

Title: Clinical Research Design and Critical Thinking Course for Newly Trained Prosthodontists

Sponsored by: Japanese Prosthodontic Society and Showa University

Instructors: Dr. Glenn Clark and Dr. Roseann Mulligan

Time Period: July 12, 2010 to October 4, 2010 (Holidays 8/16; 8/23; 9/6)



Textbook: Designing Clinical Research: An Epidemiologic Approach. 3rd Edition. 2006

Authors: Hulley, Cummings, Browner, Grady, Newman. **ISBN-10:** 0781782104.

Japanese Link: <http://www.neowing.co.jp/detailview.html?KEY=NEOBK-540868>

English Link: <http://www.amazon.com/Designing-Clinical-Research-Epidemiologic-Approach/dp/0781722187>

Brief Description: This course is a 10 week course and it is provided as a strictly online course. The target audience (students) will be newly graduated Prosthodontic faculty from various Universities across Japan. The course will focus on the basic elements of clinical research design and how to critically assess the literature. The course has several elements including:

(#1) Lectures: a series of 9 lectures will be placed online for viewing. These lectures cover the core elements of research study design including [case reports, diagnostic matrix analysis, observational studies and experimental studies], subject selection and specification methods; bias control methods [blinding, controls and drop-outs] and the process of making causal inferences.

(#2) Weekly Lecture Quiz: Each online lecture has an associated online multiple choice quiz where students have to sign on and take the quiz after viewing the lecture.

(#3) Weekly Article Review/Critique: There will be several articles placed online for the residents to read, review and write a detailed critique. Specifically, each week two articles will be posted and from them the students will select one of these article to write a critique. This critique must be uploaded to the course website by the due date. Dr. Clark and Dr. Mulligan will send out their critiques on these article after all students submit their critiques.

(#4) Weekly Step-by-Step Protocol Write-up: Each student must write and submit a detailed research protocol in this course. This protocol will be developed in a step-by-step fashion and will include the following elements: (1) Overall Goal & Specific Aims; (2) Background Justification, Rationale and Null Hypothesis; (3) Subject selection and inclusion/exclusion criteria; (4) Outcome measures including their precision; (5) Study Design Details including groups, and interventions; (6) Sample Size Justification and Statistical Analysis Plan; (7) Bias Control measures; (8) Pitfalls, Limitations and Expected Outcomes. Weekly this homework is submitted electronically to the course website.

(#5) Weekly video conference discussion: At a weekly video conference, Dr. Clark and Dr. Mulligan will answer questions, discuss the article critiques and protocol submissions with the student group. We anticipate the group will meet for 1 hour a week using video skype and MeBeam. Students will need a webcam, a headphone and a highspeed connection for their laptop.

Faculty: Dr. Clark's role is to developing the original design of the course, creating the web site, and managing all aspects of the course and Dr. Mulligan will contribute various lectures in this course and perform protocol submission critiques.

Schedule (*each student must attend the 6:00 to 7:00 PM weekly video conference):

| Date | Lecture Title and Web Conference | Assignment Due |
|-------------|---|--|
| 7/12 | 01 - Research Design: The Anatomy and Physiology of a Protocol & Selecting a Question; Web Conference #1: 6-7 PM | No assignment due today |
| 7/19 | 02 - Selecting Subjects, Sample Size and Outcome Measures; Web Conference #2: 6-7 PM | Protocol Part 1 Due Article Critique #1 Due |
| 7/26 | 03 - Establishing the Precision of your Measurements; Web Conference #3: 6-7 PM | Protocol Part 2 Due Article Critique #2 Due |
| 8/2 | 04 - Study Design: Cohort, Cross-Sectional and Case-Control Studies; Web Conference #4: 6-7 PM | Protocol Part 3 Due Article Critique #3 Due |
| 8/9 | 05 - Enhancing Causal Inference; Web Conference #5: 6-7 PM | Protocol Part 4 Due Article Critique #4 Due |
| 8/16 | Holiday | |
| 8/23 | Holiday | |
| 8/30 | 06 - Writing your Hypothesis, Establishing your Alpha, Power and Sample Size; Web Conference #6: 6-7 PM | Protocol Part 5 Due Article Critique #5 Due |
| 9/6 | Holiday | |
| 9/13 | 07 - Research Studies: Diagnostic Testing; Web Conference #7: 6-7 PM | Protocol Part 6 Due Article Critique #6 Due |
| 9/20 | 08 - True Experimental Studies; Web Conference #8: 6-7 PM | Protocol Part 7 Due Article Critique #7 Due |
| 9/27 | 09 - Ethics of Human Experimentation and Planning the Flow of your study; Web Conference #9: 6-7 PM | Article Critique #8 Due |
| 10/4 | 10 – No Lecture; Web Conference #10: 6-7 PM | Final Protocol Due |

Course Requirements and Grading/Evaluation: This online course in July 2010 and ends the first week of October 2010. The enrolled student must (1) view each weekly lecture, (2) take and pass the weekly quiz; (3) read, write and upload their critique of each week's assigned article; attend the weekly 1-hour video conference session of the course and (5) submit the portion of their research protocol that is due each week (the final protocol due on October 4th, 2010).

