SUMMARY OF EXPECTED TESTIMONY OF ERNEST PRENTICE, PH.D.

Ernest Prentice, Ph.D. is Associate Vice Chancellor for Academic Affairs and Regulatory Compliance at the University of Nebraska. Dr. Prentice was the Chairman of the Institutional Review Board at the University of Nebraska from 1981 to 2006. He has been Executive Chairman since 2006. He operates the Office of Regulatory Affairs. Dr. Prentice's educational background and work experiences are described in his curriculum vitae, a copy of which is attached. The testimony and opinions of Dr. Prentice will be based upon his educational background, work experiences, and his review of records and depositions relating to this case, including but not limited to documents from the Institutional Review Board. Dr. Prentice reserves the right to supplement his opinions if additional information becomes available.

Dr. Prentice will testify that the University of Minnesota's Institutional Review Board (IRB) acted reasonably and appropriately with respect to the following study at the University of Minnesota site: "Efficacy and Tolerability of Olanzapine, Quetiapine and Risperidone in the Treatment of First Episode Psychosis: A Randomized Double-Blind 52-Week Comparison – The Café Study." Dr. Prentice will testify that he disagrees with the opinions of plaintiff's experts, including the May 15, 2007 affidavits of Harrison G. Pope, Jr., M.D., M.P.H. and James I. Hudson, M.D., that the IRB violated standards of care for protection of human subjects and oversight of research activity conducted with human subjects. Dr. Prentice will testify that the IRB complied with the requirements of the federal government, with the usual and customary practices of IRBs, and followed standards of care of IRB's. He will testify that the death by suicide of Mr. Dan Markingson was not caused by the University of Minnesota IRB.

By way of background, Dr. Prentice will explain that AstraZeneca Pharmaceuticals, L.P. ("AstraZeneca") was the sponsor of the Café Study. The principal investigator at the University of Minnesota site was Dr. Stephen Olson, Associate Professor of Psychiatry, and the co-investigators were Dr. Charles Schulz, who is Director of the Department of Psychiatry at the University of Minnesota, and John P. Vuchetich, M.D., Ph.D. AstraZeneca approved the multi-site Café Study on October 12, 2001.

Dr. Prentice will testify about the written request by Dr. Olson for approval of the Café Study at the University of Minnesota site, which request was submitted by Dr. Olson to the IRB on February 11, 2002 ("Request For The Approval For The Use Of Human Subjects in Research Health and Biological Sciences.")

With respect to risks, the document submitted by Dr. Olson advised the IRB that each potential participant would be evaluated regarding his or her competency to give informed consent. Dr. Prentice will explain that it was reasonable for the IRB to conclude that the competency questionnaire used by Dr. Olson to evaluate potential study participants would serve as a useful tool in the evaluation of the competency of potential participants. Dr. Prentice will further testify that the Request form specifically asks: "what questions will be asked to assess the Subjects' understanding," and that Dr. Olson stated "the informed consent process for this study will include a formal procedure for assessing competency. The evaluation will be completed immediately prior to signature of informed consent. Persons who demonstrate adequate decisional capacity to participate in this research study will be allowed to sign the consent form.

Please refer to the competency evaluation located in the application's supporting documentation."

Dr. Prentice will also testify that Dr. Olson submitted additional information to the IRB about the process by which informed consent would be obtained from potential participants in the Café Study, including copies of consent forms such as the proposed Adult Consent Form. Dr. Prentice will note that Dr. Olson disclosed what would be said to subjects to introduce the research and confirmed that written consent would be obtained prior to all study procedures. He also disclosed to the IRB that all study participants would have an advocate, who would typically be a case manager, nurse, or family member or friend. Dr. Prentice will explain that in the case of Dan Markingson it later turned out that David Pettit, a Dakota County Case Manager, advocated for Mr. Dan Markingson. He will note that Mr. Pettit has testified that he approved of Mr. Markingson's participation in the Café Study. In addition, Dr. Olson submitted to the IRB the Café Study proposal that was approved by Astrazeneca on October 12, 2001, along with Appendices.

Dr. Prentice will explain that in the Request for Approval Dr. Olson also identified benefits of the study, including that subjects would receive psychiatric evaluations, physical exams, bloodwork, electrocardiograms, and study medications at no cost. They would receive $20 per visit as compensation for time and inconveniences associated with research participation, along with parking/travel expenses.

Dr. Prentice will explain that the process used by the IRB to review Dr. Olson's proposal was reasonable and appropriate. Dr. Prentice will explain that it is reasonable and appropriate for an IRB to designate a member to serve as a primary reviewer, and to assign that person the responsibility of presenting the proposed study to the committee responsible for determining whether or not to grant approval for a study. Dr. Prentice may testify about notes made by the primary reviewer about the Café Study proposal on a form entitled Review of Medical Science Request for Approval, including notes about risks and benefits of the study, groups included in the study, and consent issues. Dr. Prentice will testify that these are appropriate topics for consideration by the IRB.

Dr. Prentice will explain that the IRB's Health and Biological Services panel of the Human Subjects Committee reviewed the Café Study on February 27, 2002 and approved the Café Study, subject to certain stipulations. The IRB advised Dr. Olson via letter dated March 6, 2002 that certain stipulations must be resolved and approved by the IRB prior to the IRB giving final approval to the Café Study. The IRB advised Dr. Olson by letter dated April 22, 2002 that his response to the IRB's stipulations had been received. The IRB granted a one-year approval of the CAFÉ Study at the University of Minnesota, including the written consent form to be used, and noted the approval date of the Café Study as February 27, 2002. On January 29, 2003, January 28, 2004, and January 26, 2005 the IRB approved the CAFÉ Study for additional one-year periods.

Dr. Prentice will testify that the IRB reasonably and appropriately in its review and approval of the Café Study, including review and approval of the Adult Consent Form that would be utilized for the Café Study and was in fact, used in the case of Dan Markingson. He will testify about the

various components of the form, including its statement that the participant's healthcare provider may be an investigator for the project, and that in the latter role he or she "is interested in both your clinical welfare and in the conduct of this study." In addition, the form advises the participant that he or she may ask for a second opinion before or during the study, and that "you are not under any obligation to participate in a research project offered by your doctor." Dr. Prentice will testify that the foregoing language provided participants with sufficient information about the principal investigator's role and the participant's right to seek decline to participate and/or seek a second opinion.

Dr. Prentice will also testify about the Consent Form's discussion of risks, including that the participant's symptoms may not respond to the study medication, one's condition may worsen, and a discussion of side effects and risks. The Form also addresses alternative treatments, stating "you do not have to participate in this research study in order to receive treatment for your condition. All of the medications we will study are available to you through your study doctor. Your study doctor will discuss these alternatives with you before you agree to participate in this study." Another section in the Form states that participation in the study is voluntary, and that the participant can "refuse to participate or withdraw from this study at any time, without penalty or loss of benefits to which you are otherwise entitled." The right to withdraw at any time is also included in a subsequent section. Dr. Prentice will testify that it was reasonable and appropriate for the IRB to conclude the foregoing language was appropriate and sufficient regarding risks, side effects, and alternatives. Dr. Prentice will testify that it was reasonable for the IRB to conclude that the consent document adequately informed prospective study participants, including Mr. Markingson, that they could decline to participate in the study and could elect to be treated by a different physician and/or with different medications.

Dr. Prentice will point out that the IRB received notice from Dr. Olson on May 12, 2004 of a Serious Adverse Event involving subject 00100013 (Mr. Dan Markingson). Dr. Prentice will testify that the IRB acted reasonably and appropriately by requesting information from Dr. Olson regarding the event. He will explain that Dr. Olson provided additional information to the IRB by letter dated May 17, 2004. Dr. Prentice will testify that Richard W. Bianco, the Institutional Official for Human Subjects Protections, acted reasonably and appropriately by reporting the unanticipated serious adverse event to the Office for Human Research Protections via an Official Notification of Serious Adverse Event Involving a Research Subject on or about May 13, 2004.

Dr. Prentice will testify that the IRB acted reasonably and appropriately monitored the Café Study and utilized a continuing review form. He will discuss the components of that form, including the use of the form on more than one occasion during the Café Study. For example, Dr. Prentice will testify about the Continuing Review of IRB-Approved Medical Research that Dr. Olson signed on December 17, 2004. The form requests information relating to the study, including any unanticipated problems, subject withdraws, complaints about research, and serious and unexpected adverse events, all of which are appropriate topics of continuing review.

Dr. Prentice will also testify that there is no evidence that Mr. Markingson, the participant, complained about the Café Study to the IRB. Moreover, no one complained to the IRB about Mr. Markingson's involvement in the study while he was a participant in it. He will point out

that there is nothing in the federal regulations requiring complaints to be forwarded to the IRB unless there is an unanticipated problem regarding risk.

Dr. Prentice will testify about the meaning and scope of federal regulations applicable to the IRB, as delineated by the Office of Human Research Protections (OHRP) under 45 C.F.R. § 46 (Protection of Human Subjects), Subpart A (Basic HHS Policy for Protection of Human Subjects), Sections 46.101-46.124). Dr. Prentice will describe the applicable federal regulations and testify that the University of Minnesota's IRB complied with those regulations with respect to the Café Study. Dr. Prentice will testify that the IRB's approval of the informed consent form and competency evaluation document was consistent with the foregoing regulations.

Dr. Prentice will explain the basic elements of informed consent that must be provided to each subject pursuant to section 45 C.F.R. 46.116(a)(1-8). He will testify that the form approved by the IRB included the information required under the sections of the foregoing regulation. In addition, Dr. Prentice will testify that the IRB appropriately required documentation of the informed consent, as required by section 46.109(c) and section 46.117.

Dr. Prentice will testify that there is no legal requirement for an evaluation of potential study participants by a third party to determine competency or to obtain informed consent. Dr. Prentice will explain that the Declaration of Helsinki has not been universally accepted in the United States and is not mentioned in the federal regulations and does not create or impose legal duties on an IRB in the United States, including the University of Minnesota IRB. Dr. Prentice will explain that the statements contained in the Nurenberg Code, the Declaration of Helsinki, and the Belmont Report do not create legal duties for an IRB. Dr. Prentice will disagree with any testimony by plaintiffs' experts' suggesting that the IRB was obligated to require that informed consent be obtained by an independent examiner from hospitalized potential subjects receiving treatment by Dr. Olson for mental health disorders.

Dr. Prentice will explain the approval criteria set forth under 45 C.F.R. 46.111, including the requirements that must be satisfied for the IRB to approve research, and will testify that the University of Minnesota IRB met these criteria before giving final approval for the CAFÉ Study. Dr. Prentice will testify that the IRB appropriately determined that risks to subjects in the CAFÉ Study were minimized by using procedures consistent with sound research design and when appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes. He will also testify that it was reasonable for the IRB to conclude that risks to subjects in the CAFÉ study were reasonable in relation to anticipated benefits to subjects and the importance of the knowledge that may reasonably be expected to result.

Dr. Prentice will also testify that it was reasonable for the IRB to conclude that selection of subjects was equitable. He will explain that it was reasonable for the IRB to conclude that the assessment of competency questionnaire and use of advocates would appropriately address any issues relevant to a patient population that was to include vulnerable patients. He will state that the foregoing safeguards served to protect the rights and welfare of subjects who were likely to be vulnerable to coercion or undue influence, including mentally disabled persons, as set forth under 46.111(b). Dr. Prentice will testify that he disagrees with any opinion that the IRB failed to provide sufficient safeguards for potential participants in the Café Study. Dr. Prentice will

further testify the IRB appropriately determined that informed consent would be sought from each prospective subject or the subject's legally authorized representative, in accordance with § 46.116. Dr. Prentice will also testify that the IRB satisfied the remaining criteria of this section.

Dr. Prentice will explain that that the IRB has authority pursuant to 45 C.F.R. § 46.113 to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Dr. Prentice will testify that the IRB was not required to suspend or terminate its approval of the Cafe Study. The IRB did not receive any complaints from Mr. Markingson or anyone else regarding Mr. Markingson. If it had received such complaints, appropriate investigation could have been undertaken. Dr. Prentice will also testify that the IRB met its responsibility to protect human subjects in research and oversee the conduct of research on human subjects.

Dr. Prentice will testify that it was reasonable for the IRB to believe that Dr. Olson did not have a financial conflict of interest in the study. He will state that the financing of the study used an appropriate financial model that did not create any such conflict. Dr. Prentice will explain that when additional individuals enter a study, there are increased costs to conduct the study. He will testify that he disagrees with any opinion of plaintiffs' experts suggesting that Dr. Olson had a financial conflict of interest that discouraged Dr. Olson from seeking consultation with other physicians about the care of Mr. Markingson because of a concern that a different physician might recommend Mr. Markingson's removal from the study, or that Mr. Markingson might want to change physicians.

Dr. Prentice will testify that he disagrees with the opinion of plaintiffs' experts that the informed consent form violates that portion of 45 C.F.R. 46.116(a)(4), requiring "A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject." Dr. Prentice will testify that the informed consent form approved by the IRB and utilized with respect to Mr. Markingson met the foregoing federal requirements.

Dr. Prentice will disagree with any plaintiffs' experts' opinion suggesting that Mr. Markingson was not fully informed, or that he would have either declined to enroll in the study or would have withdrawn from it.

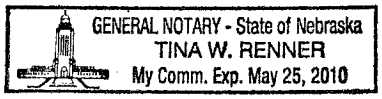
Dr. Prentice will testify that the IRB complied with its duty regarding potential complaints about the CAFÉ study. He will testify that he disagrees with plaintiffs' experts' opinion that the IRB failed to have an appropriate mechanism for handling reports of complaints, or that it violated "federal requirements" in this regard.

Dr. Prentice will also testify that he disagrees with the opinions set forth in the disclosures of Keith A. Horton, M.D. dated October 12, 2007 and Paul Root Wolpe, Ph.D. dated October 11, 2007. Dr. Prentice disagrees with their characterizations of Dr. Olson and their opinions about the IRB.

ERNEST PRENTICE, PH.D.

