DAVID MICHAEL VULCANO

CURRENT SUMMARY

Education:

Master of Business Administration, Louisiana State University, 1997
Master of Social Work, Louisiana State University, 1992
Bachelors of Science, Louisiana State University, 1990

Current Clinical Licenses:

LCSW, Tennessee Board of Social Workers # 4031, 2000 – Present

Current Certifications:

RAC, Regulatory Affairs Professional Society, 2007 – Present
CIP, Council for Certification of IRB Professionals, 2003 – Present

Current Employer:

Hospital Corporation of America (HCA). (AVP, Clinical Research), 2007 – Present

Current Board Positions:

Association of Clinical Research Professionals
-Board of Trustees Member: 2007 – Present
Vice Chair: 2008
Chair: 2009
Clinical Trial Magnifier
-Advisory Board Member

Current Financial/Governance Conflict of Interest Disclosures:

Employee and Stock Options, Hospital Corporation of America (HCA)
Limited Partner, Ardent Health Services, LLC
Member, Board of Trustees, Association of Clinical Research Professionals (Uncompensated)

International Exposure:

United States, Canada, European Union, Australia, Serbia, India, and other emerging markets.

Public Speaking

American Academy of Pharmaceutical Physicians (AAPP), (Note, became APPI under ACRP in 2006), American Conference Institute (ACI), American Health Lawyers Association (AHLA), Association of Clinical Research Professionals (ACRP), Drug Information Association (DIA), Institute for International Research (IIR), International Institute for Business Information & Growth (iiBIG), Strategic Research Institute (SRI)

EDUCATION, LICENSURE & CERTIFICATIONS

Master of Business Administration (1994 - 1997)
Louisiana State University, Baton Rouge, LA.

Master of Social Work (1990 - 1992)
Louisiana State University, Baton Rouge, LA.

Bachelor of Science (1987 - 1990) Major: Psychology; Minor: Philosophy
Louisiana State University, Baton Rouge, LA.

Clinical Licensure:

2000 – Present:	Tennessee **LCSW** #4031
1994 – 2000:	Louisiana **BCSW** # 3600 (Elected to Expire)

Certifications:

2007 - Present:	Regulatory Affairs Professionals Society **Regulatory Affairs Certification (RAC)**
2004 – Present:	Model Agreement Group Initiative: **Clinical Research Contract Professional (CRCP)**
2003 – Present:	Council for Certification of IRB Professionals: **Certified Institutional Review Board Professional (CIP)** Certificate #2030490
2001 – Present:	Trainer: Hazardous Material Packing (DOT/IATA Standards): -UN2814- Infectious Substances, Affecting Humans -UN2900- Infectious Substances, Affecting Animals -UN3373- Biological Substance, Category B (Formerly Diagnostic Specimen) -UN1845- Dry Ice
1996 – Present:	Critical Incident Stress Debriefing (Mitchell Model)

EMPLOYMENT HISTORY

Hospital Corporation of America (HCA, Inc.)

2007 – Present: AVP, Clinical Research; Corporate Office (Nashville, Tennessee)

Serve as Responsible Executive (RE) for clinical research related operations or care delivery in a multi-site health system comprising of over 170 hospitals and over 200 surgery centers treating nearly all medical specialties. Provide

overall strategic vision and leadership for the corporation and assist local site CEOs with their market-based strategies and human subject protection plans as they pertain to interventional, data, observational or other clinical research and its integration within the larger organization. Integrate clinical research functionality into the system-wide electronic health record. Develop and provide support for SOP development, training, contracting, billing, audits, communications and other functions necessary for successful research operations its ethical review through in-house or external Institutional Review Boards and Institutional Biosafety Committies.

Psychiatric Solutions, Inc.

2005 – 2007: Director, Clinical Trials; Corporate Office (Franklin, Tennessee)

Serve as Chief Research Officer for all research operations for a multi-site system focusing exclusively on disorders of the Central Nervous Systems. Provide overall strategic vision and leadership for the corporation as well as assist local CEOs with theirs as it pertains to clinical, data and genetic research and it's integration within the larger organization. Establish SOP, QA and Human Subject Protection program for multi-state, federal (FDA and OHRP) and international GCP, NIH, DOT/IATA, HIPAA, FWA, TJC (formerly JCAHO), CMS and local law compliance as they pertain to clinical research. Oversight of human subject protection plans, site selection, sponsor/CRO contracting, internal IRB operations/external IRB relations, budgets, outsourcing, billing compliance, corporate and site training as well as business development. Part of corporate management team for all operations, particularly as it pertains to hospital pharmacy operations/compliance.

