

**CURRICULUM VITAE**  
***Department of Radiology***  
*University of California, San Francisco*

NAME:                   **Ying Lu, Ph.D.**

CURRENT TITLE:   Professor in Residence  
 Department of Radiology  
 Department of Epidemiology and Biostatistics  
 University of California, San Francisco

EDUCATION

|           |   |       |                     |
|-----------|---|-------|---------------------|
| 1978-1982 | Fudan University, Shanghai, China             | B.S.  | Mathematics         |
| 1982-1984 | Shanghai Jiaotong University, Shanghai, China | M.S.  | Applied Mathematics |
| 1985-1990 | University of California, Berkeley, CA, US    | Ph.D. | Biostatistics       |

Formal Training Courses Attended

|      |  |  |                 |
|------|--|--|-----------------|
| 1992 | Group Sequential Methods for Survival Analysis                                     | American Statistical Association (ASA) | Drs. [REDACTED] |
| 1993 | Meta-Analysis: Combining Results of Independent Studies                            | ASA                                    | Drs. [REDACTED] |
| 1994 | Multivariate Dependencies: Models, Analysis, and Interpretation                    | ASA                                    | Drs. [REDACTED] |
| 1994 | Statistical Process Monitoring And Control For The Chemical And Process Industries | ASA                                    | Dr. [REDACTED]  |
| 1998 | Everything You Always Wanted To Know About Wavelets But Were Afraid To Ask         | ASA                                    | Drs. [REDACTED] |
| 1998 | Validating SAS Programs  | Executive Consultant Services          | Drs. [REDACTED] |
| 1998 | West Coast Data Management and Biostatistics                                       | Drug Information Association (DIA)     |                 |

|      |   |   |                 |
|------|---|---|-----------------|
| 1999 | Analysis of Survival Data and Multiple Events Data    | ASA                                     | Dr. [REDACTED]  |
| 2000 | Medical Imaging in Clinical Trials                    | DIA                                     |                 |
| 2004 | Statistical Learning and Data Mining                  |   | Drs. [REDACTED] |
| 2004 | Practical Guidance of Generalized Linear Mixed Models | International Chinese Stat. Association | Dr. [REDACTED]  |
| 2006 | Statistical Methods for Analysis of Missing Data      | WNAR                                    | Dr. [REDACTED]  |

ACADEMIC EMPLOYMENT*Outside of the University of California School of Medicine*

|             |  |  |
|-------------|--|--|
| 10/84-08/85 | Department of Applied Mathematics<br>Shanghai Jiaotong University  | Assistant Teacher<br>(Faculty, equivalent to<br>Assistant Professor) |
| 07/90-02/94 | Department of Epidemiology and Public Health,<br>School of Medicine, University of Miami, Miami,<br>Florida. | Assistant Professor  |

In the University of California School of Medicine

|               |  |                                     |
|---------------|--|-------------------------------------|
| 03/94-06/98   | Department of Radiology, UCSF  | Assistant Adjunct Professor         |
| 03/94-08/99   | Biostatistics Lab., Osteoporosis and<br>Arthritis Research Group, Department of<br>Radiology, UCSF | Director                            |
| 03/94-06/96   | DXA Quality Assurance Center,<br>Osteoporosis Research Group,<br>Department of Radiology, UCSF     | Associate Director                  |
| 07/98-06/03   | Department of Radiology, UCSF  | Associate Adjunct Professor         |
| 07/03-06/05   | Department of Radiology, UCSF  | Associate Professor in<br>Residence |
| 07/06-present | Department of Radiology, UCSF  | Professor in Residence              |

OTHER POSITIONS HELD CONCURRENTLY

Professor Department of Epidemiology and Biostatistics  
 UCSF/UCB Graduate Program in Bioengineering  
 Director Biostatistics Core, UCSF Comprehensive Cancer Center  
 Core Faculty UCSF/UCB Bioengineering Graduate Program

### HONORS AND AWARDS

- 1980-81, and 81-82 *Distinguished Student of City (Shanghai)*
- 1985-86, 86-87 and 87-88 *University Fellowship, UC, Berkeley.*
- 1989 *Public Health Alumni Association Scholarship, UC Berkeley*
- 05/18/90 *The Evelyn Fix Memorial Award (Medal and Citation) for excellent dissertation, Department of Statistics, University of California, Berkeley.*  
 Awarded to 1-2 PhD students per year showing the greatest promise in statistical research, with preference for applications to biology and problems of health.
- 12/97 and 03/99 *The “Chun-Hui” Fellowship from The Chinese National Education Commission to Lecture in China*
- 10/ 2003 *Healthstar Osteoporosis Medical Research Award (HOMA) for Achievements in Osteoporosis Research, The Chinese Development Foundation for Science and Technology*  
 This is a biennial award for achievement in Osteoporosis by the Committee of Pharmaceutical Science Developmental Foundation of the Chinese Developmental Foundation of Science and Technology. Candidates are recommended by Chinese national and international professional organizations and reviewed by an independent committee of experts from the Chinese Academy of Science, the Chinese Medical Association, the Chinese Pharmaceutical Association, and international consultants. There were 6 HOMA awards in 2003 (the second time since 2001) to senior researchers in China and US (<http://www.cof.org.cn/ENGLISH/2003IOC/over/title05-2.htm>). The citation for Dr. Lu was for his important contributions in (1) standardization of hip BMD and research in osteoporosis diagnosis; (2) his contributions in quality control and quality assurance for densitometry in major osteoporosis clinical trials; and (3) his teaching, consulting, and promoting osteoporosis research in China.
- 2004 First Statistical Research Award (Book), Chinese Bureau of Statistics. For the book entitled “Advanced Medical Statistics.”

11/2004

*IAR Efficacy Award*, Health of the Population Integrated Review Group, Center for Scientific Review, NIH.

KEY WORDS/AREA OF INTEREST: Statistics in innovative medical diagnoses, outcome research and medical decision making, clinical trials, radiology, osteoporosis, oncology, neurology, quality control and quality assurance of diagnostic/imaging techniques.

PROFESSIONAL ACTIVITIES:

Director, Biostatistics Shared Resources, the UCSF Comprehensive Cancer Center in the last 6 years

Member, Executive Research Council, Department of Radiology

Head, the Biostatistics Laboratory, Department of Radiology, last 8 years

Director, Biostatistics and Outcome Specialized Research Group, Department of Radiology

Summary of Professional Activities:

In the UCSF Comprehensive Cancer Center, I lead the Biostatistics Core to support university wide oncology research and provide daily interactions with clinical and basic science investigators. In the Department of Radiology, I also provide statistical support to clinicians in developing and validating new diagnostic techniques, as well as provide statistical expertise and consultation for the basic and applied scientists in the Department covering a wide range of imaging disciplines (*e.g.*, oncology, neurology, cardiology, musculoskeletal).

