

Michael P. Busch, MD, PhD

Current Positions:

- Co-Director, BSRI
- Senior Vice President, Research and Scientific Affairs, Blood Systems Inc., Scottsdale, Arizona
- Professor of Laboratory Medicine, University of California, San Francisco



Contact Information:

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Education:

- B.Sc., Pharmacology, University of California, Santa Barbara
- M.Sc., Experimental Pathology, University of Southern California
- M.D., University of Southern California (magna cum laude)
- Ph.D., Experimental Pathology, University of Southern California

Research Interests:

- Understanding transfusion-transmitted viral infections; including the risks of established and emerging agents and the consequences of infections in donors and recipients.
- The development and implementation of improved laboratory methods for detection, evaluation, management and prevention of blood-borne infections.
- Understanding the body's immune response to transfusion, organ transplant and pregnancy, including the mechanisms of tolerance and graft-vs.-host disease, donor white blood cell (leukocyte) proliferation and microchimerism.

Background:

Michael P. Busch, M.D., Ph.D., is one of the world's leading transfusion medicine scientists. He publishes prolifically, and is well-known for his innovative and productive research. Dr. Busch is an acknowledged national leader in laboratory issues as they apply to transfusion-transmitted diseases. He has advanced the general knowledge of viral dynamics and virus-host interactions, and has been instrumental in bringing nucleic acid technology (NAT) to practical application.

A pioneer in tracking the transmission of HIV infection in the nation's blood supply, Dr. Busch was on the front lines during this national health crisis. His research in the mid-1980s led to an accurate calculation of the window period for HIV infection and the first accurate estimates of the risk of HIV transmission by transfusion in the United States. His efforts were central to the formation of national policy and have been applied to other emerging pathogens including HCV, HBV and West Nile virus (WNV).

WNV has spread rapidly throughout the United States since its detection in New York City in 1999. Dr. Busch was a pivotal figure in documenting the risk of transfusion of WNV, developing and implementing new technology for the detection of the virus in the nation's blood supply, and creating public guidelines for blood centers.

In addition to his leadership and design of many key studies in transfusion medicine, Dr. Busch is a member of the Transfusion Transmitted Disease Committees of the American Association of Blood Banks and American's Blood Centers; and the Research and Development Advisory Committee of the Canadian Blood Services. He serves ad hoc for several European government and international task forces, and also sits on several World Health Organization panels. He is an associate editor of the medical journal "**Transfusion**" and serves on the editorial board of "**Transfusion Medicine**" and advises on the editorial board of the "**Journal of Human Virology**."

Curriculum Vitae
Michael Paul Busch, M.D., Ph.D.

CURRENT POSITIONS:

Senior Vice-President, Research and Scientific Affairs, Blood Systems, Inc., Scottsdale, Arizona
Director, Blood Systems Research Institute, San Francisco, California
Professor of Laboratory Medicine, University of California, San Francisco

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EDUCATION:

1977 B.A., Pharmacology, U.C. Santa Barbara (UCSB), cum laude
1982 M.S., Experimental Pathology, University of Southern California (USC), Los Angeles
1982 M.D., USC, magna cum laude
1985 Ph.D., Experimental Pathology, USC

RESEARCH FELLOWSHIP TRAINING:

1976 Edmondson Research Fellowship, USC
1977 Cancer Center Research Fellowship, USC
1978 Cancer Center Research Fellowship, USC
1980 Cancer Center Research Fellowship, USC

POST GRADUATE TRAINING:

1982-1984 Internship/Residency, Anatomic Pathology, University of California, San Francisco (UCSF)
1983-1984 Chief Resident, Anatomic Pathology, Veterans Administration Medical Center, San Francisco (SF VAMC)
1984-1985 Residency, Laboratory Medicine, UCSF
1985-1986 Chief Resident, Laboratory Medicine, UCSF

PROFESSIONAL EMPLOYMENT HISTORY, POST-RESIDENCY

1986-present Department of Laboratory Medicine, UCSF:
 1986-1992 Assistant Professor, in Residence
 1992-1996 Associate Professor, in Residence
 1996-1998 Professor, in Residence
 1999-present Adjunct Professor
1986-2003 Blood Centers of the Pacific (BCP), San Francisco, California
 [BCP was formed in 1998 as a merger of Irwin Memorial Blood Centers, San Francisco (IMBC),
 and Peninsula Blood Bank, Burlingame CA. Pre-1998 appointments were with IMBC].
 1986-1989 Assistant Scientific Director
 1989-1990 Associate Scientific Director
 1990-1994 Scientific Director
 1994-2003 Vice-President, Research and Scientific Affairs
1999-present Blood Systems, Inc. (BSI), Scottsdale AZ
 [In 1999, BCP affiliated with BSI]
 1999-2011 Vice-President, Research and Scientific Affairs
 2001-2003 Acting President, Blood Systems Foundation (BSF), Scottsdale AZ / San Francisco CA
 2004-2011 Vice-President, BSI; President, Blood Systems Research Institute (BSRI)
 [effective 2004, the former Division of Research and Scientific Services of BCP became a
 separate, independent unit of BSI, located at BCP.]