Ardent Health Services, LLC (Formerly known as Behavioral Healthcare Corporation 1996-2001 and as Community Psychiatric Centers 1993-1996)

1999 – 2006: Director, Clinical Trials; Corporate Office (Nashville, Tennessee)

Serve as company's first Chief Research Officer and create a centralized clinical trials division as well as supportive infrastructure within the company's nationwide medical and behavioral hospital/clinic site operations as well as affiliated Institutional Review Boards and Central Laboratory Services. Provide overall strategic vision and leadership for the corporation as well as assist local CEOs with theirs as it pertains to clinical, data and genetic research and it's integration within the larger organization. Establish SOP, QA and Human Subject Protection Program for multi-state, federal (FDA and OHRP) and international GCP, NIH, DOT/IATA, HIPAA, FWA, TJC (formerly JCAHO), CMS and local law compliance as they pertain to clinical research and accreditation of their Human Research Protection Program. Oversight of site selection, sponsor/CRO contracting, internal IRB operations/external IRB relations, IBCs, budgets, outsourcing, billing compliance, corporate and site

training as well as business development. Part of corporate management team for all operations.

1999: **CEO; Community Behavioral Health Systems (Metairie, Louisiana)**
Turnaround position of a Managed Behavioral Healthcare Organization. Managed over 70k lives (blend of commercial risk and Medicare risk) and a network of over 400 behavioral health providers in the State of Louisiana. Established NCQA compliance program and HEDIS reporting capabilities. Developed Louisiana's first discount network for behavioral health services.

1998 – 1999: **Executive Director; Quality Psychiatric Services (Baton Rouge, Louisiana)**
Turnaround Director of a Managed Behavioral Health Organization. Began rebuilding a closed operation until the decision was made to merge it with Community Behavioral Health Systems (listed above). Prior to facilitating the merger, rebuilt core business to include a repricing contract and a network access contract with a start-up HMO. Diversified business portfolio for revenue generation to include a management contract for an 8-bed group home for female adolescents.

1995 – 1998: **Director of Case Management; Meadow Wood Hospital (Baton Rouge, Louisiana)**
Transition existing operations of an 85 bed psychiatric continuum including PHP and IOP services to a case management model facility while integrating the assessment/referral and utilization management functions. Supervised management of HMO, Medicare, Medicaid and commercial shared-risk payor mix. Within two years, increased market share of commercial business by 25%. Piloted projects for corporate-wide implementation such as Seamless Medical Record, Integrated Assessment, Assessment & Referral database system, 23 Hour Observation, Psychiatric Intensive Outpatient Programs and case rate admissions. Wrote customized case management database, Medicaid utilization management program and discharge summary writer program. Participate in senior management team of hospital (administrator on-call, assist in budget etc.).

1993 – 1995: **Director of Psychiatric Assessment Team; Meadow Wood Hospital (Baton Rouge, Louisiana)**
Supervise Assessment & Referral Function. Facilitate and manage ER contracts comprising of up to 40% admissions as well as other off-site functions. Perform business development activities.

State of Louisiana

1992 – 1993: **Mental Health Social Worker; Greenwell Springs Hospital (Greenwell Springs, Louisiana)**
Primary responsibilities were direct care on 24 bed adolescent unit. Voluntarily wrote computerized treatment plan program for 24 bed adolescent

unit and 44 bed pediatric unit. Participated in the programming and implementation of PIP (a statewide treatment database for Louisiana).

1991 – 1992: **Intern; Greenwell Springs Hospital (Greenwell Springs, Louisiana)**
Clinical Internship on 48 bed adult unit. Voluntarily wrote computerized treatment plan program for entire adult units.

1990 – 1991: **Intern; Baton Rouge Mental Health Center (Baton Rouge, Louisiana)**
Direct care and crisis management of chronic mentally ill patients.

1987 – 1992: **Various Positions; Department of Residential Housing- Louisiana State University (Baton Rouge, Louisiana)**
Various positions in residence halls management including Resident Assistant, Senior Office Assistant and Head Resident of Male Honors Dormitory.

