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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San Francisco, California 94118
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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 - present	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 - 2008	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 - 2010	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 - 2010	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 - 2010	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, NIAID Viral Panels Working Group.
2011 - present	Member, Endowed Lectures Committee, Dept of Laboratory Medicine, UCSF
2012 - 2016	Member, 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 - 2014	Committee, Vaccine-Induced Seroreactivity (VISR)
2012 - present	Member, Clinical Trials Subcommittee, IAVI
2012 - 2014	Member, HCV Workgroup, APHL and CDC
2014 - 2015	Vice-Chair, ASH Scientific Committee on Transfusion Medicine
2014 - present	Co-Chair, ACTG Reservoir Assay Working Group
2014 - present	Member, Alliance of Blood Operators Research Leaders Working Group
2015 - 2016	Chair, ASH Scientific Committee on Transfusion Medicine
2015 - present	Member, ISBT Global Blood Safety Working Party

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 - 2012	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
Vox Sanguinis

RESEARCH INTERESTS:

1) The epidemiology, pathogenesis and laboratory evaluation of transfusion-associated viral infections, including HIV-1/2; HTLV-I/II, HBV, and HCV, as well as blood safety implications of new and emerging transfusion-transmissible infectious diseases (e.g., Zika virus, West Nile Virus, Dengue Viruses, chikungunya virus, T. cruzi, babesia, etc.):

Characterization of infection dynamics and pathogenesis of established and emerging TT-infections

To address blood safety concerns over viral and parasite infections and to evaluate the utility of tests to detect and prevent TT of infections, it is critical to rigorously characterize the evolving dynamics of molecular and serological markers from acute viremia/parasitemia through seroconversion, followed by subsequent resolution of infection or establishment of long-term persistent infection. My group at BSRI has executed dozens of studies to achieve this understanding with implications for blood safety policy development (estimation of risk in context of different donor screening options, including yield and residual risk subsequent to screening based on incidence/window period models my team developed; potential for leukoreduction of pathogen to eliminate risk; development of assay interpretations and confirmatory test algorithms to enable accurate notification and counselling of donors or recipients who test reactive on screening assays), as well as broader implications for epidemiology, public health and pathogenesis. Examples include extensive work on established transfusion-transmitted viruses (HIV, HBV, HCV, HTLV-I/II) and numerous studies executed in response to concerns and opportunities (consequent to large scale studies based on screening donors and recipients) for EIDs (e.g., WNV, *T cruzi,* DENV, B microti).

a. Glynn SA, Wright DJ, Kleinman SH, Hirschkorn D, Tu Y, Heldebrant C, Smith R Giachetti C, Gallarda J, **Busch MP**. Dynamics of Viremia in Early Hepatitis C Virus Infection. Transfusion, 45:994-1002, 2005. PMID: 15934999.
b. **Busch MP**, Murthy KK, Kleinman SH, Hirschkorn DF, Herring BL, Delwart E, Racanelli V, Yoon JC, Rehermann B, Alter HJ. Infectivity in Chimpanzees (*Pan troglodytes*) of Plasma Collected before HCV RNA Detectability by FDA-Licensed Assays: Implications for Transfusion Safety and HCV Infection Outcomes. Blood 2012;119:6326-34**.** PMID: 224987432.
c. **Busch MP**, Kleinman SH, Tobler LH, Kamel HT, Norris PJ, Walsh I, Matud JL, Prince HE, Lanciotti RS, Wright DJ, Linnen JM, Caglioti S. Viral and Antibody Dynamics in Acute West Nile Virus Infection. J Infect Dis, 198(7):984-993, 2008. PMID: 18729783
d. Petersen LR, Carson P, Biggerstaff B, Custer B, Borchardt S, **Busch M**. Estimated Cumulative Incidence of West Nile Virus in United States Adults, 1999-2010. Epidemiology & Infection, 2012;28:1-5. PMID: 22640592

Responses to Emerging Infectious Diseases (EID) to Assure Blood Safety

Despite dramatic progress over the past 5 decades in understanding and reducing risk from established transfusion-transmitted (TT) viral infections, emerging infectious threats to blood safety continue to be identified (1). My team at BSRI, and collaborators in the REDS programs, ARC and globally, have responded to numerous blood safety threats with rigorous studies in multiple countries to verify and quantify rates of infected donations, and consequent risks of transmission to and disease outcomes in recipients. Representative examples include parvovirus B19, Human Herpes Virus Type 8 (HHV-8), *T. cruzi* (Chagas disease), West Nile virus (WNV), dengue virus (DENV), XMRV, SFTSV, and Babesia microti. For some agents we demonstrated significant risk that led to implementation and subsequent enhancements of blood donor screening (e.g., WNV and Chagas) while for others we established the agents did not pose a risk to recipients (e.g., B19, HHV-8, XMRV, SFTSV) or more limited or regional screening was warranted (e.g., DENV and B microti). We continue to lead studies to address risks of EIDs with current studies focused on Chikungunya and Zeka viruses.

