Course Syllabus
(Subject to change)

General Course Information:
Fundamentals of Clinical Research Management I & II
Thursdays 5:30 pm – 8:00 pm
Farrell Teaching and Learning Center, Room 202 except Oct. 17th Room 207

Instructor Information:
Sarah Fowler-Dixon, PhD
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Blackboard: bb.wustl.edu

Required Text Books:


Book 3 (If you already have this book, you may use this book instead of Book 2): Conducting Clinical Research: A Practical Guide for Physicians, Nurses, Study Coordinators and Investigators, First edition by Judy, Stone, MD.

Note: Books can be purchased at the WU Medical School Bookstore, Amazon.com or Half.com.

Course Description:
Fundamentals of Clinical Research Management I & II, is an introductory course which provides the basic foundation for the application, concepts and theories of clinical research. The historical evolution of research is explored, linking it to the current regulations and guidelines for good clinical practice. Course material includes research roles and responsibilities, institutional review boards, phases of drug development, the informed consent process, human subject protections and an overview of study conduct.

Students will complete institutional review board paperwork, writing an informed consent and developing source documents.

Course Requirements:
Attendance and Class Participation 5%
CITI complete 5%
Regulatory report 20%

Consent document 20%

Community-Engaged Research example 10%

Source Document and/or Case Report Form 20%
  • Each student will create and turn in two source documents or case report forms for the mock submission. Examples include:
    o Advertisement & Recruitment Plan & Cost
    o Source Documents
    o Budgets
    o Participant Visit Schema
    o Curriculum Vitae
    o Create a Regulatory Binder
    o Create A Participant Research Record

Case study assignments 20%

Course Agenda
(Subject to change)

In preparation for this class: Complete the CITI track, Biomedical Research Team using your student WUSTL key and following the directions titled “WUSTL employee & Student sign-on instructions: found at: http://hrpohome.wustl.edu/study_team/CITI/HRPO_CITI.aspx. This will take 4 to 8 hours to complete.

Week One:
  • Syllabus
  • The Evolution of Human Experimentation Regulation and Overview of Clinical Research

Suggested readings:
Book 1: Chapter 1
Book 2: Chapter 1, pages 1 – 9 (Why do Studies? Liability, Jargon, Who’s Who); Chapter 8, pages 244 – 248 (Historical Context)
Book 3: Chapter 1, pages 1 – 9 (Why do Studies? Liability, Jargon, Who’s Who); Chapter 7, pages 146 – 150 (Historical Context)

Week Two:
• Current Federal Regulations and Agencies involved in Human Research
  o OHRP Guidance
  o FDA regulations
  o Medicare
  o Stark Laws
  o Institutional policies and guidance

• Chapter 3 State Regulation of Human Research
  o State Statues

Suggested readings:
Book 1: Chapters 2 and 3

Book 2: Chapter 1, pages 38 – 40 (Evolution of US Drug Law); Chapter 4, pages 115 – 120 (New Regulations)

Book 3: Chapter 1, pages 20 – 22 (Evolution of US Drug Law)

**Week Three:**

• **Regulatory Reports**
  • Selection and Recruitment of Research Subjects
    o Coercion vs. undue influence
    o Advertisements
    o Recruiting one’s own patients
    o Recruiting employees and students
    o Vulnerable populations
    o Non-English speaking populations
    o Inclusion of Women and Minorities
    o Community Partners

Suggested readings:
Book 1: Chapter 4

Book 2: Chapter 5, pages 164 – 180 (Volunteer Recruitment Strategies, Advertising, Web Advertising, Approaching the Patient); Chapter 8, pages 255 – 257 (Special Populations)


**Week Four:**

• Informed Consent in Clinical Trials
- Sample consent documents
- Sample consent processes
- Waivers of consent
- Waivers of consent vs. waivers of authorization
- Assent vs. consent
- Wards of the State

- Confidentiality of Clinical Trial Information
  - Certificates of confidentiality
  - Levels of de-identification what they are and how they affect consent
  - Privacy vs. confidentiality
  - HIPAA and HI-Tech
  - Protections afforded by the institution

- The Investigator
  - Qualifications
  - Disclosures
  - Training required
  - Study responsibilities: ICH vs. NIH
  - Drug/Device Accountability
  - Codes of Conduct
  - Conflicts of Interest
  - Reporting responsibilities
  - Monitoring
  - Investigator-sponsor

Suggested readings:
Book 1: Chapters 5 and 6

Book 2: Chapter 4, pages 125 – 129 (HIPAA); Chapter 5, pages 147 – 159 (Informed Consent)

Book 3: Chapter 4, pages 88 – 90 (HIPAA); Chapter 5, pages 99 – 103 (Informed Consent)

**Week Five: NO CLASS**

- Case Studies due

Suggested readings:
Book 1: Chapters 7 and 8
Week Six:

- Research Protocols
  - Protocol types
  - Investigator Brochure or Device Pamphlet
  - Study types
    - Special concern studies: vaccine, radioactive materials, HIV, organ transplantation, gene therapy, genetic studies, database studies
    - Standard operating procedures vs. protocol vs. IRB submission
    - Common compliance issues: consent, protocol adherence, reporting/tracking events

- The Institutional Review Board
  - 21 CFR 50 and 45 CFR 46
  - Mission
  - When to submit to the IRB; when not to submit
  - FWA and other assurances
  - Part of the research enterprise: what it does, what it does not do
  - ICH review vs. regular review
  - Composition
  - Record-keeping
  - Institutional vs. central vs. commercial IRBs
  - Reviewers, chairs, use of consultants
  - Institutional official
  - Review and risk assessment
  - Annual review
  - Not human studies
  - Reviewer training
  - Review of the grant and other administrative duties/reviews
  - Pre-IRB reviews

- **Mock Submission.** You will need your WUSTL Key.

