Data Management & Informatics in Clinical Research

The following contains information about:
1. Faculty
2. Educational Objectives
3. Concept Project
4. Work Groups
5. Homework
6. Quizzes
7. Evaluation
   a. Student Evaluation (grades)
   b. Course Evaluation

1. Faculty
   • Joe Ramsdell, M.D. (Module Director)
   • Zia Agha, M.D.
   • Brian Clay, M.D.
   • Robert El-Kareh, M.D. MPH
   • Lucila Ohno-Machado, MD, Ph.D.
   • Carl Stepnowsky, Ph.D.
   • Rick Nelesen, Ph.D.
   • Module Support: Rick Nelesen, nelesen@icloud.com
     – Facilitator
     – Quiz and home work grader
     – Source of practical advice on data management

2. Educational Objectives: Core Competencies for Data Management of Informatics and Clinical Research
   • Define data management factors consistent with the project’s statistical approach
   • Determine data management resources needed in a clinical research plan.
   • Define the basic requirements of data management and manipulation software
   • Design quality assurance and control procedures for different designs and analysis
   • Define the components necessary for data and safety monitoring plans.
• Apply the main rules, guidelines, codes, and professional standards for the conduct of clinical and translational research to the design of the data management system.
• Develop protocols utilizing computer technology for data acquisition and management
• Describe the essential functions of the electronic health record (EHR)
• Explain the role that health information technology standards
• Collaborate with bioinformatics specialists in research design and implementation
• Describe best practices in informatics for the organization of biomedical information.

At the end of the course, the participant will

• Discuss 3 principles that make the foundation of the FDA’s Clinical Practice Guidelines in clinical research
• Create a rational form design that will include concepts for ease of completion, ease of computerized data-entry, and validation and reliability checks.
• List 3 methods for data confidentiality of Personal Health Information
• Discuss the differences between database management and clinical research, medical informatics and viral informatics
• Create and write a data management plan
• Review and critique data management plans for clinical trials.

3. Concept Project- Prepare a Data Management Plan for a hypothetical (or real) project to include:

• A synopsis of the research goals of the clinical study and its general design (this would normally be elsewhere is a project proposal but is needed so that reviewers can understand the context and requirements for the data management section of the proposal) < 1 page

• A Data Management Overview (up to 3 pages) that addresses each of the following elements:
  o Data management goals
  o High level description of procedures for data management
  o Data completeness
  o Data accuracy (correctness)
  o Source verification (auditing)
  o Data security and methods for maintaining confidentiality
Data availability

Study Communications and Coordination functions

- An Appendix (no limit on length) that includes:
  - A table of contents
  - A sample on-study enrollment form
  - One study-event-related form
  - Other detail associated with the elements described in #1 above, as needed to “make it obvious” the study is well planned

- A Budget in PHS 398 format and narrative budget justification

4. Workgroups (For NIH Study Section Exercise)
   - Will be pre-assigned and posted on BlackBoard
   - Work together (as a NIH Study Section would) during class.

5. Homework: CREST policy is that there are two hours of homework for every one hour of class time. It is anticipated that the homework necessary for this module should take about three hours.

6. Quizzes: Each week, quizzes based from the assigned readings will post on the blackboard. These are due at the beginning of the class on posted dates.

   - Student Performance
     - Class attendance and participation 10%
     - Attendance (per CREST policy – 4 or more absences result in a failing grade) 5%
     - Participation 5%
     - Concept Project 50%
       - Title and summary paragraph 5% (due session 3)
       - Interim drafts 15% (due Session 6)
       - Final project 25% (due Session 10)
         - Grading based on
           - Completeness
           - Relevance to research question
           - Creativity
       - Participation in mock the study section 5%
     - Quizzes 35%
       - Quizzes to insure credit
       - Posted on Assignments in Blackboard, may be edited in word & reloaded to Blackboard
     - Protecting Human Research Subject Certificate (due session 9) 5%
Course Evaluation (Important): We appreciate your feedback and welcome evaluations for each individual session (NOT REQUIRED, BUT WELCOMED) which may be completed and turned at your leisure.