Curriculum Vitae

Michael J. Daniels
Department of Statistics
University of Florida
102C Griffin-Floyd Hall
Gainesville, FL 32611

Education

AB	Applied Mathematics	Brown University (**magna cum laude**)	1991
ScD	Biostatistics	Harvard University	1995
	Thesis:	*Hierarchical Regression Models with Applications*	
	Minors:		
	Theoretical Statistics		
	Cancer Biology		

Academic Appointments

1995-1997	Visiting Assistant Professor
	Department of Statistics
	Carnegie Mellon University, Pittsburgh, PA
	— supported in part by Psychiatric Statistics Postdoctoral Fellowship
1997-2002	Assistant Professor
	Department of Statistics
	Iowa State University, Ames, IA
2002-2007	Associate Professor (with tenure)
	Department of Statistics
	University of Florida, Gainesville, FL
2005-	Executive Committee and Leader of Biostatistics, Data Management, and Methodology C
	Institute on Aging, University of Florida
2006-2007	Chief of Division of Biostatistics
	Associate Professor (with tenure)
	Department of Epidemiology and Biostatistics
	Department of Statistics (joint appointment)
2007-2008	Professor
	Department of Epidemiology and Biostatistics
2007-	Professor
	Department of Statistics
2008-2009	Interim Chair, Department of Statistics
2009-	Chair, Department of Statistics

Grants

NIH

PI : Covariance estimation in longitudinal cancer studies (NIH, R01), $150,000, 2001-2004.

co-PI : Analyzing complex longitudinal data in behavior science (NIH, R01), $180,000 (direct costs: subcontract from Brown University, PI on subcontract), 2004-2008.

PI : Bayesian methods for longitudinal cancer data (NIH, R01), $300,000 (direct costs), 2004-2009.

co-PI (Leader of Biostatistics and Data Management Core): Claude D. Pepper Older Americans Independence Center (OAIC), $600,000 /per year (direct costs). 2007-2012.

Co-I: ACE inhibition and physical performance in aged rats (NIH R01), $1.1 million (direct costs), 2005-2010.

co-I: Rural Lifestyle Intervention Treatment Effectiveness Trial (Rural Lite), NIH, $3.6 million (direct costs), 2008-2013.

co-PI : CMS Nonpayment for Nosocomial Injury and Risk of Falls in Hospitals (NIH, R01), $1.6 million, pending.

co-I (Leader of Data Management and Biostatistics Core), Autophagy in aging, (NIH, P01), $7.9 million, pending.

co-I: Therapeutic strategies to augment muscle rehabilitation, (NIH, P01), $6.7 million (direct costs), pending.

co-I: Magnetic Resonance Imaging and Biomarkers for Muscular Dystrophy (NIH, R01), $10.6 million, pending.

co-I: Mechanism of apoptosis in the development of sarcopenia and frailty in old age, (NIH, R01), $3.6 million, pending.

PI: Bayesian methods for (incomplete) longitudinal cancer data (NIH, R01), $320,000 (direct costs), 2009-2013.

NSF

Co-PI : Development of Conditionally Specified Statistical Models for Analysis of Environmental Studies (NSF), $300,000, 1998-2001.

co-PI : Conference on Data mining and Bioinformatics (NSF), January 2004, $17,500.

PI: Workshop on semiparametric methodology, NSF, 2008-2009, $5,000.

Other

Co-PI : Spatial Statistics Research Applied to Ecological Resource Monitoring Programs (EPA, CR822919-01-0), 1997-1998.

Co-PI: Statistical Treatment of Class Evidence (FBI through Ames Lab), $150,000 1998-1999.

PI : Improved estimation of correlations in longitudinal and spatial data (University Research Grant, Iowa State University), $12,000, 1998-1999

Co-PI : Effect of Prenatal Stress on the Health and Well-Being of Swine (USDA), $205,000, 2000-2003.

PI : Quantification of Animal Well Being, (USDA Cooperative Agreement), $33,000, 2002-2007.

