

**TITLE: HS 265:** Challenges in Clinical Health Services Research—Spring 2007

**CLASS INFO:**

<http://www.registrar.ucla.edu/schedule/detselect.aspx?termsel=07S&subareasel=HLT+SER&idxcrs=0265++++>

**LOCATION:** 911 Broxton Ave, Room 214, otherwise noted

**INSTRUCTORS:** Martin Shapiro MD, Neil Wenger MD, Carol Mangione MD, Katherine Kahn MD, Douglas Bell MD, Honghu Liu PhD, Sarah Fox PhD, Dominick Frosch PhD, Allison Diamant MD, Ron Hays PhD.

**GOAL:**

The goal of this course is to prepare the student for the often complex challenges involved in conducting health services research on clinical topics and clinical populations. Topics to be covered include formulating appropriate questions, identifying sources of data, issues involved in studying a range of important populations and topics, challenges in the mechanics of conducting field studies (negotiating with providers, developing practical sampling strategies, dealing with institutional review boards, enrolling patients, etc.), as well as identifying funding sources, writing grants and publishing findings.

**LEARNING OBJECTIVES:**

- To gain practical understanding of issues involved in formulating and executing clinical research studies.
- To master some of the challenges involved in the use of specific methodologies, and studying specific content areas in clinical health services research.
- To gain some insights into the practicalities of getting funded and publishing research findings.

**EVALUATING STUDENT PERFORMANCE:**

Class Participation **55%**

- Specific Aims Presentation 5%
- Research Design Presentation 20%
- General Class Participation 30%

Written Materials **45%**

- Specific Aims 5%
- IRB Proposal 10%
- Research Design and Methods 30%

## **COURSE PROSPECTUS:**

- Framing questions that are clinically relevant
- Sources of information
- Using claims data
- Studying disadvantaged populations
- Studying the doctor-patient relationship
- Studying clinical ethics
- Studying structure of health care
- Measuring inpatient care
- Measuring ambulatory care
- Sampling strategies for health services research
- Challenges in conducting field research
- Negotiating with healthcare providers
- Challenges in dealing with IRBs
- Enrolling patients
- Studying medicine on the web/informatics
- Developing a multidisciplinary team
- Identifying funding source
- Writing a research grant
- Publication strategies

## **COURSE READING MATERIALS:**

**Text book:** Designing Clinical Research. Hulley et al. 3<sup>rd</sup> Edition.  
Available at UCLA bookstore or online.

[http://www.uclaestore.com/ucla/textbook\\_express.asp](http://www.uclaestore.com/ucla/textbook_express.asp) OR  
<http://www.lww.com/product/?978-0-7817-8210-4>

### **Shapiro. April 3 Lecture**

Read text book Chapters 1 and 2:

1. Getting Started: The Anatomy and Physiology of Clinical Research  
*Stephen B. Hulley, Thomas B. Newman, and Steven R. Cummings*
2. Conceiving the Research Question  
*Steven R. Cummings, Warren S. Browner, and Stephen B. Hulley*

### **Domick Frosch. April 24 Lecture**

You will find all IRB related forms at <http://www.oprs.ucla.edu/human/forms/>

For HS 1, 4, 7, 9, find them under Application Forms & Checklists  
<http://www.oprs.ucla.edu/human/forms/checklists>

For HS-2 and 3 forms, click on informed consent biomedical  
<http://www.oprs.ucla.edu/human/forms/biomedical-informed-consent>  
orgeneral <http://www.oprs.ucla.edu/human/forms/informed-consent-general>

For HIPPA, <http://www.oprs.ucla.edu/human/forms/HIPAA>

The main website for UCLA's Office for the Protection of Research Subjects is  
<http://www.oprs.ucla.edu> if you want more information on Human Subjects or refer to  
Investigator's manual.