2011-present Senior Vice-President, Research and Scientific Programs, BSI; President, BSRI

HONORS / AWARDS:

1980 Medical Student Research Award, USC
1982 Merck Manual Award for Academic Achievement, USC
1982 Upjohn Award for Academic Excellence, USC
1986 Resident Research Award, American Society of Clinical Pathology (ASCP) and College of American Pathologists (CAP)
1994 Alsever Award, United Blood Services
1997 Robert Race Scientific Lecturer, South Central Association of Blood Centers
1998 Morton Grove-Rasmussen Award, American Association of Blood Banks
1999 Charles S. Shepard Science Award for publication, Centers for Disease Control
1999 Tibor Greenwalt Scientific Lectureship, American Association of Blood Banks
2000 Quest Distinguished Visiting Professor of Pathology, Johns Hopkins University, Baltimore
2004 Owen Thomas, MD Award, California Blood Bank Society
2005 President's Award, Society for the Advancement of Blood Management
2005 Emily Cooley Award, American Association of Blood Banks
2007 Visiting Professor, Rita and Taft Schreiber Lecture, Cedars-Sinai Medical Center, Los Angeles
2011 Outstanding Speaker - 2010, American Association for Clinical Chemistry

BOARD CERTIFICATION:

1989 Clinical Pathology, CAP
1989 Blood Banking and Transfusion Medicine, CAP

PROFESSIONAL SOCIETY MEMBERSHIPS:

1981 - present Alpha Omega Alpha, Honor Medical Society
1982 - present Phi Kappa Phi, All University Honor Society
1984 - present American Society of Clinical Pathology
1985 - present American Association for Advancement of Science
1986 - present American Association of Blood Banks
1986 - present California Blood Bank Society
1988 - present American Society for Microbiology
1991 - 2002 Academy of Clinical Laboratory Physicians and Scientists
1996 - present International Society of Blood Transfusion
1996 - present Infectious Diseases Society of America
1999 - 2002 American Society for Blood and Marrow Transplantation
2000 - 2003 HIV Medicine Association of IDSA
2000 - present American Society of Hematology

PROFESSIONAL APPOINTMENTS:

1988 -1995 Steering Committee, Transfusion Safety Study (TSS), National Heart, Lung and Blood Institute (NHLBI)
1988 - 1995 Publications Committee, TSS
1988 - 1995 Chair, Virology Working Group, TSS
1988 - 1990 Committee on Transfusion Transmitted Diseases, California Blood Bank Society (CBBS) (Chair, 1989-90)
1989 - 1994 AIDS Advisory Committee, NHLBI
1989 - 1997 Selection of Scientific Abstracts Committee, American Association of Blood Banks (AABB) (Chair, 1991-96)
1990 - 1991 Technical Scientific Workshops Committee, AABB
1990 - 1991 Hepatitis B and C Advisory Group, US Public Health Service (USPHS), Centers for Disease Control and Prevention (CDC)
1990 - 1993 Physicians Committee, CBBS

1990 - 1993 Scientific Program Committee, CBBS
1991 - 2002 Chair, Laboratory Committee, Retrovirus Epidemiology in Donors Study, Part I (REDS-I), NHLBI

1991 - 2002 Transfusion-Transmitted Diseases Committee, AABB
1991 - 1997 Liaison, Scientific Program Committee, AABB
1991 - 1995 Annual Meeting Planning Committee, AABB
1992 - 1995 Blood Products Advisory Committee, US Food and Drug Administration (FDA)
1992 - present **TRANSFUSION** Editorial Board, AABB
1992 - 1994 Chair, ad hoc Working Group on Idiopathic CD4 T- Lymphocytopenia, AABB/ARC/CCBC
1993 - 1994 ad hoc Consultant on Hepatitis Virus Screening, Scientific Advisory Committee, Canadian Blood Agency

1994 - 1998 ad hoc Non-Voting Member, FDA Anti-Viral Drug Advisory Committee
1994 - 2002 NIH Office of AIDS Research Advisory Committee
1994 - 1997 NIH Office of AIDS Research, ad hoc Committee for Planning Fiscal Years 1996/97
1994 - 2000 Chair, Laboratory Committee; Viral Activation in Transfusion Study (VATS), NHLBI
1994 - 2000 Steering Committee, VATS
1995 - present ad hoc Consultant/Reviewer, NIH AIDS and Related Research Study Section
1995 - 1998 ad hoc Non-Voting Member, FDA Anti-Viral Drug Advisory Committee
1995 - 2000 member, ad hoc Committee for Review of Donor Criteria, AABB (Chair, 1995-96)
1996 - 2007 **TRANSFUSION MEDICINE** Editorial Board (British Blood Transfusion Society)
1996 ad hoc Consultant/Reviewer, NIH NIAID Special Emphasis Panel
1997 - 2001 Steering Committee, UCSF AIDS Research Institute (ARI)
1997 - 2001 Advisory Committee on Blood Safety and Availability, US Dept of Health and Human Services (HHS)