Professional Organizations

Memberships in Scientific Professional Organizations

|              |   |
|--------------|---|
| 1986-present | American Statistical Association              |
| 1986-present | International Biometrics Society (IBS)        |
| 1986-1999    | Institute of Mathematical Statistics          |
| 1994-1998    | American Public Health Association            |
| 1989-present | International Chinese Statistics Association  |
| 1996-present | American Society of Bone and Mineral Research |
| 1998-2000    | Drug Information Society                      |

| Year             | Organization   | Roles   |
|------------------|--|---|
| 1995-2000        | International Committee for Standardization in Bone Measurement  | Committee Member: As the only statistician in this Committee, I developed statistical methods and derived formulas to calculate the standardized hip bone mineral density (BMD) that is used to diagnose hip osteoporosis. I also participated in discussions about design of comparative calibration studies and involved in standardization for forearm BMD.  |
| 1995-present     | The American Statistical Association, San Francisco Bay Area Chapter   | Vice President of Biostatistics (1995-97): Responsible for arranging biostatistics seminars (8-10 per year);<br><br>President-Elect (1997-98, 2004-05) and President (1998-99, 2005-06): Led development of a new e-mail based member information system that reduced Chapter financial burdens; developed K-12 award program for Bay Area schools to participate in the Joint Statistical Meetings (JSM) student paper competitions; developed short courses and seminars.<br><br>Chapter Council Representative (2007-) |
| 2001-2004        | Program Committee of 2003-2004 International Chinese Statistical Association (ICSA) Applied Statistical Symposium      | Chair of the Short-Course Committee and Member of Program Committee: Responsible for organizing 5 short-courses and two invited sessions.   |
| 2002, 2003, 2005 | Program Committees of three International Osteoporosis Conferences in China  | Committee Member for Scientific Programs, organized and chaired sessions  |
| 2003             | Local Committee, the ICSA Annual Meeting   | Chair: arranged the ICSA booth, annual member meeting and banquet in the Joint Statistical Meetings (JSM)   |
| 2005-2006        | Program Committee, The Western North American Region (WANR) of The International Biometric Society 2006 Annual Meeting | Chair: Responsible for developing conference themes, all invited sessions, keynote speakers, contributed paper sessions, and short courses, coordinating the meeting with local organization committee and secretary of the Institute of Mathematics Statistics (IMS)   |
| 2005             | Committee on Standards in Bone Measurements, the International Society for   | Committee Member: Responsible for development of position papers; performed a meta-analysis of densitometry precision and quality control studies;  |

|           |   |   |
|-----------|---|---|
|           | Clinical Densitometry   | developed statistical procedures for cross-calibration for scanner changes and prediction errors; and participated in committee meetings and discussions. |
| 2007      | Vice Chair, Program Committee, the 5 <sup>th</sup> Sino-US Medical Symposium for 21 <sup>st</sup> Century | Committee Vice Chair, responsible to organize the program of evidence-based medicine, clinical trials, and cutting edge technology.                       |
| 2007      | Co-Chair, Organization Committee, 2009 ICASA Applied Statistical Symposium                                | Responsible to organize the conference.   |
| 2007-2009 | Member, WNAR Regional Committee   | At- large representative  |
| 2007 -    | Member  | International Advisory Board, Med-X Center, Shanghai Jiao Tong University, Shanghai, China  |

## Service for Professional Publications:

2005- Editor of Book Series: Application of Statistics in Medical Sciences, Imperial College Press/World Scientific Publication Corp

|              |   |          |
|--------------|---|----------|
| 1994         | American Journal of Roentgenology         | Reviewer |
| 1995-2000    | Calcified Tissue International            | Reviewer |
| 1996         | Australia Journal of Statistics           | Reviewer |
| 1996         | American Journal of Medicine              | Reviewer |
| 1994-present | Bone                                      | Reviewer |
| 1995-2003    | Statistics in Medicine                    | Reviewer |
| 1995-present | Journal of Bone and Mineral Research      | Reviewer |
| 1996-2002    | Biometrics                                | Reviewer |
| 2000-present | American Journal of Neuroradiology (AJNR) | Reviewer |
| 2002-2003    | Journal of Clinical Nutrition             | Reviewer |
| 2004-present | Journal of Clinical Oncology (JCO)        | Reviewer |
| 2004-present | Mathematical and Computing Modeling       | Reviewer |
| 2005-present | Mathematics Review                        | Reviewer |

Name: Ying Lu, Ph.D.

Department of Radiology

Date Prepared: July 1, 2008

2006 - present      Medical Decision Making

Reviewer

**INVITED LECTURES***International*

| Date | Location   | Title  |
|------|--|--|
| 1995 | Shanghai Jiao Tong Univ (SJTU), China                                  | Correlation Coefficient in Longitudinal Studies  |
| 1997 | Guangdong Health Statistics Association, China                         | Statistics in Medical Decision Making  |
| 1997 | SJTU, China  | Latent structured models and their applications  |
| 1999 | Beijing Medical University, China                                      | Applications of Statistics in Osteoporosis Research  |
| 1999 | Peking Union Medical College, China                                    | Instrument Quality Control in Osteoporosis Research  |
| 2001 | 1 <sup>st</sup> International Osteoporosis Conference (IOC), Beijing   | Statistics Issues in Classification and Diagnosis of Osteoporosis  |
| 2001 | 1 <sup>st</sup> Int. DXA QA Workshop, China                            | QA Data Processing Recommendations   |
| 2002 | Invited Talk, 15 <sup>th</sup> Int. Bone Densitometry Workshop, CA     | Can We Monitor Hip BMD Based on Longitudinal Data of Spine Phantoms?   |
| 2002 | Plenary Talk, 2002 IOC, Shanghai, China                                | Cost-effective Identification for Women with High Risk of Hip Fracture                                       |
| 2002 | 2 <sup>nd</sup> Int. DXA QA Workshop, China                            | QA Data Processing Recommendations   |
| 2003 | Plenary Talk, 2003 IOC, Beijing, China                                 | Cost-Effective Analysis for Osteoporosis Screening and Treatment, a Critical Review                          |
| 2003 | 3 <sup>rd</sup> Int. DXA QA Workshop, China                            | A Procedure to Evaluate Odds Ratios for Osteoporotic Fractures from Different Cross-Sectional Study Cohorts. |
| 2004 | Plenary Talk, 16 <sup>th</sup> Int. Bone Densitometry Workshop, France | Least Significant Change in Bone Densitometry for Individuals Measured on Different Devices                  |
| 2004 | Plenary Talk, 16 <sup>th</sup> Int. Bone Densitometry Workshop,        | Using Propensity Scores To Evaluate And Compare Odds Ratios For Osteoporotic Fractures From                  |

|      |  |   |
|------|--|---|
|      | France   | Different Cross-Sectional Study Cohorts   |
| 2004 | Medical School of Shanghai Jiao Tong University                            | On Comparison of Classification Methods with Survival Endpoints and a New Algorithm for Tree Structured Survival Analysis |
| 2004 | First People Hospital of Shanghai, China                                   | Recursive Partitioning Method and Its Applications in MR Imaging Studies of Brain Tumors                                  |
| 2005 | ICSA Applied Statistical Symposium   | A New Phase II Cancer Trial Design for Safety and Efficacy Endpoints.   |
| 2005 | Plenary Talk, 2005 IOC, Hongzhou, China                                    | On the Evaluation of Low Cost Diagnostic Methods of Osteoporosis  |
| 2006 | International Neurological Disease Symposium, SJTU and Univ. of California | Number matters! Appropriate Uses of Statistics in Clinical Studies  |
| 2006 | Plenary Talk, 2006 IOC, Beijing, China                                     | Risk Factors for Pediatric Bone Fracture  |
| 2007 | Plenary Talk, 2007 Sino-US Medical Symposium for 21 <sup>st</sup> Century  | Clinical Trials on Imaging Techniques   |
| 2007 | Plenary Talk, 2007 IOC, Beijing, China                                     | Application of the Cost-effective Models to Determine the Treatment Non-inferior Margins                                  |