BOARD/COMMITTEE POSITIONS

2009 – Present Member- Advisory Board, Clinical Trials Magnifier
2008: Member- Board of Trustees, Academy of Clinical Research Professionals
2007 – Present: Member- Health Improvement Institute's Steering Committee for the Award for Excellence in Human Subject Protection
2007 – 2008: Member- Finance Committee, Association of Clinical Research Professionals
2007 – Present: Elected Member- Board of Trustees, Association of Clinical Research Professionals (Elected as Vice Chair for 2008 and as Chair in 2009)
2005 – 2008: President- Fairview Soccer Association (a 501(c)(3) corporation)
2004 – 2007: Co-Founder & Chair- Ethics & Public Policy Committee, Association of Clinical Research Professionals
2004 – Present: Judge- Health Improvement Institute- Annual Award for Excellence in Human Research Protections
2003 – 2006: Treasurer- Fairview Soccer Association (a 501(c)(3) corporation)
2003 – 2004: Co-Secretary- Westwood Elementary PTO
1998 – 1999: Vice President: Capital Area Human Services District Mental Health Advisory Board
1996 – 1998: Board Member: Capital Area Human Services District Mental Health Advisory Board

HONORS & AWARDS

2005: Regulatory Jeopardy! Champion (2005 Annual DIA Meeting)
2004: Regulatory Jeopardy! Champion (2004 Annual DIA Meeting- Inaugural Year)
1990: Recipient- Louisiana Governor's Award for Leadership
1989 – 1990: Inductee- Leadership LSU (Inaugural Year for Program)

MEMBERSHIPS

2008 – Present: Public Responsibility in Medicine & Research (PRIM&R)

2008 – Present: Member- Leadership Healthcare (Nashville Health Care Council)
2008 – Present: Member- Healthcare Executives Forum of Middle Tennessee (American College of Healthcare Executives)
2006 – Present: Member- Regulatory Affairs Professional Society (RAPS)
2002 – 2003: Member- United Way Sennet Society
2002 – Present: Level Two Member: International Critical Incident Stress Foundation
2002 – Present: Member- Association of Clinical Research Professionals
1999 – Present: Member- Drug Information Association
1998 – 1998: Member- River City Kiwanis
1994 – 1996: Member- Baton Rouge Anti-Drug Task Force

COMPUTER SKILLS

Proficient in standard office products (e.g. Microsoft Office). Written and performed numerous multimedia presentations and designed several websites, database and Windows applications. Known languages include Visual Basic, HTML and SQL.

CURRENT FINANCIAL DISCLOSURES

2007 – Present: Employee and Stock Options, Hospital Corporation of America (HCA)
2001 – Present: Limited Partner, Ardent Health Services, LLC

MISCELLANEOUS PROJECTS

2004 – 2007: **Partners for Human Research Protections (www.PHRP.org)**
Accreditation Surveyor for IRBs and Academic/Non-Academic Research Institutions and Hospitals. This was a 3 year joint venture between NCQA and TJC (formerly JCAHO).

2004 – 2006: **National Committee for Quality Assurance (http://www.ncqa.org)**
Accreditation Surveyor for VA Human Research Protection Accreditation Program (VAHRPAP).

2002 – Present: **Jason Foundation (www.JasonFoundation.com)**
Wrote and maintain software program for Jason Foundation's regional call centers and national database. The Jason Foundation sponsors the 24-hour CARL-Line and offers training for the prevention of teen suicide.

2001: **Bristol-Myers Squibb (www.BMS.com)**
Served as pre-marketing advisor for compound under a New Drug Application with the Food and Drug Administration.

1999: **Health Resource Associates (San Juan, Puerto Rico)**
Served as NCQA-HEDIS auditor for 'Triple C', which managed half of the Puerto Rico Medicaid population at that time (over 3 million lives).

1998 – 1999: **Patient's Choice HMO (Baton Rouge, Louisiana)**

Served as consultant for startup-HMO in utilization management, clinical case management, network management, benefits design and business development as they pertained to behavioral health benefits.

1998: **Holiday Inn Express (Baton Rouge, Louisiana)**
Wrote add-on to the Holidex program for better utilization analysis of beds on standard and regional factors for a local hotel.

1998: **Physician's Practice (Baton Rouge, Louisiana)**
Began writing Outpatient progress note program for psychiatrist to improve his NCQA compliance in managed care audits.

1996: **Physician's Practice (Baton Rouge, Louisiana)**
Serve as consultant to improve payor mix in psychiatrist group practice.