Grading Criteria: The grade (pass, not-pass) in this course is based on a combination of four elements including (1) the weekly online quiz, (2) the weekly article review critiques, (3) the research protocol submission and (4) attendance and participation in the weekly video conference. Each of these elements will be graded as "below expectations =1", "acceptable = 2" or "above expectations =3". To pass this course with a **Passing** grade the student must achieve an overall score of acceptable or 2.0 on each element of the course. One student will be selected for an award "best new research protocol for 2010" by Dr. Clark and Dr. Mulligan and this award will be presented at the 2010 Japanese Society of Prosthodontics meeting October 16 and 17, 2010 in Tokyo. Failure to gain an overall score of 2.0 or acceptable on each of the 4 elements of the course will result in a **Not Passing** grade.

Remediation: If a student gets a not passing grade, they will have specific written instruction on what they need to do to correct the problem; they will also be given a clear and specific timeline to make these correction. Failure to pass the remediation test/activity will mean the students final grade will be a Not-Pass.

Biosketch of Instructors



Dr. Glenn Clark joined the faculty of the USC School of Dentistry in 2003, as a full Professor in the Division of Diagnostic Sciences. His administrative title and duties include being the Director of the Center for Orofacial Pain and Oral Medicine and serving as the Founding Graduate Program Director of the newly established dual certificate residency program in Orofacial Pain and Oral Medicine. Dr. Clark's academic career began at UCLA, when he became a faculty member of the School of Dentistry. He was promoted to the rank of full Professor in 1984 and at UCLA he held various administrative posts including Director of the Clinical Research Center, Director of the Dental Research Institute, Associate Dean of Research, Chair of the Sections of Orofacial Pain, Oral Diagnostic Sciences and Oral Medicine. Dr. Clark began his research work focusing on both temporomandibular disorders and trigeminal motor function and dysfunction including bruxism, dystonia, and chronic myofascial pain disorders of the jaw system in human subjects. In 1986 Dr. Clark's expanded his research work to include studies on the diagnosis and treatment of Obstructive Sleep Apnea. This work has involved him as Principal Investigator on several National Institute for Dental Research grants. Dr. Clark has written over 145 research articles, review papers, or chapters in textbooks. He has served as editor or co-editor of three books on Temporomandibular Problems published by Quintessence International and of two books on Diagnostic and Surgical Arthroscopy by Saunders Publishing and has a new book in preparation on Orofacial Pain Medications to be published by Wiley-Blackwell Inc. in 2010. Dr. Clark is past President of the Neuroscience Group of the International Association of Dental Research; the Southern California Association of Dental Research; and the Association of University Temporomandibular & Orofacial Pain programs. He current is a member of the prestigious Council on Scientific Affairs of the American Dental Association. He has been awarded membership as a Diplomat of the American Board of Orofacial Pain (since 1996); he was voted alumnus of the Year of the UCLA School of Dentistry (1990). Dr. Clark was given the Pierre Robin Award for Academic Excellence (2001) by the Academy of Dental Sleep Medicine and in 2004 he was awarded fellowship in the American Academy of Oral Medicine. Finally in 2006, he was given a lifetime achievement award by the American Academy of Orofacial Pain.



Dr. Roseann Mulligan is a Professor of Dentistry at the University of Southern California, School of Dentistry and holds a joint appointment in the School of Gerontology. She is the Associate Dean for Community Health Programs at the dental school. Since 1993 she has served as the Director of Dental Education for the 4 state Pacific AIDS Education and Training Center. She is also the Co- Principal Investigator of the USC California Endowment Pipeline, Profession and Practice project and the Oral Health Needs Assessment of the Children of Los Angeles County Project. In 1984 she established and continues to direct the USCSD Special Patients Clinic. She also established and directed a General Practice Residency Program at Rancho Los Amigos Medical Center and an Advanced Education in General Dentistry Residency Program at USCSD. Dr. Mulligan received her DDS from UCLA, her General Practice Residency Certificate from Rancho Los Amigos Medical Center and her MS in Gerontology from USC. Dr. Mulligan is a past-president of the Special Care Dentistry Association. Previously she completed terms as the President of the American Society for Geriatric Dentistry and as the President of the Academy of Dentistry for the Handicapped. She has also served as the Editor in Chief of the journal, Special Care in Dentistry; and was the founding president of the International Association of Dental Research's Geriatric Oral Research Group. She holds Fellowships in the Gerontological Society of America, the American and International Colleges of Dentistry, the Pierre Fauchard Academy, the Academy of Dentistry for Persons with Disabilities (ADPD) and the Society for Clinical and Experimental Hypnosis. She is a Diplomate of the American Board of Special Care Dentistry and also of the American Board of Hypnosis in Dentistry. She received the Harold Berk Award from the Academy of Dentistry for Persons with Disabilities and was appointed by HHS Secretary Donna Shalala as a Delegate to the 1995 White House Conference on Aging. Dr. Mulligan has published research papers focusing on oral health disparities of underserved populations including patients who are developmentally disabled, medically compromised and the elderly. She has established a wide range of experiential community based public health dentistry experiences for dental students and residents and has promoted learning models for students and clinicians that are evidence-based and advance critical thinking.