


# Research: An Introduction





# Learning Objectives

- Participants will be able to:
  - discuss what research is, why it is important, and how it is conducted
  - describe the research process including the IRB
  - list the CORE resources available.



# Overview

- Research: What, Why, and How
- Research Process
- Research Resources at the CORE

# Research: An Overview



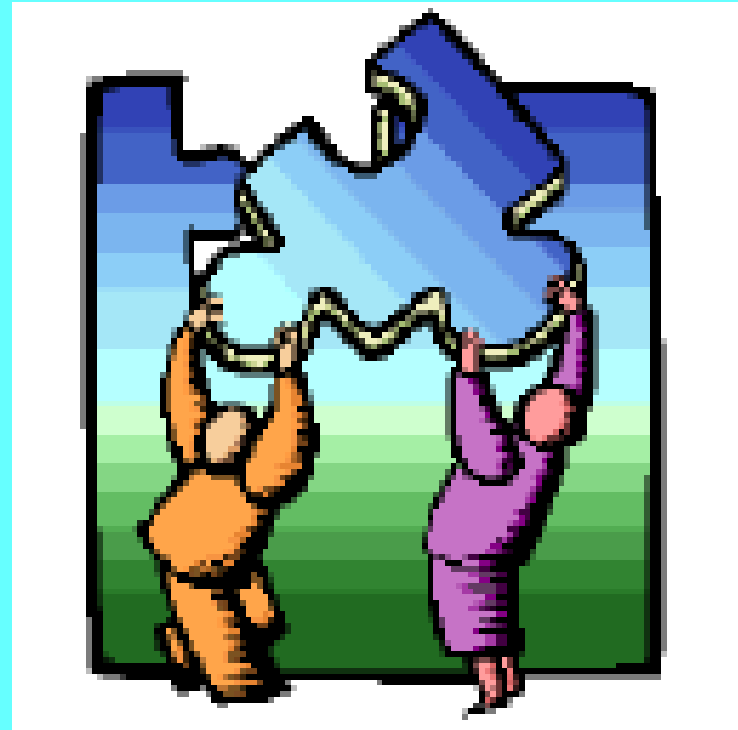


# What is Research?

- 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. It requires:

- A strategy or plan
- Critical thinking
- Motivation
- Diligence
- A good environment
- Organizational skills
- Permission
- Monetary support
- Common sense!



# Why Do Research?

- Clinical research drives evidence-based medicine, which in turn, impacts clinical practice.
- Professional development and growth depends on having adequate skills to:
  - Critically read and evaluate journal articles
  - Understand and engage in conference workshops and presentations.

# Why Do Research?, cont.

- Research is required by all specialty colleges.
  - Click [http://do-online.osteotech.org/index.cfm?PageID=acc\\_postdocstdspeclist](http://do-online.osteotech.org/index.cfm?PageID=acc_postdocstdspeclist) to check the AOA requirements specific to your specialty college
- Faculty positions require evidence of competency in research methods. Tenure criteria usually include research productivity.
- By mastering basic research skills, physicians will be better prepared to critically assess the veracity and integrity of published medical literature.
- The osteopathic voice needs to be present in the research arena.

# Why Do Research?, cont.

- 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.
- Research provides an active learning environment in which to obtain such experiences and to practice newly acquired skills.



# How is Research Done?

## Key Steps to Conducting Research Within the CORE System

- Grow your idea into a research question.
  - Residents → Program Director
  - Students → Assistant Dean
- Complete the CORE Short Form located at [www.ohiocoreonline.org](http://www.ohiocoreonline.org)
- Await further instructions from the CORE Research Office.
- Prepare a research protocol designed to address your question(s).

# How is Research Done?...cont.



- Contact the CORE Biostatistician to review methodology:
  - Sample space (size and composition)
  - Design and methodology.
- When notified by the CORE Research Office, prepare the necessary paperwork for IRB review process.
- Resident-based research projects are no longer required to go through a double-IRB review (there are rare exceptions).

# How is Research Done?...cont.



- Wait for IRB approval.
- Conduct your study
  - Recruit participants
  - Collect relevant data
- Analyze resulting data
  - Interpret analyses
- Transform protocol into a final paper for publication and disseminate research findings through posters and presentations.