SUBSCRIBED and SWORN to before me this 27th day of November, 2007

Notary Public



UNIVERSITY OF Nebraska Medical Center

CURRICULUM VITAE

Ernest D. Prentice, Ph.D.
Associate Vice Chancellor for Academic Affairs
and Regulatory Compliance
Professor of Genetics, Cell Biology, and Anatomy
Courtesy Professor, School of Public Health

University of Nebraska Medical Center
987830 Nebraska Medical Center
Omaha, NE 68198-7830

Phone 402-559-6045
Fax 402-559-3300
Email edprenti@unmc.edu

Education

1967	University of South Florida	B.A.
1971	University of Iowa	M.A.
1976	University of Nebraska	Ph.D.

Military Service

1960-64 United States Air Force

Administrative Appointments – University of Nebraska Medical Center

2000-Present	Associate Vice Chancellor for Academic Affairs and Regulatory Compliance (1 FTE)
1992-03	Associate Dean for Research (.80 FTE)
1985- 92	Assistant Dean for Research (.80 FTE)
1981-85	Director, Institutional Review Board (.70 FTE)

Academic Appointments

University of Nebraska Medical Center

1991-Present	Professor, Department of Genetics, Cell Biology, and Anatomy
1991-Present	Professor, Department of Preventive and Societal Medicine (Courtesy)
1982-91	Associate Professor, Department of Anatomy
1978-82	Assistant Professor, Department of Anatomy
1975-78	Instructor, Department of Anatomy
1973-75	Research Associate, Department of Anatomy
1979	Appointed Fellow of the Graduate College
1981	Tenure Granted

University of Iowa

1971-73	NIH Predoctoral Fellow
1969-71	Teaching and Research Assistant

Ernest D. Prentice, Ph.D.
Associate Vice Chancellor for Academic Affairs and Regulatory Compliance

Public School System

1967-69	Physical Science Teacher Plant City Senior High School, Plant City, Florida

Membership and Roles in Professional Societies

1987-2006	Member, Applied Research Ethics National Association (ARENA)
1990-Present	Member, American Association for Laboratory Animal Science (AALAS)
1991-95	Council, Applied Research Ethics National Association (ARENA)
1993-98	Board of Trustees, Scientists Center for Animal Welfare (SCAW)
1994-96	President, Scientists Center for Animal Welfare (SCAW)
1995-Present	Member, American Society of Law, Medicine and Ethics (ASLME)
2000-2005	Advisory Committee, Scientists Center for Animal Welfare (SCAW)
2002-Present	Member, Association of Clinical Research Professionals (ACRP)
2002-2007	Council, Association for Accreditation of Human Research Protection Program (AAHRPP)
2005-2007	Board of Trustees, Scientists Center for Animal Welfare (SCAW)

Publications

1. Prentice ED, Metcalf WK, Metcalf NF, and Sharp JG: A multi-media approach to teaching human anatomy. Behavior Res. and Tech. in Higher Education, pp 125-137, 1974.

2. Prentice ED and Metcalf WK: A teaching workshop for medical educators. J. Med. Educ., 49:1031-1034, 1974.

3. Prentice ED, Metcalf WK, Metcalf NF, and Holyoke EA: The changing emphasis in gross anatomy. Nebr. Med.J., 59:434-435, 1974.

4. Prentice ED and Metcalf WK: The Nebraska approach to quality medical education. Nebr. Med . J.,60:44-45, 1974.

5. Sharp JG, Jensen RH, Prentice ED and Metcalf WK: Undergraduate grade point average, science grade point average, and science hours as predicators of medical, physical therapy, and physician's assistant students' performance in gross anatomy. Nebr. Med. J., 61:452-457, 1

6. Prentice ED, Metcalf WK, Sharp JG, and Hard WL: Training teachers in the anatomical sciences. J. Med. Educ., 51:1006-1009, 1976.

7. Prentice ED, Lipscomb H, Metcalf WK and Sharp JG: A characterization of the cellular immune status of hypophysectomized rats. Scand. J. Immunol., 5:955-961, 1976.

8. Prentice ED, Metcalf WK, Metcalf NF, Gallagher TF and Sharp JG: Functional-clinical anatomy for physician's assistant students. Nebr. Med. J., 62:104-108, 1977.

9. Prentice ED, Metcalf WK, Quinn TH and Holyoke EA: Replacement of traditional anatomical dissection by a stereoscopic slide-based auto-instructional program. Proc AAMC 15th Annual Conf. on Res. in Med. Educ., pp 181-186, November 1976.

10. Metcalf NF, Prentice ED, Erickson D, Povey CM and Metcalf WK: Experiences of a basic science department in launching a satellite audiovisual learning center. Biomedical Communications, 5(5):15-17, 1977.

11. Prentice ED, Metcalf WK and Metcalf NF: Development and evaluation of individual learning systems in the anatomical sciences. Aspects of Educational Technology XI. Hills P and Gilbert J (eds) pp 174-179, 1977, Kogan Page, London, England.

12. Prentice ED, Metcalf WK, Quinn TH, Sharp JG, Jensen RH and Holyoke EA: Stereoscopic anatomy auto-instruction: Evaluation of a new teaching system in human gross anatomy. J. Med. Educ., 52:758-763, 1977.

13. Gardner PJ and Prentice ED: Review: Histology laboratory exercises. J. Biocomm., 4:27-28, 1977.

14. Prentice ED, Sharp JG, Quinn TH, Holyoke EA and Metcalf WK: Stereoscopic anatomy auto-instruction: A new teaching system for undergraduate human anatomy courses. Proceedings of the Nebraska Academy of Sciences ,5:29-34, 1978.

15. Prentice ED, Sharp JG, Quinn TH, Holyoke EA and Metcalf WK: Stereoscopic anatomy auto-instruction: A new teaching system for undergraduate human anatomy courses. Proceedings of the Nebraska Academy of Sciences ,5:29-34, 1978.

16. Prentice ED, Metcalf NF, Metcalf WK and Stinson WW: The use of peer group models in breast, pelvic and rectal examination instruction as an integral part of medical gross anatomy. Proc AAMC 17th Annual Conf. on Res. in Med. Educ., pp 269-274, 1978.

17. Metcalf NF, Prentice ED, Metcalf WK and Stinson WW: Peer group models in examination instruction as an integral part of medical gross anatomy. J. Med Educ.,57:641-644, 1982.

18. Prentice ED and Zetterman RK: Evaluation, structure and function of the institutional review board. Nebr. Med. J.,68(9):293-295, 1984.

19. Prentice ED and Zetterman RK: Informed consent of human research subjects. Nebr. Med. J., 68(9):296-300, 1984.

20. Prentice ED: Review of human subjects research: A handbook for IRB's (a review). Bulletin of the American Academy of Psychiatry and the Law, 1985.

21. Prentice ED, Zucker IH, and Jameton A: Ethics of animal welfare in research: The institution's attempt to achieve appropriate social balance. Physiologist, 29:18-21, 1986.

22. Prentice ED and Antonson DL: A protocol review guide to reduce IRB inconsistency. IRB A Review of Human Subject Research, 9(1):9-11, 1987.

23. Prentice ED and Zucker IH: The University of Nebraska Medical Center's protocol review system for animal research. SCAW, 9(4):5-9, 1987.

24. Hutcheson L, Latin RW, Berg KE, Prentice ED: Body impedance analysis and body water loss. Research Quarterly for Exercise and Sport, 59(4):359-362, 1988.

25. Prentice ED, Jameton A, Antonson DL and Zucker IH: Prior ethical review of animal versus human subjects research. Invest. Radiol., 23(9):695-697, 1988.

26. Prentice ED, Antonson DL, Jameton A, Graber B, and Sears TD: Can children be enrolled in a placebo controlled randomized clinical trial of synthetic growth hormone? IRB A Review of Human Subjects Research, 11(1):6-10, 1989.

27. Prentice ED, Crouse DA, and Rings RW: Approaches to increasing the ethical consistency of prior review of animal research. Invest. Radiol., 25(3):271-274, 1990.

28. Prentice ED, Wiltse JC, Sharp JG, and Antonson DL: An institutional policy on the right to benefit from the commercialization of human biological material. Law, Medicine and Health Care 18:162-167, 1990.

29. Prentice ED: Ethical and legal considerations in obtaining consent to participate in research from patients with neurofibromatosis. Neurofibromatosis, 2(1), 1990.

30. Prentice ED and Rayburn WF: Research involving fetal drug therapy: Ethical and legal considerations. Controversies in fetal drug therapy. WF Rayburn, Ed. Clinical Obstetrics and Gynecology, 34(2):360-368, 1991.

31. Mann MD, Crouse DA and Prentice ED: Appropriate animal numbers in biomedical research in light of animal welfare considerations. Laboratory Animal Science, 41:6-14, 1991.

32. Prentice ED, Crouse DA and Mann MD: The IACUC protocol review form: One of the keys to a successful review. Laboratory Animal Science Bulletin, 30:10-16, 1991.

33. Prentice ED, Crouse DA and Mann MD: Scientific Merit Review: The Role of the IACUC. Inst. Lab Animal Res., 34:15-19, 1992.

34. Prentice ED, Antonson DL, Reitemeier PJ, Kelso TK and Jameton A: Bill of Rights for Research Subjects. IRB: A Review of Human Subjects Research, 15(2):7-9, 1993.

35. Prentice ED, Antonson DL, Leibrock LG, Kelso TK, and Sears TD: IRB review of a phase II randomized clinical trial involving incompetent patients suffering from severe closed head injury. IRB: A Review of Human Subjects Research, 15(5):1-7, 1993.

36. Prentice ED, Antonson DL, Leibrock LG, Prabhu VC, Kelso TK, and Sears TD: An update on the PEG-SOD study involving incompetent subjects: FDA permits an exception from informed consent requirements. IRB: A Review of Human Subjects Research,16(1):16-18, 1994.

37. Prentice ED, Fox IJ, Dixon RS, Antonson DL and Lawson TA: History, donor considerations and ethics of xenotransplantation and xenoperfusion. In: Research Animal Anesthesia, Analgesia and Surgery. Eds. AC Smith and MM Swindle, SCAW 1994.

38. Prentice ED, Fox IJ, Dixon RS, Antonson DL and Lawson TA: Ethics of xenotransplantation. In: Current Issues and New Frontiers in Animal Research. Eds. KL Bayne, M Greene and ED Prentice, SCAW 1995.

39. Crouse DA, Mann MD and Prentice EP: The logical determination of "N" in animal experimentation. In: Current Issues and New Frontiers in Animal Research. Eds. KL Bayne, M Greene and ED Prentice, SCAW 1995.

40. Anderson JR, Jameton A, Reitemeier PJ and Prentice ED: The case of two devices: disclosure to subjects following phase IV (post-marketing) research. IRB: A Review of Human Subjects Research, 17(3):6-9, 1995.

41. Nesser TW, Latin RW, Beng K and Prentice, ED: Physiological determinants of 40 meter sprint performance in young male athletes. J Strength and Conditioning Research, 10(4):263-67, 1996.

42. Oki GSF, Prentice ED, Garnett NL, Schwindaman DL and Wiggleworth CY: A model for performing IACUC continuing review of animal research. Contemporary Topics in Laboratory Animal Science, 35(5):53-56, 1996.

43. Prentice ED and Oki GSF: Ethical considerations in informed consent for potential future use of tissue samples. IRB: A Review of Human Subjects Research, 18(2):6-7, 1996.

44. Gordon B, Prentice ED and Reitemeier P: Case study: The use of normal children as participants in therapeutic research. IRB: A Review of Human Subjects Research, 18(3):5-8, 1996.

45. Prentice ED, Gordon BG, Oki GSF and Zaia JA: Informed consent in oncology clinical trials. Cancer Management, 2(4): 6-11, 1997.

46. Prentice ED, Gordon BG and Lin MH: Determining when a clinical activity should be classified as research requiring institutional review board review. J. Extra-Corporeal Technology, 29(2):88-91, 1997.

47. Prentice ED and Gordon BG: Continuing review of research involving human subjects: approach to the problem and remaining areas of concern. IRB: A Review of Human Subjects Research, 19(2):8-11, 1997.

48. Prentice ED and Gordon BG: IRB review of adverse events. IRB: A Review of Human Subjects Research, 19(6): 1-4, 1997.

49. Hammel JM, Prentice ED and Fox IJ: Current status of xenotransplantation. Problems in General Surgery, 15(3): 189-201, 1998

50. Gordon BG and Prentice ED: Selective Review of External Adverse Events: One IRB's response to the avalanche of IND safety reports, IRB: A Review of Human Subjects Research, 21(3): 10-11, 1999.

51. Prentice ED: Informed Consent: The most important protector, Academic Emergency Med., 6(8): 774-775, 1999.

52. Gordon BG, Prentice ED and Anderson J: Case Study: Conflict between research design and minimization of risks in pediatric research, IRB: A Review of Human Subjects Research, 22(3):1-6, 2000.

53. Gordon BG and Prentice ED: Protection of human subjects in research: A short history, J. Public Health Management and Practice, 6(6):1-8, 2000.

54. Prentice ED and Gordon BG: IRB Assessment of the risk-benefit relationship in human subjects research. National Bioethics Advisory Commission (A contracted paper) July 10, 2000.

55. Prentice ED, Oki GSF, Gordon BG, and Zaia JA: The Institutional Review Board's adverse event dilemma. Medical Research Law and Policy Report, 1(11):339-343, 2002.

56. Prentice ED, Mann SL and Gordon BG: HIPAA authorization in the research informed consent process, Medical Research Law and Policy Report, 1(16):512-513, 2002.

57. Prentice ED, Mann SL, Wrobel S and Gordon BG: Nebraska Medical Center IRB primer on the HIPAA privacy rule, Medical Research Law and Policy Report, 2(3):117-121, 2003.

58. Anderson JR, Schonfeld T, Kelso T and Prentice ED: Women in early phase trials: An IRB's deliberation, IRB: Ethics and Human Research, 25(4):7-11, 2003.

59. Gordon BG, Kessinger A, Mann SL and Prentice ED: The impact of escalating regulatory requirements on the conduct of clinical research, Cytotherapy, 5(4):309, 2003.

60. Nelson BM, Prentice ED, and Hammerschmidt, DE: The process of federal panel review of research protocols involving children, Medical Research Law and Policy Report, 1(19): 613-615, 2003.

61. Mann MD and Prentice ED: Scientific merit review by the IACUC, Lab Animal, 33(1): 26-31, 2004.

62. Prentice ED, Gordon BG, Mann SL, Kotulak GD, Paulsen GA, and Epperson KJ: Evaluation of the process of consent during protocol review, Medical Research Law and Policy Report, 3(12):489-490, 2004.

63. Prentice ED, Gordon BG, Mann SL, Kotulak GD, Paulsen GA, and Epperson KJ: Use of an IRB application to enhance review of human subject research, Medical Research Law and Policy Report, 3(18):722-733, 2004.

64. Prentice ED, Mann SL, Paulsen GA, and Gordon BG: Management of conflict of interest of IRB members, Medical Research Law and Policy Report, 4(24):952-954, 2005.

65. Kratochvil CJ, Prentice ED, and March J: Guidance for IRBs on placebo and alternatives to placebo in randomized controlled trials. Medical Research Law and Policy Report. 5(6): 220-224, 2006.

66. Mann MD and Prentice ED: Verification of IACUC approval and just in time procedure. ILAR E-Journal. Vol. 47(3). June 1, 2006; ILAR E-Journal. Vol. 48(1), 2007.

67. Fisher CB, Kornetsky SZ, and Prentice ED: Determinng risk in pediatric research with no prospect of direct benefit: Time for a national consensus on the interpretation of federal regulations. American Journal of Bioethics. (in press).

Books/Chapters

1. Metcalf WK, Prentice ED, Quinn TH and Holyoke EA (Eds): Regional Human Gross Anatomy, Vol I Head and Neck. Brady Co. of Prentice-Hall, 1980.

2. Prentice ED, Metcalf WK and Holyoke EA: Regional Human Gross Anatomy, Vol II Thorax. Brady Co. of Prentice-Hall, 1980.

3. Metcalf WK, Prentice ED and Holyoke EA: Gross Anatomy Review, 3rd Edition. Medical Examination Publishing Co., Flushing, NY, 1981.