a. **Busch MP**, Caglioti S, Robertson EF, McAuley JD, Tobler LH, Kamel H, Linnen JM, Shyamala V, Tomasulo PA, Kleinman SH. Screening the Blood Supply for West Nile Virus RNA by Nucleic Acid Amplification Testing. N Engl J Med, 353:460-7, 2005. PMID: 16079369.
b. **Busch MP**, Wright DJ, Tobler LH, Stramer SL, Custer B, Kleinman SH, Prince HE, Bianco C, Foster G, Petersen LR, Nemo G, Glynn SA. West Nile Virus Infections Projected from Blood Donor Screening Data, United States, 2003. Emerg Infect Dis, 12(3):395-402, 2006. PMID: 16704775.
c. Sabino EC, Ribeiro AL, Salemi VMC, …**Busch MP**, Murphy EL. Ten-year Incidence of Chagas cardiomyopathy among asymptomatic, T. cruzi seropositive former blood donors. Circulation 2013 Mar 12;127(10):1105-15, PMCID:PMC3643805.
d. Simmons G, Glynn SA, Komaroff AL, …, **Busch MP**, for the Blood XMRV Scientific Research Working Group (SRWG). Failure to Confirm Murine Leukemia Virus-Related Viruses in the Blood of Patients with Chronic Fatigue Syndrome and Healthy Donors in a Multi-laboratory Blinded Panel Study. Science, 334(6057):814-817. PMCID:PMC3299483.

2) Development and implementation of new or improved laboratory assays and blood donor screening protocols, clinical evaluation and management, and possible prevention by pathogen inactivation of blood-borne infections, with particular focus on new techniques for mass screening of blood donations using nucleic acid amplification technology (NAT) to reduce the infectious window period and detect new and emerging infectious diseases:

Diagnosis and Staging Early HIV Infection

My early studies in the mid-1980s focused on understanding the residual risk of HIV infection from transfusions following implantation of HIV antibody screening in 1985. These included application of viral culture and then novel PCR methods to pooled seronegative donor samples from San Francisco and studies of serial samples from acutely infected participants in the gay male cohort studies to determine the timing of detection of HIV RNA and p24 Ag in plasma and DNA in cells as well as HIV antibodies detectable by 2nd and 3rd generation immunoassays. To refine our understanding of the timing of detectable blood markers following acquisition of HIV infection, I led a series of studies using infected plasma donor seroconversion panels to establish a novel approach for "cross sectional staging" of acute and early HIV infection based on laboratory parameters, now globally adopted as the "Fiebig Staging" system (derived from the name of a fellow in my lab who was first author on that paper). This near universally adopted approach to staging HIV infection and access to plasma donor seroconversion panels has enabled detailed characterization of "transmitted founder viruses" and subsequent evolution of HIV in the context of evolving host immune responses.

a. **Busch MP**, Eble BE, Khayam-Bashi H, Murphy EL, … Vyas GN. Evaluation of Screened Blood Donations for Human Immunodeficiency Virus Type 1 Infection by Culture and DNA Amplification of Pooled Cells. N Engl J Med, 325:1-5, 1991.
b. **Busch MP**, Lee LLL, Satten GA, Henrard DR, Farzadegan H, Nelson KE, Read S, Dodd RY, Petersen LR. Time Course of Detection of Viral and Serological Markers Preceding HIV-1 Seroconversion; Implications for Blood and Tissue Donor Screening. Transfusion, 35:91-97, 1995.
c. Fiebig EW, Wright DJ, Rawal BD, Garrett PE, Schumacher RT, Peddada L, Heldebrant C, Smith R, Conrad A, Kleinman SH, **Busch MP**. Dynamics of HIV Viremia and Antibody Seroconversion in Plasma Donors: Implications for Diagnosis and Staging of Primary HIV Infection. AIDS, 17(13):1871-9, 2003. PMID: 12960819.
d. Keele BF, Giorgi EE, Salazar-Gonzalez JF, Decker JM…, **Busch MP…**, Shaw G. Identification and Characterization of Transmitted and Early Founder Viruses in Primary HIV-1 Infection. PNAS USA, 105(21):7552-7, 2008. PMID: 18490567.

Recency Testing for estimating HIV incidence

While pursing work to close the pre-seroconversion HIV window period by adopting enhanced antibody, antigen and nucleic acid amplification technology (NAT) assays in order to maximize blood safety, I realized that the approach we developed to predict yield of new assays (based on understanding the length of window period closure achieved by new assays and incidence of HIV infection in repeat blood donors), could be modified to develop laboratory-based strategies to estimate HIV incidence from cross-sectional serosurveys based on detection of participants with recently acquired infections. This required systematic modifications of HIV antibody assays to delay detection of seroconversion, relative to increasingly sensitive diagnostic screening assays, based on "detuning" of assay protocols or avidity treatment of HIV seropositive samples prior to testing. This work, originally published in JAMA, has evolved into a major field of recency assay development and application, funded extensively by NIH, WHO and the Gates Foundation.