Awards and Honors

Member of Sigma Xi Scientific Honor Society, 1991-1994

National Institutes of Health Training Grant Recipient, 1991-92

Generalized Linear Models Conference Travel Award, 1994

Howard Hughes Medical Institute Predoctoral Fellowship in Biological Sciences, 1992-1995

Eastern North American Region of Biometrics Society Student Travel Award, 1995

National Research Service Award in Psychiatric Statistics (NIMH), 1995-1997

Fellow of the American Statistical association (elected 2007)

Professional Societies

American Statistical Association, International Biometric Society, Institute of Mathematical Statistics, International Society for Bayesian Analysis

Research Interests

Bayesian methodology, Bayesian biostatistics, Covariance structures, Hierarchical modelling, Longitudinal data models, Missing data models, Spatial models

Applications in cancer, nutrition, health services, the environment, and forensics

Books

Daniels, M.J. and Hogan, J.W. (2008) Missing data in longitudinal studies: Strategies for Bayesian Modeling and Sensitivity Analysis. Chapman & Hall (CRC Press).

Papers

Published (Refereed)

Lenhard R, Daniels M, Oken M, Glick J, Ettinger D, Kalish L, O'Connell M (1994) An Aggressive High Dose Cyclophosphamide and Prednisone Regimen for Advanced Multiple Myeloma. *Leukemia and Lymphoma.* 13:485-489.

Devlin B, Daniels M, Roeder K. (1997) Heritability of IQ. *Nature.* 388:468-471.

Daniels M, Hughes M. (1997) Meta-Analysis for the evaluation of potential surrogate markers. *Statistics in Medicine.* 16:1965-1982.

Daniels M, Gatsonis C. (1997) Hierarchical Polytomous Regression Models with Applications to Health Services Research. *Statistics in Medicine.* 16:2311-2325.

Hughes MD, Daniels MJ, Fischl MA, Kim S, Schooley RT. (1998) CD4 cell count as a surrogate endpoint in HIV clinical trials: a meta-analysis of studies of the AIDS Clinical Trials Group. *AIDS.* 12:1823-1832.

Daniels M, Kass R. (1998) A note on first stage approximation in two stage hierarchical models. *Sankhya, Series B.* 60:19-30.

Daniels M, Gatsonis C. (1999) Hierarchical Generalized Linear Models in the Analysis of Variations in Health Care Utilization. *Journal of the American Statistical Association.* 94:29-42.

Daniels M. (1999) A prior for the variance in hierarchical models. *Canadian Journal of Statistics.* 27:569-580.

Lay, D.C., Jr., M.F. Haussman, H.S. Buchanan, and M.J. Daniels. (1999) Danger to piglets due to crushing can be reduced by the use of a simulated udder. *Journal of Animal Science.* 77:2060-2064.

Cressie N, Kaiser M, Daniels M, Aldworth J, Lee J, Lahiri S, Cox L. (1999) Spatial analysis of particulate matter in an urban environment, In *geoENV II - Geostatistics for Environmental Applications: Proceedings of the Second European Conference on Geostatistics for Environmental Applications*, eds. J. Gomez-Hernandez, A. Soares, R. Froidevaux, 41-52.

Daniels M, Kass R. (1999) Nonconjugate Bayesian estimation of covariance matrices in hierarchical models. *Journal of the American Statistical Association*, 94, 1254-1263.

Lay D., Haussmann M, Daniels M. (2000) Hoop Housing for feeder pigs offers a welfare friendly environment compared to a non-bedded system. *Journal of Animal Welfare Science*, 3:33-48.

Sidorenko, L.V., Li, X., Cocciolone, S.M., Chopra, S., Tagliani, L., Bowen, B., Daniels, M. and Peterson, T. (2000) Complex structure of a maize Myb gene promoter: functional analysis in transgenic plants. *The Plant Journal*, 22:1-14.

Daniels M, Dominici F, Samet J., Zeger, S. (2000) Estimating particulate matter-mortality dose-response curves and threshold levels: An analysis of daily time series data for the 20 largest U.S. cities (with invited commentary). *American Journal of Epidemiology*, 152, 397-406.

Haussmann, M.F., Carroll, J.A., Weesner, G.D., Daniels, M.J., Matteri, and Lay, D.C. Jr. (2000) Administration of ACTH to restrained, pregnant sows alters their pigs hypothalamic-pituitary-adrenal (HPA) axis. *Journal of Animal Science*, 78:2399-2411.

