

CLRES 2500	Course instructors:
Introduction to Patient Oriented Research in Aging and Chronic Disease	Stephanie Studenski, MD, MPH Susan Hardy, MD, PhD

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I. Course description:

This course provides an overview of conceptual and pragmatic issues in the design and implementation of patient oriented research involving older adults. The course will provide an overview of the epidemiology of aging and the principles of aging that affect the design of aging research, followed by a systematic study of the effects of aging and chronic disease on research including data sources, sampling, recruitment, consent, measurement, censoring, intervention, analysis, underrepresented minorities and research in special settings. This course is a required component of the Aging Concentration in the CRTP but is open to others with permission of the instructor.

II. Course objectives:

1. Understand conceptual and pragmatic issues that influence the design and implementation of research with older adults.
2. Be able to apply these concepts to published, proposed and ongoing aging research.

III. Course requirements:

Prerequisites: Familiarity with basic research and statistical methods through completion of the CRTP core courses, equivalent coursework or permission of the instructor.

IV. Time and Location:

Monday 11:00am to 12:50pm
Large Conference Room, Center for Aging and Population Health
130 N. Bellefield Ave, 5th Floor

Three additional 1 hour workshops, time and location to be determined

V. Course credits and contact hours:

3 credits; 48 contact hours

VI. Grading:

Quizzes and class participation	20%
Critique of published articles	20%
Written report and presentation of field work	20%
Final Project	30%
Class presentation of final project	10%

VII. Readings:

For an overview of principles of aging research read the following chapter, available on the Blackboard Site:

Studenski S, Ferrucci L, Resnick NM. Geriatrics. In Robertson D, Williams GH, eds. *Clinical and Translational Science: Principles of Human Research*. Burlington, MA: Elsevier; 2009: 477-495.

Readings for each session will be posted before class on the Course Blackboard site prior to the class.

VIII. Teaching methodology:

The class will use a combination of lectures and workshops led by the course instructors and guest speakers, supported by readings and field work with an ongoing aging research study. Students are expected to prepare for sessions with assigned readings. Students who have already developed a research proposal can refine it using the concepts and approaches presented in this class. Students who do not have a research proposal can provide a written critique of an existing research proposal or published studies with recommendations for revisions and next steps.

IX Assignments

1. *Quizzes:* After each class session, a brief multiple choice quiz highlighting the key points will be posted on the Blackboard site. These quizzes should be completed before the next class. We will briefly discuss the quizzes and answers at the beginning of the next class. Full credit is given for coming to class with the quiz completed.

2. *Written critique of published research studies:* Each student read a manuscript of a clinical trial and a cohort study and write a critique using topics discussed in class.

3. *Field work:* The student will become familiar with the ongoing aging studies at the University of Pittsburgh. 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.

4. *Final project:* There are several options for the final project, each involving a written report and class presentation. These are described individually below:

a) Original grant proposal: Present a proposal for a clinical research project in aging. This can be either a new proposal or one that you are working on. In class you will present the background and gaps in knowledge (with attention to limitations in any previous studies), and then describe your project emphasizing the ways in which your research will overcome these limitations and address these gaps.

b) Existing grant proposal: Review an existing grant proposal for a clinical research project in aging. You can use a grant available to you in your area of interest or discuss with the instructors to obtain an appropriate grant. Provide a written critique of the grant with a focus on the methodologic issues we have discussed in class. In class, you will provide a critique of the grant with suggestions for how potential problems could be addressed and the proposal improved.

c) Published studies: Select 2-3 published manuscripts reporting clinical aging research in your area of interest. Provide a written critical review of these manuscripts and discuss proposed future directions for aging research in this area. In class, you will present your critique and proposed next steps, with a focus on addressing methodologic limitations of the reviewed studies.

X. Class sessions

Date	Topic	Instructor
8/31/2009	Overview of course and assignments	Instructors
	Study design issues in the older population	Elsa Strotmeyer, PhD, MPH
9/7/09	HOLIDAY	
9/14/09	Demography – Facts on Aging and Defining an aging research question	Stephanie Studenski, MD, MPH
	<i>Workshop I: class discussion of design and results of clinical trials</i> Due: Submit article chosen for final assignment	Elsa Strotmeyer, PhD, MPH
9/21/09	Intervention studies: Special issues in the older population	Stephanie Studenski, MD, MPH
	<i>Workshop II: class discussion of design and results of cohort studies</i> Due: Written critique of a clinical trial (Checklist #1)	Caterina Rosano, MD, MPH
9/28/09	Special methodological issues in research with hospitalized older adults and nursing home residents	Susan Hardy, MD, PhD
	<i>Workshop III: Furthering research questions to address issues in older populations - for final assignment (Checklist #3)</i> Due: Written critique of a cohort study (Checklist #2)	Instructors/Students
10/5/09	Measurement of comorbid health conditions	Jane Cauley, DrPH
	Long term retention of older adults for longitudinal studies	Elsa Strotmeyer, PhD, MPH
Tuesday 10/13/09*	<i>Workshop IV: Explain goals for field work (Checklist #4)</i>	Elsa Strotmeyer, PhD, MPH / Kira Leishear, MS
	<i>Workshop V: Student presentation on rationale for chosen paper - why is it an important health concern for older adults?</i>	Instructors/Students
10/19/09	Assessing physical function and disability	Susan Hardy, MD, PhD
	Physical activity assessment	Kristi Storti, PhD
10/26/09	Assessing brain structure and function	Caterina Rosano, MD, MPH
	Mental health: diagnosis and intervention	Ellen Whyte, MD
11/2/09	Medication use: methods of ascertainment and analysis	Joseph Hanlon, PharmD, MS