4. Bayne KA, Greene M and Prentice ED (eds): Current Issues and New Frontiers in Animal Research. SCAW, Greenbelt, MD, 1995.

5. Gonder, J, Prentice ED and Russow, LM (eds): Genetic Engineering and Animal Welfare. SCAW, Greenbelt, MD, 1999.

6. Prentice ED and Purtillo R: The Use and Protection of Human and Animal Subjects. In: Research in Physical Therapy. Bork CE (Ed), J.B. Lippincott, Philadelphia, PA, 1992.

7. Prentice ED and Oki GSF (Chapter editors): Chapter 9: General Concepts of Protocol Review. In: IACUC Handbook, Silverman, J, Suckow, M, Murthy, S. (Book editors), CRC Press, 2000.

8. Prentice ED (Chapter editor): Chapter 11: Continuing Review of Proposals. In: IACUC Handbook, Silverman, J, Suckow, M, Murthy, S. (Book editors), CRC Press, 2000.

9. MacCabbin PD, Gordon BG, and Prentice ED: Protecting Human Subjects in Public Health Research. In: Public Health Administration, Novick LE and Mays GD (Book editors), Aspen 2001

10. Prentice ED, Mann SL, and Gordon BG: "Chapter 2-1. Administrative Reporting Structure for the IRB." Robert Amdur and Elizabeth Bankert, editors, In: Institutional Review Board: Management and Function, Jones and Bartlett, Sudbury, MA, 2002, pp. 35-36.

11. Prentice ED, Selwitz A, Oki GSF: "Chapter 2-6: Audit Systems". Robert Amdur and Elizabeth Bankert, editors, In: Institutional Review Board: Management and Function, Jones and Bartlett, Sudbury, MA, 2002, pp. 66-74.

12. Prentice ED, Mann SL, and Gordon BG: "Chapter 2-7: Charging for IRB Review." Robert Amdur and Elizabeth Bankert, editors, In: Institutional Review Board: Management and Function, Jones and Bartlett, Sudbury, MA, 2002, pp. 75-76.

13. Prentice ED, and Oki GSF: "Chapter 4-1: Exempt from IRB Review." Robert Amdur and Elizabeth Bankert, editors, In: Institutional Review Board: Management and Function, Jones and Bartlett, Sudbury, MA, 2002, pp. 111-113.

14. Gordon BG and Prentice ED: "Chapter 5-5: Requiring Birth Control to Participate in Research." Robert Amdur and Elizabeth Bankert, editors, In: Institutional Review Board: Management and Function, Jones and Bartlett, Sudbury, MA, 2002, pp. 165-168.

15. Gordon BG, Brown J, Kratochvil CJ and Prentice ED: "Chapter 5-9: Paying Research Subjects." Robert Amdur and Elizabeth Bankert, editors, In: Institutional Review Board: Management and Function, Jones and Bartlett, Sudbury, MA, 2002, pp. 185-190.

16. Prentice ED, Epperson KJ, Kratochvil CJ, and Gordon BG: "Chapter 7-3. IRB Review of Adverse Events." Robert Amdur and Elizabeth Bankert, editors, In: Institutional Review Board: Management and Function, Jones and Bartlett, Sudbury, MA, 2002, pp. 297-302.

17. Prentice ED, Gordon BG, Kratochvil CJ and Kotulak GD: "Chapter 9-5: Research Involving Prisoners." Robert Amdur and Elizabeth Bankert, editors, In: Institutional Review Board: Management and Function, Jones and Bartlett, Sudbury, MA, 2002, pp. 394-398.

18. Gordon BG, Swindells SB, Mann SL and Prentice ED: "Conflict of Interest in Clinical Research." Cotton, AJ, Japour A, Cotton D, In: Where Science Meets Ethics in Clinical Trials: The AIDS Paradigm, Kluwer Academic Publishers, 2003 (in press).

Abstracts

1. Prentice ED and Metcalf WK: The theory and practice of teaching in the medical sciences. Anat Rec 178:500-501, 1974.

2. Metcalf WK and Prentice ED: A practicum in teaching basic medical sciences. Proc 85th Annual Mtg of the Assoc of American Medical Colleges, November 1974.

3. Prentice ED, Sharp JG and Lipscomb H: Contact sensitivity to dinitrochlorobenzene (DNCB) in hypophysectomized and non-hypophysectomized rats. Proc Midwest Anat Soc pp 47, 1974.

4. Prentice ED, Metcalf WK, Quinn TH and Holyoke EA: The Nebraska stereoscopic auto-instructional approach to teaching human gross anatomy. Proc Midwest Anat Soc pp 46, 1974.

5. Metcalf NF, Prentice ED and Metcalf WK: Correlative clinical anatomy: An introduction to physical diagnosis. Proc Midwest Anat Soc pp 44, 1974.

6. Prentice ED, Metcalf WK, Metcalf NF and Sharp JG: A multi-media approach to teaching human anatomy. Proc 2nd Nat Conf on Research and Technology in Higher Education, Atlanta, GA, 1974.

7. Prentice ED and Lipscomb H: Cellular immunological status of hypophysectomized rats. Anat Rec 181:452-453, 1975.

8. Prentice ED and Metcalf WK: The Nebraska teacher training program for graduate students in anatomy. Proc Midwest Anat Soc pp 37, 1975.

9. Metcalf WK, Prentice ED, Metcalf NF, Sharp JG and Quinn TH: Student centered learning in anatomy. Proc Midwest Anat Soc pp 35, 1975.

10. Prentice ED and Metcalf WK: The changing emphasis in graduate education in the basic medical sciences: Instructor training. Proc AAMC 14th Annual Conf on Res in Med Educ pp 309, 1975.

11. Sharp JG, Prentice ED and Metcalf WK: An auto-instructional approach to the teaching of radiological anatomy to medical and allied health students. Proc Midwest Anat Soc pp 40, 1975.

12. Prentice ED, Metcalf WK, Sharp JG, Quinn TH and Holyoke EA: Packaged anatomical education: I. Stereoscopic Gross Anatomy. J Anat 120(3):628-629, 1975.

13. Sharp JG, Prentice ED and Metcalf WK: Packaged anatomical education: II. Radiological Anatomy. J Anat 120(3):629, 1975.

14. Prentice ED, Metcalf WK, Quinn TH and Holyoke EA: Three dimensional self-instructional units for teaching human gross anatomy. Proc HEMA-HeSCA Conf, 1975.

15. Prentice ED and Metcalf WK: Keying the instructional approach to individual learner needs. Proc 18th Annual Meeting of HeSCA pp 15, 1976.

16. Prentice ED, Metcalf WK, Quinn TH and Sharp JG: The Nebraska stereoscopic anatomy auto-instructional program for physician's assistant students. Proc 4th Annual Conf on New Health Pract pp 20, 1976.

17. Prentice ED and Metcalf WK: Stereoscopic anatomy auto-instruction vs. dissection as a learning activity. Anat Rec 184:504-505, 1976.

18. Metcalf WK, Prentice ED, Quinn TH, Sharp JG and Metcalf NF: Replacement of dissection by a stereoscopic anatomy auto-instructional laboratory. J Anat 122:748, 1976.

19. Bauer T, Metcalf WK, Metcalf NF, and Prentice ED: Auto-instruction in histology and cell biology as a substitute for traditional laboratory activities. J Physiol 258:54, 1976.

20. Prentice ED: Individualized instruction: Stating objectives. Proc 18th Annual Meeting of the HeSCA pp 2, 1976.

21. Prentice ED and Benschoter RA: Improving the quality of teaching in the medical school environment. Proc of 1977 HeSCA Conf.

22. Prentice ED, Sharp JG, and Metcalf WK: Analysis of the effect of extrinsic factors on medical student performance on subjective examinations. Proc NSPI Conf pp 24, April 1977.

23. Prentice ED, Metcalf WK and Metcalf NF: Development and evaluation of individual learning systems in the anatomical sciences. Proc of 1977 International APLET Conf, Surrey, Great Britain.

24. Jensen RH, Bukowski EL, Lohr WH and Prentice ED: Anatomical auto-instruction units vs. textbooks as a method of review for the physical therapist. Anat Rec 187:614-615, 1977.

25. Prentice ED, Metcalf WK, Quinn TH, Sharp JG and Holyoke EA: Stereoscopic anatomy auto-instruction: A new teaching system for undergraduate human anatomy courses. Proc Nebr Acad Sci pp 56, April 1977.

26. Metcalf NF, Prentice ED, Stinson WW and Metcalf WK: Functional anatomy: Logical basis for patient examination. Anat Rec 189:549, 1977.

27. Adams HG, Prentice ED, Jelinek EH, Stinson WW, Jensen RH and Metcalf WK: Anatomy in cross-section: Correlation with axial-whole body scans. Anat Rec 189:534, 1977.

28. Prentice ED, Metcalf NF, Stinson, WW and Metcalf WK: The Nebraska approach to breast, pelvic and rectal examination instruction as an integrated part of gross anatomy. Anat Rec 190:601, 1978.

29. Metcalf NF, Metcalf WK, Prentice ED and Sharp JG: Early introduction to clinically orientated embryology: Its role in the achievement of maximal fetal growth and well-being from sperm to term. Proc of Developmental Path Meeting, Aberdeen, Scotland, p. 2, April 1978.

30. Metcalf WK, Metcalf NF and Prentice ED: Using the peer group student-model for teaching the living anatomy of socially-sensitive areas of the body. J Anat 127:202, 1978.

31. Lipscomb HL and Prentice ED: Cellular immune function in hypophysectomized and nonhypophysectomized rats. Nebr Med J, October 1976.

32. Stinson WW, Prentice ED, Metcalf NF and Metcalf WK: Clinical anatomy for undergraduates: A new approach. Anat Rec 193:736, 1979.

33. Metcalf NF, Metcalf WK, Prentice ED and Stinson WW: Experiences with a satellite learning resources center. Anat Rec 194:625, 1979.

34. Prentice ED, Metcalf WK, Stinson WW and Benschoter RA: The role of the biomedical communication specialist in the evaluation and improvement of communication in the classroom. Proc of the 1979 HeSCA Conf.

35. Prentice ED, Metcalf WK and Metcalf NF: Problems associated with medical curriculum development and implementation in Nigeria. Proc 3rd Annual Third World Conf, October 1979.

36. Prentice ED: Scientific aspects of prescriptive exercise. Proc of AAPA Conf, May 1980.

37. Prentice ED, Levy M and Fasser C: Prescriptive running. Proc of AAPA Conf, April 1981.

38. Lydiatt DD, Prentice ED, Davis LF and Metcalf WK: The effects of immobilization on the rabbit temporomandibular joint. Anat Rec 208: 301, 1984.

39. Prentice ED and Metcalf WK: Microteaching workshop in the anatomical sciences. Anat Rec 211(3):364, 1985.

40. Hutcheson L, Latin RW, Berg K, Prentice ED: A comparison of body composition determination at two hydration levels using bioelectrical impedance analysis (BIA). Proc of 1987 AAHPER.

Letters to the Editor

1. Prentice ED: Letter to the editor on consistency in interpreting federal regulations. IRB: A Review of Human Subjects Research 15(1):11, 1993.

2. Prentice ED, Crouse DA and Mann MD: Letter to the editor on scientific merit review in animal research. Inst Lab Animal Res 35(1):1-3, 1993.

Administrative Guidelines/Documents

1. IRB Guidelines for the Protection of Human Subjects at the University of Nebraska. (1st Edition, 1981; 2nd Edition, 1987; 3rd Edition, 1992; 4th Edition, 1999)

2. IACUC Guidelines for Investigators. (1st Edition, 1986; 2nd Edition, 1992; 3rd Edition, 1995)

Ernest D. Prentice, Ph.D.
Associate Vice Chancellor for Academic Affairs and Regulatory Compliance

Teaching Programs

Instructional Videotapes

1. "How Not to Instruct on Television". Biomedical Communications Department, University of Nebraska College of Medicine, Omaha, NE, 1974. (Videotape with Quinn TH)

2. The Nebraska Video-Sector Series in Human Anatomy (with Quinn TH and Metcalf WK): A series of nine 8-22 minute instructional videotapes.

3. Anatomy of the Thoracic Cavity. NETCHE, Nebraska Educational Television, 1981.

4. Anatomy of the Heart, NETCHE, Nebraska Educational Television, 1981.

Auto-Instructional Programs

1. The Nebraska Stereoscopic Auto-Instructional Program in Human Gross Anatomy (with Metcalf WK, Quinn TH and Holyoke EA). The program consists of 32 units. Each stereoscopic auto-instructional unit is 15-20 minutes in length and employs stereoscopic slides of sequential anatomical dissections and a written and cassette recorded script. All units on reserve in the UNMC Library Learning Resource Center.

Awarded Grants

1. Co-Investigator, National Science Foundation, "Improving Living Anatomy Laboratory for Health Science Undergraduates", $5,300 (08/01/79 - 08/01/80).

2. Project Evaluator, National Institute of Health, "Developmental Basis of Infant Morbidity and Mortality", $155,966 (07/01/77 - 06/30/80).

3. Project Evaluator, National Science Foundation (RIAS), "Endocrinology of Reproduction and Development", $131,000 (07/01/77 - 06/30/81).

4. Principal Investigator, Nebraska Medical Foundation, #CD1343, "Development of the Nebraska Videosector Series in Human Anatomy", $5,000 (03/01/75 - 06/30/78).

5. Co-Investigator, National Fund for Medical Education, #57-73A, "Developing 3-Dimensional Self-Instructional Units for Teaching Gross Anatomy", $47,500 (07/01/74 - 06/30/78).

6. Principal Investigator, University of Nebraska Seed Grant, #22-271-782, "Role of the Hypophysis in Immune Function", $2,400 (12/01/73 - 01/31/74).

7. Principal Investigator, National Institutes of Health, "Electronic Enhancement of IRB Safety Monitoring," $100,000 (09/10/02 - 09/10/03).

8. Principal Investigator, National Institutes of Health, "IRB Training Through a Web Based Protocol Review Form," $100,000 (09/10/03 - 09/10/04).

Ernest D. Prentice, Ph.D.
Associate Vice Chancellor for Academic Affairs and Regulatory Compliance

Educational Demonstrations

National and International Conferences

Nov. 15, 1974 — Metcalf WK and Prentice ED: A practicum in teaching basic medical science. Demonstrated at the 85th Annual Meeting of the Association of American Medical Colleges, Chicago, IL.

June 12, 1975 — Prentice ED, Metcalf WK, Sharp JG, Quinn TH and Holyoke EA: Packaged anatomical education: I. Stereoscopic gross anatomy. Demonstrated at the Anat. Soc. Meeting of Great Britain.

Nov. 19, 1975 — Metcalf WK, Prentice ED, Metcalf NF, Sharp JG and Quinn TH: The Nebraska auto-instructional approach to medical education. Demonstrated at the 1975 Association of American Medical Colleges Meeting, Washington, DC.

Apr. 4, 1975 — Metcalf WK, Prentice ED, Metcalf NF, Sharp JG, Quinn TH and Bauer T: Cognitive styles and learning: A solution in anatomy. Demonstration at the 1975 HEMA-HeSCA Conference, Atlanta, GA. First Place Award.