1997 - 2003 **JOURNAL OF HUMAN VIROLOGY** Editorial Board
1997 - 2007 NHLBI Biological Specimen Repository Utilization Committee
1997 - 2000 ad hoc Committee on PCR Testing, AABB
1997 - 2005 International Consortium (*originally* International Task Force, ITFBS) on Blood Safety (ICBS)

1998 - present ad hoc Special Government Employee (SGE), invited expert consultant/presenter, FDA BPAC
1998 - 2005 Basic Science Sub-Committee, University of California, San Francisco (UCSF) AIDS Research Institute (ARI)
1999 - 2002 ad hoc Committee on Nucleic Acid Technology (NAT) Testing, (*originally* Genomic Acid Technology, GAT) AABB
1999 - 2002 Scientific and Technical Advisory Committee (STAC), Canadian Blood Services (CBS)
1999 - present Executive Council, UCSF AIDS Research Institute (ARI)
1999 - present Biological Specimens Central Storage Committee, UCSF
2000 - present Associate Editor, **TRANSFUSION**
2000 - present Scientific/Medical/Technical (SMT) Committee, America's Blood Centers (ABC)
2000 - present ABC SMT, Subcommittee on Future Donor Testing Strategies
2000 - present ABC SMT, Subcommittee on Impact of Future Scientific Developments
2000 - present Submissions Reviewer, Canadian Blood Services 2000/2001 Intramural Grants Competition

2001 - present Member, Disease Stage Working Group, of the CDC/NIH Acute [HIV] Infection Early Detection Research Program (AIEDRP).
2001 - 2008 Member, Pathogenesis Working Group, of the CDC/NIH Acute [HIV] Infection Early Detection Research Program (AIEDRP).
2002 - 2008 ad hoc Special Government Employee (SGE), invited expert consultant/presenter, DHHS ACBSA

2002 ad hoc Grant Application Reviewer, NIH Center for Scientific Review
2002 Member, Special External Expert Review Panel, Viral Epidemiology Branch (VEB), National Cancer Institute (NCI)

2002 - present Scientific and Research Advisory Committee (SRAC), Canadian Blood Services (CBS) (*pre-2005: Science, Technical, Research & Development. STRDC*)
2002 - 2004 Scientific Advisory Board, International Society of Blood Transfusion (ISBT), 2004 Annual Meeting.

2002 - present Member, Programme Committee, annual joint International Plasma Fractionation Association (IPFA) / Paul-Ehrlich Institute (PEI) NAT Workshop. (*prior to June 2005, the "European Plasma Fractionation Association, EPFA)*

2002 - present Member, West Nile Virus (WNV) Joint Task Force, AABB/ARC/ABC/CDC/FDA.

2003 - 2006 Scientific Committee on Transfusion Medicine, American Society of Hematology (ASH)

2003 - 2006 Biomedical Excellence for Safer Transfusion (BEST) Working Party, ISBT

2003 - present Affiliated Faculty Member, UCSF-UCB, Institute for Global Health (IGH)

2003 - present Member, Blue Ribbon Medical Panel, Blood Risk Catastrophe Medical and Litigation Model Update Policy, Canadian Blood Services Insurance Com., Ltd / Risk Management Consultants of Canada / Canadian Blood Services.

2003 - 2008 Transfusion-Transmitted Diseases Committee, AABB

2004 - 2008 Member, Board of Directors, Suzanne Ledin Memorial Foundation (SLMF)

2004 - 2006 Member, Medical / Scientific Advisory Committee, Haemonetics Inc.

2004 - 2011 Member, Steering Committee, Retrovirus Epidemiology Donor Study - Part II (REDS-II)

2004 - 2011 Chair, Infectious Diseases Working Group of the Steering Committee, REDS-II

2004 - 2005 Member, Scientific Advisory Committee, International Association for Biologicals (IABs). Biennial Symposium 2005, Sydney, Australia.

2005 - present Member, Medical Advisory Council, American Red Cross (ARC)

2005 - present Member, Special Working Group on Transfusion-Transmissible Diseases, ISBT

2006 - present Honorary Member, Biomedical Excellence for Safer Transfusion (BEST) Collaborative (*formerly BEST Working Party of ISBT)*

2006 - 2010 Associate Editor, **BIOLOGICALS**

2006 - 2008 Member, Scientific Committee, International Association for Biologicals (IABs). World Congress 2007, Sao Paulo, Brazil.