HIV Surrogate Marker Collaborative Group (2000) Human Immunodeficiency Virus Type I RNA Level and CD4 Count as Prognostic Markers and Surrogate Endpoints: A Meta-Analysis. *AIDS Research and Human Retroviruses*, 16, 1123-1133.

Daniels M, Hogan J. (2000) Reparameterizing the pattern mixture model for sensitivity analysis under informative dropout in longitudinal studies. *Biometrics*, 56, 1241-1249.

Daniels M, Cressie N. (2001) A hierarchical approach to covariance function estimation for time series. *Journal of Time Series Analysis*, 22, 253-266.

Daniels M, Lee Y-D, Kaiser M. (2001) Assessing sources of variability in measurement of ambient particulate matter. *Environmetrics*, 12, 547-558.

Hellmich, R.L., Siegfried, B.D., Sears, M.K., Stanley-Horn, D.E., Daniels, M.J., Mattila, H.R., Spencer, T., Bidne, K.G., and Lewis, L.C. (2001) Monarch larvae sensitivity to *Bacillus thuringiensis* - purified proteins and pollen. *Proceedings of the National Academy of Sciences*, 98: 11925-11930.

Carriquiry A., Daniels M. (2001) Adjusting for measurement error of a dietary risk factor in age-related maculopathy. *Bayesian Methods with Applications to Science, Policy, and Official Statistics: Selected Papers from ISBA 2000: The Sixth World Meeting of the International Society for Bayesian Analysis.*

Daniels M.J., Kass R.E. (2001) Shrinkage estimators for covariance matrices. *Biometrics*, 57: 1173-1184.

Daniels, M.J., and Carriquiry, A.L. (2001) Computing the posterior distribution of individual level usual intakes with application to disease models. *Research in Official Statistics*, 4: 67-79.

Hogan J, Daniels M. (2002) A hierarchical modelling approach to analysing longitudinal measurements with dropout and non-compliance, with application to an equivalence trial in paediatric acquired immune deficiency syndrome. *Applied Statistics (JRSS-C)*, 51:1-21.

Dominici, F., Daniels, M., Zeger S., Samet J. (2002) National models for estimating the effect of particulate matter on mortality in U.S. cities. *Journal of the American Statistical Association*, 97:100-111.

Pourahmadi M, Daniels M. (2002) Dynamic conditionally linear mixed models. *Biometrics*, 58:225-231.

Daniels, M. Pourahmadi, M. (2002) Bayesian analysis of covariance matrices and dynamic models for longitudinal data. *Biometrika*, 89, 553-566.

Kaiser, M., Daniels, M., Furakawa, K., Dixon, P. (2002) Analysis of particulate matter air pollution using markov random field models of spatial dependence. *Environmetrics*, 13, 615-628.

Pogranichnyy, R.M., Yoon K-J., Harms, P.A., Sorden, S.D., Daniels M. (2002) Case-control study on association of porcine circovirus type 2 and other swine viruses in postweaning multisystemic wasting syndrome. *Journal of Veterinary Diagnostic Laboratory Investigation*, 14, 449-456.

Daniels, M. and Zhao, Y. (2003) Modelling the random effects covariance matrix in longitudinal data. *Statistics in Medicine*, 22, 1631-1647.

Sidorenko, L, Bruce W., Maddock, S., Tagliani, L., Li, X., Daniels, M., Peterson, T. (2003) Functional analysis of two matrix attachment region (MAR) elements in transgenic maize plants. *Transgenic Research*, 12, 137-154.

Scharfstein D, Daniels M, Robins J. (2003) Incorporating prior beliefs about selection bias into the analysis of randomized trials with missing outcomes. *Biostatistics*, 4: 495-512.

Daniels, M.J., Dominici, F., Zeger, S. (2004) Underestimation of standard errors in multi site time series studies. *Epidemiology*, 15: 57-62.

Daniels, M.J. (2005) Shrinkage priors for the dependence structure in longitudinal data. *Journal of Statistical Planning and Inference*, 127: 119-130.