COMMUNITY SERVICE

2008 - Present	Boy Scouts of America
2008 - Present	Habitat for Humanity
2007	Nashville Rescue Mission

SPEAKING ENGAGEMENT SPONSORS

American Academy of Pharmaceutical Physicians (AAPP)
(Note, became APPI under ACRP in 2006)
American Conference Institute (ACI)
American Health Lawyers Association (AHLA)
Association of Clinical Research Professionals (ACRP)
Drug Information Association (DIA)
Institute for International Research (IIR)
International Institute for Business Information & Growth (iiBIG)
Strategic Research Institute (SRI)

PUBLIC PRESENTATIONS (RESEARCH INDUSTRY RELATED)

Scheduled Co-Presenter: "Preparing For and Undergoing an FDA Site or IRB Audit". Audioconference (American Health Lawyers Association). Date TBA.

Co-Facilitator: Conducting a Basic Audit of IRBs. 2009 Research Compliance Conference (Health Care Compliance Association). Minneapolis, MN. October 18, 2009

Expert Panel Member: "Stump The Experts". MAGI's Clinical Trial Agreements & Budgets Conference- East 2009 (International Institute for Business Information & Growth, LLC). Miami, FL. June 2, 2009.

Session Chair: "Special Topics: Risk Based Computer Validation for Compliant Clinical Research/Subject Data Privacy and Security"". MAGI's Clinical Trial Agreements & Budgets

Conference- East 2009 (International Institute for Business Information & Growth, LLC). Miami, FL. June 2, 2009.

Presenter: “Quality Management for Sites”. MAGI’s Clinical Trial Agreements & Budgets Conference- East 2009 (International Institute for Business Information & Growth, LLC). Miami, FL. June 1, 2009.

Presenter: “Chairman’s Address: State of the Industry”. 2009 Global Conference & Exhibition. Association for Clinical Research Professionals. Denver, CO. April 26, 2009.

Panel Member: "Walking the Line in Academic Research: Ethics, Regulation, and Science". 2009 Translational Research Trials Office Symposium (Cincinnati Children's Hospital Medical Center). March 30, 2009.

Presenter. “Avoiding the Frankenstein Effect in Clinical Research”. 2009 Translational Research Trials Office Symposium (Cincinnati Children's Hospital Medical Center). March 30, 2009.

Co-Presenter. “Identifying and Overcoming Challenges in Negotiations Between the Sponsor and the CRO”. Managing Legal Risks in the Structuring and Conducting of Clinical Trials (American Conference Institute). New York, NY. February 24, 2009.

Keynote Speaker. “Clinical Research Industry and Profession Trends”. Annual Holiday Event (Northern California Chapter, Association of Clinical Professionals). Palo Alto, California. December 11, 2008.

Presenter. “Inside the OIG’s Toolbox”. MAGI’s Clinical Trial Agreements & Budgets Conference- West 2008 (International Institute for Business Information & Growth, LLC). Las Vegas, NV. October 14, 2008.

Session Chair. “Medicare Reimbursement for Clinical Trials”. MAGI’s Clinical Trial Agreements & Budgets Conference- West 2008 (International Institute for Business Information & Growth, LLC). Las Vegas, NV. October 13, 2008.

Presenter. “IRB Basics: Members, Quorums and Rosters (A Primer For Legal Compliance, Accreditation or Certification)”. Healthstream. September 30, 2008.

Co-Presenter. “The Honeymoon’s Over: When Sponsors Sue Sites”. 44th Annual Meeting (Drug Information Association). Boston, MA. June 26, 2008.

Presenter. “Inside the OIG’s Toolbox”. MAGI’s Clinical Trial Agreements & Budgets Conference- East 2008 (International Institute for Business Information & Growth, LLC). Arlington, VA. May 19, 2008.

Track Chair. “Profitable Clinical Research for Physician Offices & Clinics”. MAGI’s Clinical Trial Agreements & Budgets Conference 2008 (International Institute for Business Information & Growth, LLC). Arlington, VA. May 19, 2008.

Session Chair/Co-Presenter. “The Best Medicine: The Use of Humor in the Research Industry”. 2008 Global Conference & Exhibition (Association for Clinical Research Professionals). Boston, MA. April 28, 2008.

Session Chair/Co-Presenter. “Walking Through The New Unified Code of Ethics for ACRP and APPI ”. 2008 Global Conference & Exhibition (Association for Clinical Research Professionals). Boston, MA. April 28, 2008.