2006 - present Member, External Advisory Committee, P01-AI-066314, "Primate Core" (Adaptive Immunity, Mechanisms of Protection, in Live- Attenuated AIDS Vaccines). UC Davis.

2006 - present Associate Member, Liver Center, UCSF

2006 - present Member, Working Group on HIV Laboratory Algorithms, Association of Public Health Laboratories (APHL); CDC Western Blot Criteria Review Workgroup of the APHL/CDC HIV Steering Committee.

2006 - present Member, Special Working Group on Cost-Effectiveness Analysis of Blood Safety Interventions Worldwide, ISBT

2006 - present Member, International Working Group on Evaluation of Laboratory Tests for the Detection of Recent HIV Infection, World Health Organization (WHO)

2007 Invited Observer, Madrid & Geneva meetings, Global Collaboration for Blood Safety, WHO

2007 - present Chair, Donor Repository Allocation Working Group, NIH, NHLBI

2007 - present ad hoc Working Group on Transfusion Recipient Outcomes, NIH, NHLBI

2008 - 2011 Resource Allocation Program (RAP) Committee, UCSF

2008 - 2010 Scientific Program Committee, CBBS

2008 - present HIV Subtype Panel Working Group, NIH, NIAID, DAIDS, Vaccine Clinical Research Branch

2008 - present Member, Editorial Board, **Journal of Transfusion Medicine** (Poland). Inst of Hematology and Transfusion Medicine, Warsaw, Poland

2009 - present Consultant to Transfusion-Transmitted Diseases Committee, AABB

2009 - 2012 Member, Editorial Board, **Chimerism** (journal to launch 2010)

2009 - 2010 Member, Scientific Program Committee, ISBT, 2010 Annual Meeting

2009 - present Member, US DHHS Inter-Agency ad hoc Committee on Xenotropic Murine-Leukemia Virus-Related Virus (XMRV) / Chronic Fatigue Syndrome (CFS)

2010 - present Member, Gates Foundation, Incidence Assay Critical Path Working Group

2010 - present ad hoc Member, NIAID Intramural Data and Safety Monitoring Board (DSMB)

2010 - 2012 Member, Awards Committee, AABB

2010 - 2012 HIV Advisory Board, Ortho Clinical Diagnostics [Johnson & Johnson]

2010 - present Member, Medical Advisory Board, Creative Testing Solutions (a division of Blood Systems, Inc.)

2010 - present Member, ad hoc Working Group on Alloimmunization, NIH, NHLBI

- 2011 - present Member, External Quality Assurance Program Oversight Laboratory (EQAPOL) Scientific Advisory Board, Center for HIV/AIDS Vaccine Immunology / Duke Human Vaccine Institute, Duke University
- 2011 - present Member, Steering Committee, Recipient Epidemiology and Donor Evaluation Study-III (REDS-III)
- 2011 - present Co-Chair, Infectious Disease and Repositories Working Group, *of the* Steering Committee, Recipient Epidemiology and Donor Evaluation Study-III (REDS-III)
- 2011 - present Chair, RBC Variability Working Group, *of the* Steering Committee, Recipient Epidemiology and Donor Evaluation Study-III (REDS-III)
- 2011 - present Member, Observational Study Monitoring Board (OSMB), Recipient Epidemiology and Donor Evaluation Study-III (REDS-III)
- 2011 - present Member, NIAID Viral Panels Working Group.
- 2011 ad hoc reviewer, 2012 Conference on Retroviruses and Opportunistic Infections (CROI)
- 2011 - present Member, Endowed Lectures Committee, Dept of Laboratory Medicine, UCSF
- 2011 - present ad hoc reviewer 2011, Limited Submission Program Advisory Committee, *for* Doris Duke Clinical Scientist Development Award, 2012.
- 2012 - 2016 Scientific Committee on Transfusion Medicine, American Society of Hematology (ASH)
- 2012 – 2016 Chair, International Society of Blood Transfusion (ISBT) Working Party for Transfusion Transmitted Infectious Diseases
- 2012 - present Committee, Vaccine-Induced Seroreactivity (VISR)
- 2012 - present Committee, Transfusion Transmitted Diseases, AABB
- 2012 - present Member, Clinical Trials Subcommittee, IAVI
- 2012 - present Member, HCV Workgroup, APHL and CDC
- 2014 – 2015 Vice-Chair, ASH Scientific Committee on Transfusion Medicine
- 2015 – 2016 Chari, ASH Scientific Committee on Transfusion Medicine

MEMBER, ADVISOR / EXAMINER COMMITTEES, for Graduate Students:

- 2000 - 2002 Doctoral Thesis Advisor ("MD with Thesis"), UCSF, *for* Eric Chow.
- 2007 - 2008 Examiner, PhD Thesis Defense, Karolinska Institut, Stockholm, *for* Gustav Edgren, .
- 2009 - present Member, Applied Research Project (ARP) Committee (Master's), A.T.Still Univ/AZ School Health Sciences, Mesa AZ, *for* Lori Lai.
- 2009 - 2010 Examiner, PhD Thesis Defense, University of Western Australia, Crawley, *for* Clive Seed

INVITED REVIEWER, Professional Journals:

Acquired Immune Deficiency Syndrome (AIDS)
 AIDS Research and Human Retroviruses
 Anesthesiology
 Annals of Haematology
 Blood
 Canadian Medical Association Journal
 Cancer
 Clinical Chemistry
 Hepatology
 Journal of Acquired Immune Deficiency Syndrome (J AIDS)
 Journal of the American Medical Association (JAMA)
 Journal of Clinical Immunology
 Journal of Clinical Microbiology
 Journal of Human Virology
 Journal of Infectious Diseases
 Journal of Transfusion Medicine [Poland]
 Journal of Virology
 New England Journal of Medicine (NEJM)
 PLoS Medicine (Public Library of Science)
 Transfusion
 Transfusion Medicine
 Transfusion Medicine Reviews

RESEARCH INTERESTS:

1) The pathogenesis and clinical laboratory evaluation of transfusion-associated viral infections, including epidemiology and natural history of human retroviral (HIV-1/2; HTLV-I/II) and other (HBV, HCV, HHV-8, CMV, EBV) infections in blood donor and recipient populations, with special emphasis on new and emerging infectious agents (SARS, West Nile Virus, Dengue Virus, and influenza viruses); and mechanisms of viral latency, disease, and viral reactivation following transfusion or other immunological stimulus;

2) The development and implementation of improved or new laboratory assays and blood donor screening protocols, clinical evaluation and management, and possible prevention of blood-borne infections; development of new techniques (e.g. nucleic acid amplification testing, NAT; sensitive/less-sensitive enzyme immunoassay, S/LS-EIA, "detuned EIA") to reduce the infectious window period before infection is directly detectable;

3) Immunological and other consequences of transfusion (graft-vs-host disease, GvHD; transfusion-related acute lung injury, TRALI); the mechanisms of allogeneic donor leukocyte clearance post-transfusion, versus enhancement of persistent chimerism and tolerance, and approaches to their reduction or elimination.

These interests are pursued through individual and several multi-center collaborative epidemiologic, clinical, and laboratory-based studies with colleagues at university, government, and commercial research organizations. At BSRI, I am responsible for a growing staff of researchers and technologists; I take pride in our record of recruiting new scientists who are establishing their own research programs, and in mentoring students from universities and blood banking institutions around the world in pursuing their own studies at BSRI; some current investigations focus on the evolution of HIV quasi-species in donor/recipient clusters; development and use of the S/LS EIA to identify and "stage" very early HIV infection; and development of mathematical models for cost/benefit analysis of new screening strategies. Finally, all our activities are directed toward 1) enhancing the safety and availability of the blood supply, and of public health generally, worldwide; 2) developing better techniques to educate, counsel, and care for infected donors and recipients, and 3) taking an active part in national and international health policy development.

CURRENT FUNDED RESEARCH STUDIES:

1. R01-AI-087145 (PI, BSRI sub) 9/10 - 9/11
NIH / NIAID
Impact of Early Antiretroviral Therapy on HIV Persistence and Inflammation
The goal of this study is to determine the effect of immunosuppressive therapy on the size of the HIV reservoir during long-term highly active antiretroviral therapy (HAART).
2. 1R01-AI-090677 (KI, UCSF: PI, BSRI sub) 7/10 - 6/14
NIH / NIAID
Impact of Tolerance in the Newborn on Lentiviral Infection
BSRI will, during the first year, develop and optimize one or more assays to determine whether cells from the mother rhesus macaque move into the fetus during the course of pregnancy.
3. R01-AI-084109 (KI, UCSF, PI, BSRI sub) 7/09 - 6/13
NIH / NIAID
Interruption of Maternal / Fetal Transmission of HIV
The experiments of this proposal address a novel approach towards vaccination against HIV disease, namely: to create a vaccine that will prevent, rather than to elicit, a robust immune response against the virus.
4. N01-HB-57181 (co-PI, UCSF; PI, BSRI sub) 3/05 - 6/11
NIH / NHLBI
Retrovirus Epidemiology Donor Study, Part II (REDS-II) - **Central Laboratory**

Established and directs central laboratory for all REDS-II specimens (from 6 blood centers). Special attention is given to identification, detection, and characterization of new and emerging viruses, development of new assays for them.

