

- Course Number and Title: CLRES 2500 **Clinical Research in Aging and Chronic Disease**
- Term/Academic Year: **Fall 2008**
- Credits: 3, **full term course**

Logistics/Contact Information:

- Instructor(s): **Stephanie Studenski MD MPH**
 - **Caterina Rosano, MD, MPH**
 - Anne B. Newman, MD, MPH**
 - Elsa Strotmeyer, PhD, MPH**
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- Office hours:
 - Dr. Studenski: by appointment
 - Dr. Rosano: **by appointment**
 - Dr. Newman: **Friday 9:00-11:00**
 - Dr. Strotmeyer: **Monday 9:30-11:00 or by appointment**
- Class location: **Large Conference Room CAPH, 130 N. Bellefield Ave, 5th floor**
- Class schedule: **Monday 11:00-12:50**

Summary of course

Purpose of the course. To introduce students to the methodological aspects of epidemiologic and clinical research in the field of aging and to learn how to design a research project that addresses relevant concerns in the study of older adults. The course will focus on: demography, study design, sampling, recruitment, measurement of key variables and special populations. Throughout the course, a Problem Solving Learning Method will be applied by prompting the students to solve pragmatic issues. Examples include: How to measure a specific outcome? What type of chronic health conditions may be related to the research question? How to operationalize specific measures of interest (e.g.: how to create a composite score for co-morbidity assessment?)

Students will be asked to identify a research question of interest early in the course and then spend the remainder of the semester designing a research project that addresses this question. Each class of the course has been formulated to provide the students with the “building blocks” of research methods to study aging. By the end of this course, the students will be able to construct various components of a study to answer their research question.

Field work. The student will become familiar with the ongoing aging studies either at the Bellefield Clinic and/or the Mon Valley Clinic or another active aging research site of interest to the trainee. Activities of the field work will consist of: an observation of an actual clinic research evaluation for these major studies and review of the manual of operations. Field work at the research clinic will consolidate the theoretical knowledge of the research methodology as the student will personally experience the components of a real visit for an epidemiological study of aging. Students will also write a brief evaluation of one methodology, including a literature review of the test characteristics of the methodology and alternative approaches.

Teaching/Learning Objectives.

Goal 1: The student will develop an understanding of the methodological aspects of epidemiologic and clinical research in aging.

When critiquing cohort studies and clinical trials in aging, students will identify and discuss concerns specific to the study of older adults.

Goal 2: The student will gain an appreciation for the practical components of studies currently in the field.

When observing a clinic visit, students will consult the manual of operations (MOP) for the study with the goal of correlating the practical aspects of the clinic visit with the MOP and the current literature.

Goal 3: The student will be able to construct the various components of an epidemiologic or clinical study of older adults.

When designing their own projects, students will draw upon the knowledge of published studies, fieldwork and class workshops to answer their research question addressing health issues in older adults..

Texts: Recommended (not required)

Textbooks for background information are on reserve for the course at Falk Library. Copies are also available in the offices of the course directors or from the teaching assistant.

The Epidemiologic Study of the Elderly, RB Wallace, RF Woolson, eds. Oxford University Press. 1992.

Epidemiology of Aging: An Ecological Approach, WA Satariano, Jones and Barlett Publishers, Inc. 2006.

Supplemental Readings/Bibliography

1. Journal Articles:
References will be provided for individual classes.

Student Performance Evaluation (Factors and Weights)

- 1) Field work (attendance and submit written report): 20%

Scores are weighted as follows:

- o Description of study measurement using MOP = **20%**
- o Critical discussion of advantages and disadvantages of study measurement = **20%**
- o Consult literature to identify similar study measures and discuss strengths and limitations = **30%**
- o In-class presentation = **30%**

- 2) Written critiques of studies: 20%

- 3) Written proposal of an epidemiological or clinical aging study: 40%

Scores are weighted as follows:

- o Identify one research question = **15%**

- Identify methodological issues and relevant variables for this question = **20%**
- Design a type of study to address the question = **15%**
- Explain how to conduct the study = population, screening, consent, recruitment, retention, events = **50%**

4) In-class participation in workshops and presentation of research project proposal: 20%

Assignment/Project Description The assignments in this course include written critiques of 3 important epidemiological studies of aging, readings with structured observations of many of the methods reviewed in the course, structured written reports of methods observed during field work and proposing a new research project to address a research question.

1. Readings:

Students will read manuscripts describing three existing cohort studies and clinical trials and read papers that illustrate important methods needed to conduct such studies in older adults.

2. Fieldwork:

Students will observe studies which are currently in the field for observation, including but not limited to the Study of Osteoporotic Fracture (SOF), Gingko Evaluation of Memory (GEM) and Health ABC. The teaching assistants will organize the schedule for these observations. Each student is expected to observe the clinic visit, including, if possible, the consenting process. The student is expected to consult the Manual of operations and correlate the practical aspects of the clinic visit with the MOP forms and the current literature.