Jan. 22, 1976 — Prentice, ED, Metcalf WK, Quinn TH, Metcalf NF and Stinson WW: Packaged anatomical education by the stereoscopic auto-instructional method. Demonstrated at the 1976 HEMA Conference, New Orleans, LA. First Place Award.

Oct. 17, 1978 — Metcalf WK, Prentice ED, Metcalf NF and Stinson WW: Breast-genital exams in anatomy. Demonstrated at the 1978 Association of American Medical Colleges Meeting, New Orleans, LA.

Regional Conferences

Oct. 15, 1976 — Metcalf NF, Prentice ED and Stinson WW: Stereo-anatomy, "A new solution to an old problem". Demonstrated at Midwest Clinical Society Meeting, Omaha, NE. First Place Award for Scientific Excellence.

Invited Lectures

National Level

Sept. 16, 1980 — The Development of Effective Lecture Technique. National Library of Medicine, Washington, DC.

June 18, 1981 — Sports Technology, Science and Medicine. University of Lagos College of Medicine, Lagos, Nigeria.

Oct. 31, 1988 — Ethics and Regulation of Clinical Research. Association of Physician Assistant Programs, San Juan, Puerto Rico.

Aug. 17, 1989 — Characteristics of IRB Review. OPRR/FDA Conference on Ethical Issues in Biomedical and Behavioral Research, NIH, Bethesda, MD.

Sept. 19, 1989 — IRB Protocol Review Using Systematic Definitive Criteria. OPRR/FDA Conference on Ethical Issues in Biomedical and Behavioral Research, NIH, Bethesda, MD.

Oct. 11, 1989	Increasing the Validity of IACUC Review. ARENA (Applied Research Ethics National Association) Conference, Boston, MA.
Oct. 2, 1989	Issues for IRBs in the 1990s: Commercial Interests, Conflict of Interest, and the IRB. Invited Panel Discussion Commentator, PRIM&R (PubliC Responsibility in Medicine and Research) Conference, Boston, MA.
July 19, 1990	Ethical and Legal Considerations in Conducting Placebo Based RCTs in Children. NIH/FDA Conference on Protection of Human Subjects, St. Louis, MO.
Oct. 29, 1990	How to Increase the Ethical Consistency of IACUC Review of Animal Research. Scientists Center for Animal Welfare Conference, Baltimore, MD.
June 1-2, 1991	Scientific Merit Review in Animal Research: Role of the IACUC. Scientists Center for Animal Welfare Conference, Philadelphia, PA.
Oct. 20, 1991	Effective Animal Care and Use Committees. Society of Research Administrators Conference, Vancouver, B.C.
Apr. 24, 1992	Nazi Doctors and Their Crimes Against Humanity. Washington University School of Medicine Program for the Humanities in Medicine, St. Louis, MO.
June 19, 1992	Addressing Scientific Quality of Animal Research Not Externally Reviewed. OPRR/ Columbia University Health Sciences Conference, New York, N.Y.
Feb. 12, 1993	Ethical Responsibilities of the IACUC. American Association for Advancement of Science, Boston, MA.
Mar. 17, 1993	Keynote Address - Scientific Merit in Animal Research: Whose Responsibility Is It? ARENA IACUC Conference, Boston, MA.
Oct. 20, 1993	Keynote Address - The Nuremberg Doctors Trial: Genesis of the IRB. ARENA IRB Conference, Boston, MA.
Mar. 23, 1994	The 1946 Nuremberg Doctors Trial: Genesis of Informed Consent in Clinical Research. 18th annual meeting of the Associates of Clinical Pharmacology, San Antonio, TX.
May 12, 1994	Ethics and Science of Xenoperfusion and Xenotransplantation. Scientists Center for Animal Welfare Conference: Research Animal Anesthesia, Analgesia and Surgery, Atlanta, GA.
Nov. 11, 1994	History Repeats Itself - The Development and Importance of IRBs. University of Texas Southwestern Medical Center/Tarrant County Community IRB, Conference on Trends in Research Involving Human Participants. Fort Worth, TX.
Dec. 9, 1994	Ethics of Xenotransplantation. SCAW (Scientists Center for Animal Welfare) Conference: New Frontiers in Animal Research. San Antonio, Texas. (Conference Chair).
Jan. 10, 1995	PEG-SOD Case Study. FDA/NIH Public Forum on Informed Consent in Clinical Research Conducted Under Emergency Circumstances. Bethesda, MD.

May 5, 1995	Xenotransplantation: Medical Adventurism or Justifiable Clinical Research. OPRR/ Washington University School of Medicine Conference. St. Louis, MO.
May 5, 1995	Ethics and Regulation of Emergency Research. OPRR/Washington University School of Medicine Conference. St. Louis, MO.
May 6, 1995	Keynote Address - From Nazi War Crimes to the Nuremberg Code. OPRR/ Washington University School of Medicine Conference. St. Louis, MO.
May 22, 1995	Ethical Issues in Xenotransplantation. Bio 95 International Biotech Conference. San Francisco, CA.
June 6, 1995	Ethics of Xenotransplantation and Transgenic Animal Donors. North Carolina Biotechnology Conference. Research Triangle Park, NC.
Sept. 18, 1995	Keynote Address. Historical Perspectives in the Evolution of Human Subjects Protection. NIH/FDA Conference on Protection of Human Subjects. Oxford, MI.
Sept. 18, 1995	Research with Children. NIH/FDA Conference on Protection of Human Subjects. Oxford, MI.
Mar. 13, 1996	Review of Clinical Xenotransplantation. ARENA IACUC Conference. Boston, MA.
Apr. 10, 1996	Legal Issues Regarding Pediatric Research Subjects. OPRR/FDA/Emory University Conference. Atlanta, GA.
Apr. 11, 1996	Prison Research: Behavioral Studies Involving Inmates. OPRR/FDA/Emory University Conference. Atlanta, GA.
Apr. 17, 1996	Informed Consent: Current Issues. Medical College of Pennsylvania and Hahnemann University Symposium. Philadelphia, PA.
Apr. 17, 1996	Problems Affecting IACUC Review. Medical College of Pennsylvania and Hahnemann University Symposium. Philadelphia, PA.
May 16, 1996	IACUC Membership. OPRR - Wright State University National Animal Welfare Education Workshop. Dayton, OH.
Sept. 5, 1996	History of Xenotransplantation and Current Concerns. SCAW Genetic Engineering Conference. Chicago, IL (Conference Chair).
Sept. 16, 1996	In-Service for the NIH Office for Protection from Research Risks (OPRR) on Research Involving Prisoners and Children. Rockville, MD.
Sept. 27, 1996	Preparing for the FDA IRB Inspection. OPRR-NIMH-NIH-FDA University of Illinois Conference. Peoria, IL.
Oct. 31, 1996	Current Ethical, Scientific and Social Issues Concerning the Use of Animal Organs as Spare Parts. Cleveland Clinic, Cleveland, OH.

Nov. 9, 1996	Commercialization of Human Biological Materials. ARENA IRB Conference. San Diego, CA.
Dec. 5, 1996	Protocol Review Results of the SCAW IACUC Study. SCAW Conference. San Antonio, TX.
June 24, 1997	Increasing the Effectiveness of Informed Consent in Clinical Studies. The 33rd Annual Drug Information Meeting. Montreal, Canada.
Aug. 20, 1997	Additional Protections for Vulnerable Subject Populations. University of Washington School of Medicine/OPRR/FDA Human Subjects Protections Workshop. Seattle, WA.
Dec. 7, 1997	Is Annual IRB Continuing Review a Myth or Reality? ARENA IRB Conference. Boston, MA.
Dec. 11, 1997	Xenotransplantation: What's Old and What's New? SCAW Conference. San Antonio, TX.
Mar. 14, 1998	What Does Informed Consent Mean in Clinical Research and How Can We Improve Its Quality? Columbia Presbyterian Medical Center. New York, NY.
Mar. 28, 1998	History of Xenotransplantation and Overview of Current Issues. PRIM&R IACUC Conference. Boston, MA.
Apr. 16, 1998	Commercialization of Cord Blood and Other Biological Material: Who Owns It and Other Issues? St. Vincent's Medical Center of Richmond. Staten Island, NY.
June 1, 1998	Ethical Cost Benefit Assessment in Animal Research. OPRR/USDA/University of Nevada Conference. Reno, NV.
Aug. 6, 1998	Nuremberg and Tuskegee: Defining Events in Research Ethics. OPRR/FDA/ University of Rochester Conference. Rochester, NY.
Aug. 20, 1998	Who Owns the Human Body: Issues of Biological Property Rights, Societal Values, and IRB Responsibilities. Western IRB 14th Annual Conference. Seattle, WA.
Dec. 7, 1998	Justifying Animal Research Using Ethical Cost Benefit Assessment. SCAW Conference. San Antonio, TX.
Jan. 15, 1999	Who Owns the Human Body and Its Parts: Issues of Property Law, Ethics and Societal Values. El Camino Hospital Ethics Series, El Camino, CA.
Mar.20, 1999	Protocol Review: IACUC 101—A Primer for Effective Animal Care and Use Programs. AALAS/PRIM&R/ARENA, San Diego, CA.
Mar. 5, 1999	Perception Versus Reality in the IRB World: View From the Trenches. FDA Protection of Human Subjects Conference. Bethesda, MD.
Apr. 30, 1999	Guidelines for Responding to Allegations of Non-Compliance with 21 CFR 50, 56 and 45 CFR 46. University of Miami/FDA/Veteran's Administration Medical Center Conference on Protection of Human Subjects, Miami, FL.

Ernest D. Prentice, Ph.D.
Associate Vice Chancellor for Academic Affairs and Regulatory Compliance

May 21, 1999	The Ethics of Using Animal Organs as Spare Parts for Humans. St. Vincent's Medical Center Ethics Seminar Series. Long Island, NY.
May 27, 1999	Reflections on the IRB of Yesteryear, Today, and Tomorrow. University of Illinois IRB Continuing Education Program, Peoria, IL.
June 30, 1999	The OIG Report, the Federal Compliance "Hammer" and IRB Perspectives. Drug Information Agency (DIA) 35th Annual Meeting, Baltimore, MD.
July 29, 1999	A Historical and Contemporary Look at the IRB with an Eye to the Future. Spartanburg Regional Medical Center, Spartanburg, SC.
Sept. 10, 1999	IRB Assessment of Research Risk. Veteran's Affairs Ethics Center Conference, Minneapolis, MN.
Oct. 6, 1999	The IRB and the Clinical Investigator as Partners in Protecting Research Subjects. Winthrop University, Mineola, NY.
Nov. 7, 1999	Basic Elements of Protocol Review: IACUC 101. AALAS Annual Meeting, Indianapolis, IN.
Nov. 18, 1999	Informed Consent Issues. Infectious Diseases Society of America Annual Conference, Philadelphia, PA.
Nov. 20, 1999	History, Problems and Dilemmas Which Impact on the Modern IRB. Schulman IRB Annual Workshop, Cincinnati, OH.
Dec. 5, 1999	Should Institutions Charge for IRB Review. ARENA IRB Conference, Boston MA.
Mar. 9, 2000	Compliance with FDA and HHS Regulations Is Serious Business. Barnett International Conference, Philadelphia, PA.
Mar. 12, 2000	Alternative Searches and Inherent Frustrations: The IACUC's Perspective. ARENA Conference, Boston, MA.
June 14, 2000	Recruitment of Study Subjects. The IRB's Perspective. DIA Meeting, San Diego, CA.
July 11, 2000	Risk Assessment in Research. National Bioethic Advisory Commission (NBAC) Meeting, Bethesda, MD.
Aug. 2, 2000	International Historical Perspectives and Current Protections of Human Subjects. International Association for the Scientific Study of Intellectual Disability. Seattle, WA.
Sept. 25, 2000	Current HHS and FDA Compliance Standards. Institute for International Research, Princeton, NJ.
Oct. 2, 2000	Issues Regarding Financial Conflicts of Interest in Clinical Research. Association of Independent Research Institutions, Santa Monica, CA.
Oct. 9, 2000	IRB Review of Recruitment Strategies. Institute for International Research, Orlando, FL.

Ernest D. Prentice, Ph.D.
Associate Vice Chancellor for Academic Affairs and Regulatory Compliance

Oct. 26, 2000	Understanding the Current Climate of Research Accountability and Compliance in the U.S. Barnett International Conference, San Diego, CA.
Oct. 29, 2000	Perception Versus Reality in the IRB World. ARENA IRB Conference, San Diego, CA.
Dec. 4, 2000	Ethics, Public Policy and IRB/IACUC Responsibility for Research Involving Xenotransplantation. SCAW Conference, San Antonio, TX.
Mar. 2, 2001	Human Research Protection and Lessons from History. University of Wisconsin Systems Meeting, Stevens Point, WI.
Mar. 19, 2001	Genesis of the IRB from Nuremberg to Gene Transfer, Barnett International Conference, Philadelphia, PA.
May 1, 2001	Evolution and Ethical Basis of Regulations for the Protection of Human Subjects. ACRP Annual Conference, San Francisco, CA.
July 11, 2001	IRB Review of Adverse Events. Midwest Bioethics Center, Kansas City, MO.
Aug. 16, 2001	Development and Review of Animal Use Protocols. ARS-NADC Training for Russian Scientists, Ames, IA.
Oct. 24, 2001	Changes and Reforms on the Horizon in Human Subject Protection. NAADConference, New Orleans, LA.
Nov. 6, 2001	IRBs: A System in Jeopardy. RAPS Annual Conference, Baltimore, MD.
Dec. 27, 2001	Conflict of Interest Management. Harbor UCLA Medical Center, Torrance, CA.
Jan. 22, 2002	Current Status of Human Subjects Protection. Pacific Health Research Institute, Consortium of Ten Institutions, Honolulu, HI.
Jan. 29, 2002	Conflict of Interest: A Challenge for the Times. DIA Conference, Washington, DC.
Feb. 22, 2002	Conflicts of Interests in Clinical Research and Their Management. SAIRB Annual Conference, Cincinnati, OH.
Mar. 5, 2002	Forces Driving the IRB System in the U.S. and Their Impact on Clinical Research, DIA Conference, Washington, DC.
Apr. 15, 2002	The Belmont Report: Is it Applicable to Modern Day Clinical Research. ACRP Annual Conference, Toronto, Canada.
Apr. 25, 2002	Defining Events in Research From Nuremburg to 2002. Saint Vincent Medical Center, Staten Island, NY.
June 15, 2002	Ethics and Regulation of Research Involving Children. 49th Annual SNM Conference, Los Angeles, CA.

