Integration of Evidence Based Inquiry and Research (EBIR) into the LSI Curriculum
An Overview

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Ginny Bumgardner MD PhD
Associate Dean for Research Education
Professor of Surgery
Comprehensive Transplant Center,
OSUWMC

Improving People's Lives Through Innovations in Personalized Health Care
EBIR Learning Objectives

1) Define EBIR
2) Identify the 4 components of EBIR in LSI
3) Describe the role that patient care has in generating research questions
4) Describe the critical role of scientific discovery in advancing clinical practice
5) Describe the basis for EBIR in physician training
6) List research literacy skills acquired through research training which are included in the research advanced competency
1. Rationale for EBIR in LSI:
   - LCME ED-17A
2. LSI, EBIR Team & Philosophy
3. The Patient Care & EBIR Continuum
4. EBIR 4 Key Components
5. Competencies in Clinical & Translational Research
6. EBIR in Pts 1, 2, and 3 of LSI
7. Advanced Competency in Research
8. EBIR Pt 1 Content
ED-17-A. The curriculum of a medical education program must introduce medical students to the **basic scientific and ethical principles** of clinical and translational research, **including the ways in which such research is conducted, evaluated, explained to patients, and applied to patient care.**
The EBIR Team

- Co-Chair, Ginny L. Bumgardner MD PhD
- Co-Chair, John Davis PhD MD
- Courtney Lynch PhD MPH
- Stephanie Schulte, MLIS
- Carol Powel Librarian (ret)
- Troy Schaffernocker MD
- Ad hoc Faculty
- Medical Student Focus Groups

LSI EBIR Pt. 1 Team Leads
EBIR: Why? & Who?

- Clinical encounters should lead to important research questions
- Scientific discoveries (including new research tools) should be applied to important clinical questions
- Biomedical Research contributes to existing evidence based clinical care
- Patient participation in research through clinical trials offers patients advanced treatment opportunities
- Patients expect physicians and other caregivers to lead research which will improve health
- Development of critical thinking skills is necessary for physicians to become successful lifelong learners, even if they never wish to perform research themselves
The Continuum of Patient Care & Evidence Based Inquiry & Research
EBIR and Physician Training
Problem Solving
Health-----Disease-----Intervention-----Outcome & Assessment

In the new LSI……

- **Ask** Important Health Related Questions
- **Critical analysis** of the Status Quo
- **Learn** how to Develop an Action Plan to Answer the Question
- **Action** (Intervention/Research)
- **Analyze** the Results of the Action Plan
- **Communicate** the Conclusions

- **Inquiry**
- **Literature review**
- **Research Plan/Design**
- **Methods**
- **Critique**
- **Publications, Presentations**
EBIR
4 Components

1. Inquiry
   • Analytical Approach to the Biomedical Literature

2. Epidemiology/Biostatistics
   • Analytical Approach to the Biomedical Literature

3. Research Ethics

4. Research Literacy: Mentored Research Project
   ▪ Hypothesis Development
   ▪ Research Design
   ▪ Data Analysis
   ▪ Science Presentation/Writing

LSI

- LSI Part I, Year 1
- LSI Part I, Year 2
- LSI Part II, Year 3
- LSI Part I, Year 1
- Summer Research Experience between Year 1 and 2
- LSI Part III, Year 4, Research Advanced Competency
- 1 year LOA (Yr 2/3, Yr 3/4)
- Part-time throughout Years 1-4
Competencies in Clinical & Translational Research

I. Clinical & Translational Research Questions:
   Identify major clinical/public health problems and relevant translational research questions

II. Literature Critique:
   Identify/interpret/critique literature/assess state of knowledge regarding problem

III. Study Design:
   Design and write protocol for clinical/translational research study for peer review

IV. Research Implementation:
   Study Methods/Design/Implementation

V. Sources of Error:
   Laboratory, Clinical and Population Research Methods

VI. Statistical Methods & Analysis

VII. Biomedical Informatics
Competencies in Clinical & Translational Research

Research Ethics

VIII. Conduct of Ethically Responsible Research

Research Literacy

IX. Scientific Communication
X. Cultural Diversity
XI. Translational Teamwork
XII. Leadership (*including mentorship*)
XIII. Cross-disciplinary Training
XIV. Community Engagement
EBIR in Year 1, LSI Part I

- EBIR Overview (8.26.15)
- Epi/Biostats: Disease Frequency
- Epi/Biostats: Describing Data
- Epi/Biostats: Diagnostic & Screening Tests
- Intro to Inquiry
- Epi/Biostats: RCTs
- Epi/Biostats: Describing Data II
- CITI Research Ethics Training
EBIR in Year 1, LSI Part I

- Inquiry: Searching the literature for evidence
- Epi/Biostats: Describing Data II
- Epi/Biostats: Cohort Studies
- Epi/Biostats: Case-Control Studies
- EBIR Team-Based Learning
- Epi/Biostats: Interpreting Survival Curves
Year 3: LSI Part II and EBIR extensions in small group discussions, inpatient/outpatient rounds, journal clubs, specialty specific seminars