Suggested readings:
Book 1: Chapter 9

Book 2: Chapter 4, pages 123 – 125 (IRBs); Chapter 8, pages 279 – 281 (IRB-Related Ethical Issues)

Book 3: Chapter 4, pages 85 – 87 (IRBs); Chapter 7, pages 166 (IRB-Related Ethical Issues)

**Week Seven:**

- Patient Safety in Clinical Trials Research
  - Data safety monitoring
  - Ways to minimize risk
  - Adverse event reporting
  - Adverse events vs. Serious adverse events vs. unanticipated problems
    - What is tracked vs. what is reported to the IRB
  - When to change the consent form and tell the participants
  - Stopping a study
  - Patient referrals

- Research Under the Food, Drug & Cosmetic Act
  - IND, IDE, 510K
  - Drug phases
  - Device classifications
  - Emergency use setting

Suggested readings:
Book 1: Chapter 10 and 11

Book 2: Chapter 4, pages 121 – 122 (Form FDA 1572); Chapter 4, pages 129 – 130 (Drug Accountability); Chapter 8, pages 271 – 274 (Adverse Events); Chapter 8, pages 277 – 279 (Practice Guidelines and Off-Label Uses); Chapter 8, pages 281 – 285 (Unanticipated Risk in Clinical Trials)

Book 3: Chapter 4, pages 84 – 85 (Form FDA 1572); Chapter 4, pages 90 (Drug Accountability); Chapter 8, pages 163 – 165 (Adverse Events)

**Week Eight:**

- Behavior Research
  - Qualitative vs. quantitative research
  - Behavioral techniques
Behavioral/Biomedical combinations
Similarities/differences with clinical trials
QI vs. QA
Community research
Epidemiological research; oral histories; program development

- Multisite and Collaborative Studies
  - Assurances
  - Agreements; MOUs
  - Lead site vs. coordinating center vs. data coordinating center; responsibilities
  - International sites; international FWAs

- Consent document for mock protocol due.

Suggested readings:
Book 1: Chapter 12 and 13
Human Research Protection Office Community Engaged Research website at:
http://hrpohome.wustl.edu/community_research/cbr.aspx or go to
http://hrpohome.wustl.edu under Community Engaged Research (CEnR)

Week Nine:
- Community Engagement
  
  - Community-Engaged Research example. Find one current (last 10 years) example of a research study conducted that partnered with a community person or organization or that targeted a specific community. How does the study you found match up with the conference findings?

Week Ten:
- Ethics in Human Research
  - World Health Organization: placebo studies
  - Sham surgeries
  - Other new issues/developments/stories/findings

- International Research
  - International FWA
  - International Ethical Guidelines
o Embargoed countries
o Infrastructure
o Ethics Committees
o European directive
o Applying ICH to international sites

Suggested readings:
Book 1: Chapters 17 and 18

Book 2: Chapter 7 and 9; Chapter 8, pages 265 – 270 (Whose Body is It? Patient-Prompted Ethical Issues); Chapter 8, pages 275 – 277 (Publication Ethics); Chapter 8, page 286 - 290 (Whose Minding the Store?)

Book 3: Chapter 1 pages 22 – 23 (Costs of Clinical Trials, Breaking the Scientific Bottleneck); Chapter 8, pages 167-171 (Whose Minding the Store?)

Week Eleven:
• Feasibility, Budgets and Contracts
• Study Start-up

Suggested readings:
Book 2: Chapter 3; Chapter 5, pages 157 – 164 (Start-Up in Theory, Start-Up in Practice; Initiation Visit; Electronic Medical Record)

Book 3: Chapter 3; Chapter 5, pages 104 – 107 (Start-Up in Theory, Start-Up in Practice; Initiation Visit)

Week Twelve:
• Study Activities: Strategies and Tools

Suggested readings:
Book 2: Chapter 6
Book 3: Chapter 6

Week Thirteen: Mock Review
• Source Document/Case Report Form due

Week Fourteen: NO CLASS THANKSGIVING BREAK

Week Fifteen:
• How to critique an article
  o Guest speaker: Susan Fowler, Becker Medical Library

Week Sixteen:
• Medical Malpractice Liability in Human Research
• Quality Improvement, Accreditation, and Risk Management in Clinical Trials
  o Audits: FDA, internal, by the study team
  o Risk management
  o Working with legal counsel and public affairs
  o OHRP QA self-assessment tool

• Corporate Compliance and Human Research
  o Institutional Conflicts of Interest
  o Personal conflicts of interest
  o Financial conflicts of interest; new rule
  o Payroll; tax office; HR; grants and contracts
  o Whistleblowers
  o ORI

Suggested readings:
Book 1: Chapter 14, 15, and 16

Book 2: Chapter 4, pages 132 – 145 (Audits, How to Prepare for an Audit);
Chapter 8, pages 258 (Individual Research Practice, Financial Pressure and Conflict of Interest)

Book 3: Chapter 4, pages 91 – 97 (Audits, How to Prepare for an Audit)