Ernest D. Prentice, Ph.D.
Associate Vice Chancellor for Academic Affairs and Regulatory Compliance

June 17, 2002	A Primer on HIPAA. DIA Conference, Chicago, IL.
Sept. 10, 2002	Conflicts of Interest in the Biomedical Industry. Strategic Research Institute 10th International Conference, San Francisco, CA.
Sept. 20, 2002	Applying Subpart D in IRB's Oversight of Pediatric Clinical Trials. Barnett International Conference, Philadelphia, PA.
Oct. 1, 2002	Impact of Research Scandals and Lawsuits on Clinical Research. Barnett International Conference, Philadelphia, PA.
Oct. 7, 2002	History and Evolution of the IRB. RAPS Annual Conference, Washington, DC.
Oct. 8, 2002	What the Clinical Trials Industry Needs to Know about the Wave of Law Suits. RAPS Annual Conference, Washington, DC.
Oct. 8, 2002	Hot Topics in the IRB World. RAPS Annual Conference, Washington, DC.
Oct. 22, 2002	Ethics and Regulation of Placebo Controlled Clinical Trials in Children. American Academy of Child and Adolescent Psychiatry, San Francisco, CA.
Dec. 10, 2002	How to Handle and Report Allegations of Non-Compliance to OLAW and USDA. SCAW Annual Conference, New Orleans, LA.
Dec. 26, 2002	Research with Children: The Ethical Imperative is Don't Underprotect or Overprotect. Harbor UCLA Medical Center, Torrence, CA.
Feb. 22, 2003	The Interpretation and Application of SubpartD in the IRB's Review of Pediatric Research. Emory University IRB Retreat, Atlanta, GA.
Feb. 22, 2003	Conflict of Interest in Clinical Research. Emory University IRB Retreat, Atlanta, GA.
Mar. 6, 2003	Update on SACHRP. Medical Research Summit Conference, Washington, DC.
Mar. 6, 2003	The Pediatric Smallpox Vaccine Trial: 407 Review. Medical Research Summit Conference, Washington, DC.
Mar. 11, 2003	Alteration or Waiver of Authorization/Consent Under HIPAA. International Pharmaceutical Privacy Consortium, Washington, DC.
Mar. 14, 2003	Key Lawsuits in Clinical Research and Their Impact on Investigators, Institutions and IRBs. ACRP Baltimore Chapter, Baltimore, MD.
Apr. 9, 2003	Issues in Clinical Research and Human Subject Protection. ACRP Annual Conference, Philadelphia, PA.
June 16, 2003	Regulatory, Criminal and Civil Liability From Clinical Research. DIA 2003 Conference, San Antonio, TX.

Aug. 18, 2003	Challenges Facing the New HHS Secretary's Advisory Committee. Western IRB Annual Conference, Seattle, WA.
Sept. 10, 2003	Forces Driving Changes in the IRB System: Why Life is Not the Same for Either Clinical Researchers or the IRB. Henry Ford Health System, Detroit, MI.
Sept. 19, 2003	Keynote Address: The Past, Present and Future of Human Experimentation. Schulman Associates, University of Cincinnati, Cincinnati, OH.
Sept. 23, 2003	Update on SACHRP. Friends Research Institute/UCSF IRB Conference, San Francisco, CA.
Nov. 17, 2003	National Concerns and Challenges in the Field of Research Subject Protection. Community Research Forum for Central Iowa, Des Moines, IA.
Dec. 10, 2003	Moore and Greenberg: Un-consented Use of Human Tissue for Commercial Purposes. CBI's Forum on Limiting Exposure to Liability in Clinical Trials, Philadelphia, PA.
Mar. 12, 2004	The Impact of Litigation on Clinical Research, Investigators and IRBs. ACRP Baltimore-DC Chapter Meeting, Baltimore, MD.
Apr. 22, 2004	Ethical Pediatric Research Requires Balanced Protection. NIGMJ/NIH Step Forum, Bethesda, MD.
Apr. 23, 2004	Update on the DHHS Advisory Committee on Human Research Protections, 4th Annual Medical Research Summit, Baltimore, MD.
Apr. 28, 2004	Kids Participating in Research Should Not Be Overprotected or Under-Protected. University of Iowa, Iowa City, IA.
Apr. 28, 2004	The Intrusion and Consequences of Litigation in the Clinical Research Environment. University of Iowa, Iowa City, IA.
May 6, 2004	Keynote Address: The Wings of Change in the Ethics, Regulation, and Conduct of Research. Temple University, Philadelphia, PA.
June 29, 2004	Keynote Address: Balancing Animal Welfare With Scientific Need Using an Ethical Cost-Benefit Assessment, Michigan Society for Medical Research, Detroit, MI.
July 16, 2004	The Nazi Doctor Experiments, Chesapeake Research Review, Inc. Seminar, Columbia, MD.
Sept. 10, 2004	The Ethics of Placebo Controlled Clinical Trials in the US and Elsewhere. Schulman Associates, UK, UC Annual Conference, Cincinnati, OH.
Sept. 11, 2004	IRB Reporting Requirements for Review of Adverse Event Reports (AERs). Emory University IRB Retreat, Emerald Point, GA.
Sept. 21, 2004	Keynote Address: Balancing Flexibility With Compliance in IRB Review of Behavioral Research. University of Texas at Austin IRB Conference, Austin, TX.

Sept. 25, 2004	The IRB's View of Placebo Ethics in Pediatric Research. DCRI Pediatric Psychopharmacology "Think Tank" Meeting, Washington, DC.
Sept. 30, 2004	Understanding IRB Requirements for Review and Oversight of Pediatric Trials. Barnett International 5th Annual Pediatric Clinical Trials Conference, Philadelphia, PA.
Oct. 10, 2004	The Definition and Clarification of Human Subject Research. NHG Annual Scientific Congress 2004, Singapore.
Oct. 10, 2004	The Ethics and Regulation of Databases. NHG Annual Scientific Congress 2004, Singapore.
Nov. 6, 2004	The Genesis, Interpretation, and Application of Subpart D to Pediatric Research. Chesapeake Research Review, Inc. Retreat, Queenstown, MD.
Nov. 12, 2004	Evolution of the Ethics and Regulation of Human and Animal Research. Fred Hutchinson Cancer Research Center, Seattle, WA.
Nov. 14, 2004	Keynote Address: Challenges Facing the Contemporary Local IRB. Northwest Association for Biomedical Research (NWABR) Annual Conference, Bellevue, WA.
Nov. 15, 2004	Perils of a Litigious Climate. Northwest Association for Biomedical Research (NWABR) Annual Conference, Bellevue, WA.
Nov. 19, 2004	Ethics and Regulatory Oversight of Clinical Research. Palm Beach Garden Medical Center, Palm Beach, FL.
Dec. 27, 2004	Informed Consent is Not a Piece of Paper. Harbor UCLA Medical Center, Torrence, CA.
Jan. 10, 2005	Use of "Minimal Risk" as a Threshold Standard of Risk. APA-Fordham University Conference on Minimal Risk, New York, NY.
Feb. 4, 2005	Customer Service and Human Subject Protection is Job One for All IRBs. Chesapeake Research Review, Inc. Retreat, Cambridge, MD.
Mar. 14, 2005	Making the Case for Accreditation. AAHRPP Annual Conference, Atlanta, GA.
Mar. 23, 2005	The Impact of Adverse Litigation on Clinical Research. The Society of Clinical Research Associations, Inc. (SOCRA), Crystal City, DC.
Apr. 5, 2005	The Secretary's Advisory Committee on Human Research Protection: Two Years of Progress. ACRP 2005 Annual North American Conference, Orlando, FL (co-presented with Tom Adams).
May 1, 2005	Genesis and Role of the IACUC. ARVO Annual Conference, Ft. Lauderdale, FL.
May 13, 2005	Conflict of Interest in Clinical Research: What Is It, How Bad Is It, What Should We Do About It? ACRP Baltimore-DC Chapter Meeting, Ellicott City, MD.
May 18, 2005	Keynote Address: Evolution of the Ethics and Regulation of Animal Research. Michigan Society for Medical Research Annual Meeting, Brighton, MI.

May 27, 2005	Protecting Children While Advancing Science is Key. Yale University, New Haven, CT.
June 2, 2005	Keynote Address: The Winds of Change in the Ethics and Regulation of Research. Medical College of Wisconsin-OHRP Conference, Milwaukee, WI.
June 2, 2005	Investigating Allegations of Non-Compliance at the Institutional Level. Medical College of Wisconsin-OHRP Conference, Milwaukee, WI.
July 11, 2005	Building and Sustaining a Tribal IRB: Guiding Principles of the Belmont Report are the Cornerstones of Human Subject Protection Research. American Indian/Alaska Native (AI/AN) Conference, Rapid City, SD.
June 17, 2005	How to Conduct Research in AI/AN Communities: The Validity of Informed Consent is Dependent Upon the Process, Not the Document. AI/AN Conference, Fort Yates, ND.
July 22, 2005	Analysis and Use of "Minimal Risk" as a Threshold Standard of Risk in IRB Decision Making. Chesapeake Research Review, Inc. Seminar, Columbia, MD.
Aug. 16, 2005	Keynote Address: Protecting Human Subjects in a Changing Research Environment: From Belmont to SACHRP and Beyond. Youngstown State University-OHRP Conference, Youngstown, OH.
Sept. 30, 2005	SACHRP: Advancing Human Subject Protection for the Benefit of Science and Society. Schulman Associates, UK, and UC Annual Conference, Cincinnati, OH.
Nov. 10, 2005	The Winds of Change in Human Subject Protection. Western IRB Annual Dinner, Olympia WA.
Nov. 12, 2005	The Impact of Lawsuits in the Clinical Research Arena. Chesapeake Research Review, Inc. Retreat, Aspen Wye River, MD.
Mar. 6, 2006	Keynote Address: A Walk Through the History of Research Ethics. University of Las Vegas Conference, Las Vegas, NV.
Mar. 7, 2006	Issues of Informed Consent in Internet Research. University of Las Vegas Conference, Las Vegas, NV.
Mar. 28, 2006	On Being An Institutional Official. PRIM&R IACUC Conference, Boston, MA.
Apr. 6, 2006	The Identification and Management of Investigator and IRB Member COI. The Society of Clinical Research Association, Inc. (SOCRA), Crystal City, DC.
Apr. 13, 2006	Lessons Learned From Clinical Trial Litigation. Kansas University Medical Center, Kansas City, MO.
Apr. 24, 2006	US Regulatory Oversight of Clinical Research. 2nd Annual Clinical Research in Canada Conference, Toronto, Canada.
Apr. 27, 2006	Team Approach to Compliance. University of California at Davis, Davis, CA.

Ernest D. Prentice, Ph.D.
Associate Vice Chancellor for Academic Affairs and Regulatory Compliance

May 1, 2006	SACHRP: Three Years of History Making Recommendations and Challenges. ACRP 2006 Annual North America Conference, Phoenix, AZ (Co-Presented with Tom Adams).
May 2, 2006	Case Studies. ACRP 2006 Annual North American Conference, Phoenix, AZ (Co-Presented with Linda Strause).
June 1, 2006	History, Organization, and Mission of the Modern IRB That Define Challenges Today. American Society of Gene Transfer (ACTG), Baltimore, MD.
June 2, 2006	Keynote Address: SACHRP: Overview, Mission, and Current Initiatives. University of Colorado Health Science Center Conference, Denver, CO.
June 7, 2006	Principle One of the Nuremberg Code is the Ethical Basis of Informed Consent. University of Maryland, Baltimore, MD.
June 7, 2006	Role and Composition of the IRB. Chesapeake Research Review, Inc., Columbia, MD.
June 8, 2006	The Crossroads of Clinical Research: Applied Ethics, Litigation, and Medical Practice. 5th Annual Donovan Research Ethics Lecture, Baltimore, MD.
June 14, 2006	What You Need to Know About Regulations and the Law Concerning Research With Human Biological Material. Walter Reed Army Research Institute, Washington, DC.
June 14, 2006	The Classification of Risk Levels Using the Minimal Risk Threshold. Walter Reed Army Research Institute, Washington, DC.
June 15, 2006	What's Wrong With This IACUC? They Just Don't Get It. SCAW Focus Group, National Academy of Science, Washington, DC.
June 21, 2006	SACHRP Update: Recommendation and New Challenges. DIA 42nd Annual Conference, Philadelphia, PA (Co-Presented with Tom Adams).
June 22, 2006	Dilemma of Role Conflicts. DIA 42nd Annual Conference, Philadelphia, PA.
Sept. 8, 2006	SACHRP: Working to Enhance Human Subject Protection While Reducing Regulatory Burden. Western IRB Annual Conference, Seattle, WA.
Sept. 13, 2006	SACHRP IN ACTION: Genesis, Challenges, and Achievements. Case Western University, Cleveland, OH.
Sept. 27, 2006	How to Get to Know and Love Your IACUC. Safety Pharmacology Society, San Diego, CA.
Sept. 29, 2006	Keynote Address: SACHRP: It's Genesis, Mission, and Current Activities. North Dakota State University, Fargo, ND.
Nov. 4, 2006	To Evaluate or Not to Evaluate IRB Members: That is the Question. Chesapeake Research Review, Inc. Annual Retreat, Baltimore, MD.

Nov. 15, 2006	SACHRP and Hot Topics for Institutional Officials. PRIM&R 2006 Annual Pre-Conference, Washington, DC.
Mar. 7, 2007	Genesis of Additional Protection in Research Involving Special Populations. AHRQ, Rockville, MD.
Apr. 20, 2007	SACHRP: Reflections on Four Years of Challenges and Achievements. 2007 ACRP Global Conference, Seattle, WA (Scheduled).
May 7, 2007	Research Ethics Didn't Evolve Naturally: It Was Driven. Front Range ACRP Meeting, Denver CO (Scheduled).
June 2, 2007	Integrated Human Subject Protection Using the NCI Central IRB, Chicago, IL (Scheduled).
June 7, 2007	Keynote Address: Between "The Rock and the Hard Place" Dealing With Therapeutic Misconception, Medical College of Wisconsin, Milwaukee, WI (Scheduled).
Oct. 19, 2007	Investigator and IRB Member Conflicts of Interest Must Be Scrupulously Managed: UC, UK, and Schulman Human Protection Conference, Covington, KY (Scheduled).

Invited Lectures

Regional Level

Apr. 26, 1980	Physiological Adaptation to Chronic Aerobic Exercise. Nebraska Association of Physician Assistants (NAPA) Conference on Exercise, Athletes and Medicine, Lincoln, NE.
June 4, 1980	The Anatomical Basis of Sports Injuries. UNO Department of Physical Education, Omaha, NE.
March 1, 1981	Scientific Principles of Strength Training. UNMC Department of Orthopedics and Sports Medicine, Omaha, NE.
Apr. 8, 1981	Principles of Conditioning for Distance Runners. UNMC Department of Orthopedics and Sports Medicine, Omaha, NE.
Sept. 12, 1981	Cause and Prevention of Sports Injuries. UNO Department of Physical Education, Omaha, NE.
May 2, 1982	The Mechanical Basis of Injuries to Runners. Nebraska Medical Association, Omaha, NE.
Nov. 19, 1982	Holistic Medicine and Its Relationship to Aerobic Exercise. UNMC College of Dentistry, Omaha, NE.
June 10, 1983	Sports Medicine. UNO Department of Physical Education, Omaha, NE.
June 4, 1984	Overuse Injuries in Runners. UNO Department of Physical Education, Omaha, NE.
Oct. 29, 1984	Role of the IRB in Biomedical Research. UNMC Family Practice Continuing Education, Omaha, NE.