# 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

# Navigating the IRB Process Within the CORE System

**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. There are exceptions, but only the CORE Research Director can make this determination for CORE-based projects.

# Points that Need to be Clear

- 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?

# FAQs and Answers

- What if the study is survey based?

- As a rule, yes, 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.

# FAQs and Answers, cont.

- 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.

# FAQs and Answers, cont.

- 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. Such case reports still must be reported to the CORE Research Director so that a letter of exemption can be issued to the investigator.

# FAQs and Answers, cont.

- 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.

# Data Safety Monitoring Boards (DSMB)



- 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.

**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

- 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).
- This means that subjects can withdraw at **ANY** time, without recrimination, penalty or repercussion.

# Ingredients of a Consent Form, cont.

- In order to facilitate good communication, be sure to keep the text simple. Write between an 8<sup>th</sup> and 10<sup>th</sup> 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.

# Ingredients of a Consent Form, cont.

- 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.

# Ingredients of a Consent Form, cont.

- 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.

# Resources: Support and Funding



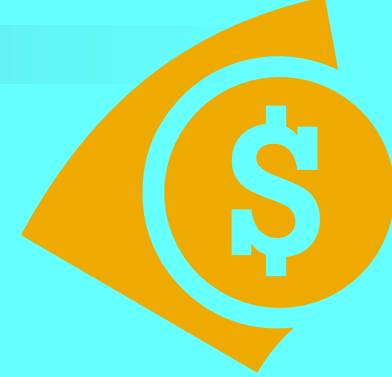
# CORE Research Support

- Methodological and statistical support
  - CORE Research Director: Joy Matthews-López, Ph.D., 415 Grosvenor Hall, OUCOM, Athens, OH 45701, (740) 593-2380 (phone), (740) 593-2320 (fax), [joy.matthews-lopez.1@ohio.edu](mailto:joy.matthews-lopez.1@ohio.edu) (e-mail)
  - CORE Biostatistician: Grace Brannan, Ph.D., 408 Grosvenor Hall, OUCOM, Athens, OH 45701, (740) 593-2325 (phone)
  - Statistical software packages with support manuals are currently available on 2 computers per CORE site. The software is titled SPSS®.

# CORE Research Support, cont.

- Faculty development support
  - Steve Davis, Ph.D., (740) 593-2190 (phone), [daviss2@ohio.edu](mailto:daviss2@ohio.edu) (email)
  - Robbin Kirkland, Ph.D., (614) 297-4130 (phone), [kirkland@oucom.ohiou.edu](mailto:kirkland@oucom.ohiou.edu) (email)
  - Olivia Sheehan, Ph.D., (740) 594-8302 x 4007 (phone), [sheehan@oucom.ohiou.edu](mailto:sheehan@oucom.ohiou.edu) (email)

# Funding Sources



## ■ CORE Research Committee

### □ Funds available

- Photocopying, licensing fees (for established survey instruments), advertising fees (for public awareness campaigns), travel due to data collection, travel due to research presentations (of CORE-sponsored or funded research) and postal expenses

### □ Requires a formal request to be filed with the CORE Research Committee.

## ■ External Funding

- Professional organizations, government agencies, private foundations.

# Final Reminder!

- Make a note of your residents' timeline. Tell them not to wait until the last minute to get started!
- Remember that ALL scholarly work needs to go through the CRD.



# Workshop Activity

- Using the FINER criteria, assess your research question:

Feasible	Yes/No
Interesting	Yes/No
Novel	Yes/No
Ethical	Yes/No
Relevant	Yes/No

# Workshop Activity, cont.

- Refer back to your research question:
  - Write down your hypothesis.
  - Identify what sources you would use.
  - Identify the type of study (case review, retrospective, prospective, meta-analyses) you plan to do and justify.
  - Think about your methodology (research design: interventional, observational, meta-analyses).
  - Discuss how you would prepare for the IRB.
- Any barriers to overcome – budget/time/resources?



# Summary

- Participants were able to:
  - discuss what research is and why it is important
  - describe the research process including the IRB
  - list the CORE resources available.