Dominici F., McDermott A., Daniels, M., Zeger S.L, Samet J.M. (2005) Revised analyses of the National Morbidity, Mortality, and Air Pollution Study: mortality among resident of 90 cities. *Journal of Toxicology and Environmental Health Part A.*, 68, 1071-1092.

Daniels, M., Normand, S-L.(2006) Longitudinal profiling of health care units based on mixed multivariate patient outcomes. *Biostatistics*, 7, 1-15.

Krieger, J.W., Sitren, H.S., Daniels, M.J., Landkamp-Henken, B. (2006) Effects of variation in protein and carbohydrate intake on body mass and composition during energy restriction: a meta-analysis. *American Journal of Clinical Nutrition*, 83: 260-274.

Daniels, M., Zhou, Z, and Zou, H. (2006) Conditionally specified space-time models for multivariate processes. *Journal of Computational and Graphical Statistics*, 15, 157-177.

Botts, C., Daniels, M. (2006) A shrinkage estimator for the spectral densities. *Biometrika*, 93, 179-195.

Daniels, M.J. (2006) Bayesian modelling of several covariance matrices and some results on the propriety of the posterior for linear regression with correlated and/or heterogeneous errors. *Journal of Multivariate Analysis*, 97, 1185-1207.

Scharfstein, D.O., Halloran, M.E., Chu, H., and Daniels, M.J. (2006) On Estimation of Vaccine Efficacy Using Validation Samples with Selection Bias. *Biostatistics*, 7, 615-629.

Liu, X. and Daniels, M.J. (2006) A new algorithm for simulating a correlation matrix based on parameter expansion and re-parameterization. *Journal of Computational and Graphical Statistics*, 15, 897-914.

Pourahmadi, M., Daniels M., Park, T. (2007) Simultaneuous modelling of covariance matrices using the modified Choleski decomposition with applications. *Journal of Multivariate Analysis*, 98, 568-587.

Ilk O., Daniels, M. (2007) Marginalized transition random effects models for multivariate longitudinal binary data. *Canadian Journal of Statistics*, 35, 105-123.

Lee, K., Daniels, M.J. (2007) A class of Markov models for longitudinal ordinal data. *Biometrics*, 63, 1060-1067.

Lay, D., Kattesh, H., Cunnick, J., Daniels, M.J., McMunn, K., Toscano, M. and Roberts, M. (2008) Prenatal stress on pig development and response to weaning. *Journal of Animal Science*, 86, 1316-1324.

Roy, J. and Daniels, M.J. (2008) A General Class of Pattern Mixture Models for Nonignorable Dropout with Many Possible Dropout Times. *Biometrics*, 64, 538-545.

Lee, K. and Daniels, M.J. (2008) Marginalized models for longitudinal ordinal data with application to quality of life studies. *Statistics in Medicine*, 27, 4359-4380.

Botts, C. and Daniels, M.J. (2008) A flexible approach to Bayesian multiple curve fitting. *Computational Statistics and Data Analysis*, 52, 5100-5120.

Perri, M.G., Limacher, M.C., Durning, P.E., Janicke, D.M., Lutes, L.D., Bobroff, L.B., Dale, M.S., Daniels, M.J., Radcliff, T.A., and Martin, A.D. (2008) Treatment of Obesity in Underserved Rural Settings (TOURS): A Randomized Trial of Extended-Care Programs for Weight Management in Women. *Archives of Internal Medicine*, 168, 2347-2354.

Judge, M.K., Zhang, J., Tumer, N., Carter, C., Daniels, M.J., and Scarpace, P.J. (2008) Prolonged hyperphagia with HF feeding contributes to exacerbated weight gain in rats with adult-onset obesity. *American Journal of Physiology - Regulatory, Integrative, and Comparative Physiology*, 295, R773-R780.

Martin, D.J., Martin, T.D., Hess, P.J., Daniels, M.J., Feezor, R.J., and Lee, W.A.L. (2009) Spinal Cord Ischemia after TEVAR in Patients with Abdominal Aortic Aneurysms. *Journal of Vascular Surgery*, 49, 302-306.

Daniels, M.J. and Wang, C. (2009) Discussion of "Missing Data in longitudinal studies: A review" by Ibrahim and Molenberghs. *TEST*, 18, 51-58.