National

| <u>Date</u> | <u>Location</u>   | <u>Title</u>  |
|-------------|---|---|
| 1990        | Joint Statistical Meetings (JSM), California  | Point Processes Arising from Carcinogenicity Experiments with Multiple Tumor Types      |
| 1992        | Florida International University  | EM Algorithm and Estimating of Tumor Incidence Rates                                    |
| 1993        |  | On the Estimates of Tumor Transition Rates in Animal Survival Sacrifice Experiments     |
| 1994        | American Public Health Association Annual Meeting                                   | On the Sample Size for One-Sided Equivalence of Sensitivities Based Upon McNemar's Test |
| 1996        | Dept. of Statistics, Rutgers University   | Comparative Calibration Without Gold Standard   |
| 1996        | Dept. of Biostatistics, Georgetown University                                       | Comparative Calibration Without Gold Standard   |

|      |   |   |
|------|---|---|
| 1996 | ██████████  | Statistical Quality Control and Their Applications in Longitudinal Osteoporosis Clinical Trials                           |
| 1996 | Memorial Sloan-Kettering Cancer Center, NY                                      | Recent Development in Comparative Calibrations  |
| 1996 | Neyman's Seminar, UC Berkeley, CA   | Recent Development in Comparative Calibrations  |
| 1996 | UC Irvine, CA   | Surgically Defined Prognostic Parameters in Early Cervical Carcinoma: A Tree Structured Survival Analysis                 |
| 1998 | ██████████ USA  | Statistical Quality Control and Quality Assurance for Osteoporosis Clinical Trials  |
| 2000 | UCLA, Department of Biostatistics   | Evaluating Prospective Information from a Cross-sectional Correlation with an Established Marker.                         |
| 2000 | Dept. of Public Health and Epidemiology, Univ. of Miami                         | Evaluating Prospective Information from a Cross-sectional Correlation with an Established Marker.                         |
| 2002 | Dept. of Biostatistics, UC Davis, CA  | Statistics issues in Classification and Diagnosis of Osteoporosis   |
| 2004 | University of California, Davis, Department of Statistics                       | A New Design for Phase II Cancer Trials with Total and Partial Responses.   |
| 2004 | ██████████  | A New Design for Phase II Cancer Trials with Total and Partial Responses.   |
| 2005 | Dept. of Biostatistics, Tulane Univ., LA  | A New Design for Phase II Cancer Trials with Total and Partial Responses.   |
| 2005 | Division of Biostatistics, Cancer Center, University of Alabama, Birmingham, AL | On Comparison of Classification Methods with Survival Endpoints and a New Algorithm for Tree Structured Survival Analysis |
| 2005 | Sylvester Comprehensive Cancer Center, University of Miami School of Medicine   | New Designs for Phase II Cancer Clinical Trials   |
| 2007 | Department of Biostatistics, UCLA   | On the Optimum Combination of Diagnostic Variables  |
| 2007 | ASA San Francisco Bay   | On the Optimum Combination of Diagnostic  |

|      |  |  |
|------|--|--|
|      | Area Chapter                                   | Variables  |
| 2007 | Biostatistics Workshop,<br>Stanford University | Discriminating Grade II Astrocytomas and<br>Oligodendrogliomas Using the Magnetic Resonance<br>Spectroscopy (MRS) Parameters |
| 2007 | Department of Biostatistics,<br>UCLA           | Research Questions in Statistical Design of Phase II<br>Cancer Clinical Trials   |

*UCSF Postgraduate Courses*

|      |   |  |
|------|---|--|
| 1998 | Osteoporosis Update, 1998<br>Dept. of Radiology, San<br>Francisco, CA | Precision and Accuracy of Bone Densitometry        |
| 1998 | Osteoporosis Update, 1998<br>Dept. of Radiology, San<br>Francisco, CA | Quality Control for Densitometry Data              |
| 1999 | Ultrasound Workshop   | Understanding QUS Research - Clinical Implications |

## INTERNATIONAL WORKSHOP

Course Director and Faculty. *Key Elements for Conducting High Quality Clinical Trials*, A Pre-Conference Workshop of the 5<sup>th</sup> Sino-US Symposium on Medicine in the 21<sup>st</sup> Century, October 11, 2007, Shanghai, China

## VISITING PROFESSORSHIP

2006 - Fudan University School of Public Health, Shanghai, China

## RESEARCH ROUNDS

|      |   |   |
|------|---|---|
| 1996 | Biostatistics Seminar, Department<br>of Epidemiology and Public<br>Health | Comparative Calibration Without Gold Standards                            |
| 2002 | Biostatistics Seminar, Department<br>of Epidemiology and Public<br>Health | On Non-inferiority of Sensitivity and Specificity<br>of a Diagnostic Test |
| 2002 | Progress in Radiology, Dept. of<br>Radiology, San Francisco, CA           | Statistical Considerations in Diagnosis and<br>Screening Imaging Trials   |

GOVERNMENT AND OTHER PROFESSIONAL SERVICE

|         |   |                 |
|---------|---|-----------------|
| 10/2001 | Project Grant Review Section, National Cancer Institute | Ad hoc Reviewer |
| 09/2002 | Project Grant Review Section, National Cancer Institute | Ad hoc Reviewer |

|          |  |                  |
|----------|--|------------------|
| 06/2004  | NIH Epidemiology of Clinical Disorders and Aging Study Section   | Temporary member |
| 10/2004  | NIH Epidemiology of Clinical Disorders and Aging Study Section   | Temporary member |
| 11/2004  | Special Emphasis Panel (SEP) for ECDA Study Section  | Reviewer         |
| 02/2005  | NIH Epidemiology of Clinical Disorders and Aging Study Section   | Temporary member |
| 06/2005  | NIH Neurological, Aging, and Musculoskeletal Epidemiology (NAME) Study Section (former ECDA Study Section)         | Temporary member |
| 10/2006- | NIH Neurological, Aging, and Musculoskeletal Epidemiology (NAME) Study Section (former ECDA Study Section)         | Member           |
| 11/2006- | American Joint Committee on Cancer (AJCC) Statistical Task Force for 9 <sup>th</sup> Edition of AJCC Tumor Staging | Member           |
| 11/2007- | FDA Advisory Panel on Peripheral CNS Diseases  | Member           |
| 2007 -   | Organization Committee of 2009 ICSA Applied Statistical Symposium  | Co-Chair         |

## UNIVERSITY AND PUBLIC SERVICE

### University Service

#### *System-Wide*

|           |   |
|-----------|---|
| 2003-2007 | Data Safety Monitoring Committee of a Phase III trial, UC Davis Cancer Center, University of California, Davis                  |
| 2005      | Biostatistics Shared Resource Advisory Committee, The Chao Family Comprehensive Cancer Center, University of California, Irvine |
| 2006-     | Contact person for UC 10+10 Program with Shanghai Jiao Tong University  |

#### *Campus*

|               |  |
|---------------|--|
| 09/99-present | Protocol Review Committee, UCSF Comprehensive Cancer Center                          |
| 09/99-present | Member, Site Protocol Committees, Cutaneous Oncology Program and GI Oncology Program |
| 2002-present  | Clinical Research Steering Committee, UCSF Comprehensive Cancer Center               |
| 2002-present  | Shared Resources Oversight Committee, UCSF Comprehensive Cancer Center               |

#### *Departmental*

|      |  |
|------|--|
| 1994 | Member, Faculty Search Committees for Assistant Adjunct Professor (Biostatistics), |
|------|--|

## Osteoporosis and Arthritis Research Group, Department of Radiology, UCSF

- 03/94-present Statistical Consultant for Faculty and other members in the Department of Radiology
- 1996-99 Member, Research Council, Osteoporosis and Arthritis Research Group, Department of Radiology, UCSF
- 1996-99 Member, Quality Assurance Council, Osteoporosis and Arthritis Research Group, Department of Radiology, UCSF
- 1996 Member, Faculty Search Committee for Director of Computer Lab, Osteoporosis and Arthritis Research Group, Department of Radiology, UCSF
- 1998 Member, Faculty Search Committees for Assistant Adjunct Professor (Biostatistics), Osteoporosis and Arthritis Research Group, Department of Radiology, UCSF
- 1998 Member, Organizing Committee, Osteoporosis Update, 1998, May 27-39
- 2001 Member, Committee for Adjunct Faculty, Department Retreat, Department of Radiology, UCSF
- 2002 Chair, Faculty Search Committee for Associate Adjunct Professor, Biostatistics Core, UCSF Comprehensive Cancer Center
- 2004 Member, Faculty Search Committee for Assistant Adjunct Professor (Biostatistics), Department of Radiology, UCSF
- 2005 Member, Faculty Search Committee for Assistant Adjunct Professor (Biostatistics), Department of Radiology, VA Medical Center, UCSF
- 2007 Member, Faculty Search Committee for Assistant Adjunct Professor (Biostatistics), Department of Neurological Surgery, UCSF
- 2007 Member, Executive Research Council, Department of Radiology

*Outside Consultant*

- 1998  Teaching the use of statistical process control procedures for osteoporosis clinical trials
- 2002-2004 Harvard Medical School Statistical consultant for an R03 research grant on automatic algorithm to detect arthritis
- 2001-2003 Chinese Osteoporosis Foundation Statistical consultant for design and analysis of the Study of Normative Values of the Chinese Bone Mineral Density

2003- [REDACTED] Statistical consultant for a Chinese herb medicine clinical trial

2005-06 [REDACTED] Statistical consultant for clinical trial design methodology

2005-06 [REDACTED] Data Safety Monitoring Board

2003- [REDACTED] Statistical consultant for clinical trial design, comparison of biomarkers, and quality control for clinical trials.