A. Investigator's Manual: Should read.  
<http://www.oprs.ucla.edu/human/documents/pdf/investigatormanual.pdf>

Chapter 1. Introduction  
Research Defined  
Research: A Shared Responsibility  
The Foundation of 45 CFR 46: The Belmont Report  
Respect  
Beneficence  
Justice

Chapter 4  
Informed Consent Requirements  
The Process of Informed Consent  
Writing the Consent Form

Chapter 12. Application Forms (Forms attached)

Application to Involve Human Subjects in Research (Form HS-1)  
Sample Consent Form for Medical Research (Form HS-2)  
Sample Assent Form (Form HS-3a)  
Claim of Exemption from Human Subject Protection Committee Review (Form HS-7)

**B. NIH Grants Related items: (NOT ATTACHED)**

1. home page: <http://grants1.nih.gov/grants/oer.htm>
2. where to find application and various forms: <http://grants1.nih.gov/grants/forms.htm>
3. 398 related forms and instruction: <http://grants1.nih.gov/grants/funding/phs398/phs398.html>
  - a. human subjects <http://grants1.nih.gov/grants/funding/phs398/HumanSubjects.pdf>

**C. HIPAA related items:**

<http://www.oprs.ucla.edu/human/forms/HIPAA>

**1. Human Research HIPAA Guidance for:**

- a. submitting UCLA IRB applications to ensure HIPAA compliance for applicable human research, and
  - b. using the UCLA "HIPAA Authorization".
- 2. A new HIPAA - specific Form HS-1(a) supplement for the existing Form HS-1 (Application to Involve Human Subjects in Research)**
- 3. Two UCLA specific HIPAA compliant "Authorization for Release of Personal Health Information (Protected Health Information) for Research Purposes" or "HIPAA Authorization" forms**
- a. requests general medical information and Specific Authorizations for information on mental health, HIV/AIDS, drug/alcohol use, and genetic information and
  - b. requests general medical information.

The information and documents are available at: [www.oprs.ucla.edu](http://www.oprs.ucla.edu).

All forms available at <http://www.oprs.ucla.edu/human/forms/checklists>

Improving the System for Protecting Human Subjects: Counteracting IRB "Mission Creep."  
<http://www.law.uiuc.edu/conferences/whitepaper/papers/SSRN-id902995.pdf>

Rosnow RL, Rotheram-Borus MJ, Ceci SJ, et al. The Institutional Review Board as a Mirror of Scientific and Ethical Standards. *American Psychologist*. 1993. 48(7):821-826.  
[http://ft1.csa.com/ids70/resolver.php?sessid=87bc2f40f0339c907f1d9dfd111cf482&server=www-md2.csa.com&check=834e02ee66db5f7851ca846dfe7a8c45&db=psycarticles-set-c&key=AMP%2F48%2Famp\\_48\\_7\\_821&mode=pdf](http://ft1.csa.com/ids70/resolver.php?sessid=87bc2f40f0339c907f1d9dfd111cf482&server=www-md2.csa.com&check=834e02ee66db5f7851ca846dfe7a8c45&db=psycarticles-set-c&key=AMP%2F48%2Famp_48_7_821&mode=pdf)

## **Domick Frosch. April 26 Lecture**

Bergner M, Rothman ML. Health status measures: an overview and guide for selection. *Annu Rev Public Health*. 1987;8:191-210. Review.  
<http://arjournals.annualreviews.org/doi/pdf/10.1146/annurev.pu.08.050187.001203>

McHorney CA. Health status assessment methods for adults: past accomplishments and future challenges. *Annu Rev Public Health*. 1999;20:309-35. Review.  
<http://arjournals.annualreviews.org/doi/pdf/10.1146/annurev.publhealth.20.1.309>

## **Honghu Liu. May 1 Lecture**

(1) The Concept of Power Analyses, Chapter 1 of "Jacob Cohen, Statistical Power Analysis for the Behavioral Sciences. Second Edition. Hillsdale, New Jersey, 1988"

References (you may not need this at this point):

R. Barker Bausell & Yu-Fang Li. Power Analysis for Experimental Research. Cambridge University PRESS. 2002.

PASS 2002 Power Analysis and Sample Size for Windows. NCSS. Kaysville, Utah, 2002.