successor proposal submitted, pending

5. N01-HB-47175 (prime, Westat); HHSN268200417175C; 8067-S-002 (sub, BSRI) (PI, BSRI sub)
NIH / NHLBI 2/06-8/12

Retrovirus Epidemiology Donor Study, - Part II (REDS-II) - **International Component – Brazil**

Building upon 3 decades BSRI/UCSF blood safety & policy research, and 12+ years collaborative research and training with transfusion medicine (TM) colleagues in Brazil. Compilation of extensive blood donor/donation demographic & epidemiological data and specimens; oversee 4 separate transfusion medicine research projects in Latin America: 1) HIV relative to donation type, donor demographic & behavioral characteristics, residual risk of HIV transmission, impact of new screening technologies, track & characterize variant and drug-resistant strains; 2) Case-control & survey studies to analyze epidemiological and donor motivation factors impacting safety and availability of blood donations; 3) Retrospective cohort study of *T. cruzi* infection & Chagas' Disease in blood donors; 4) Studies of Dengue virus.

successor proposal submitted, pending

6. R01-DA-021550 (prime, SUNY; formerly Weill/Cornell) (PI, BSRI sub) 6/08 - 5/13
NIH / NIDA

Acute HCV Infection in Injection Drug Users

successor to R01-DA-016159, 11/1/04-5/31/08. Subcontract to B.Edlin, SUNY AHI-IDU study. To determine the risks of acquiring HCV infection associated with specific injection practices in a cohort of young, high-risk injection drug users (IDUs) on the Lower East Side of Manhattan, and the possible protective effect of pre-existing HCV-specific immune responses. Selected blood samples from injection drug users shipped to BSRI Viral Reference Laboratory & Repository Core (VRLRC), for testing by ECI and other advanced assays. VRLRC also processes samples for further testing by dHCV TMA at Novartis/Chiron, and maintains a sample repository at BSRI.

7. R01-HL-088388 (Principal Investigator, BSRI) 9/06-7/11
NIH / NHLBI

Mechanisms and Clinical Effects of Microchimerism in Transfused Trauma Patients

Investigating the frequency of persistence of donor leukocytes in patients transfused following severe injury. The grant includes both retrospective (registry) and prospective studies of severely injured subjects with detailed laboratory and clinical studies to investigate mechanisms and clinical consequences of persistent donor leukocyte microchimerism.

8. RC2-HL-101632 (Principal Investigator) 9/09-9/11
NIH/NHLBI

Viral/immune parameters of Dengue and WNV in donors: blood safety implications

The goals of this grant are to establish the infectivity of low-level WNV viremic units in the early convalescent stage of infection not detected by current NAT screening, to implement sensitive NAT screening in Puerto Rico under an FDA IND, and to launch follow-up studies of DENV+ donors. In addition, we will establish an NHLBI repository of extensively characterized, longitudinal specimens from Dengue and WNV infected donors to advance research into the pathogenesis of these important agents.

COMPLETED RESEARCH STUDIES:

1. R01-HL-076902 (Principal Investigator) 9/03-8/10
NIH / NHLBI

Natural History of Acute and Chronic HCV in Blood Donors

Clinical and epidemiologic research: 1) epidemiologic studies of 10,000 HCV seropositive donors identified at BSI/BCP since 1990 to ascertain long-term mortality, morbidity and health care utilization of infected donors relative to matched controls; 2) longitudinal laboratory-focused case-control study of HCV-positive persons with probable resolved versus persistent viremia to confirm long-term infection status, identify immunological and other correlates of viral resolution; 3) establish a prospective cohort of donors

with acute HCV infection (RNA-positive / Antibody-negative) as detected by NAT screening – these donors will be followed carefully with extensive viral and immunological characterization to better understand the host-virus interactions during the processes of seroconversion and establishment of resolved or persistent infection.