Liu, X, Daniels, M., Marcus, B. (2009) Joint models for the association of a longitudinal binary and continuous process. *Journal of the American Statistical Association*, 104, 429-439.

Daniels, M.J. and Pourahmadi, M. (2009) Modeling covariance matrices using partial autocorrelations. *Journal of Multivariate Analysis*, 100, 2352-2363.

Carter, C.S., Leeuwenburgh, C., Daniels, M.J., and Foster, T.C. (2009) Influence of calorie restriction on measures of age-related cognitive decline: Role of increased physical activity. *Journal of Gerontology: Biological Sciences*, 64, 850-859.

Lee, K., Daniels, M.J., and Sargent, D. (2009) Causal effects of treatments for informative missing data due to progression/death. To appear in *Journal of the American Statistical Association.*

Peer Reviewed

Daniels, M, Dominici F, Samet J., Zeger, S. (2004) The National Morbidity-Mortality, and Air Pollution Study Part III: Concentration Response Curves and Thresholds for the 20 Largest U.S. Cities, The Health Effects Institute, Cambridge, MA.

Dominici F., McDermott A. Daniels, M. Samet J.M. Zeger S.L. (2004) A Report to the Health Effects Institute on Reanalyses of the NMMAPS Database, The Health Effects Institute, Cambridge, MA.

Daniels M, Dominici F, Samet J., Zeger, S. (2001) Reply to the letter of Tobias and Saez re: "Estimating particulate matter-mortality dose-response curves and threshold levels: An analysis of daily time series data for the 20 largest U.S. cities." *American Journal of Epidemiology*, 153, 1027-1028.

Submitted

Wang, C. and Daniels, M.J. (2009) A Note on MAR, Identifying Restrictions, and Sensitivity Analysis in Pattern Mixture Models With and Without Covariates for Incomplete Data. Submitted.

Wang, C., Daniels, M.J., Scharfstein, D.O., and Land, S. (2009) A Bayesian Shrinkage Model for Incomplete Longitudinal Binary Data with Application to the Breast Cancer Prevention Trial. Under revision.

Yang, Y., Halloran, M.E., Daniels, M.J., and Longini, I.M. (2009) Modeling competing infectious pathogens from a Bayesian perspective: Application to influenza studies with incomplete laboratory results. Submitted.

Published (Non-Refereed)

Daniels M, Devlin B, Roeder K (1997) 'Of Genes and IQ' in *Intelligence, Genes, and Success: Scientists respond to "The Bell Curve"*, editors B Devlin, S Fienberg, D Resnick, and K Roeder, New York: Springer-Verlag.

Daniels M. (1998) Computing posterior distributions for covariance matrices in *Computing Science and Statistics, Volume 30, Proceedings of the 30th Symposium on the Interface*, editor S. Weisberg, p. 192-196.

Daniels, M., Carriquiry A. (1999) Dietary assessment and estimation of intake densities. In: Paulino, C.D., Pacheco, A., and Ferreira da Cunha, A.P. (eds.) *Afirmar a Estatistica: Um Desafio para o Seculo XXI*, Sociedade Portugeusa de Estatistica, Lisboa, Portugal.

Daniels, M., Zhang, Y, Erdman, M., Harris IT. (2001) Experience with the Danish Mix-ELISA in the United States. *Proceedings of the 4th International Symposium on the Epidemiology and Control of Salmonella and other food-borne pathogens in Pork (Salinpork 2001)*, ed. PJ van der Wolf, 492-495.

Daniels, MJ, Zhang, Y., Erdmann, M., Harris, IT (2002) Estimating the accuracy of the DME in the U.S. *Proceedings of the 17th International Pig Veterinary Society (IPVS) Congress*, Ames, Iowa, June 2-5, 2002, p. 243.

Daniels, MJ (2003) Review of "Contemporary Statistical Models for the Plant and Soil Sciences" for *Journal of the American Statistical Association*, 98, 1080-1082.