	Special issues in minority aging	Steve Albert, PhD, MSPH, MA
11/9/09	Human subject protection and informed consent in older adults and other IRB issues Recruitment, retention, adherence	Robert Sweet, MD Janet Bonk, MPH, RN / Piera Kost, BA / Cheryl Albig, CMA
11/16/09	Health-related quality of life <i>Workshop VI: Practice for final assignment (Checklist #3)</i>	Mark Unruh, MD, MS Students
11/23/09	NO CLASS SCHEDULED - for field work time	
11/30/09	Ascertaining health events from medical records, protocols for abstraction and HIPAA OPEN HOUR – for field work time	Diane Ives, MPH
12/7/09	Final presentation of critical review and comment <i>Due: Written critical review and comment (Checklist #3)</i>	Students
12/14/09	Presentation of field work <i>Due: Written report of field work (Checklist #4)</i>	Students

*Due to Fall Break on Monday, October 12, the classes regularly held on Monday will take place on Tuesday October 13, 2009.

XI. Additional Workshops

Session 1: Secondary and Administrative Data Hardy Oct 5 1p

Topics:

Sources of public use and administrative data
Opportunities and challenges of working with secondary data

Session Objectives:

Be able to identify types and sources of public use data for aging research
Be able to list major advantages and disadvantages of using this type of data.

Class Discussion:

What kind of questions related to your interests could you pursue with secondary data?
What kind of expertise is needed to accomplish this work?

Readings:

Medicare Current Beneficiary Survey (MCBS) Overview
Growing Older in America: the Health and Retirement Study, Intro

Session 2: Data Management and Analysis Rubio, Perera Oct 19 1pm

Topics:

Data management: tracking, quality control
Analytic strategies for assessing and managing missing data and informative censoring
Outcome analysis: rates, survival analysis, competing events, combined outcomes
Accounting for baseline differences and heterogeneity

Session Objectives:

Understand the importance of good data management to a successful study
Be able to anticipate and then assess the extent of missing data
Be able to assess the bias due to drop outs and missing data
Weigh the pros and cons of various options for primary and secondary outcomes

Class Discussion:

What analytic approach is most appropriate for your main dependent variables?
What is your plan for managing missing data?
What is your plan for managing baseline differences?

Readings:

Hardy SE, Allore H, Studenski SA. Missing data: a special challenge in aging research. *J Am Geriatr Soc.* 2009; 57: 722-729.

Petkova E Teresi J Some statistical issues in the analyses of data from longitudinal studies of elderly chronic care populations *Psychosomatic Medicine* 2002 64:531-547

Fairclough DL Patient reported outcomes as endpoints in medical research *Statistical methods in Medical Research* 2004 13:115-138

Naveh-Benjamin M Craik FI Presenting and analyzing results in aging research *Experimental Aging Research* 1998 24:83-98

Session 3: Interventions: Drugs and Exercise

VanSwearingen, Greenspan Oct 26 1p

Topics:

Pharmacologic interventions:

- Special issues in medication trials in older adults

Exercise interventions:

- operationalizing and dosing
- comparison arm intervention issues
- combined versus single exercise interventions

Session Objectives:

Describe challenges in doing drug studies in older adults
Describe the indications, challenges and opportunities of exercise interventions
Describe methods of monitoring and sustaining adherence to exercise interventions.
Recognize generalizability concerns of some methods of maximizing adherence
Discuss pros and cons of comparison arm intervention options

Class Discussion:

What changes in study design or analysis for studying drugs in older adults?
What are the opportunities and challenges of exercise interventions for older adults?

What strategies for adherence promotion are appropriate, given particular trial goals?

Readings:

Le Quintrec JL, Bussy C, Golmard JL, Herve C, Baulon A, Piette F. Randomized controlled drug trials on very elderly subjects: descriptive and methodological analysis of trials published between 1990 and 2002 and comparison with trials on adults. *J Gerontol A Biol Sci Med Sci.* 60(3):340-4, 2005 Mar.

Guzman J, Esmail R, Karjalainen K, Malmivaara A, Irvin E, Bombardier C. Multidisciplinary bio-psycho-social rehabilitation for chronic low back pain. *Cochrane Database Syst Rev.* 2002;(1):CD000963.

Life Study Investigators, Pahor M, Blair SN, *et al.* Effects of a physical activity intervention on measures of physical performance: Results of the lifestyle interventions and independence for Elders Pilot (LIFE-P) study. *J Gerontol A Biol Sci Med Sci.* 2006;**61**: 1157-1165.