## **Ron Hays. May 3 Lecture**

Weech-Maldonado R, Morales LS, Elliott M, Spritzer K, Marshall G, Hays RD. Race/ethnicity, language, and patients' assessments of care in Medicaid managed care. Health Serv Res. 2003 Jun;38(3):789-808. <http://www.blackwell-synergy.com/doi/abs/10.1111/1475-6773.00147>

Farley DO, Short PF, Elliott MN, Kanouse DE, Brown JA, Hays RD. Effects of CAHPS health plan performance information on plan choices by New Jersey Medicaid beneficiaries. Health Serv Res. 2002 Aug;37(4):985-1007. <http://www.blackwell-synergy.com/doi/abs/10.1034/j.1600-0560.2002.62.x>

Wilson IB, Ding L, Hays RD, Shapiro MF, Bozzette SA, Cleary PD. HIV patients experiences with inpatient and outpatient care: Results of a national survey. Medical Care. 2002; 40, 1149-1160.

<http://gateway.ut.ovid.com/gw1/ovidweb.cgi?WebLinkFrameset=1&S=IDNJHKKKACKBCN00D&returnUrl=http%3a%2f%2fgateway.ut.ovid.com%2fgw1%2fovidweb.cgi%3f%26Full%2bText%3dL%257cS.sh.15.16%257c0%257c00005650-200212000-00003%26S%3dIDNJHKKKACKBCN00D&directlink=http%3a%2f%2fgraphics.ovid.com%2fovftpdfs%2fidNJHKKKACKBCN00D%2ffs027%2fovft%2flive%2fqv008%2f00005650%2f00005650-200212000-00003.pdf>

Spranca M, Kanouse DE, Elliott M, Short PF, Farley DO, Hays RD. Do consumer reports of health plan quality affect health plan selection? Health Services Research, 2000; 35, 933-947. <http://www.pubmedcentral.nih.gov/picrender.fcgi?artid=1089177&blobtype=pdf>

Snyder R, Cunningham W, Nakazono TT, Hays RD. Access to medical care reported by Asians and Pacific Islanders in a West Coast physician group association. Medical Care Research and Review. 2000;57,196-215.

<http://mcr.sagepub.com/cgi/content/abstract/57/2/196>

Solomon L, Hays RD, Zaslavsky A, Cleary PD. Psychometric properties of the Group-Level Consumer Assessment of Health Plans Study (G-CAHPSO) instrument. Med Care. 200; Jan;43(1):53-60.

<http://gateway.ut.ovid.com/gw1/ovidweb.cgi?WebLinkFrameset=1&S=IDNJHJKBAFLCN00D&returnUrl=http%3a%2f%2fgateway.ut.ovid.com%2fgw1%2fovidweb.cgi%3f%26Full%2bText%3dL%257cS.sh.15.16%257c0%257c00005650-200501000-00008%26S%3dIDNJHJKBAFLCN00D&directlink=http%3a%2f%2fgraphics.ovid.com%2fovftpdfs%2fidNJHJKBAFLCN00D%2ffs047%2fovft%2flive%2fqv024%2f00005650%2f00005650-200501000-00008.pdf>

Vazirani S, Hays RD, Shapiro MF, Cowan M. Effect of a multidisciplinary intervention on communication and collaboration among physicians and nurses. *Am J Crit Care*. 2005 Jan;14(1):71-7. <http://ajcc.aacnjournals.org/cgi/reprint/14/1/71>

Weech-Maldonado R, Elliott MN, Morales LS, Spritzer K, Marshall GN, Hays RD. Health plan effects on patient assessments of Medicaid managed care among racial/ethnic minorities. *Journal of General Internal Medicine*. 2004;19, 136-145. <http://www.blackwell-synergy.com/doi/abs/10.1111/j.1525-1497.2004.30235.x>