*Service at the University of Miami School of Medicine*

1992-94 Member, Protocol Review Committee, Sylvester Comprehensive Cancer Center, University of Miami School of Medicine, responsible for review all cancer protocols and grant applications

1991-94 Member, Computer Committee, the Department of Epidemiology and Public Health, University of Miami School of Medicine, with a responsibility for policies of statistical computing and other computer applications.

**SUMMARY OF SERVICE ACTIVITIES**

My main service activities are as the director of the Biostatistics Core of the UCSF Comprehensive Cancer Center. I manage a core of 9 biostatisticians including 4 full time staff members and 5 part-time faculty members. The biostatistics core provides full services to all cancer center members for their research, including basic sciences, population studies, therapeutic trials, and diagnoses. As a director, I maintain the core budget, set priorities, develop new statistical areas to support new needs for cancer center members, participate in cancer management committees, etc. During my watch, the Biostatistics Core has grown from 5 senior biostatisticians into 9 senior biostatisticians.

My service in the Department of Radiology includes managing the Biostatistics group and Biostatistics consulting services within the department. We provide statistical support for grant preparation, clinical study design and data analysis, preparation of publications, and mentoring junior statisticians within the department, and provide statistical training to junior faculty members, post-doctoral and fellows.

In addition, I have provided services for NIH grant review and program committees for the International Osteoporosis Conferences, International Biometrics Society Western-Northern American Region, International Chinese Statistical Association, American Statistical Association San Francisco Bay Area Chapters, etc. I was elected as the Chapter President for 1998-99 and 2005-06. I have also served as a member of the Biostatistics Shared Resource Advisory Committee, the Chao Family Comprehensive Cancer Center, the University of California, Irvine, 2005 and the Data Safety Monitoring Committee for clinical trials of the University of California, Davis (2003-present) and the [REDACTED] (2005-).

TEACHING and MENTORING (2004-5)Formal TeachingCourse in Biostatistics (Within UCSF)

| Quarter / Semester | Course #/Seminar   | Teaching Contribution   | Lecture                                     | Hours Preparation   |
|--------------------|--|---|---|---|
| Spring 95          | Clinical Research Training Program, Department of Epidemiology and Biostatistics, UCSF                     | Teaching topics on regression analysis for survival data                        | 2 hours lecture<br>2 hours statistical labs | 12 hours  |
| Spring 97          | Workshop on Longitudinal Data Analysis, Department of Epidemiology and Biostatistics, UCSD                 | Lecture on "Exploring longitudinal data"  | 1 hour                                      | 4 hours   |
| Spring 98          | Workshop on Modeling Survival Data in Medicine, Department of Epidemiology and Biostatistics, UCSF         | Lecture on "Modeling Survival Data in Medical Research"                         | 1 hour                                      | 4 hours   |
| May 98             | Osteoporosis Update 1998, Radiology Continuing Education, UCSF   | Faculty for two lectures  | 2 hours                                     | 16 hours, including planning of the workshop                            |
| 1998               | Biostatistics Brown Bag Lectures, Osteoporosis and Arthritis Research Group, Department of Radiology, UCSF | Course director (10 lecture series) and faculty                                 | 4.5 hours                                   | 40 hours (including creating, planning, and helping for other lectures) |
| March 99           | International Ultrasound Workshop  | Faculty to give lecture on "Understanding QUS Research – Clinical Implications" | 45 minutes                                  | 4 hours including planning  |
| Fall 99            | Neuro-radiology Research Rounds, Department of   | Statistics for Radiologists   | 4 hours                                     | 20 hours  |

## Radiology, UCSF

|                      |  |  |                 |  |
|----------------------|--|--|-----------------|--|
| Fall 2000            | Biostatistics 250. Individual Instruction on Multivariate Statistics, Department of Epidemiology and Biostatistics, UCSF               | Instructor of a Ph.D. student in UCB/UCSF Bioengineering Program   | 10 hours        | 20 hours   |
| Spring 2001          | Biostatistics 250. Individual Instruction on Statistical Methods for Repeated Data, Department of Epidemiology and Biostatistics, UCSF | Instructor of a Ph.D. student in UCB/UCSF Bioengineering Program   | 10 hours        | 20 hours   |
| Spring, 2001         | Biostat 250 Individual instruction on Survival Analysis, Department of Epidemiology and Biostatistics, UCSF                            | Instructor of a Ph.D. student in UCB/UCSF Bioengineering Program   | 5 hours         | 10 hours   |
| Jan, 2002            | Grand Rounds: Progress in Radiology, Department of Radiology, UCSF   | Statistics in Imaging and Diagnostic Clinical Trials               | 1 hour          | 4 hours  |
| Feb, 2002            | Neuro-radiology Research Rounds, Department of Radiology, UCSF   | Lecture of Statistics for Radiologists                             | 2 hours         | 8 hours  |
| Fall 2002            | Biostat 250 Individual instruction on Recursive Partitioning Methods, Department of Epidemiology and Biostatistics, UCSF               | Instructor of a Ph.D. student in UCB/UCSF Bioengineering Program   | 10 hours        | 20 hours   |
| Spring, 2003         | Neuro-radiology Research Rounds, Department of Radiology, UCSF   | Lecture of Statistics for Radiologists                             | 4 hours         | 12 hours   |
| Sept. 04-<br>May, 05 | Lecture Series, Department of Radiology, UCSF  | Course Director and Faculty, "Statistics in Radiological Research" | 5 hours lecture | 30 hours, including creating, planning, & organizing the course and help |

|                             |   |  |         | other<br>lectures |
|-----------------------------|---|--|---------|-------------------|
| Apr.<br>2006                | Overview: Statistics in Cancer<br>Clinical Trials | Course Director<br>and Faculty for<br>UCSF<br>Comprehensive<br>Cancer Center | 2 hour  | 4 hours           |
| Sept. 06 –<br>October<br>06 | Statistics for Radiology Study                    | Grand rounds for<br>Radiology<br>Residents                                   | 2 hours | 4 hours           |

*At the University of Miami School of Medicine*

| <b>Semester</b> | <b>Course</b> | <b>Title</b>             | <b>Total Hours</b> |
|-----------------|---------------|--------------------------|--------------------|
| Spring 91       | EPH502        | Medical Biostatistics II | 64 hours           |
| Fall 91         | EPH501        | Medical Biostatistics I  | 90 hours           |
| Fall 92         | Residents     | Clinical Trials          | 4 hours            |
| Spring 93       | EPH501        | Medical Biostatistics I  | 90 hours           |