- Clinical Syndrome
  - GI Bleeding: Symptoms, Physical Exam, Evaluation, Diagnosis, Treatment Options
  - Etiology of the GI Bleed...Peptic Ulcer Disease...H pylori

EBIR Extension:
- Discovery of H pylori----→ Koch’s postulates, Standard of care, Nobel Prize 2005
- Current research on H pylori, mutagenesis, carcinogenesis, H pylori genetic evolution and host/microbe interactions
- Current research on H pylori and immunity
Year 4: LSI Part III
Advanced Competency in Research

- Research Literacy: Mentored Research Project
  - Background, Unanswered Question & Significance
  - Hypothesis Development
  - Research Design
  - Experimental Methods
  - Data Analysis
  - Science Oral Presentation
  - Scientific Writing
    - Publication
    - Research Grant Awards
  - Scientific Interactions in Lab Meetings, Seminars, National Meetings (Debate & Critical Thinking)
  - Team Interactions & Collaboration
  - Awareness and Integration of Ethical Conduct of Research
Potential Timing of Research Experiences

- **Med VI**  Advanced Competency in Research
  - Leave of Absence for year long research experience (LOA)

- **Med III**
  - Leave of Absence for year long research experience or
  - Year Long part time research project (LOA)

- **Med II**
  - Summer Research Project 8-10 weeks

- **Med I**
1. Quality clinical care should be informed by biomedical research.

2. Clinically important problems should stimulate biomedical research.

3. The appropriate use of clinical tests/algorithms can improve patient care and outcomes, but requires an appreciation of the context and limitations of the research on which they are based.

4. The value of biomedical research to society relies on the application of high ethical and professional standards to the responsible conduct of biomedical research.
5. Research literacy is integral to the development of all physicians as lifelong learners.

6. Independent scholarly work in evidence based inquiry and biomedical research is an important mechanism to develop critical thinking skills and establish a foundation for future growth and career development.

7. Given the interrelatedness and complexity of human disease, advances in modern biomedical research and evidence-based clinical care require physicians with mastery of multidisciplinary, collaborative, team-based skills.
Integration of EBIR Across LSI Curriculum
Improving People's Lives Through Innovations in Personalized Health Care

HIPAA/HITECH:
Medical Student Access for Research Purposes

Frank White, MS, JD
Director of Research Compliance

College of Medicine
Office of Research

The Ohio State University
Wexner Medical Center
What is HIPAA/HITECH

- **HIPAA:** Healthcare Insurance Portability and Accountability Act
  - Applies to Covered Entities (CE)
  - Creates various standards for Protected Health Information (PHI)
    - Privacy
    - Security
    - Coding Standards

- **HITECH:** Health Information Technology for Economic and Clinical Health Act
  - Strengthens HIPAA
    - Adds additional obligations for CE
    - Increasing monetary fines ($1.5M per violations)
HIPAA: Clinical Practice

- TPO: Allowed to view patient health information for Treatment, Payment, and healthcare Operations
  - Treatment
    - provision, coordination, or management of health care and related services among health care providers...
  - Payment*
    - various activities to obtain payment
  - Operations*
    - Certain administrative, financial, legal, and quality improvement activities including education

*Minimum necessary applies: CE must develop and implement policies that reasonably limit the use/disclosure of PHI to the minimum necessary amount required to complete the function
HIPAA and Research

- HIPAA Research Restrictions: Allowed to utilize PHI for research subject to various restrictions:
  - Without patient authorization
    - IRB approval
  - With patient authorization
    - IRB approves the language of authorization
  - Accounting of Disclosures
  - Minimum necessary applies
Summer Research Requirements

- Must obtain IRB approval and added as key personnel on protocol before you use your IHIS accounts to conduct research.
  - Key personnel: assurance you are working on an active protocol.

- Three types of applications
  - Projects with IRB approval
  - Projects that are pending approval
  - Projects that have not been submitted

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**Summer Funding: Key Dates**

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<tr>
<th>Date</th>
<th>Phase 1: Funding Deadline</th>
<th>Phase 2: Funding Deadline</th>
<th>Mid-March</th>
<th>May 1st</th>
<th>June:</th>
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<td>Dec. 14th</td>
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<td>Review complete: Must have IRB approval</td>
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<td>Request to be added as key personnel</td>
<td>Request account modification after IRB approval and added as key personnel</td>
<td>Begin Research</td>
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<td>Begin Research</td>
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How to Access

- MDSR website has a handout showing how request to modify your account
- COMOR website will have a link with instructions
- Contact information
  - Frank White, Director of Clinical Research Compliance, Frank.White@osumc.edu, 614-685-1734
  - Abby Larsen, Regulatory Manager, Abigail.Larsen@osumc.edu, 614-685-1739
Questions?