Editorial Boards

Corresponding Editor for Institute of Mathematical Statistics Bulletin, 1998-2001

Associate Editor for Biometrics, 2003-2010 (3 terms)

Associate Editor for Journal of the American Statistical Association, Applications and Case Studies, 2005-2010

Associate Editor for Statistics & Probability Letters, July 2007-June 2010

Professional activities

Member of EPA FIFRA Scientific Advisory Panel, September, 1999

Review Committee for ENAR Student Paper Awards, 1999-2000

Co-organized ENAR invited session on informative missing data, 2000.

NIH Study Section (Small grants program for cancer), Spring and Fall 2001

Member of EPA Scientific Advisory Panel on Water Quality, December 2001

Organized ENAR invited session on longitudinal data, 2002.

ENAR Regional Advisory Board, 2003-2005.

Organized JSM invited session on modelling dependence, 2004.

ad hoc member, NIH BMRD Study Section, 2004, 2006.

HPSS Section Representative to ENAR, 2004-2005.

Member of ENAR Program Committee, 2005

Organized invited session on Bayesian Biostatistics, International Workshop/Conference on Bayesian Statistics and its Applications, India, January, 2005.

Organized JSM invited session on longitudinal data, 2005.

Biometrics section program chair for JSM 2006

Nominated to stand for election as member of International Society for Bayesian Analysis (ISBA) Board, Spring 2007 (election).

Review Committee for Student Paper Awards for Section on Bayesian Statistical Science (SBSS) of the ASA, 2007.

Program Chair Elect, Section on Bayesian Statistical Science (SBSS) of the ASA, 2008 (elected in 2007).

Savage Thesis Award Committee, 2007-2008, 2008-2009

Council of Sections Representative, Biometrics Section of the ASA, 2008 (elected in 2007).

ad hoc member, NIH ACE Study Section, 2008.

Program Chair, Section on Bayesian Statistical Science (SBSS) of the ASA, 2009.

Program Chair, ENAR Spring Meetings 2010, New Orleans.

Refereeing/Reviewing

Refereed papers for JASA,JRSS-B,Environmetrics,Canadian Journal of Statistics,JCGS, JBES, JABES, Archives of General Psychiatry, Case Studies in Bayesian Statistics, Journal of Clinical Oncology, Statistics in Medicine, Biostatistics, American Journal of Epidemiology, Biometrics, Health Services and Outcomes Research Methodology, Annals of Internal Medicine, Psychological Bulletin, Journal of Statistical Planning and Inference, Statistical Science, Environmental Health Perspectives, Science for the Total Environment, Biometrika, Statistical Modelling, Lifetime Data Analysis, Biometrical Journal, JRSS-A, Atmospheric Environment, Statistica Sinica, Annals of Statistics, Ecology, Journal of Clinical Epidemiology, Bayesian Analysis, Statistics and Computing

Grant reviewer for NSF, NIH, and HEI (Health Effects Institute)

Reviewed manuscripts for Springer-Verlage, Duxbury Press, and Addison Wesley Longman

External thesis examiner for F.K. Wong's PhD thesis, Australian Graduate School of Management, 2004

Consulting/Collaborations

Boston Medical Area (Consulting Lab), 1993-1994

Western Psychiatric Institute and Clinic, in designing and analyzing studies, grant preparation, 1995-1996

Legal Firm (Freedman and Lockhart), analysis of data regarding potentially forged document, 1996

Carnegie Mellon History Department, analysis of educational data, 1996-1997

HIV RNA Surrogate Marker Collaborative Group, analysis of surrogate markers in AIDS trials, 1997-1999

Iowa State University, Department of Animal Science, Agronomy, Zoology and Genetics, and Veterinary Medicine, 1997-

Des Moines hospitals, analysis of perinatology data, design of survey on factors related to having genetic counseling, 1998-

Pfizer, study design and data analysis for drug testing, 1998-1999

Nextran, risk factors in Xenotransplantation, 1999-

Iowa State University, Department of Microbiology and School of Veterinary Medicine: project involving eventual eradiction of multi-drug resistant salmonella in swine, 2001-

Environomics, review document on water quality regulations, 2004

Asthmatx, Member of Mock FDA panel, 2009.