## PREDOCTORAL STUDENTS

| Dates              | Name                | Program   | Faculty Role   | Current Position                                     |
|--------------------|---------------------|---|--|--|
| 1992               | ██████████          | MPH, University of<br>Miami School of<br>Medicine | Thesis Committee   | Unknown  |
| 1992               | ██████████          | MPH, University of<br>Miami School of<br>Medicine | Thesis Advisor   | Unknown  |
| Mar,01<br>-Jul. 01 | ██████████<br>DDS   | Orthodontics Program,<br>UCSF Dental School       | MPH Thesis<br>Statistical Advisory   | Private Practice                                     |
| Mar,01<br>-Jul. 01 | ██████████,<br>DDS  | Orthodontics Program,<br>UCSF Dental School       | MPH Thesis<br>Statistical Advisory   | Private Practice                                     |
| 2003               | ██████████<br>Ph.D. | UCB/UCSF<br>Bioengineering                        | Member, Dissertation<br>Committee,<br>Statistical advisory<br>for Ph.D. dissertation | Assistant<br>Researcher, Dept. of<br>Radiology, UCSF |
| 1/1/05-            | ██████████          | UCB/UCSF<br>Bioengineering                        | Member, Qualifying<br>Committee and  | Ph.D. Candidate                                      |

|         |                  |  |  |  |
|---------|------------------|--|--|--|
|         |                  | Graduate Student                               | Dissertation<br>Committee  |  |
| 02/2006 | [REDACTED]       | UCB/UCSF<br>Bioengineering<br>Graduate Student | Member, Qualifying<br>Committee and<br>Dissertation<br>Committee | Ph.D. Candidate  |
| 05/2006 | [REDACTED], MD   | UCB/UCSF<br>Bioengineering<br>Graduate Student | Member, Qualifying<br>Committee and<br>Dissertation<br>Committee | Ph.D. Candidate  |
| 01/2007 | [REDACTED]<br>MS | Visiting Ph.D Student                          | Thesis advisor   | Ph.D. Candidate,<br>Dept. of Medical<br>Statistics, Sun Yat-<br>Sen University,<br>China |

POSTDOCTORAL FELLOWS AND RESIDENTS DIRECTLY SUPERVISED OR MENTORED

| Dates                | Name                | Position                | Faculty Role                       | Current Position                                   |
|----------------------|---------------------|-------------------------|------------------------------------|--|
| 06/2006-             | [REDACTED]          | Post-doctoral<br>fellow | Research Advisor<br>and Supervisor |  |
| 8/15/01-<br>08/12/04 | [REDACTED]<br>Ph.D. | Post-doctoral<br>fellow | Research Advisor<br>and Supervisor | Professor, [REDACTED]                              |
| 1996-1999            | [REDACTED], Ph.D.   | Post-doctoral<br>fellow | Research Advisor<br>and Supervisor | Specialist, Department of<br>Neurology, [REDACTED] |

WORKSHOP

|      |                                |  |
|------|--------------------------------|--|
| 2007 | Course Director<br>and Faculty | <i>Key Elements for Conducting High Quality Clinical Trials, A Pre-Conference Workshop of the 5<sup>th</sup> Sino-US Symposium on Medicine in the 21<sup>st</sup> Century, October 11, 2007, Shanghai, China</i> |
|------|--------------------------------|--|

INFORMAL TEACHING (Describe nature of this teaching since last advancement)

My informal teaching includes individual teaching of statistics to the graduate students in the UCB/UCSF Bioengineering program in helping them to prepare their qualifying examinations and to write their dissertations; to students of UCSF Medical School and Dental School and visiting students in helping them to write their theses and to perform short-term research projects that require study designs, sample size calculations and proper statistical analyses; to clinical radiology fellows, post-doctoral researchers, and post-doctoral fellows supervised by members of UCSF Comprehensive Cancer Center in helping them to use proper statistical design and analysis methods in their research projects; and helping junior faculty members in the Department of Radiology to use correct statistics in their research. Because the clinical and research questions are diverse, individual teaching is the most efficient method to cover the related statistical topics.

(date) (description of teaching, mentoring of students, trainees)

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- 2003-2004 Total of 199 hours for individual teaching to 1 UCB/UCSF Bioengineering Ph.D. student, 14 clinical (MD) and post-doctoral (Ph.D.) fellows in Radiology, and 1 medical student.
- 2004-2005 Total of 103 hours for individual teaching for 6 UCB/UCSF Bioengineering Ph.D. students, 3 UCSF medical students, and 10 clinical fellows (MD) and post-doctoral fellows (Ph.D.) in the Department of Radiology and Department of Surgery and a supervising post-doctoral fellow.
- 2005-2006 Total of 156 hours for individual teaching for 4 UCB/UCSF Bioengineering Ph.D. students, 1 PhD/MD Student, 5 UCSF medical students, and 8 clinical fellows (MD) and post-doctoral fellows (Ph.D.) in the Department of Radiology and Department of Surgery and a supervising post-doctoral fellow

## FACULTY MENTORING

### FACULTY MENTORED

| Dates        | Name       | Position while Mentored | Mentoring Role      | Current Position   |
|--------------|------------|-------------------------|---------------------|--|
| 1994-97      | [REDACTED] | Assistant Adj. Prof.    | OARG mentor         | General Manager, [REDACTED]                                  |
| 1997-00      | [REDACTED] | Assistant Adj. Prof.    | OARG mentor         | Associate Professor, Department of Biostatistics, [REDACTED] |
| 2004-present | [REDACTED] | Assistant Adj. Prof.    | Departmental mentor | Assistant Prof in Resident.                                  |

|               |            |                      |                                    |                             |
|---------------|------------|----------------------|------------------------------------|-----------------------------|
| 2004-present  | [REDACTED] | Assistant Adj. Prof. | Departmental mentor                | Assistant Adj. Prof.        |
| 09/04 – 06/05 | [REDACTED] | Assistant Adj. Prof. | Supervision                        | Assistant Prof., [REDACTED] |
| 2004-present  | [REDACTED] | Assistant Adj. Prof. | Informal mentoring and supervision | Assistant Adj. Prof.        |

**SUMMARY OF TECHING HOURS**

| Date    | Summary Hours   | Lecture | Preparation |
|---------|---|---------|-------------|
| 2003-04 | 199 Total Hours of teaching during 2003-04  |         |             |
|         | Formal class or course teaching hours   | 4       | 12*         |
|         | Informal/Clinical Teaching  | 83      | 0           |
|         | Mentoring hours of post-doctoral fellow   | 100     | 0           |
| 2004-05 | 138 Total Hours of teaching during 2004-05  |         |             |
|         | Formal class or course teaching hours   | 5       | 30*         |
|         | Informal/Clinical Teaching  | 83      | 0           |
|         | Mentoring hours of post-doctoral fellow   | 20      | 0           |
| 2005-06 | 157 total hours of teaching   | 2       | 4           |
|         | Formal class or course teaching hours   | 156     |             |
|         | Informal/Clinical Teaching  |         |             |
| 2006-07 | Planned 4 teaching sessions for resident fellows and a workshop for research fellows, and additional 150 hours of individual teaching | 150     | 4           |

\* The number of hours for preparation reflects hours of creating, planning, and helping other lectures as well as a course on different statistical topics.

**TEACHING NARRATIVE**

My teaching includes course design, organization and presentation of the lecture series on “Statistical Methods for Radiology Research” in 2004-2005. The 10 lecture series covered statistical topics specific and unique to radiology research. They were well attended and the average class size was 20. These lectures were announced to the entire UCSF campus and included formal evaluations. They are designed for radiology fellows, post-doctoral researchers, junior clinical faculty and staff, and graduate students. The teaching evaluation was 76% of “excellent” and 20% of “very good” for the contents, delivery, syllabus, and practical values. I also gave research rounds to Neuro-Radiology fellows focusing statistical applications to clinical research. A new course has been planned for the Spring 2006 research rounds for all radiology residents, clinical fellows, post-doctoral fellows, and junior faculty members on “Statistical Methods in Radiology Research.” There is no similar course at UCSF.

My other teaching activities include individual teaching for UCB/UCSF Bioengineering graduate students, medical students, post-doctoral fellows, clinical fellows, and junior faculty members, and other researchers in the Department of Radiology. These teaching activities include formal biostatistics individual studies (Biostat 250) on quarterly basis and individual study sessions on hourly basis.

## RESEARCH AND CREATIVE ACTIVITIES

### RESEARCH AWARDS AND GRANTS

#### CURRENT

#### Ongoing Support

R01EB004079-01A2 (PI, Lu) 04/01/2006-03/31/2009 NIH

Statistical Methods for Evaluation and Validation of Diagnostic Tests.

\$180,000 direct/year 1

\$560,000 years 1-3

Study Aim: This grant is to develop statistical methods for evaluation of non-inferiority test and for accurate estimation of relative risk using cross-sectional and short-term follow-up data.