2. U19-AI-067854 (Principal Investigator, BSRI) 9/09-6/10
NIH/NIAID
Study to characterize global HIV genetic diversity in recently infected donors.
As part of Duke Univ Center for HIV-AIDS Vaccine Immunology (CHAVI), this "Panels" study viral isolate sequences in conjunction with viral load and Fiebig stage from blood donors from 3-5 different countries.
3. N01-HB-47174 (co-PI, UCSF; co-PI, BCP sub) 9/04-8/09
NIH / NHLBI
Retrovirus Epidemiology Donors Study, Part II (REDS-II) - **Blood Center**
A continuation of highly successful 15-year REDS-I epidemiological and clinical studies of transfusion safety and blood supply. Six blood centers participate in a network doing epidemiologic and clinical laboratory studies addressing multiple issues: transfusion-related infections, transfusion-related lung injury (TRALI), iron balance in blood donors, among others.
4. R01-HL-062235 (co-Principal Investigator, UCSF; Principal Investigator, BSRI) 4/99-1/09
NIH / NHLBI
Pathophysiology of HTLV-I and HTLV-II Infection "HOST"
A prospective cohort study of HTLV-I and HTLV-II health outcomes in former blood donors; builds upon REDS-I.
5. R01-CI-000214 (PI) 9/04 - 9/08
NIH / NCI, & CDC / NCID
Natural History and Pathogenesis of WNV in Viremic Blood Donors
Identify and enroll blood donors with early (pre-seroconversion), acute, and/or resolved WNV infection, characterize the dynamics and kinetics of acute viremia, and time course of immune response in primary WNV infection. Additional studies will investigate T-cell responses, antigen specificity, and cytokine perturbations, and attempt to define viral and humoral immune parameters that correlate with control of viremia.
6. R01-DA-016159 (PI, BSRI sub) 11/04 - 5/08
(succeeded by R01-DA-021550)
NIH / NIDA
Acute HCV Infection in Injection Drug Users
Subcontract to Weill/Cornell AHI-IDU study. Selected blood samples from injection drug users shipped to BSRI Viral Reference Laboratory & Repository Core (VRLRC), for testing by ECi and other advanced assays. VRLRC also processes samples for further testing by dHCV TMA at Chiron Corp, and maintains a sample repository at BSRI.
7. U01-AI-41531 (Principal Investigator, BCP/BSRI sub-contract) 7/02-6/07
NIH / NIAID
Immunologic and Virologic Features of Early HIV Infection
An HIV Primary Infection / Early Disease Research Unit has been established at UCSF as part of Acute Infection, Early Disease Research Program (AIEDRP) / , to assess disease stage/progression and conduct treatment trials. BSRI conducts extensive lab tests (PCR monitoring of viral load in blood, PBMC, and other body tissues; cytokine levels, T-cell activation, etc.) to establish timelines and markers of infection, study viral pathogenesis and reactivation, measure patient response to treatments, etc., for the unit, and participates in interpretation of data and publication of results.
8. P50-HL-54476 (Principal Investigator, BCP/BRSI sub-contract) 2/96-12/06
NIH / NHLBI
Specialized Center of Research (SCOR) Grant in Transfusion Medicine
(UCSF/BCP Project 6): Donor Leukocyte Activation/ Proliferation Post-Transfusion

Project 6 goals: define factors influencing newly observed proliferation/expansion of donor white cells in recipients; characterize immunophenotype and specificity of donor cells; determine minimum number of white cells needed to produce a detectable peak; correlate phenomenon with development of recipient immune activation and alloimmunization in humans.

9. N01-HB-47114 (co-Principal Investigator, UCSF; Principal Investigator, BCP sub)
NIH / NHLBI 1989 - 2004
Retrovirus Epidemiology Donor Study, REDS-I
Established/maintained various repositories of blood donor sera; enrolled and followed HTLV-I/II positive donors; studied demographics and behavioral characteristics of donors; determined current risk of viral transmission; responded to new concerns over infectious risks of blood transfusions. This project included multiple substudies:
 - a) REDS Allogeneic Donor and Recipient Repository - "RADAR" substudy, designed to permit future rapid, retrospective analysis of any new possible, transfusion-transmitted disease through storage of both the frozen donor samples and the matching recipient blood samples from both pre- and post transfusion.
 - b) Nucleic Acid Testing (NAT) Surveillance Study, the purpose of which was to assess the sensitivity of NAT assays for HIV and HCV, evaluate the optimal size for mini-pooling of specimens, and to evaluate performance of test kits from different manufacturers, with the overall goal of reducing or eliminating HIV and HCV transfusion transmissions.
 - c) West Nile Virus Prevalence Pilot Study. Characterized WNV serologic and viremic levels using RADAR Repository samples and developed a model of WNV residual risk for 2002 and 2003. Tested other RADAR 2002 and 2003 samples from around the country to collect data used to quantitate WNV incidence and prevalence in one or more selected regions and develop a model of WNV transfusion transmission risk.
10. U64-CCU-902948 (Principal Investigator, BCP) 1987 - 2002
CDC
AIDS Epidemiologic Study of Blood Donors
Monitor HIV-1 infection in blood donors, assess risk factors and motivations of infected donors. In the early years of the epidemic transfusion recipients and their sexual partners were also involved. Current sub-studies include (1) genetic sequencing of HIV to identify geographic and newly-evolving variants, by use of the latest techniques (PCR DNA sequencing, HMA); and (2) development of a modified "de-tuned" antibody test to actually make it less sensitive. By identifying persons who test positive by standard assays but negative on the de-tuned assay, we can identify the sub-set of infected persons who are newly infected, allowing focused investigation into their demographics, risk factors, and viral strain characteristics, targeted contact tracing, and design of new treatment regimens and public education campaigns, since newly-infected persons present the greatest risk to the blood supply, and "drive" the over-all epidemic.
11. N01-HB-57126 (Principal Investigator, BCP) 1994 - 2000
NIH / NHLBI
Viral Activation in Transfusion Study, VATS - Central Laboratory
Virologic and immunologic studies for a clinical trial of blood transfusion (e.g. leukoreduced versus non-leukoreduced; whole blood versus packed red cells) in AIDS patients. Central laboratory performed all testing for multiple clinical centers, developed and optimized new PCR & other techniques.
12. R01-CA-59706 (Responsible Head of Lab, BCP; non-funded Supervisor/Consultant, IMBC sub)
NIH / NC 1994 - 1999
Pancreatic Cancer Case-Control Study in San Francisco
13. N01-AI-82515 (Principal Investigator, IMBC sub) 1988 - 1996
NIH / NIAID
Natural History of AIDS in Homosexual Men ("San Francisco Men's Health Study", SFMHS);
14. R01-HL-48367 (Principal Investigator, UCSF / IMBC) 1992 - 1996
NIH / NHLBI
HIV Diversity/Pathogenesis in Donor/Recipient Clusters
15. N01-HB-97074 (Principal Investigator, UCSF / IMBC sub) 1984 - 1996