Miscellaneous

discussed 1997 Nature paper on radio shows in Texas and Minnesota

January 7, 2009

Supplement to Cal/EPA External Scientific Peer Review Guidelines – "Exhibit F" in Cal/EPA Interagency Agreement with University of California Gerald W. Bowes, Ph.D.

Guidance to Staff:

1. Revisions. If you have revised any part of the initial request, please stamp "Revised" on each page where a change has been made, and the date of the change. Clearly describe the revision in the cover letter to reviewers, which transmits the material to be reviewed. The approved reviewers have seen your original request letter and attachments during the solicitation process, and must be made aware of changes.

2. Documents requiring review. All important scientific underpinnings of a proposed science-based rule must be submitted for external peer review. The underpinnings would include all publications (including conference proceedings), reports, and raw data upon which the proposal is based. If there is a question about the value of a particular document, or parts of a document, I should be contacted.

3. Documents not requiring review. The Cal/EPA External Peer Review Guidelines note that there are circumstances where external peer review of supporting scientific documents is not required. An example would be "A particular work product that has been peer reviewed with a known record by a recognized expert or expert body." I would treat this allowance with caution. If you have any doubt about the quality of such external review, or of the reviewers' independence and objectivity, that work product – which could be a component of the proposal - should be provided to the reviewers.

4. Implementation review. Publications which have a solid peer review record, such as a US EPA Criteria document, do not always include an implementation strategy. The Cal/EPA Guidelines require that the implementation of the scientific components of a proposal, or other initiative, must be submitted for external review.

5. Identity of external reviewers. External reviewers should not be informed about the identity of other external reviewers. Our goal has always been to solicit truly independent comments from each reviewer. Allowing the reviewers to know the identity of others sets up the potential for discussions between them that could devalue the independence of the reviews.

6. Panel Formation. Formation of reviewer panels is not appropriate. Panels can take on the appearance of scientific advisory committees and the external reviewers identified through the Cal/EPA process are not to be used as scientific advisors.

7. Conference calls with reviewers. Conference calls with one or more reviewers can be interpreted as seeking collaborative scientific input instead of critical review. Conference calls with reviewers are not allowed.

January 7, 2009

Guidance to Reviewers from Staff:

1. Discussion of review.

   Reviewers are not allowed to discuss the proposal with individuals who participated in development of the proposal. These individuals are listed in Attachment 3 of the review request.

   Discussions between staff and reviewers are not permitted. Reviewers may request clarification of certain aspects of the review process or the documents sent to them.

   Clarification questions and responses must be in writing. Clarification questions about reviewers' comments by staff and others affiliated with the organization requesting the review, and the responses to them, also must be in writing. These communications will become part of the administrative record.

   The organization requesting independent review should be careful that organization-reviewer communications do not become collaboration, or are perceived by others to have become so. The reviewers are not technical advisors. As such, they would be considered participants in the development of the proposal, and would not be considered by the University of California as external reviewers for future revisions of this or related proposals. The statute requiring external review of science-based rules proposed by Cal/EPA organizations prohibits participants serving as peer reviewers..

2. Disclosure of reviewer Identity and release of review comments.

   Confidentiality begins at the point a potential candidate is contacted by the University of California. Candidates who agree to complete the conflict of interest disclosure form should keep this matter confidential, and should not inform others about their possible role as reviewer.

   Reviewer identity may be kept confidential until review comments are received by the organization that requested the review. After the comments are received, reviewer identity and comments must be made available to anyone requesting them.

   Reviewers are under no obligation to disclose their identity to anyone enquiring. It is recommended reviewers keep their role confidential until after their reviews have been submitted.

3. Requests to reviewers by third parties to discuss comments.

   After they have submitted their reviews, reviewers may be approached by third parties representing special interests, the press, or by colleagues. Reviewers are under no obligation to discuss their comments with them, and we recommend that they do not.

   All outside parties are provided an opportunity to address a proposed regulatory action during the public comment period and at the Cal/EPA organization meeting where the proposal is considered for adoption. Discussions outside these provided avenues for comment could seriously impede the orderly process for vetting the proposal under consideration.

4. Reviewer contact information.

The reviewer's name and professional affiliation should accompany each review. Home address and other personal contact information are considered confidential and should not be part of the comment submittal.