This is a major area of research activity including the COPD CRN, the VA Multi-Center Cooperative Trials Group, and the NHLBI COPD Gene study — along with follow up studies using the Lung Health Database. Multiple trainees have utilized this opportunity, such as Dr. Ken Kunisaki — a new junior trainer. Dr. Kathy Rice, Associate Professor of Medicine, carries out VA-funded clinical trials of case management in COPD.

**Dennis Niewoehner, MD**, Professor of Medicine

**COPD Clinical Trials:** I am currently the PI for one of the clinical sites in the NIH COPD Clinical Research Network (CRN). I also have been a Principal Investigator for several large COPD trials funded by the Department of Veterans Affairs and other entities. We are currently participating in several multicenter clinical trials in COPD along with smaller internally funded studies. Two of our current fellows have played an active role in the design, protocol development, and execution of a Phase 2 trial assessing a novel therapy for COPD. Dr. Ken Kunisaki, a recent research trainee now a Staff Physician and Assistant Professor at the Minneapolis VA Medical Center and has his own research support (R01 HL096453).

**John Connett, PhD**, Professor of Biostatistics; Director, CTSI Biostatistical Design & Analysis Center

**COPD Clinical Trials and Lung Epidemiology:** I have access to a number of large lung-related datasets that provide outstanding training opportunities, including the Lung Health Study (LHS), the NIH FORTE study (Feasibility of Retinoid Therapy of Emphysema), and ongoing trials in the NIH COPD CRN. Possible projects for trainees include: 1) to determine, using an intent-to-treat analysis, whether the LHS smoking intervention significantly reduces the incidence of clinically important respiratory and cardiovascular disease and mortality over a 12 to 15-year period following study enrollment; 2) to determine whether the beneficial effect of the smoking intervention program on measures of lung function persists through 11 to 12 years follow-up; and 3) to estimate the magnitude of the effects of FEV1 and FVC on the risks of cardiovascular and respiratory morbidity and mortality, after controlling for smoking history. All surviving participants of the Lung Health Study were invited to participate (sample size, 5600). The COPD-CRN has undertaken 5 clinical trials: (1) portable lightweight portable oxygen tanks versus large and heavy E-cylinders; (2) two vaccines for streptococcal infections; (3) leukotriene inhibitor in patients hospitalized for a COPD exacerbation; (4) daily macrolide antibiotic (azithromycin) to prevent COPD exacerbations; (5) daily simvastatin effect on COPD exacerbations. The latter study should be completed in 2015. The azithromycin trial's primary results were published (NEJM August, 2011) and additional papers are being written on biomarkers, risk factors for exacerbations, and other aspects. Trainees can contribute to analyses and initiate additional studies of this and other datasets.

**Ken Kunisaki, MD** *,**, Assistant Professor of Medicine

**Emphysema and HIV infection.** My research currently focuses on the pulmonary complications of HIV infection, particularly COPD. My R01 award funds an 85-site, 21-country pulmonary function substudy nested within a randomized trial of early vs. deferred antiretrovirals in patients with early HIV infection. We have enrolled 750 patients to date and we expect to close enrollment in the next 4-6 months. I am preparing several new NIH proposals about lung disease in HIV infection. I also have regional VA funding for an observational cohort study of veterans being evaluated for suspected obstructive sleep apnea. I also have several ongoing projects related to sleep apnea in patients with HIV infection.