NIH / NHLBI
Transfusion Safety Study (TSS)

16. no number assigned (Principal Investigator, IMBC) 1993 - 1995
Becton Dickinson Immunocytometry Systems, Inc. (BDIS)
Retrospective Correlative Studies of Immune Activation and AIDS Progression" (2 studies)
17. 500339-14-PG (Principal Investigator, IMBC) 1993 - 1994
Pediatric AIDS Foundation/American Foundation for AIDS Research (PAF/AMFAR)
Mother-Fetal Transfusion and Perinatal HIV Infection
18. no number assigned (Principal Investigator, IMBC) 1993 - 1994
Pall Biomedical Products Corp
Effects of Leukodepleted Blood Transfusions" (2 studies)
19. no number assigned (co-Principal Investigator, IMBC) 1992 - 1994
American Red Cross
Impact of High Efficiency Leukocyte Filtration on HIV Burden in Cellular and Fluid Fractions of Blood from Asymptomatic, Seropositive Donors
20. no number assigned (Principal Investigator, IMBC) 1993 - 1994
American Red Cross (Holland Labs)
2 studies: 1) HIV Distribution in Donated Blood; 2) Removal of HIV from RBC/Platelets by Washing
21. no number assigned (co-Principal Investigator, IMBC) 1992 - 1993
American Association of Blood Banks (AABB) National Blood Foundation (NBF)
Impact of Homologous Blood Transfusion on HIV Replication and Disease in vivo
22. N01-HB-9-7024 (Principal Investigator, IMBC sub) 1986 - 1993
NIH / NHLBI
Effectiveness of HTLV-III HIV-1 Screening
[NOTE: HIV-1 was originally known as HTLV-III]
23. U62-CCU-902947 (Principal Investigator, IMBC) 1987 - 1992
CDC
Epidemiologic Study of Heterosexual Transmission of HIV from Persons with Transfusion-Associated Infections ("Partner Study").
24. N01-HB-6-7020 (Principal Investigator, IMBC sub) 1986 - 1992
NIH / NHLBI
Development/Evaluation of New Screening Tests for HTLV-III HIV-1 Antibodies/Antigens/Nucleic Acids
25. P01-36589, Program Project Grant (co-Principal Investigator, IMBC sub) 1986 - 1991
NIH / NHLBI
Transfusion-Related Viral Infections and Immune Response
26. R01-HL-41361 (Co-Investigator, UCSF; Princ. Investigator, IMBC sub) 1988 - 1991
NIH / NHLBI
Removal/Inactivation of Viruses in Blood
27. no number assigned (Principal Investigator, IMBC) 1990 - 1991
American Association of Blood Banks (AABB) National Blood Foundation (NBF)
Adaptation of Capillary Separation to PCR Amplification for Infectious Disease Screening of Blood Donors
28. no number assigned (Principal Investigator, IMBC) 1989 - 1990
UCSF AIDS Clinical Research Center

HIV Proviral Load: Prognostic Value and Pathogenic Relevance

29. CCU-900829 (Co-Investigator, IMBC sub) 1987 - 1989
CDC
Collaborative Study of Patients Transfused with Blood from Persons with Acquired Immunodeficiency Syndrome (AIDS) or AIDS-Related Conditions (ARC)
30. *number not available* (non-funded Consultant to SFSU researcher) 1995 - 1998
NIH Academic Research Enhancement Award program
Transcriptional Processivity in HIV-1 Latency

For publications, please see separate file.

August 17, 2012