Role: Principal Investigator

P30 CA82103-01 McCormick (PI) 08/01/02-05/31/07 NCI  
Cancer Center Support Grant 3<sup>rd</sup> yr direct costs \$323,046

This grant provides support for Cancer Center infrastructure. Dr. Lu is the Biostatistics Core Director for the UCSF Comprehensive Cancer Center.

Role: Director of Biostatistics Core

1 R01 CA102303-01 (Fong, Larry, P.I.) 04/1/04-03/31/09 \$205,000 1<sup>st</sup> yr directs

Title: Dendritics Cell Immunotherapy for Colorectal Cancer

Role: Co-Investigator

The Objective of this project is to evaluate novel approaches to generating antigen-pulsed dendritic cells (DC) for the treatment of colorectal cancer.

1 R01 CA109418 (Fong, Larry, P.I.) 04/1/04-03/31/09

Title: Modifying T Cells Responses to Tumor Vaccines

Role: Co-Investigator

NNJ04HF78G (Lang, PI) 06/04-06/07 5%  
NASA \$151,846 direct/1 yr

The Effect of Long-Duration Spaceflight on the BioMechanics of the Proximal Femur

The goal of this project is to study spaceflight-related changes in strength using finite element analysis.

Role: Co-Investigator

Research Grant of Aircast Foundation (Li, Xiaojuan PI)

Title: Assessment of cartilage and subchondral bone injury of the knee with high field MRI

Role: Consultant

R01 CA116041-O1A1

07/01/06-5/31/11

NCI

Title: Identification of MRS Markers of Glioma Progression

Role: Co-Investigator

Agency: NCI-R01

PI: Tracy McKnight, Ph.D.

Role: Co-Investigator

2R01-CA69587 (Competing Renewal) (Hylton) 04/01/06-12/31/11 NCI

Title: Anatomic and Biologic Staging of Breast Disease With MRI

Agency: NCI-R01

PI: Nola Hylton, Ph.D.

The goal of this study is to evaluate the effectiveness of quantitative measurements derived from contrast enhanced MRI for assessing primary breast tumors, to support their use as in-vivo predictive markers that can be used to guide treatment.

Role: Co-investigator

NIH R01 CA116182 (Hylton) 08/01/06-07/31/11

National Institutes of Health

***MRI for Staging DCIS and Assessing Response to Treatment***

The primary study aim is to refine existing contrast-enhanced (CE) MR methods for characterizing ductal carcinoma in situ (DCIS) to better identify DCIS and define its extent, for application to assessing response to neoadjuvant hormonal and statin treatment.

Role: Co-Investigator

Title: Evaluation of MRI & MR Spectroscopic Markers in Non-Alcoholic Fatty Liver Disease

Agency: NIH-R01

PI. Aliya Qayyum, MD

The goal of the study is to use MRI and MR spectroscopic biomarker to characterize the live fat and the related diseases.

Role: Co-Investigator

Title: Dynamic Magnetic Resonance Imaging of the Knee – the Effect of Ligament Injury and Reconstruction

Role: Co-Investigator

Agency: Orthopaedic Research and Education Foundation

PI: [REDACTED], MD

Role: Consultant

Title: Image Guided determination of Functional Pathways in Neurological Oncology

Role: Co-Investigator

Agency: NIH/NCI-R01

P.I., Roland Henry, Ph.D.

The study will use statistical methods to study the MR/DTI imaging for neuron-tracking for brain tumor patients.

Role: Co-Investigator

Title: Age-Related Changes of Proximal Femoral Strength in Men and Women

Agency: NIH/NCI-R01

P.I., Thomas Lang, Ph.D.

The goal is to use QCT to monitor age related changes of proximal femoral strength and determine the factors affect age related changes.

Role: Co-Investigator

Title: The proximal femoral musculature: a new risk factor for hip fracture

Role: Co-Investigator

Agency: NIH/NCI-R01

P.I., Thomas Lang, Ph.D.

## Completed

### Completed Research Support

|   |                   |                                  |     |
|---|-------------------|----------------------------------|-----|
| R01 AR46197-01 Lang (PI)                                | 04/01/01-03/31/05 | NIAMS                            | 10% |
| Race Differences in Hip Strength, Density, and Geometry |                   | \$213,750 4 <sup>th</sup> yr dir |     |

The aim of this project is to attribute the differences in hip fracture risk between Africa and White Americans to the racial differences in hip geometry, density, and strength via CT and finite element models.

Role: Co-Investigator

|   |           |                  |
|---|-----------|------------------|
| ██████ (PI)                               | -12/31/01 | Komen Foundation |
| Role: Co-Investigator and Biostatistician |           |                  |

|  |                   |      |
|--|-------------------|------|
| HEDS-04/05 Lang (PI)   | 1/1/99-12/31/2000 | NASA |
| Subregional Assessment Of Bone Loss In The Axial Skeleton In Long-Term Spaceflight |                   |      |

We will utilize volumetric QCT of the hip and spine to determine compartmental bone loss in astronauts making long-duration spaceflights on the International Space Station.

Role: Co-Investigator and Biostatistician

|  |             |       |
|--|-------------|-------|
| NIH R01 AR43691 Peterfy (PI)                           | 1994 – 1999 | NIAMS |
| MRI Of Early Osteoarthritis Following Meniscal Surgery |             |       |
| Role: Co-Investigator and Biostatistician              |             |       |

|                                      |                   |       |
|--------------------------------------|-------------------|-------|
| R03 AR47104-01 Lu (PI)               | 04/01/01-01/31/05 | NIAMS |
| Utility of Multiple Diagnostic Tests |                   |       |

The aim of this project is to develop statistical tools to evaluate the utility of combinations of multiple diagnostic tests in diagnosis of osteoporosis and fracture risk assessment.

Role: PI

R01 AR 46905 Majumdar (PI) 04/01/01-01/31/05 NIAMS  
MRI to study cartilage bone interaction

We will study injury induced joint degenerate and subsequent repair mechanisms and manifested changes in articular cartilage, subchondral bone and peri-articular trabecular bone.  
Role: Co-Investigator

Lu (PI) [redacted] (Co-PI) 08/01/02-07/31/03 International Osteoporosis Foundation

“Optimizing the accuracy & comparability of estimates of predictive power from limited data sources”

This is a collaborative travel grant between UCSF and University of Kiel in Germany to standardize the comparisons of bone densitometry modalities.

R01 CA 69587 Hylton (PI) 03/01/01-12/31/05 NCI 10%  
Anatomic and Biologic Staging of Breast Diseases with MRI \$175,000 yr 8 dir  
Role: Co-Investigator (10%)

The aim of this project is to use MRI to improve staging for breast tumor patients.  
Role: Co-Investigator

RO1 NS40117-01 Vigneron (PI) 12/01/00-1/31/06 NINDS 5%  
3D MR spectroscopic imaging of the newborn brain. \$225,000 5<sup>th</sup> yr dir

The goal of this bioengineering research project is to develop and implement advanced Magnetic Resonance Spectroscopic imaging techniques to detect the distribution of metabolite levels throughout the brain of neonates. This information will define the normal variation in metabolite levels with anatomic location and post-conceptual age. The database of normal MRSI spectra will improve our understanding of brain development and provide a reference for detecting abnormal metabolism in neonatal patients with neurologic damage. No Overlap  
Role: Co-Investigator

**Pending Grants**

[redacted]