Presenter. “Careers in Clinical Research with Tips to Make You Competitive”. Student Chapter Brown Bag Seminar (Tennessee Biotechnology Association). Vanderbilt University, Nashville, TN. April 7, 2008.

Presenter. “What Happens When Things Go Wrong?”. Chapter Meeting (Association for Clinical Research Professionals: Southeast Louisiana Chapter). New Orleans, LA. December 4, 2007.

Session Chair/Co-Presenter. “When Sponsors Sue Sites (A Real Life Case History)”. 43rd Annual Meeting (Drug Information Association). Atlanta, GA. June 18, 2007.

Co-Facilitator (Half-Day Workshop). “Dissecting a Clinical Trial Agreement”. MAGI’s Clinical Trial Agreements & Budgets Conference 2007 (International Institute for Business Information & Growth, LLC). Atlantic City, NJ. May 23, 2007.

Presenter. “Computing Overhead Rates”. MAGI’s Clinical Trial Agreements & Budgets Conference 2007 (International Institute for Business Information & Growth, LLC). Atlantic City, NJ. May 22, 2007.

Track Chair. “Clinical Trial Agreements in Canada and Outside U.S.”. MAGI’s Clinical Trial Agreements & Budgets Conference 2007 (International Institute for Business Information & Growth, LLC). Atlantic City, NJ. May 22, 2007.

Session Chair/Co-Presenter. “Trends in Warning and Determination Letters to IRBs and Investigators Parts 1 and 2”. 2007 Global Conference (Association of Clinical Research Professionals). Seattle, WA. April 23, 2007.

Presenter. “Trends in Warning Letters to IRBs”. Audioconference (Washington Information Source Co. a.k.a. fdainfo.com & ExpertBriefings.com). November 8, 2006.

Presenter. “Managing Sponsor/Investigator Relationships”. Managing Legal Risks in Structuring and Promoting Clinical Trials (American Conference Institute). Boston, MA. September 27, 2006.

Co-Presenter. “Practical Payment Terms”. 17th International Contracting & Negotiating Clinical Trials Conference (Strategic Research Institute). San Francisco, CA. September 25, 2006.

Co-Presenter. “Don’t Forget the Other Contract Terms”. 17th International Contracting & Negotiating Clinical Trials Conference (Strategic Research Institute). San Francisco, CA. September 25, 2006.

Presenter. “Developing Successful Clinical Trial Contracts and Budgets in CNS Studies”. Collegium Internationale Neuropsychopharmacologicum (CINP) Clinical Trials Course. Chicago, IL. July 14, 2006.

Session Chair/Co-Presenter. “Trends in Warning and Determination Letters to IRBs and Investigators”. 42nd Annual Meeting (Drug Information Association). Philadelphia, PA. June 22, 2006.

Session Chair. “The Fundamentals”. 17th International Contracting & Negotiating Clinical Trials Conference (Strategic Research Institute). Cambridge, MA. May 22, 2006.

Co-Presenter. “Contract Essentials for Non-Academic Sites”. 17th International Contracting & Negotiating Clinical Trials Conference (Strategic Research Institute). Cambridge, MA. May 22, 2006.

Presenter. “Developing Successful Clinical Trial Budgets”. BiMonthly Meeting (Association for Clinical Research Professionals: Nashville Chapter). Nashville, TN. December 5, 2005.

Co-Presenter. “Basic Training for IRB Members & Their Council”. Audioconference (American Health Lawyers Association). October 20, 2005.

Presenter. “Launching Clinical Trials in a Multi-Site Hospital Setting”. 41st Annual Meeting (Drug Information Association). Washington DC. June 28, 2005.

Presenter. “Trials and Tribulations (Pun Intended): What the GCPs Don’t Teach”. BiMonthly Meeting (Association for Clinical Research Professionals: Nashville Chapter). Nashville, TN. December 6, 2004.

Presenter. “Issues in Site Indemnification”. Annual Meeting 2004 (American Academy of Pharmaceutical Physicians). Atlanta, GA. November 6, 2004.

Co-Presenter. “The Contract Is Just the Beginning: Administering Contracts and Managing Relationships”. Contracting and Negotiating Clinical Trials (Strategic Research Institute). La Jolla, CA. September 28, 2004.

Co-Presenter. “Informed Consent Shoot-Out”. 40th Annual Meeting (Drug Information Association). Washington DC. June 16, 2004.

