

Designing Outcomes & Clinical (DOC) Research Fall 2016 Course Syllabus

Wednesdays: 4:00-6:15 p.m. August 31-December 14

Class Location: The General Medical Sciences (GMS) Classroom in the Taylor Avenue Building (TAB), which is labelled, "Institute of Public Health." After you enter the TAB walk past the BJC WellAware Center gym through the (unmarked) door and zig-zag down the long yellow-green hallways.

Office Location: GMS, Suite 155 in the TAB.

Credits: 3

Textbook: Stephen Hulley et al. **Designing Clinical Research.** Lippincott Williams & Wilkins. 4th edition is recommended and is available online as an e-book via Bernard-Becker library.

Supplementary textbook (optional): Translational and Experimental Medicine, by Dan Schuster and William Powers. Published by Lippincott Williams & Wilkins.

Handouts: printouts available at each class; electronic copy on <https://bb.wustl.edu>.

Course master: [Brian F. Gage, MD, MSc](#). TA: [Julianne Sefko, MPH](#)

Office hours: Tuesdays, 9:20-11:00 AM in Dr. Gage's office except Nov 15. To make an appointment at a different time, email Dr. Gage.

Target audience: Students who already have or are pursuing any of the following degrees: MSCI, MPH, MSPH, ANP, MD, DO, DPT, OTD, Pharm D, or a PhD in nursing, rehabilitation/participation science, or medical anthropology. Although there is no formal prerequisite, a clinical background is assumed.

Academic Integrity Policy: Students are expected to abide by and uphold the Academic Integrity Policy for Graduate Students from the Graduate School of Arts & Sciences.

Pagers and Cellular Phones: Although clinicians may be expected to be available by pager or cellular phone, please limit their use during class.

Students with disabilities: Washington University is committed to providing accommodations and/or services to students with documented disabilities. Students who are seeking support for a disability (or a suspected disability) should contact the Disability Resource Center (DRC) at 5-4062 on the lower level of the Women's Building (drc@dosa.wustl.edu). The DRC is responsible for approving and arranging all accommodations for University students.

Grading:

A+	98.5-100%
A	92.5-98.4%
A-	90.0-92.4%
B+	87.5-89.9%
B	82.0-87.4%
B-	80.0-81.9%
C+	77.5-79.9% etc.

The final is 40% of the course grade, the protocol outline ~8%, the problem sets ~52%. If a student's average falls between two grades, in-class participation will be used to determine whether the grade should be rounded up or down.

Late Assignments:

Assignments are due at the beginning of class. For each day (calculated at 12:01 AM) that an assignment (except for assignment 1) is late the score is multiplied by 0.92. For example, a perfect assignment submitted 2 days late would score 85%. To avoid a late penalty if you will be away when an assignment is due, email it to [Julianne Sefko, MPH](#) with this subject line: **DOC Research Problem Set N**, (where **N** is the problem set #).

Date & Times	Topics	Assignments Reading should be done prior to lectures (except lecture 1). Readings in parentheses are optional.	Hulley Chapter
31-Aug 4:00 5:05	Refining the research question & FINER research: Dr. Evanoff Course overview; protocol outline Dr. Gage	Get Problem Set 1 and Syllabus (will be updated Oct 1) Revising a Research Protocol (handout) Kahn, CR. <i>Picking a Research Problem: The Critical Decision</i> N Engl J Med 1994 Outline of a Study Protocol (handout)	1,2
7-Sep 4:00 4:40	Reproducibility in research; type I & II errors; Ho & Ha; p-values Normal distribution, α , β , Power, and continuous data; t-test.	Due: Problem set #1; Get Problem Set 2 (Optional: Haynes RB. <i>Forming Research Questions</i> . (Optional: Install Excel data analysis pac: Excel button> Excel options > Add-ins > Analysis Toolpack > Go) (Optional: Bigby M, Gadenne AS. Understanding and evaluating clinical trials. J Am Acad Dermatol. 1996;34:563-77. ; if interested, you can read the whole article.)	5, 6
6:00	Preview: observational study designs		
8-Sep		Last day to drop w/out receiving a "W" on your transcript	
14-Sep 4:00 4:50 5:25	Cohort studies: incidence rates, RR, confounding Chi-square, Power Analyses of binary data Cross-sectional & case-control studies: OR	Due: Problem set #2; Get Problem Set 3 Carlsson L. et al. Bariatric Surgery and Prevention of Type 2 Diabetes in Swedish Obese Subjects N Engl J Med 2012. Ray et al. Dual-cohort study of Azithromycin N Engl J Med 2012 Lagergren J. et al. Symptomatic gastroesophageal reflux as a risk factor for esophageal adenocarcinoma N Engl J Med 1999.	3 & appendix 12A 7,8
21-Sep 4:00 5:10 5:50	Accuracy, precision, & Agreement: Dr. Yusen Case cross-over studies Preview: Dx testing & RCTs	Due: Problem set #3; Get Problem Set 4	4 p. 108
28-Sep 4:00 5:10	Diagnostic testing: sensitivity, specificity, predictive value and ROC curves Randomized Trials: Dr. Kollef	Due: Problem set #4; Get Problem Set # 5	12 10
5-Oct		Due: Problem set #5; Get Problem Set #6 Due: Bring 5 copies of your Protocol outline 3 pages if 1.5-spaced (excluding references)	