[Redacted text block]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

#### Research Funding at the University of Miami School of Medicine (1990-1994)

| <b>Roles</b>           | <b>% Efforts</b> | <b>Grant Name</b>   | <b>P.I.</b> | <b>Direct Cost</b> |
|------------------------|------------------|---|-------------|--------------------|
| Co-<br>Investigator    | 20%              | NOMH 1Ro1 MH50239<br>Nutrition Aspect of HIV-<br>Infections in HIVU's                     | [REDACTED]  | \$ [REDACTED]      |
| Co-<br>Investigator    | 15%              | NIH 5Ro1 AG09661<br>Epidemiology of Alzheimer<br>Disease in 3 Ethnic Groups               | R. Prineas  | \$642,978.00       |
| Co-<br>Investigator    | 10%              | NIH 5Ro1 AG09661<br>Supplement<br>Epidemiology of Alzheimer<br>Disease in 3 Ethnic Groups | R. Prineas  | \$404,625.00       |
| Co-<br>Investigator    | 20%              | NINDS 5 PSO NS30291<br>Nerotrauma Center Core   | F. Stitt    | \$249,706.00       |
| Co-<br>Investigator    | 35%              | NCI 5P30 CA14395-20<br>Cancer Center Core   | A. Morales  | \$1,358,495.00     |
| Assistant<br>Professor | 5%               | MPH Teaching Grant  | [REDACTED]  | \$ [REDACTED]      |

|                 |    |  |            |              |
|-----------------|----|--|------------|--------------|
| Co-Investigator | 5% | NIH 1R01 HD28891<br>High Risk Reduction for HIV<br>in Zambia | D. Feldman | \$190,975.00 |
|-----------------|----|--|------------|--------------|

## PUBLICATIONS

### Peer-Reviewed Journal Articles

1. 1987 Lu Y. Some opportunistic replacement models, Journal of Shanghai Jiaotong Univ. 1987, 127 (2): 10--20; MR0907811 (88h:90090)\* (In Chinese)
2. 1991 Stitt FW, Lu Y., Dickinson GM, and Klimas NG. Automated severity classification of AIDS hospitalizations. Medical Decision Making 11:S41-S45.
3. 1992 Shor-Posner G, Mantero-Atienza E, Beach R, Javier J, Feaster D, Sotomayor M, Cabrejos C, Fletcher MA, Lu Y., Sauberlich H, Baum MK. Association of nutritional abnormalities and immune parameters in HIV-1 seronegative homosexual men. Journal of Immunology and Infectious Disease 2:209-216.
4. 1992 Baum MK, Shor-Posner G, Cassette I, Bowen P, Lu Y., Beach RS, Mantero-Atienza E. Influence of HIV-1 infection on vitamin status and requirements. N.Y. Academy of Science 669:165-174.
5. 1992 Beach RS, Morgan R, Wilkie F, Mantero-Atienza E, Blaney N, Shor-Posner G, Lu Y., Eisdorfer C, Baum MK. Plasma cobalamin levels as a potential cofactor in studies of HIV-1 related cognitive changes. Archives of Neurology 49:501-506.
6. 1992 Jonas MM, Zilleruelo GE, LaRue SI, Abitbol C, Strauss J, Lu Y. Hepatitis C Infection in a pediatric dialysis population. Archives of Pediatrics 89:707-709.
7. 1993 Malani HM, Lu Y. Animal carcinogenicity experiments with and without serial Sacrifice. Communications in Statistics—Theory and Methods 22:1557-1584.
8. 1993 Shor-Posner G, Basit A, Lu Y., Cabrejos C, Peck M, Chang J, Fletcher MA, Mantero-Atienza E, Baum MK. Hypocholesteremia is associated with immune dysfunction in early HIV-1 infection. American Journal of Medicine 94:515-519.
9. 1993 Peck MD, Mantero-Atienza E, Beach RS, Cabrejos C, Lu Y., Shor-Posner G, Baum MK. The esterified plasma fatty acid is altered in early HIV-1 infection. Lipids 28:593-597.
10. 1994 Lu Y., Stitt FW. Using Markov processes to describe the prognosis of HIV-1 infection. Medical Decision Making 14:266-272.

11. 1994 Lu Y, Malani HM. Estimating multiple tumor transition rates based on data from survival/sacrifice experiments. *Mathematical Biosciences* 122:95-125.
12. 1994 Baum MK, Shor-Posner G, Lu Y. Normal triglyceride levels in early HIV-1 infection. *Journal of AIDS* 8:131-132.
13. 1994 Baum MK, Cassetti LI, Bonvehi PE, Shor-Posner G, Lu Y, Sauberlich, H. E. Inadequate dietary intake contributes to altered nutritional status in early HIV-1 Infection. *Nutrition* 10:16-29.
14. 1994 Soloway MS, Lopez AE, Patel J, Lu Y. Results of radical cystectomy for transitional cell carcinoma of the bladder and the impact of chemotherapy. *Cancer* 73:1926-31.
15. 1994 Landy HJ, Feun L, Schwade JG, Snodgrass S, Lu Y, and Gutman F. Retreatment of intracranial gliomas. *Southern Medical Journal* 87:211-214.
16. 1994 Culter RB, Fishbain DA, Lu Y, Rosomoff RS, Rosomoff HL. The prediction of pain center treatment outcome for geriatric chronic pain patients. *Journal of Clinical Pain* 10:10-17.
17. 1995 Lu Y, Bean JA. On the sample size for studies of bioequivalence based upon McNemar's test. *Statistics in Medicine* 14:1831-1839.
18. 1995 Lu Y, Malani HM. Analysis of Animal Carcinogenicity Experiments with Multiple Tumor Types. *Biometrics* 51:73-86.
19. 1995 Baum MK, Shor-Posner G, Lu Y, Rosner B, Mentero-Atienza E, Beach RS, Sauberlich HE, Fletcher M, Eisdorfer C, Buring J, Hennekens C. Micronutrients and HIV-1 diseases progression. *AIDS* 9:1051-1056.
20. 1995 Shor-Posner G, Miguez-Burbano MJ, Lu Y, Fletcher MA, Sauberlich H, Baum MK. Elevated IgE in relationship to nutritional status and immune parameters in early HIV-1 disease. *Journal of Allergy and Clinical Immunology* 95:886-92.
21. 1995 Miguez-Burbano MJ, Shor-Posner G, Fletcher MA, Lu Y, Moreno JN, Carcamo C, Page B, Quesada J, Sauberlich H, Baum MK. Immunoglobulin E levels in relationship to HIV-1 disease, route of infection, and vitamin E status. *Allergy* 50:157-61.
22. 1995 Peterfy CG, van Dijke CF, Lu Y, Nguyen A, Connick TJ, Kneland JB, Tirman PFJ, Dent S, Genant HK. Quantification of articular cartilage volume in the metacarpophalangeal joints of the hand using 3D MR imaging: Assessment of accuracy and precision. *American Journal of Roentgenology* 165:371-375.

23. 1995 Yu W, Gluer CC, Grampp S, Jergas M, Fuerst T, Wu CY, Lu Y, Fan B, Genant HK. Spinal bone mineral assessment in postmenopausal women: A comparison between dual x-ray absorptiometry and quantitative computer tomography. *Osteoporosis International* 6:433-439.
24. 1995 Yu W, Gluer CC, Fuerst T, Grampp S, Li J, Lu Y, Genant HK. Influence of degenerative joint disease on spinal bone mineral measurements in postmenopausal women. *Calcified Tissue International* 57:169-174.
25. 1995 Gluer CC, Blake G, Lu Y, Blunt BA, Jergas M, Genant HK. Accurate assessment of precision errors: How to measure the reproducibility of bone densitometry techniques. *Osteoporosis International* 5:262-270.
26. 1996 Lu Y, Mathur AK, Blunt BB, Gluer CC, Will AS, Fuerst T, Jergas MD, Andriano K, Cummings SR, Genant HK. Comparison of visual examination and processing control charts to detect change points in longitudinal dual X-ray absorptiometry quality control data. *Journal of Bone and Mineral Research* 11:626-637.
27. 1996 Sevin B-U, Lu Y, Nadji MN, Bloch D, Koechli OR, Averette HA. Surgically defined prognostic parameters in early cervical carcinoma: A tree structured survival analysis. *Cancer* 78:1438-1446.
28. 1996 Sevin BU, Method MW, Nadji M, Lu Y, Averette HA, Small cell carcinoma of the cervix treated with radical hysterectomy. *Cancer* 77:1489-93.
29. 1996 Sevin BU, Nadji M, Lampe B, Lu Y, Hilsenbeck S, Koechli OR, Averette HE. Prognostic factors of early-stage cervical cancer treated by radical hysterectomy. *Cancer* 76:1978-86.
30. 1996 Ganjei P, Dickinson B, Harrison TA, Nassiri M, Lu Y. Aspiration cytology of neoplastic ovarian cysts: Is it accurate? *International Journal of Gynecological Pathology* 15:94-101.
31. 1997 Lu Y, Ye K, Ashwini MK, Hui S, Fuerst TP, Genant HK. Comparative calibration without a gold standard. *Statistics in Medicine* 16:1889-1905.
32. 1997 Fledman DA, O'Hara P, Baboo KS, Chitalu NW, Lu Y. HIV prevention among Zambian adolescents: Developing a value utilization/norm change model. *Social Science and Medicine* 44:455-468.
33. 1997 Grampp S, Genant HK, Mathur A, Lang P, Jergas M, Takada M, Glueer CC, Lu Y, Chavez M. Comparisons of non-invasive bone mineral measurements in assessing age-related loss, fracture discrimination, and diagnostic classification. *Journal of Bone and Mineral Research* 12:697-711.