### **Douglas Bell. May 17 Lecture**

Chaudhry B, Wang J, Wu S, Maglione M, Mojica W, Roth E, Morton SC, Shekelle PG. Systematic review: impact of health information technology on quality, efficiency, and costs of medical care. *Ann Intern Med*. 2006 May 16;144(10):742-52. Epub 2006 Apr 11. Review. <http://www.annals.org/cgi/reprint/144/10/742.pdf>

R. Hillestad, J. Bigelow, A. Bower, F. Girosi, R. Meili, R. Scoville, R. Taylor. (2005). Can Electronic Medical Record Systems Transform Health Care? Potential Health Benefits, Savings, and Costs. *Health Affairs* 24(5): 1103-1117. <http://content.healthaffairs.org/cgi/reprint/24/5/1103>

Hillestad R, Bigelow J, Bower A, Girosi F, Meili R, Scoville R, Taylor R.. Role of Computerized Physician Order Entry Systems in Facilitating Medication Errors. *JAMA* 293(10): 1197-1203. <http://content.healthaffairs.org/cgi/reprint/24/5/1103>

### **Sarah Fox. May 29<sup>th</sup> Studying Communities**

Merzel, C and D'Afflitti, J. Reconsidering Community -Based Health Promotion: Promise, Performance, and Potential. *Am J of Public Health*. 2003, 93(4): 557-574. <http://www.ajph.org/cgi/reprint/93/4/557>

Pasick RJ, Hiatt RA, Paskett ED. Lessons Learned from Community-Based Cancer Screening Intervention Research. *Cancer*. 2004 Sep 1;101(5 Suppl):1146-64. <http://www3.interscience.wiley.com/cgi-bin/fulltext/109584735/PDFSTART>

Israel BA, Krieger J, Vlahov D, Ciske S, Foley M, Fortin P, Guzman JR, Lichtenstein R, McGranaghan R, Palermo AG, Tang G. Challenges and Facilitating Factors in Sustaining Community-Based Participatory Research Partnerships: Lessons Learned from the Detroit, New York City and Seattle Urban Research Centers. *J of Urban Health: Bulletin of the New York Academy of Medicine*. 2006, 83(6): 1022-1040. <http://www.pubmedcentral.nih.gov/picrender.fcgi?artid=1482932&blobtype=pdf>

Roussos ST and Fawcett SB. A Review of Collaborative Partnerships as a Strategy for Improving Community Health. *Annu. Rev. Public Health*. 2000, 21: 369-402. <http://arjournals.annualreviews.org/doi/pdf/10.1146/annurev.publhealth.21.1.369?cookieSet=1>

[Link](http://www.registrar.ucla.edu/schedule/detselect.aspx?termsel=07S&subareasel=HLT+SER&idxcrs=0265++++) to class info including text book  
<http://www.registrar.ucla.edu/schedule/detselect.aspx?termsel=07S&subareasel=HLT+SER&idxcrs=0265++++>

### **SCHEDULED LECTURES OR TOPICS TO COVER**

Apr 3	Introduction/ Framing and evaluation research ideas/questions	Shapiro
Apr 5	Selecting a study design; independent and dependent variables	Shapiro
Apr 10	Specific aims: Presentations	Shapiro
Apr 12	Writing a grant proposal	Mangione
Apr 17	Writing a grant proposal part 2	Shapiro
Apr 19	Measuring inpatient care/ Measuring ambulatory care	Kahn
Apr 24	Writing an IRB proposal/Negotiating with providers	Frosch
Apr 26	Measuring outcomes of medical care	Frosch
May 1	Data source; Sample size calculation and power analyses	Wenger/Liu
May 3	Studying doctor-pt relationship	Hays
May 8	Studying clinical ethics	Wenger
May 10	Studying structure of care	Kahn
May 15	Studying disadvantaged populations	Diamant
May 17	Studying information systems in medicine	Bell
May 22	Publication strategies	Wenger
May 24	Funding sources	Mangione
May 29	Studying communities	Fox
May 31	Presentation	Shapiro
June 5	Presentation	Shapiro
June 7	Presentation	Shapiro