, purpose and methods are needed for your IRB application.

Introduction
- literature review
- problem
- purpose
  - study objective, question or
  - (null) hypothesis

Methods
- subjects, instruments,
  - procedures, statistical analysis

Results

Conclusions

Discussion
And now a word about statistics...
The more patients in a study, the better the study.

A. true
B. false
Statistical Power (Power Analysis)

\[ p \sim \frac{\text{a measure of variability}}{\text{number of patients}} \times \frac{1}{\text{effect size}} \]

A measure of variability is standard deviation (SD).

Effect size (\( \Delta \)) is \~ the difference in outcome magnitude between the intervention group and the control group:

\[ \text{e.g., } \frac{\text{average } \text{ treatment group} - \text{average } \text{ control group}}{\text{standard deviation}} \]

*This is a model, not necessarily a mathematically correct formula.

About sample size:

Antihypertensive A mean = 140.2 mmHg

Antihypertensive B mean = 140.3 mmHg

\((p = 0.01)\)

\[ N = 1,100 \]
GUIDELINES FOR ENTERING DATA ON YOUR SPREADSHEET

Here are some suggestions that will help you set up your Excel spreadsheet:

**You should use Excel for entering data which can be transplanted into the statistical software. When entering any kind of data, it would be helpful if everything is entered as a number. If you wish to include clinical notes or information for yourself or me, it is OK if you use a separate column just for this purpose.**

**Numerical (continuous) data (eg, mmHg, cm, mg/dl, etc.) offer a higher level of analysis and generally require fewer subjects to achieve statistical power. Obviously some data are categorical or non-numerical (eg, male or female; positive or negative; small, medium or large, etc.) and this is fine as well.**

**For numerical data, it's almost always better to enter actual numerical values (eg, age 45, 47, 78, 18, 33) rather than to bracket into categories.**

- - -

**Be certain NOT to email any information/data that could be used for identifying individual patients.**

**It's always a good idea to ask your statistician to review your spreadsheet setup before you enter actual data. Also, it is suggested that you do a “pilot” run by entering the data from a few subjects before finalizing your spreadsheet layout.**

Good luck on your project!
### Patient Data Entered on Excel Spreadsheet—Sample A

<table>
<thead>
<tr>
<th>MRN</th>
<th>Hospital Arrival Date</th>
<th>Hospital Arrival Time</th>
<th>Sex</th>
<th>Age</th>
<th>Comorbid Conditions</th>
<th>Description</th>
<th>Consult Service</th>
<th>Procedure Place</th>
<th>Procedure Date</th>
<th>Proc Start Date</th>
<th>Proc Start Time</th>
<th>ED LOS</th>
<th>Diagnosis</th>
<th>Complication</th>
<th>Complication Date</th>
<th>Hospital LOS</th>
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<td>DR</td>
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<th>CT read</th>
<th>Consult ENF</th>
<th>New abx start</th>
<th>Curr on abx</th>
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<th>Phy doing exam</th>
<th>Location/set PE findings</th>
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</tbody>
</table>
Some IRBs ask for the “study type”

A Hierarchy of Study Types*

- Meta-analysis
- Randomized, controlled trial (RCT)
- Cohort study
  - start the same → exposure → finish differently?
- Case-control study
  - Those with an outcome compared to those without the outcome
- Correlation study
- Case-series
  - No control group
- Case report (single case design)

*The Evidence-Based Medicine Working Group

Be Aware of Some Common Pitfalls in Your Proposal!

1. Are the subjects appropriate for the study’s purpose? (Consider: age, gender, inclusion and exclusion criteria, comorbidities, past medical/surgical hx)
2. Is a control or reference group proposed if needed? Will subjects be randomized?
3. Will the results be unambiguous?
4. What are the anticipated limitations of the study? possible biases?
5. Important references cited? reputable? timely? primary studies?
Extracting and utilizing electronic health data from Epic for research

Alex Milinovich and Michael W. Kattan

Abstract
Many institutions would like to harness their electronic health record (EHR) data for research. However, with many EHR systems, this process is remarkably difficult. We have been using our vast EHR system for research very effectively, with substantial research support and many publications. Herein we share our process and provide recommendations for others wanting to utilize their EHR data for research.
SCSC Research Support and Clinical Research Posters

Research Support
SCS has established a program of small amounts of research funding to help support resident research projects. These awards are only available to current SCS Residents or Fellows, and limited to one per project.

https://scs.msu.edu/sa/research/support/

SCS Research Poster Day
The MSUCOM SCS sponsors its annual Research Poster Day at the University Club on the MSU campus. Submissions will be accepted from MSUCOM medical students, SCS Residents and Fellows, and MSUCOM faculty.

https://scs.msu.edu/toolbox/research/

What is your answer
Why do clinical research?

A. You can apply the knowledge gained to your practice.
B. You become skilled in evaluating new medical information presented in studies you read, including understanding the statistics.
C. You become a recognized expert on your topic especially if it is presented or published.
D. It’s fun!
E. All the above

E. ALL THE ABOVE!
E. ALL THE ABOVE!

References


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