Ernest D. Prentice, Ph.D.
Associate Vice Chancellor for Academic Affairs and Regulatory Compliance

Dec. 1, 1984	The Investigator's Challenge of the 80s: Animal and Human Review Mandates. UNMC Sigma XI, Omaha, NE.
Feb. 3, 1985	Assessing Risks in Biomedical Research: A Challenge for the IRB. UNMC Humanities Rounds, Omaha, NE.
Jan. 14, 1986	The New Public Health Service Policy on Animal Welfare. UNO Department of Biology, Omaha, NE.
Nov. 7, 1986	Wellness Lifestyle for the Cancer Patient. UNMC Hematology-Oncology Section Meeting, Omaha, NE.
Dec. 3, 1986	Concept of Wellness and Alteration of Risk Factors. UNMC Department of Pathology and Microbiology, Omaha, NE.
Jan. 19, 1987	The Institutional Review Board. UNMC College of Pharmacy, Omaha, NE.
Jan 26, 1987	The Animal Review Committee. UNMC College of Pharmacy, Omaha, NE.
Apr. 21, 1987	Importance of Maintaining Physical Fitness. UNMC Teleconference Network for Nurses, Omaha, NE
May 15, 1987	Protection of Human Subjects. UNMC Research Skills Workshop, Omaha, NE.
May 19, 1987	Peripheral Nerve Lesions. West Dodge Physical Therapy Clinic, Omaha, NE.
Oct. 28, 1987	Ethical Issues in Animal Research. UNMC Humanities Grand Rounds, Omaha, NE.
Nov. 4, 1987	Ethical Guidelines in Human and Animal Research. UNMC Department of Psychiatry, Omaha, NE.
Nov. 9, 1987	Vivisectionists vs. Antivivisectionists: Who Is Right and What Are the Issues? UNMC Department of Anatomy, Omaha, NE.
Jan. 6, 1988	Ethics of Human Experimentation. UNMC Department of Internal Medicine, Omaha, NE.
Mar. 18, 1988	Ethical Guidelines in Human and Animal Research. UNMC School of Physical Therapy, Omaha, NE.
Feb. 1, 1989	Role of the IRB in Oncology Research. Good Samaritan Hospital, Kearney, NE.
Mar. 6, 1989	History of the Regulation of Human Research. UN, Lincoln, Anthropology Department, Lincoln, NE.
Feb. 5, 1990	The Ethics of Fetal Tissue Transplantation Research. UNMC Department of Anatomy, Omaha, NE.
Nov. 17, 1990	Use of Animals in Research and Teaching at the High School and College Level. Nebraska Junior Academy of Science, Wayne State College, Wayne, NE.

Ernest D. Prentice, Ph.D.
Associate Vice Chancellor for Academic Affairs and Regulatory Compliance

Feb. 26 1992	IRB Workshop: Human Subjects. UN, Lincoln, Lincoln, NE.
Mar. 5, 1992 & Mar. 16, 1992	The Policies and Procedures of the Institutional Review Board. UNO, Omaha, NE.
Mar. 17, 1992	The Evolution of Animal Welfare Ethics in the United States. UN, Lincoln, Department of Veterinary Science, Institute of Agriculture and Natural Resources, Lincoln, NE.
Apr. 3, 1992	Evolution of the Ethics of Human Subjects Research: From Nuremberg to Desert Storm. Annual Sigma XI Lecture. UN, Kearney. Kearney, NE.
Feb. 22, 1994	Obtaining Informed Consent from Cancer Patients. Humanities and Law Rounds, UNMC. Omaha, NE.
Mar. 30, 1994	Evolution of the Animal Rights Campaign Against the Scientific Use of Animals: 1981-1993, UNO Department of Biology. Omaha, NE.
Apr. 11, 1995	Evolution of Research Ethics: Past, Present and Future. Creighton University, Omaha, NE.
Jan 3, 1997	Protection of Human Subjects in Clinical Research: Past, Present and Future. Internal Medicine Grand Rounds, UNMC, Omaha, NE.
Apr. 1, 1997	The 1946 Nuremberg Doctors Trial and Its Relevance to Modern Day Medicine. History of Medicine Club, Omaha, NE.
Apr. 5, 1997	Involvement of OPRR When an Institution Is Accused of Non-Compliance. Midwest Regional AALAS Meeting, Omaha, NE.
Apr. 7, 1999	The Ethics and Regulation of Clinical Xenotransplantation, Department of Surgery, University of Nebraska Medical Center, Omaha, NE.
May 10, 1999	Protecting the Rights and Welfare of Human Subjects. Methodist Hospital School of Nursing, Omaha, NE.
Aug. 13, 1999	Institutional and Investigator Responsibilities for Protecting the Rights and Welfare of Research Subjects, Methodist Hospital, Omaha, NE.
Aug. 31, 1999	Evolution, Structure, Function and Problems of the Modern IRB. Methodist Hospital IRB Training Conference, Omaha, NE.
May 8, 2000	Maintaining Compliance with Federal Regulations. NCURA/SRA, Omaha, NE.
Nov. 28, 2000	Regulation of Research Involving Children. Children's Hospital, Omaha, NE.
June 20, 2005	The Nazi Doctor's Crimes Against Humanity. Omaha Westside Lion's Club, Omaha, NE.
Oct. 27, 2005	Informed Consent = Is it a Piece of Paper or a Process? ACRP Nebraska Chapter Meeting, Omaha, NE.

Ernest D. Prentice, Ph.D.
Associate Vice Chancellor for Academic Affairs and Regulatory Compliance

Invited Workshops/Breakout Sessions/Training*

*Most workshops/breakout sessions involve co-faculty

National Level

April 2, 1978	The Keys to Effective Teaching. American Association of Physician Assistants (AAPA) Conference, Hollywood, FL.
May 12, 1978	Evaluation of Instructional Programs. Health Education Sciences Communications Association (HeSCA) Conference, Tucson, AZ.
Oct. 23, 1986	Mock Protocol Review of Animal Research. Scientists Center for Animal Welfare (SCAW) Conference, Toronto, Canada.
May 3, 1989	Increasing the Consistency of Protocol and Consent Form Review. NIH/FDA Conference, Omaha, NE.
Oct. 12, 1989	Developing IRB Policies and Consent Procedures for Protocols Involving the Commercialization of Therapies. Public Responsibility in Medicine and Research (PRIM&R) IRB Conference, Boston, MA.
Nov. 6, 1989	Conflicts Involving the Commercialization of Biotechnology: Who Stands to Profit? PRIM&R IRB Conference, Boston, MA.
July 19, 1990	Educating Investigators. NIH/FDA Conference on Protection of Human Subjects, St. Louis, MO.
Sept. 16, 1990	Compliance Issue: Ethical Review of Animal Research. Society of Research Administrators, Milwaukee, WI.
Nov. 1, 1990	Development of Cell Lines and Biologics: IRB Policies. PRIM&R IRB Conference, Boston, MA.
May 20-21, 1993	Research Benefits and Risks to Individuals and Communities: Legal and Ethical Perspectives. NIH/FDA/Indian Health Service Conference, University of Alaska, Anchorage, AK.
July 11, 1994	Contemporary Issues on Existing and New Research Guidelines on Women and Minority Groups: Special Emphasis on American Indians. NIH/FDA/Indian Health Service Conference, Bloomington, MN.
Mar. 14, 1995	Xenotransplantation and Xenoperfusion. PRIM&R IACUC Conference, San Diego, CA.
Mar. 16, 1997	Ethics in Animal Research. ARENA (Applied Research Ethics National Association) IACUC Conference, San Diego, CA.
Dec. 9, 1997	Handling Allegations of Non-Compliance. PRIM&R IRB Conference, Boston, MA.
Dec. 9, 1997	IRB Responsibilities for Conducting Reviews of Continuation Reports, Adverse Events, Amendments and Audits. PRIM&R IRB Conference, Boston, MA.
Mar. 26, 1998	Ethics Applied to Animal Research. ARENA IACUC Conference, Boston, MA.

Mar. 27. 1998	Protocol Review by the IACUC. PRIM&R IACUC Conference, Boston, MA.
Mar. 28, 1998	Continuing Review by the IACUC and Amendments. PRIM&R IACUC Conference, Boston, MA.
July 30, 1998	Placebo Controlled Clinical Trials in Women. OPRR/FDA/UCLA Conference Women as Research Subjects, Los Angeles, CA.
Nov. 9, 1998	IRB Review of Continuation Reports, Adverse Events and Amendments. PRIM&R IRB Conference, San Diego, CA.
Nov. 9, 1998	IRB Investigations of Non-compliance and Reporting Requirements of OPRR and FDA. PRIM&R IRB Conference, San Diego, CA.
Mar. 21, 1999	Ethical Issues for IACUCs, ARENA IACUC Conference, San Diego, CA.
Mar. 22, 1999	Ethical Considerations and Scientific Merit, PRIM&R IACUC Conference, San Diego, CA.
Mar. 23, 1999	Organizational Structure and Reporting Lines—The IACUC Chair, IACUC Administrator, Institutional Official and Investigator Interactions, PRIM&R IACUC Conference, San Diego, CA.
Mar. 23, 1999	Endpoints, Classifications, and the Use of Animals in Education, PRIM&R IACUC Conference, San Diego, CA.
Dec. 6, 1999	Enrolling Children and Adolescents in Research. PRIM&R IRB Conference, Boston, MA.
Dec. 7, 1999	Compliance Oversight Activity: Problems Frequently Identified by OPRR. PRIM&R IRB Conference, Boston, MA.
Dec. 7, 1999	Institutional Response to Allegations of Non-compliance PRIM&R IRB Conference, Boston, MA.
Jan. 27-28, 2000	Investigator and IRB Training. University of New Mexico School of Medicine, Albuquerque, NM.
Mar. 12, 2000	Ethics Applied to IACUC Review. ARENA Conference, Boston, MA.
Mar. 13, 2000	Scientific Merit Review and the IACUC. PRIM&R IACUC Conference, Boston, MA.
Mar. 14, 2000	Organization of Animal Care and Use Programs – the IACUC. PRIM&R IACUC Conference, Boston, MA.
Oct. 29, 2000	Money and Clinical Trials, PRIM&R IRB Conference, San Diego, CA.
Oct. 30, 2000	OHRP Compliance Oversight, PRIM&R IRB Conference, San Diego, CA.
Dec. 4, 2000	IACUC Responsibility to Ensure Compliance, SCAW Conference, San Antonio, TX.
Mar. 26, 2001	Protocol Review and Scientific Merit, PRIM&R IACUC Conference, San Diego, CA.
Mar. 26, 2001	Understanding and Applying Basic Protocol Review Criteria. PRIM&R IACUC Conference, San Diego, CA.

Dec. 2, 2001	Handling Subject Complaints and Allegations of Non-Compliance. ARENA IRB Conference, Boston, MA.
Dec. 2, 2001	Liability Issues for IRBs. ARENA IRB Conference, Boston, MA.
Dec. 3, 2001	Relationship of the IRB to the IBC. PRIM&R IRB Conference, Boston, MA.
Dec. 4, 2001	Ethics, Science and Politics of Stem Cell Research. PRIM&R IRB Conference, Boston, MA.
Mar. 24, 2002	Non-compliance: What to Do When Things Go Wrong. PRIM&R/ARENA IACUC Conference, Boston, MA.
Mar. 24, 2002	The Basics of Protocol Review. PRIM&R/ARENA IACUC Conference, Boston, MA.
Nov. 17, 2002	Dealing with Subpart D: Interpretation of the Children's Regulations. ARENA IRB Conference, San Diego, CA
Nov. 18, 2002	Reviewing Research with Prisoners: 45CFR46 Subpart C. PRIM&R IRB Conference, San Diego, CA.
Nov. 18, 2002	Oversight of Gene Transfer Research: IBCs and IRBs. PRIM&R IRB Conference, San Diego, CA.
Nov. 19, 2002	Common Deficiencies Cited by OHRP. PRIM&R IRB Conference, San Diego, CA.
Nov. 19, 2002	Human Gene Transfer Research and Informed Consent: Appendix M. PRIM&R IRB Conference, San Diego, CA.
Mar. 30, 2003	Scientific Justification? Scientific Merit? (Protocol Review Issues). PRIM&R/ARENA IACUC Conference, San Diego, CA.
Mar. 31, 2003	Roles and Responsibilities of IACUC Members. PRIM&R/ARENA IACUC Conference, San Diego, CA.
Nov. 14, 2003	ACRP Clinical Research Ethics Workshop. ACRP Global Headquarters, Alexandria, VA.
Dec. 7, 2003	Research With Vulnerable Populations. PRIM&R/ARENA Annual Conference, Boston, MD.
Aug. 4, 2004	IACUC Protocol Review. Eli Lilly, Indianapolis, IN.
Oct. 29, 2004	OHRP and Investigators – Working Together to Minimize Risk. PRIM&R Annual Conference, San Diego, CA.
Oct. 29, 2004	An Update From SACHRP. PRIM&R Annual Conference, San Diego, CA.
Oct. 31, 2004	Tissue Banking. PRIM&R Annual Conference, San Diego, CA.
Dec. 5, 2005	SACHRP Recommendations Involving Children. PRIM&R IRB Conference, Boston, MA.
Dec. 5, 2005	Component Analysis in IRB Review of Pediatrics Research. PRIM&R IRB Conference, Boston, MA.

Dec. 6, 2005	IRB Review of Research Involving Prisoners. PRIM&R IRB Conference, Boston, MA.
Mar. 7, 2006	IRB Mission Creep. University of Las Vegas Conference, Las Vegas, NV.
Mar. 27, 2006	Ethics, Science and Compliance. PRIM&R IACUC Conference, Boston, MA.
May 8, 2006	Clinical Trial Auditing. RX Clinical Trials Educational Program, Boston, MA.
Nov. 16, 2006	Introduction to Component Analysis. PRIM&R Annual IRB Conference, Washington, DC.
Nov. 16, 2006	Application of Component Analysis. PRIM&R Annual IRB Conference, Washington, DC.
Nov. 17, 2006	Interpretation and Application of the Minimal Risk Threshold in Research Involving Children. PRIM&R Annual IRB Conference, Washington, DC.
Mar. 27, 2007	Responding to Reports of Non-Compliance. PRIM&R IACUC Conference, San Diego, CA.
Apr. 21, 2007	Case Based Ethics. 2007 ACRP Global Conference, Seattle, WA (Scheduled).

Invited Workshops/Breakout Sessions/Training*

Regional Level

Mar. 12, 1977	Improvement of Lecture Technique. University of South Dakota School of Medicine, Vermillion, SD.
Apr. 5, 1978	Injuries Associated with Runners: Preventive Sports Medicine. University of Nebraska College of Medicine, Omaha, NE.
Oct. 30, 1980	Comprehensive Cardiac Rehabilitation Workshop. Review of Anatomy and Cardiovascular Physiology, Effects of Chronic Exercise on the CV System. Nebraska Chapter of American Association of Physical Therapists, Omaha, NE.