Co-Presenter. “Clinical Trials On Trial: Civil, Criminal, and other Liability Issues in the Performance of a Clinical Trial”. 40th Annual Meeting (Drug Information Association). Washington DC. June 14, 2004.

Presenter. “Trials and Tribulations (Pun Intended)”. Annual Training Meeting (Association for Clinical Research Professionals: Los Angeles Chapter). Beverly Hills, CA. April 7, 2004

Presenter. “How to Pick Investigative Sites That Are Trained”. Ensuring the Safety and Privacy of Human Research Subjects (Institute for International Research, Pharmaceutical Division). Princeton, NJ. September 6, 2002.

Co-Presenter. “Tomorrow’s Treatment in Clinical Trials Today”. 28th Annual Arkansas Mental Health Institute (Mental Health Council of Arkansas). Little Rock, AR. August 24, 2000.

PUBLICATIONS (RESEARCH RELATED):

IN PRESS: Vulcano, D. “Clinical Research……OF THE FUTURE!!!!!”. *The Monitor*. Volume 23, Issue 7.

IN PRESS: Vulcano, D. “After Hours and Weekend Learning… As Seen On TV”. *The Monitor*. Volume 23, Issue 6.

IN PRESS: Vulcano, D. “Swimming with the Big Fish: Career Development in the Clinical Trials Industry” *The Monitor*. Volume 23, Issue 5.

IN PRESS: Vulcano, D. “How Not To Be A Guinea Pig In Schizophrenia Clinical Trials”. *Schizophrenia Digest*.

IN PRESS: Vulcano, D. “A Youthful Perspective On Relationships in the Industry” *The Monitor*. Volume 23, Issue 4.

Vulcano, D. “AEs: Absence of Evidence vs. Evidence of Absence?” *The Monitor*. Volume 23, Issue 3. Pages 7-8.

Vulcano, D. “Interesting Times for Clinical Research”. *Journal of Clinical Research Best Practices.* Volume 5, Number 5. May 2009.

Vulcano, D. & Cormier, S. “Patients on Investigational Therapies- Better Prevention and Response Plans To Protect Their Rights, Safety and Well-Being During A Disaster”. Integrated Medical, Public Health, Preparedness and Response Training Summit (Department of Health and Human Services (HHS)). Poster. April 6, 2009.

Vulcano, D. “What Does Going ‘Global’ Really Mean?” *The Monitor*. Volume 23, Issue 2, Pages 7-8. April 2009.

Vulcano, D., Nolen, A., Miller, K. & Alpert C. *Evaluating Off-Label Use of Currently Marketed Drugs Devices and Biologics.* White Paper for HCA. March, 2009.

Vulcano, D. “Teamwork- The Final Frontier.” *The Monitor*. Volume 23, Issue 1, Pages 7-8. February 2009.

Vulcano, D. “Terrorists Can’t Open Ziploc Bags…And Other Amusing Travel Stories with Relevance to the Clinical Trials Industry.” *Potluck Wisdom for the Pharmaceutical Professional: 25 Essays By and For Members of the Clinical Research Community*. Chapter 17. ISBN: 978-0-9664806-9-6. 2008.

Vulcano, D. “Paving the Road to Success: The Importance of Strategic Planning in Clinical Research”. *ACRP Website Article* (July 2008).

Vulcano, D. “21CFR11 and HIPAA Security: Bits to Think About”. *The Monitor*. Volume 19, Issue 5 (December 2005), pp65-68.

Vulcano, D. Book Report: Ginsberg, D. et al.: *Becoming a Successful Clinical Research Investigator*. Published by Centerwatch, a division of Thomson Healthcare, Inc. 2005. Journal of Best Clinical Practice, Volume 1, Number 8 (August 2005).

EDITOR

WikiDOC’s Pages on Clinical Research

ADDITIONAL INTERVIEWS OR QUOTATIONS

BioExecutive International
- April 2007: “Mother Nature Demands Preparation by Clinical Trial Researchers”

BioResearch Compliance Report
- November 2006: “Warning letters stress operational, records issues, though on the decline”
- September 2006” “Investigator warning letters on track for 30 in 2006; IRB letters focus mostly on inadequate membership”

ClinicalTrials Today
- April 2008: “Coast IRB Receives FDA Warning Letter”

ClinPage
- July 2007: “When A Trial Went To Trial”

The Economic Report w/ Greg Gumble
- Scheduled January 2008: Title TBD

FDA News