34. 1997 Hui S, Gao S, Zhou XH, Jonston CC, Lu Y, Glueer CC, Grampp S, Genant HK. Universal standardization of bone density measurements A method with optimal properties. *Journal of Bone and Mineral Research* 12:1463-1470.
35. 1997 Lang TF, Keyak JH, Heitz MW, Augat P, Lu Y, Mathur A, Genant H, Assessment of proximal femur density and geometry using volumetric quantitative computed tomography: Precision and relation to bone strength. *Bone* 21:101-8
36. 1998 Wu CY, Glueer CC, Lu Y, Fuerst T, Hans D, Genant HK. Ultrasound characterization of bone demineralization. *Calcified Tissue International* 62:133-139.
37. 1998 Augat P, Fan B, Lane NE, Lang TF, LeHir P, Lu Y, Uffmann M, Genant HK. Assessment of bone mineral at appedicular sites in females with fractures of the proximal femur. *Bone* 22:395-402.
38. 1998 Link TM, Majumdar S, Augat P, Lin JC, Newitt D, Lu Y, Lane NE, Genant HK. In vivo high resolution MRI of the calcaneus - Differences in Trabecular Structure in Osteoporosis Patients. *Journal of Bone and Mineral Research* 13:1175-1182.
- 39.\* 1998 Majumdar S; Kothari M; Augat P; Newitt DC; Link TM; Lin JC; Lang T; Lu Y; Genant HK. High-resolution magnetic resonance imaging: Three-dimensional trabecular bone architecture and biomechanical properties. *Bone* 22:445-54.
40. 1998 Jiang Y, Zhao J, Augat P, Ouyang X, Lu Y, Majumdar S, Genant HK. Trabecular bone mineral and calculated structure of human bone specimens scanned by peripheral quantitative computed tomography: Relation to biomechanical properties. *Journal of Bone and Mineral Research* 13:1783-1790.
41. 1998 Ouyang, X; Majumdar, S; Link, TM; Lu, Y; Augat, P; Lin, J; Newitt, D; Genant, HK. Morphometric texture analysis of spinal trabecular bone structure assessed using orthogonal radiographic projections. *Medical Physics* 25:2037-45.
42. 1998 Daldrup H, Shames DM, Wendland M, Okuhata Y, Link TM, Rosenau W, Lu Y, Brasch RC. Correlation of dynamic contrast-enhanced magnetic resonance imaging with histologic tumor grade: Comparison of macromolecular and small-molecular contrast media. *Pediatric Radiology* 28:67-78.
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44. 1998 Genant HK, Jiang Y, Peterfy C, Lu Y, Redei J, Countryman P. Assessment of rheumatoid arthritis using a modified scoring method on digitized and original radiographs. *Arthritis Rheum* 41:1583-1590.
45. 1999 Kinkel K; Kaji Y; Yu KK; Segal MR; Lu Y; Powell CB; Hricak H. Radiologic staging in patients with endometrial cancer: A meta-analysis. *Radiology* 212(3):711-8.
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49. 2000 Zhao S, Xu Z, Lu Y, Long-term effectiveness evaluation and prediction of hepatitis B vaccination with a mathematical model in Shanghai. *International Journal of Epidemiology* 29:744-52, 2000.
50. 2000 Coakley FV, Lopoo JB, Lu Y, Hricak H, Albanese CT, Harrison MR, Filly RA. Volumetric assessment of normal and hypoplastic fetal lungs by prenatal single-shot RARE MR imaging *Radiology* 216: 107-111.
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53. 2000 Kinkel K, Hricak H, Lu Y, Tsuda K, Filly RA. US characterization of ovarian masses, a meta-analysis. *Radiology* 217:803-811.
54. 2000 Wefer, AE; Hricak, H; Vigneron, DB; Coakley, FV; Lu, Y; Wefer, J; Mueller-Lisse, U; Carroll, PR; Kurhanewicz, J. Sextant localization of prostate cancer: Comparison of sextant biopsy, magnetic resonance imaging and magnetic

- resonance spectroscopic imaging with step section histology [see comments]  
Journal of Urology 164(2):400-4.
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## REVIEWS and LETTERS

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**RESEARCH AND CREATIVE ACTIVITY**

My research activities focus on development and application of innovative statistical methods to evaluate and validate new diagnostic methods, and use them for outcome prediction and medical decision making. The clinical areas of these research activities are osteoporosis, cancer, and neurological diseases. My research has made significant impact on osteoporosis management, including the development of standardized total hip bone mineral density that was adopted by the International Standardization Committee of Bone Measures and by the manufacturers of DXA bone densitometers to define and diagnose hip osteoporosis. My research in quality control and quality assurance of bone densitometry and assessments of vertebral fractures was used in several major osteoporosis clinical trials that led the approvals of [REDACTED] and [REDACTED]. My recent research focuses on the following topics.

**1. Statistical Utility of Multiple Diagnostic Tests**

Osteoporosis is a major health problem in our aging society. As a silent disease, diagnosis and risk assessment of osteoporosis rely on diagnostic tests. In the past decade, a great number of diagnostic techniques have been developed to measure multiple regions of interests to assess bone density and quality. Because of the lack of appropriate statistical tools to assess diagnostic utility of combining multiple tests in their accuracy and cost-effectiveness, it is difficult to identify the optimum combination of tests. In my research, I focus on statistical methods for evaluating the utilities of combinations of multiple diagnostic tests performed in sequence or in

parallel. This project was funded by an R03 grant from NIH which was just completed with 8 peer-reviewed publications and 4 papers being reviewed or ready for submissions.

## 2. Statistical Methods in Cost-saving Diagnosis and Rapid Validation of New Techniques.

The primary research objective of this proposal is to develop innovative statistical methods to evaluate cost-saving non-inferior diagnostic techniques and to use a new cross-sectional and short-term follow-up case-control study design for rapid validation of low cost diagnostic techniques for rare diseases, such as osteoporosis and breast cancer. The statistical innovation include development of new non-inferiority tests for comparisons of the area under ROC curves under various conditions, new recursive partitioning algorithm to identify conditions when a low cost-test is inferior, superior, and non-inferior to the expensive optimum tests, simpler combinations of diagnostic markers without loss of efficiency, measurement error models, and Bayesian statistical analysis. An NIH R01 application is funded from 2006-2009..

## 3. Cancer Clinical Trials

New designs for cancer clinical trials are critically needed, in particular, with increasing availability of cytostatic agents. My research focus is on early phase cancer trials, mainly phase II and immunological trials to improve trial efficiency. This includes new designs for trade-off between toxicity and efficacy, simultaneous multiple efficacy endpoints, adaptive two stage design for composite hypotheses, and using imaging for dose escalation of combined agents. This project will directly facilitate the translational processes of new anti-tumor agents into patient care.