National IRB Training Courses*

*IRB 101 is conducted by two co-faculty

Jan. 18, 2000	IRB 101. Colorado Health Sciences Center, Denver, CO.
Apr. 21, 2000	IRB 101. Marshfield Clinic, WI.
June 23, 2000	IRB 101. Case Western University, Cleveland, OH.
Sept. 8, 2000	IRB 101. Southern Nevada Medical Center, Las Vegas, NV.
Apr. 9, 2001	IRB 101. Wilford Hall, Lackland AFB, San Antonio, TX.
Apr. 16, 2001	IRB 101. Covenant Health Systems, Lubbock, TX.

Apr. 18, 2001	IRB Training. Creighton University, Boys Town National Research Hospital, Alegent Health Systems, Omaha, NE.
May 17, 2002	IRB 101, Wausau Hospital, Wausau, WS.
Sept. 27, 2002	IRB 101, Southwestern Vermont Health Care, Bennington, VT.
Oct. 16-17, 2002	IRB 101, Texas A&M University, College Station, TX.
Mar. 22, 2003	IRB 101, Maricopa Health Systems, Phoenix, AZ.
Apr. 2, 2003	IRB 101, University of California at Irvine, Irvine, CA.
Sept. 22, 2003	IRB 101, Friends Research Institute/UCSF, San Francisco, CF.
Sept. 25-26, 2003	IRB 101, Carle Clinic, Urbana, IL.
Oct. 30-31, 2003	IRB 101, Virginia Commonwealth University, Richmond, VA.
Dec. 4, 2003	IRB 101 for Investigators, Washington, DC.
May 3, 2004	IRB 101, Northwest Regional IRB.
July 8, 2004	IRB 101, Rush University, Chicago, IL.
Nov. 15, 2004	IRB 101, University of Alabama at Birmingham, Birmingham, AL.
Mar. 17, 2005	IRB 101, Uniformed Services University of Health Sciences, Bethesda, MD.
Oct. 17, 2005	IRB Advanced, FDA, Rockville, MD.
Nov. 4, 2005	IRB Advanced, University of Alabama at Birmingham, Destin, FL.
Jan. 24-25, 2006	IRB 101, University of Michigan, Ann Arbor, MI.
Feb. 6, 2006	IRB 101, PRIM&R Regional, Atlanta, GA.
Oct. 19, 2006	IRB 101, Florida State Dept. of Health, Tallahassee, FL.
Mar. 22, 2007	IRB 101/250, Kaiser Permanenti, Rockville, MD.
May 21, 2007	IRB 101, Florida State Department of Health, Tampa FL.

National IACUC Training Courses*

*IACUC 101 is a team-taught course

Mar. 20, 1999	IACUC 101 (PRIM&R/ARENA Conference) San Diego, CA.

Ernest D. Prentice, Ph.D.
Associate Vice Chancellor for Academic Affairs and Regulatory Compliance

Nov. 7, 1999	IACUC 101 AAALAS Annual Meeting, Indianapolis, IN.
Mar. 11, 2000	IACUC 101 (PRIM&R/ARENA Conference) Boston, MA.
Mar. 21, 2001	IACUC 101 for USDA Inspectors, Bowie, MD.
Mar. 24, 2001	IACUC 101 (PRIM&R/ARENA Conference) San Diego, CA.
July 25, 2001	IACUC Training, Creighton University, Boys Town National Research Hospital, Omaha VA Medical Center, Omaha, NE.
Sept. 20, 2001	IACUC 101, Pfizer Pharmaceutical Company, Groton, CT.
Oct. 16, 2001	IACUC 101, Yale University, New Haven, CT.
Jan. 23, 2002	IACUC 101, University of Hawaii, Honolulu, HI.
Mar. 23, 2002	IACUC 101 (PRIM&R/ARENA Conference), Boston, MA.
May 9, 2002	IACUC 101, Stanford University, San Francisco, CA.
June 2, 2002	SCAW IACUC Advanced, Philadelphia, PA.
June 20, 2002	IACUC 101, Charles River Laboratories, Danvers, MA.
Sept. 25, 2002	IACUC 101, Loyola University, Chicago, IL.
Oct. 11, 2002	SCAW IACUC Advanced, SCRIPPS Research Institute, LaJolla, CA.
Nov. 22, 2002	IACUC 101, Emory University, Atlanta, GA.
Jan. 10, 2003	IACUC 101, Boehringer Ingelheim Pharmaceuticals, Ridgefield, CT.
Mar. 7, 2003	SCAW IACUC Advanced, University of South Florida, Clearwater, FL.
Mar. 29, 2003	IACUC 101, San Diego, CA.
June 5-6, 2003	IACUC 101.5, University of Maryland, Baltimore, MD.
Aug. 6, 2003	IACUC 101, Lawte Conference, Tucson, AZ.
Sept. 4, 2003	IACUC 101, Cornell University, Ithaca, NY.
Sept. 30, 2003	IACUC Training, Lackland AFB, San Antonio, TX.
Oct. 10, 2003	IACUC 101, University of Oregon, Portland, OR.
Oct. 28, 2003	SCAW IACUC Advanced, NIH, Bethesda, MD.
Nov. 4, 2003	IACUC 101, Vanderbilt University, Nashville, TN.

Nov. 21, 2003	IACUC 101, Iowa State University, Ames, IA.
Feb. 17, 2004	IACUC 101, University of Texas Southwestern Medical Center, Dallas, TX.
Mar. 5, 2004	SCAW IACUC Advanced, Johns Hopkins, Baltimore, MD.
Mar. 27, 2004	IACUC 101, (PRIM&R/ARENA Conference) Boston, MA.
May 17, 2004	IACUC 101, University of Alaska, Fairbanks, AK.
June 28, 2004	IACUC 101, University of Michigan, MISMR and University of Michigan, Detroit, MI.
July 13-24, 2004	IACUC 101/201, NCABR and University of North Carolina, Research Triangle Park, NC.
Sept. 14, 2004	IACUC 101, CBRA and University of California at Irvine, Irvine, CA.
Sept. 17, 2004	SCAW IACUC Advanced, University of Colorado Health Science Center, Denver, CO.
Nov. 2, 2004	IACUC 101, Penn State University, State College, PA.
Mar. 21, 2005	SCAW IACUC Advanced, New Orleans, LA.
May 11-12, 2005	IACUC 101/201, Florida Atlantic University, Delray Beach, FL.
Sept. 8, 2005	IACUC Training, University of Connecticut Health Center, Farmington, CT.
Sept. 21-22, 2005	IACUC 101/201, University of South Dakota, Sioux Falls, SD.
Oct. 6, 2005	IACUC 101, University of Rochester, Rochester, NY.
Oct. 14, 2005	SCAW IACUC Advanced, Northwestern University, Chicago, IL.
Nov. 5, 2005	IACUC 101, OLAW/USDA, St. Louis, MO.
Mar. 26, 2006	IACUC 101. (PRIM&R/ARENA Conference), Boston, MA.
Apr. 19-20, 2006	IACUC 101/201. Virginia Commonwealth University, Richmond, VA.
May 8, 2006	IACUC 101. University of Texas, Austin, TX.
July 13, 2006	IACUC 101. University of New England, Bidderford, ME.
Sept. 12, 2006	SCAW IACUC Advanced. Cornell University, Ithaca, NY.
Sept. 26, 2006	IACUC 101. California Association for Biomedical Research. San Francisco, CA.
Oct. 11, 2006	IACUC Training. Vanderbilt University, Nashville, TN.
Oct. 17, 2006	IACUC Training. Raleigh-Durham VA Medical Center, Durham, NC.

Nov. 8-9. 2006	IACUC 101/201. Tripler Army Medical Center, Honolulu, HI.
Feb. 21, 2007	IACUC 101. Oklahoma State University, Stillwater, OK.
Mar. 9, 2007	SCAW IACUC Advanced. University of Tennessee, Memphis, TN.
Mar. 25, 2007	IACUC 101. (PRIM&R Conference). San Diego, CA.
Apr. 13, 2007	IACUC Training. University of Indiana, Indianapolis, IN (Scheduled).
Apr. 30, 2007	SCAW IACUC Advanced. Boston, MA (Scheduled).
May 3, 2007	IACUC 101. Morehead University, Atlanta, GA (Scheduled).
June 7, 2007	IACUC Training. Medical College of Wisconsin, Milwaukee, WI (Scheduled).
Sept. 5, 2007	SCAW IACUC Advanced. University of Alaska, Anchorage, AK (Scheduled).

External Consultancies, Special Appointments, Review Panels

1977	Consultant, University of South Dakota School of Medicine, Vermillion, SD, Improvement of Faculty Teaching Skills.
1979	Consultant, University of Lagos College of Medicine, Lagos, Nigeria, 1979. Instructional Technology-Evaluation of Faculty.
1980	Consultant, National Library of Medicine (NMAC), Washington D.C., Development of a Lecture Skills Workshop.
1981	External Examiner, University of Lagos College of Medicine, Lagos, Nigeria
1981	Chair, Planning Committee, American Association of Anatomists Meeting, Omaha, NE.
1983	Chair, Planning Committee, 1983 Midwest Anatomists Meeting, Omaha, NE.
1985	IRB Consultant, Chadron State College, Chadron, NE.
1985-88	Consultant, Alpha Health Clubs, Omaha, NE. Sports Medicine.
1989	IRB Consultant, Good Samaritan Hospital, Kearney, NE.
1989	Chair, Planning Committee, NIH/FDA Conference on Protection of Vulnerable Research Subjects, Omaha, NE.
1989-90	AAMC Liaison Committee on Medical Education (LCME) Faculty Fellow. [Served as a member of the LCME accreditation team that site visited the University of Minnesota College of Medicine on May 5-10, 1990.]
1991-92	IRB Consultant, Kearney State College and University of Nebraska at Kearney (UNK), Kearney, NE.

1994 IRB Consultant, Clinical Trials Cooperative Group Chairs on Informing Subjects About Side Effects and Scientific Misconduct. National Cancer Institute, Rockville, MD. (Oct. 7)

1994-96 Member, SCAW Planning Committee on Evaluation of IACUCs, Greenbelt, MD.

1995 IRB Consultant, Orange County Childrens Hospital (CHOC). Orange County, CA. (Aug. 14-18)

1996 Co-Chair, ARENA IRB Conference. San Diego, CA

1996 Consultant to Boys Town National Research Hospital for OPRR/USDA compliance case (Sept. 8-10).

1997 Invited Participant in the NAPBC/NCI/NIH Tissue Banking Conference. Bethesda, MD (June 2)

1997 Member, PRIM&R/ARENA Tissue Banking Working Group.

1997-98 IRB Consultant, AMC Cancer Center. Denver, CO.

1997 Consultant, NIH/OPRR. Preventing Violence in Children of Mentally Ill Substance Abusing Inmate Parents. CDC Protocol #1650. Review Panel Under 45 CFR 46.306(a)(2)(D). Rockville, MD (Aug. 21)

1997 Panel Member, FDA Waiver of Informed Consent in Emergency Research. Bethesda, MD. (Sept. 29-30)

1997 Panel Member, NIH Inter-Institute Conference on Research Involving Individuals with Questionable Capacity to Consent. Rockville, MD. (Dec. 13)

1998 Panel Member, PHS Developing U.S. Public Health Policy in Xenotransplantation. Bethesda, MD. (Jan. 21-22)

1998 IRB Consultant to the Ministry of Health, Republic of China, Taipei, Taiwan. (May 8-9)

1998 Consultant, FDA Office of Health Affairs (OHA) Task Force on FDA-IRB Re-engineering. Rockville, MD (August 11)

1998 Member, AALAS Task Force on Development of a National IACUC Training Program.

1998-99 Member, PRIM&R/ARENA Task Force on Central IRBs. Washington D.C.

1999 AALAS Representative, Learning Consortium [TLC] IACUC 101 Organization Committee. Washington D.C.

1994-01 Compliance Consultant, NIH Office for Protection from Research Risks (OPRR); HHS OHRP Compliance Cases/Compliance Oversight Site Visits

- Mar. 8-10, 1994 Memorial Sloan Kettering Cancer Center, New York NY
- Aug. 31-Sept. 2, 1994 Medical University of South Carolina
- Oct. 22-24, 1996 University of Rochester, Rochester, NY
- Nov. 15, 1996 State University of New York
- July 28-29, 1998 University of California at Irvine, Irvine, CA

- Mar. 1-4, 1999 — Mount Sinai Medical Center, New York Psychiatric Institute & City University of New York, New York, NY (Fenfluramine Challenge Study in Children)
- Aug. 24-27, 1999 — University of Illinois at Chicago, Chicago, IL
- Nov. 2-5, 1999 — St. Jude Children's Research Hospital, Memphis, TN
- Aug. 8-11, 2000 — University of Wisconsin, Madison
- Sept. 11-14, 2000 — University of Texas Medical Branch, Galveston, TX
- Mar. 12-16, 2001 — St. Jude Children's Research Hospital, Memphis, TN
- Nov. 14-15, 2001 — Brookhaven National Laboratories, Long Island, NY

1985-Present Legal Consultant and Expert Witness, Litigation Involving Clinical Research (17 cases in 10 states).

1998-1999 IRB Consultant for the International Verepamil-Trandolapril Study. University of Florida Research Foundation, Inc.

1999 Member, PRIM&R/ARENA/AAALAC initial planning committee on Accreditation of IRBs and IRB Administrators. Rockville, MD.

2000 IRB Consultant, University of New Mexico Health Sciences Center (March 23-24)

2000 Invited Participant, Duke University CRI IRB Think Tank on DSMBs and IRBs (May 11-12)

2000 IRB Consultant, Harbor/UCLA Medical Center, Torrance, CA (June 1-2).

2000 IRB Consultant, Torrance Memorial Medical Center, Torrance, CA (August 24-25).

2000 Reviewer, National Institutes of Mental Health Special Emphasis Review Panel (November 20-21) Washington, D.C.

2001 Chair and Member, OHRP/HHS Children's 407 Research Panel, Bethesda, MD
- Feb. 2-4, 2001
- Aug. 28, 2001
- Sept. 27, 2001

2001 IRB Consultant, University of Illinois at Peoria (May 10-11)

2001 IRB Consultant, Fred Hutchinson Cancer Research Center, Seattle, WA (May 29-June 1)

2001 IRB Consultant, Midwest Bioethics Center, Kansas City, MO (July 10-11)

2001 Office of Biotechnology Affairs (OBA) Roundtable Discussion, Bethesda, MD (December 7-8)

2001-Present Member, Editorial Board, IRB Ethics and Human Research, Hastings Center, New York, NY

2002-2007 Member, AAHRPP Council on Accreditation, Washington D.C.