		(Optional: Short Blessed screening for dementia)	
4:00	Advanced Study Designs: Nested case-control study; Cross-over trials; Method of Zelen; Composite outcomes; & Non-inferiority trials	Freemantle N et al. Composite outcomes in randomized trials: greater precision but with greater uncertainty? JAMA 2003 (Optional: A-M Chang et al. Evening use of light-emitting eReaders negatively affects sleep, circadian timing, and next-morning alertness. PNAS 2014.) Prather et al. Behaviorally Assessed Sleep and Susceptibility to the Common Cold Sleep 2015	11
5:10	Review of protocols		
12-Oct (Yom Kippur)		Due: Problem set #6; Get Problem Set #7	
4:00	Ethics: Dr. Antes-Schuelke	Read: Belmont Report (part B), Declaration of Helsinki, (Optional Shalowitz,D Miller, F. Disclosing Individual Results of Clinical Research JAMA 2005;294:737-740)	14
5:10	Enhancing Causal Inference: Dr. Evanoff	Selby JV. A case-control study of screening sigmoidoscopy and mortality from colorectal cancer N Engl J Med 1992.	9
19-Oct		Due: Problem set #7; Get Problem Set #8	
4:00	Clinical Prediction Rules	C. Lindsey et al. Prognostic Indices for Older Adults: A Systematic Review JAMA 2012;307,182-192. (Optional: Abstract to: Wacholder S. et al. Performance of Common Genetic Variants in Breast-Cancer Risk Models N Engl J Med 2010.)	Hulley pp. 180-182
5:10	Linear regression	Katz MH. Multivariable Analysis: A Primer for Readers of Medical Research Ann Intern Med 2003.	
26-Oct		Due: Problem set #8; Get Problem Set #9	
4:00	Outcomes Research: Dr. Piccirillo		
5:10	Logistic regression		
2-Nov		Due: Problem set #9: Email your protocol outline: Subject line should use this format: "DOC Research Protocol Outline: Smith", where "Smith" is your last name	
4:00	Propensity Score	J Haukoos and R Lewis. The Propensity Score JAMA 2015	pp 128- 132 chapter 13
5:10	Cox proportional hazards regression		

9-Nov		Due: Problem set #10 Get Problem Set #11 Hüpfl , Selig, and Nagele. Chest-compression-only versus standard cardiopulmonary resuscitation: a meta-analysis Lancet . 2010.	
4:00	Meta-analysis: Dr. Nagele	M. Murad et al. How to Read a Systematic Review and Meta-analysis and Apply the Results to Patient Care Users' Guides to the Medical Literature JAMA 2014. (Optional Selective publication of antidepressant trials and its influence on apparent efficacy N Engl J Med 2008)	13
5:10	Decision Analysis	(Optional: Shah & Gage. Cost-effectiveness of dabigatran for stroke prophylaxis in atrial fibrillation. Circulation 2011;123)	Hulley 16
16-Nov		Due: Problem set #11; Get problem set #12 and practice final	9, 19
4:00	Midterm		
5:00	Data management, biorepositories, Study implementation & Quality	http://www.biostat.wustl.edu/redcap/wusm_REDCap.html , NIH policy on data sharing , PubMed Central and NIH Public Access policy	Hulley 17
23-Nov	Class cancelled	Happy Thanksgiving	
30-Nov		Due: Problem set #12; Get problem set #13 Optional: Pietrobon et al. Manuscript Architect : A web-based application for scientific writing BMC Medical Informatics and Decision Making 2005 5:15. Guyatt GH. and Haynes RB. Preparing reports for publication and responding to reviewers' comments	
4:00	Managing the Research Team (Dr. Dale)		Hulley 16
5:10	Final exam review	Practice final	
Friday 2-Dec	Final Exam offering #1	Optional final date	
7-Dec		Due: Problem set #13	
4:00	Scientific Writing (Jeanne Erdmann)		17
5:10	Case studies of pitfalls in clinical research: budgets, personnel challenges, recruitment woes, audits. Dr. Gage	TBD	
13-Dec 9:00	Extended office hours	9:00-noon	
14-Dec 4:00	Final Exam	You will <i>not</i> need a calculator nor your notes.	