3. Workshop presentation and reports:

- a. Each student will prepare a written critique of papers that address important methodological issues for 1) clinical trials in older adults, and 2) observation cohort studies of older adults. The studies will be discussed in class.
- b. Each student will prepare a written report regarding the studies that were observed and this will be presented orally in class. The report will focus on one specific exam procedure that the student has observed during the field work. The report will: summarize and describe the exam procedure by using the information in the MOP and personal observation of the exam, compare this method with other similar methods by consulting literature, describe reproducibility of the procedure, discuss the strengths and limitations of the procedure.
- c. During the course, each student will develop a research question, and will design a new research project that will appropriately address this question. Guidelines for developing a research question into a study will be discussed in class. A formal study proposal will be submitted in writing and it will also be presented orally in class.

4. Other:

Additional readings, observations and discussions will be conducted in class, thus points will be assigned for participation in the in-class workshops.

Grading Scale

The scale to be applied in grading will be as follows:

90%-100%	A
80-89%	B
70-79%	C
60-69%	D
< 60%	F

CourseWeb/BlackBoard Instruction

The instructors will be using the University's CourseWeb (Blackboard) for instructional support: reading material will be available from download from the Blackboard. Students are expected to download reading material and handouts prior to each class and also to consult the Blackboard for announcements.

Accommodation for Students with Disabilities

If you have any disability for which you may require accommodation, you are encouraged to notify both your instructor and the Office of Disability Resources and Services, 216 William Pitt Union (412-648-7890) during the first two weeks of the term.

Academic Integrity

All students are expected to adhere to the standards of academic honesty. Any work submitted by a student must represent his/her own intellectual contribution and efforts. Any student found to be engaged in cheating, plagiarism, or any other acts of academic dishonesty will be subject to a failing grade in the assignment and/or the course and to further disciplinary action.

Schedule of Sessions and Assignments

Date	Topic	Instructor
8/25/2008	Overview of course and assignments. Assign papers for 9/8/08 Cohort studies and clinical trials: Special issues in the older population	Caterina Rosano, MD,MPH / Elsa Strotmeyer, PhD, MPH Elsa Strotmeyer, PhD, MPH
9/1/2008	HOLIDAY	
9/8/2008	Demography – Facts on Aging Workshop I: class discussion of design and results of clinical trials <i>Due: research question</i>	Stephanie Studenski, MD, MPH / Anne B. Newman, MD, MPH Elsa Strotmeyer, PhD, MPH
9/15/2008	Recruitment, retention, adherence Workshop II: class discussion of design and results of cohort studies <i>Due: written critique of a clinical trial (CHECKLIST #1)</i>	Janet Bonk, MPH, RN / Piera Kost, BA / Cheryl Albig, CMA Caterina Rosano, MD, MPH / Anne B. Newman, MD, MPH
9/22/2008	Designing a study in older adults - special methodological issues in research with hospitalized older adults and nursing home residents Workshop III: Designing study proposals <i>Due: written critique of a cohort study (CHECKLIST #2)</i>	Susan Hardy, MD, PhD Caterina Rosano, MD, MPH
9/29/2008	Assessing cognitive function Workshop IV: in class practice on study proposals	Caterina Rosano, MD, MPH Students and Instructors
10/6/2008	Mental health : diagnosis and intervention Workshop V: Explain goals for field work / clinic visit <u>(CHECKLIST #4)</u> <i>Due : 1st draft of study proposal (CHECKLIST #3)</i>	Ellen Whyte, MD / Howard Aizenstein, MD, PhD Elsa Strotmeyer, PhD, MPH / TA
10/14/2008*	Measurement of comorbid health conditions Physical Activity Assessment	Anne B. Newman, MD, MPH Andrea Kriska, PhD / Kristi Storti, PhD
10/20/2008	Health Related Quality of Life Physical function and disability: method of assessment	TBD Kimberly A. Faulkner, PhD

10/27/2008	Medication use: methods of ascertainment and analysis In class presentation of study proposals- Collection of feedback forms (first ½ of the class)	Joseph Hanlon, Pharm MD, MS Students
11/3/2008	Human subject protection and informed consent in older adults and other IRB issues In class presentation of study proposals- Collection of feedback checklist forms (remaining ½ of the class)	Robert Sweet, MD Students
11/10/2008	Special issues in minority ageing	Steve Albert, PhD, MSPH, MA
11/17/2008	Ascertaining health events from medical records, protocols for abstraction. HIPAA release	Diane Ives, MPH
11/24/2008	NO CLASS SCHEDULED FIELD-WORK	
12/1/2008	Final presentation of study proposals <i>Due: written Study proposal (CHECKLIST #3)</i>	Students
12/8/2008	<i>Workshop VI: in class discussion of field work.</i> <i>Due: written report of field work (CHECKLIST #4)</i>	Students

*regularly scheduled Monday classes will be held on Tuesday this week due to Fall Break