2002 Compliance Consultant, ORCA Site Visit, Washington D.C., VA Medical Center (February 6-8)

2002 IRB Consultant, National Jewish Medical and Research Center, Denver, CO (February 26-28)

2002-Present Member, Advisory Board, BNA Medical Research Law and Policy Report

2002 Compliance Consultant, EPA Site Visit (NHEERL), Research Triangle Park, NC (Aug. 19-21)

2002 IRB Consultant, Fred Hutchinson Cancer Research Center, Seattle, WA (Oct. 24-28)

2003-2007 Chair, HHS Secretary's Advisory Committee on Human Research Protection (SACHRP)

2003 Team Leader, AAHRPP Site Visit, University of Iowa (Jan. 20-23)

2003 IRB Consultant, NIH Office of Biotechnology Assessment (OBA) Gemcris Project, Rockville, MD (Mar. 18)

2003 IRB Consultant, University of Pennsylvania, Philadelphia, PA (May 21-23)

2003 IRB Consultant, Henry Ford Hospital, Detroit, MI (Sept. 9-12)

2004 IRB Consultant, University of Arizona, Tuscon, AZ (Jan. 15-16)

2004 IRB Consultant/Trainer, Singapore National Health Group, Singapore (Jan. 26-29)

2004 Team Leader, AAHRPP Site Visit, Copernicus Review, Inc., Research Triangle Park, NC (Apr. 14-16)

2004 IACUC Consultant, UCLA, Los Angeles, CA (Sept. 15)

2004 IRB Consultant/Trainer, Singapore National Health Group, Singapore (Oct. 11-13)

2004 IRB Consultant, Palm Beach Medical Center, Palm Beach, FL (Nov. 19)

2005 IACUC Consultant, Syracuse University, Syracuse, NY (Jan. 24-26)

2005 IRB Consultant, Syracuse University, Syracuse, NY (Mar. 28-31)

2005 Compliance Consultant, EPA, Research Triangle Park, NC (Aug. 31)

2005 Team Leader, AAHRPP Site Visit, UCSF, San Francisco, CA (June 6-10)

2006 IRB Consultant/Trainer, Singapore National Health Group, Singapore (Feb. 16-19)

2006 Team Leader, AAHRPP Site Visit, University of Missouri, Columbia, MD (April 2-5)

2006 Team Leader, AAHRPP Site Visit, Long Beach California Medical Center, Long Beach, CA (Oct. 30-31)

2006-Present Member of PRIM&R Public Policy Committee

2006 Chair, CITI Executive Advisory Committee

2007 Member of Pharmaceutical Safety Institute Advisory Committee

2007	NIH Center for Scientific Review Special Emphasis Panel – Research on Ethical Issues in Human Studies (Mar. 6)
2007	ACRP Education Committee

Teaching and Service Awards

1985	American Medical Student Golden Apple Teaching Award
1986	Physical Therapy Excellence in Teaching Award
1995	Physical Therapy Excellence in Teaching Award
1995	ARENA Service Award
2003	SCAW Harry C. Roswell Award for promoting lab animal welfare
2005	ARENA Distinguished Service Award
2006	OHRP Award for Outstanding Achievement in Human Subject Protection

Teaching Experience

University of South Florida

1964-67	University of South Florida - Undergraduate Teaching Assistant in Aquatics and Water Safety

Secondary School

1967-69	Plant City Senior High School, Plant City, Florida - Physical Science Teacher

University of Iowa

1969-71	University of Iowa - Graduate Teaching Assistant in Physical Education and Exercise Physiology

University of Nebraska Medical Center

1971-72	Laboratory Instructor in Gross Anatomy, Microscopic Anatomy, Neuroanatomy, and Advanced Head and Neck Anatomy for Residents
1973-74	Instructor in Medical Gross Anatomy and Neuroanatomy
1974-01	Course Director, Teaching Workshop for Medical Educators
1975-77	Course Director, Physician Assistant Anatomy, Instructor in Medical Gross Anatomy
1977-81	Course Director, Clinical Anatomy for Undergraduates, Instructor in Medical Gross Anatomy
1981-83	Course Director, Combined Nursing/ Pharmacy Anatomy Program
1984-85	Assistant Course Director, Medical Gross Anatomy
1986-91	Instructor in Medical Gross Anatomy

1986-Present	Lecturer on Human and Animal Research Ethics in Four Separate Research Methodology Courses for Residents, Graduate Students, Physician Assistant Students, Physical Therapy Students and Nuclear Medicine Students
1989-96	Faculty Facilitator for Case Study Problem Solving
1991	Presenter in a Seminar Series: Ethical Issues that Impact on Biomedical Research
1992-93	Course Director, Limb Anatomy for Physical Therapy Students
1994-2000	Course Co-Director, Ethics in Biomedical Research
2000-Present	Faculty Facilitator for Case Studies in RCR

University Committee Service

1976-78	Admission Committee, Physician Assistant Program
1976-78	Scholastic Evaluation Committee, Physician Assistant Program
1979	Search Committee, Director of School of Physical Therapy
1979-84	Nuclear Medicine Committee
1985	Chancellor's Task Force on Evaluation of Teaching
1985-86	North Central Accreditation Committee
1980-90	Department of Anatomy Executive Graduate Committee
1986-98	Vice Chair, Institutional Animal Care and Use Committee
1991-92	Chancellor's Task Force on Cancer
1991-92	Chair, Chancellor's Task Force on the Animal Resources Facility
1991-92	Chair, Search Committee for Director of the Animal Resources Faciltiy
1989-90	LCME Self Study Subcommittee on Research
1994-95	Department of Cell Biology and Anatomy Promotions Committee Chair, 1995
1995-Present	Legislation Analysis Committee
1995-97	Image Advisory Committee
1995-96	Chair, NCA Task Force Committee
1996	UNMC Finance Restructuring Committee
1981-Present	Co-Chair, Institutional Review Board
1998-01	Institutional Official, Institutional Animal Care and Use Program
1999	UNMC New Construction Committee
2001-05	Animal Facility Oversight Committee
2001	HIPAA Executive Committee
2002	Conflict of Interest Policy Committee
2005-Present	Conflict of Interest Committee

Graduate Student Supervision

- Appointed Fellow of the Graduate College in 1979. Served as a member of the Executive Graduate Committee in the Department of Anatomy from 1980-1990.

- Served on the following MS Supervisory Committees. The year indicates when master's degree was awarded.
  1. Gene Cullan, 1978
  2. Leigh Hoppe, 1980
  3. Wayne Stuberg, 1980
  4. Phil Tarburton, 1981
  5. Don Russell, 1981
  6. Dave Staab, 1981
  7. Bunmi Dada, 1982
  8. Al Grovas, 1982
  9. Mohammad Al-Turk, 1982
  10. Daniel Olson, 1983
  11. Mark Horacek, 1983
  12. Greg Perry, 1983
  13. Patrick Keelan, 1984
  14. Robert Plambeck, 1984
  15. Godwin C. Udeaja, 1983
  16. Daniel Lydiatt, 1983
  17. Nancy Mathews, 1984
  18. Michael Essex, 1984
  19. Kyle Meyer, 1985
  20. Rocco Rotello, 1985
  21. Erin Masada, 1986
  22. Robert Sandstrom, 1986
  23. Lonn Hutchinson, 1986
  24. Shailendra Saxena, 1987
  25. Annette Klumper, 1987
  26. Wang Zin, 1987
  27. Gregory Hirz, 1988
  28. Lisa Peterson, 1990
  29. Jason Bespalec, 1990
  30. Susan Schwerdtfeger, 1990
  31. Larry Crouch, 1990
  32. Xiao-Dong Chen, 1990
  33. Anne Sojke, 1993
  34. Denise Dunning, 1995
  35. Tom Nesser, 1998

- Served on the following Ph.D. Supervisory Committees. The year indicates when doctorate degree was awarded.
  1. Gene Cullan, 1980
  2. Mark Horacek, 1986
  3. Ardith Ryberg, 1988
  4. Wayne Stuberg, 1989
  5. Robert Sandstrom, 1989
  6. Wang Zin, 1991
  7. Suzan Schuerman, 1998
  8. Gib Willett, 2006

Community Speaking Engagements and Interviews: Radio, Television, Newspaper

Oct. 1977	Conversations with Joni Baillon: Exercise and Fitness. KMTV Channel 3, Omaha, Nebraska.
Apr. 1978	Fitness for the Busy Executive: Why and How. Life Underwriters Association, Omaha, NE.
Aug. 1979	Run for Your Life. Plenary Session - HeSCA Conference, Kansas City, MO.
Sept. 1979	The Physiology of Running. Bergan Mercy Hospital, Omaha, NE.
Oct. 1979	The Effects of Jogging on Your Health. Explorers Post #54, Omaha, NE.
Oct. 1979	Exercise Life Style. Octoberfest, University of Nebraska Medical Center, Omaha, NE.
Feb. 1980	Call the Doctor: Exercising and Health. Channel 26, Lincoln, NE.
June 1980	The Physiological Effects of Aerobic Dance. Fitness Plus, Omaha, NE.
Oct. 1980	Celebration of 100 Years of Medical Education in Nebraska: Past, Present and Future. Grand Island Medical Society and the Chamber of Commerce, Grand Island, NE.
Oct. 1981	Health Beat. Aired on 40 radio stations.

Nov. 2, 1981	Sports Medicine. Tom Johnson Show, KFAB, Omaha, NE.
Nov. 6, 1981	What's NU, Teaching Technology. Nebraska Educational Television, Channel 12, Lincoln, NE.
Nov. 8, 1981	The Clinic, Exercise and You. Aired on 23 radio stations.
May 10, 1982	Stress Management and Aerobic Exercise. Jewish Community Center, Omaha, NE.
June 11, 1982	Running and Health. Forum KVNO, Station KVNO, Omaha, NE.
June 28, 1982	Exercise and Health. Good Day, KMTV Channel 3, Omaha, NE.
July 4, 1982	Exercise and Health. Good Day, KMTV Channel 3, Omaha, NE.
July 27, 1982	Selection of Running Shoes and Stretching. KETV Good Morning, Channel 7, Omaha, NE.
Aug. 14, 1982	Focus, KNEN, Norfolk, NE.
Aug. 22, 1982	Open Mike. Station KYNN, Omaha, NE.
Oct. 3, 1982	Day in the Life of a Medical Student (Documentary). Station KHGI, Omaha, NE.
Oct. 28, 1982	What's NU, The University of Nebraska IRB. Nebraska Educational Television, Channel 12, Lincoln, NE.
Jan. 9, 1983	Protection of Human Research Subjects. The Clinic, aired on 23 radio stations.
Jan. 10, 1983	Protection of Human Research Subjects. Cox Cable TV Network, Omaha, NE.
Apr. 12, 1983	KMTV Health Fair. KMTV Channel 3, Omaha, NE.
July 20, 1983	Prevention of Heat Illness. KMTV Channel 3, Omaha, NE.
Feb. 23, 1984	Interview on Health and Fitness. KGOR, Omaha, NE.
Feb. 24, 1984	The Clinic, Health and Fitness. Aired on 23 radio stations.
July1984	Prevention of Injuries in Runners. The Marathon Clinic, Omaha, NE.
June 1985	Medical Research. The Rotary Club, Omaha, NE.
Nov. 19-21, 1985	Interview on Fitness and the Aged. Channel 6, Omaha, NE.
Oct. 18, 1986	Exercise Life Style. U.S. Naval Reserve.
Oct. 31, 1987	Cross-Training. Omaha Riverfront Health and Fitness Clinic, Omaha, NE.
1987-88	Health and Fitness Tips. A series of health and fitness tips aired on two radio stations during December 1987 and January 1988.

Ernest D. Prentice, Ph.D.
Associate Vice Chancellor for Academic Affairs and Regulatory Compliance

Nov. 1, 1988	Research at UNMC. Community Health Line, Omaha, NE.
Feb. 21, 1989	Ethics of Human Experimentation. Rotary Club, Omaha, NE.
Jan. 10, 1990	Interview on Fetal Tissue Transplantation. KKAR Radio Station, Omaha, NE.
July 30, 1990	Interview on Animal Research. Channel 7, Omaha, NE.
Jan. 8, 1991	Interview on Ethical Issues Surrounding Fetal Tissue Research. Channel 7, Omaha, NE.
Nov. 6, 1991	Interview on Benefits of Animal Research. Channel 6, Omaha, NE.
Apr. 13, 1992	Interview on Body Building for Women. World Herald, Omaha, NE.
July 1, 1992	Interview on Growth Hormone Trials. Nature, Vol 358.
Aug. 7, 1992	Interview on Growth Hormone Trials. Science, Vol 257.
Sept. 22, 1992	Interview on Women and Clinical Research Participation. Channel 7, Omaha, NE.
Oct. 10, 1992	Interview on UNMC's Animal Research. Life Quest. Channel 3, Omaha, NE.
Dec. 31, 1992	Interview on Cold Weather Running. Channel 7, Omaha, NE.
Jan. 4, 1993	Interview on Cold Weather Running. World Herald, Omaha, NE.
Apr. 7, 1993	Interview on Animal Research. Channel 17, Omaha, NE.
Jan 16, 1994	Interview on Protecting Human Subjects. Los Angeles Times, Los Angeles, CA.
Feb. 10, 1994	Interview on IRBs and Contemporary Standards of Human Subjects Protection. World Herald, Omaha, NE.
June 20, 1994	Interview on Enrollment of Women in Clinical Trials. Channel 7, Omaha, NE.
Dec. 5, 1994	Interview on Porcine Xenoperfusion. Channel 3, Omaha, NE.
June 22, 1998	Interview on Xenotransplantation. Channel 7, Omaha, NE.
Oct. 29, 1998	Panelist on "A Healthy Debate on the Use of Animals in Medical Research". Cox Channel 2, Omaha, NE.
Oct. 13, 1999	UNMC Mini Medical School. Panel on Ethical, Legal, Medical and Social Issues on Genetic Testing, Omaha, NE.
May 3, 2000	Ethics, Science and Politics of Fetal Tissue Research. Annual Planned Parenthood Meeting, Omaha, NE.
July 20, 2001	Guest Appearance on the Jim Lehrer Show to discuss the OHRP Shutdown of Research at Johns Hopkins.

July 27, 2001	Interview on the Johns Hopkins Research Shutdown, New York Times.
2003 – 2007	Multiple interviews with journals and newspapers on the Activities of SACHRP.

AFFIDAVIT OF SERVICE BY MAIL

STATE OF MINNESOTA :
: SS.
COUNTY OF RAMSEY :

VIRGINIA A. PFAFF, being first duly sworn, deposes and says that she is a secretary in the office of Geraghty, O'Loughlin & Kenney, P.A., attorneys-at-law, Alliance Bank Center, Ste. 1100, 55 East Fifth Street, Saint Paul, MN 55101; that on November 12, 2007 she served the attached **SUMMARY OF EXPECTED TESTIMONY OF ERNEST PRENTICE, PH.D.** upon:

Gale D. Pearson, Esq.
PEARSON, RANDALL & SCHUMACHER
Fifth Street Towers
100 South Fifth Street, #1025
Minneapolis, MN 55402

(ATTORNEYS FOR PLAINTIFF)

by fax by placing a copy thereof in an envelope properly addressed to her at her business address, which address is the last known address of said attorney known to her, and the envelope with postage prepaid was deposited by her in the United States mail at Saint Paul, Minnesota for delivery by the United States Post Office Department, as directed by said envelope.

SUBSCRIBED and SWORN to before

me this 12th day of November, 2007

Virginia M. Wagner
Notary Public

Virginia A. Pfaff
VIRGINIA A. PFAFF

VIRGINIA M. WAGNER
Notary Public-Minnesota
My Commission Expires Jan 31, 2010