a. Stramer SL, Glynn SA, Kleinman SH, Strong DM, Caglioti S, Wright DJ, Dodd RY, **Busch MP**, for the NHLBI Nucleic Acid Test Study Group. Detection of HIV-1 and HCV Infections Among Antibody-Negative Blood Donors by Nucleic Acid-Amplification Testing. N Engl J Med, 351(8):760-8, 2004. PMID: 15317889.
b. **Busch MP**, Glynn SA, Stramer SL, Strong DM, Caglioti S, Wright DJ, Pappalardo B, Kleinman SH, for the NHLBI-REDS NAT Study Group. A New Strategy for Estimating Risks of Transfusion-Transmitted Viral Infections Based on Rates of Detection of Recently Infected Donors. Transfusion, 45(2):254-64, 2005. PMID: 15660836.
c. Janssen RS, Satten GA, Stramer SL, Rawal BD, O'Brien TR, Weiblen BJ, Hecht FM, Jack N, Cleghorn FR, Kahn JO, Chesney MA, **Busch MP**. New Testing Strategy to Detect Early HIV-1

Infection for Use in Incidence Estimates and for Clinical and Prevention Purposes. JAMA, 280(1):42-48, 1998. PMID: 9660362.

d. **Busch MP**, Pilcher CD, Mastro TD, …, for the WHO Working Group on HIV Incidence Assays. Beyond Detuning: Ten Years of Progress and New Challenges in the Development and Application of Assays for HIV Incidence Estimation from Surveys. AIDS 24(18):2763-2771. PMID: 20975514

3) Mechanisms and prevention of immunological consequences of transfusion including transfusion-induced immune modulation, viral reactivation, mirochimerism and graft-vs-host disease, transfusion-related acute lung injury and alloimmunization:

Non-infectious consequences of blood transfusions and blood donation

Although my career initially focused on infectious diseases relevant to blood safety, over the decades I have led a number of studies on non-infectious consequences of transfusions as well as efficacy of transfusions and improvements in safety and efficacy consequent to advances in blood banking. Examples include 1) a series of studies to document persistent microchimerism of donor cells in transfusion recipients (1,2), with particular focus on mechanisms and clinical relevance of donor stem cell microchimerism in transfused trauma patients, and the immunological mechanisms and prevention of transfusion-related acute lung injury (TRALI) and alloimmunization (3). I have also been involved in multiple studies of donor reactions and donor iron loss, and am now leading a large NHLBI-funded study (RBC-Omics) investigating genetic and metabolomic mechanisms underlying differing capacity of donors from diverse racial-ethnic groups to tolerate frequent RBC donation and of their donated RBC to maintain functional integrity during storage for 42 days.

a. Lee T-H, Paglieroni T, Ohto H, Holland PV, **Busch MP**. Survival of Donor Leukocyte Subpopulations in Immunocompetent Transfusion Recipients: Frequent Long-Term Microchimerism in Severe Trauma Patients. Blood, 93(9):3127-39, 1999. PMID: 10216112.
b. Utter GH, Lee T-H, Nathens AB, Reed WF, Owings JT, Nester TA, **Busch MP**. Leukoreduction of Blood Transfusions Does Not Diminish Transfusion-Associated Microchimerism in Trauma Patients. Transfusion, 46(11):1863-1869, 2006. PMID: 17076839.
c. Carrick DM, Norris PJ, Endres,… **Busch MP**. Establishing Assay Cutoffs for HLA Antibody Screening of Apheresis Donors. Transfusion, 51(10):2092-2101,2011. PMCID:PMC3108003.
d. Mold JE, Michaëlsson J, Burt TD, Muench MO, Beckerman KP, **Busch MP**, Lee T-H, Nixon DF, McCune JM. Maternal Alloantigens Promote the Development of Tolerogenic Fetal Regulatory T Cells in utero. Science, 332:1562-1565, 2008. PMCID:PMC2648820

4) Mechanisms of HIV persistence and development, validation and application of novel assays to quantify HIV reservoirs in HIV-suppressed subjects in the context of cure research interventions.

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:

HHSN268201100001I (Principal Investigator) 2011 - 2018
NIH/NHLBI
Recipient Epidemiology and Donor Evaluation Study-III – Central Laboratory
BSRI established and maintains a central laboratory for all REDS specimen testing. Program objectives are to assure safe and effective blood banking and transfusion medicine through basic, translational and clinical research.

OPP1115400 (Principal Investigator) 2014 - 2018
Bill and Melinda Gates Foundation
Validation of Existing and Ultra-Sensitive Assays for Quantifying HIV Persistence
The goals of this project are to deliver high-throughput assays with well characterized performance characteristics that are optimized for all HIV subtypes and which provide robust estimates of the size of the replication competent HIV-1 reservoir.

11388 (Principal Investigator) 2015 – 2016
Foundation of Innovative New Diagnostics (FIND)
HIV Incidence Repository to support Biomarker Discovery

HHSN272201000045C (Co-Investigator) 2010 - 2017
NIH/NIAID
EQAPOL
The goals of this program are to establish and characterize HIV plasma and viral isolate panels from samples collected from diverse geographic regions.

HHSN268201100007I (Co-Investigator) 2011 - 2018
NIH/NHLBI
Recipient Epidemiology and Donor Evaluation Study-III – International Component Brazil
Multicenter consortium of blood centers in four low and middle income countries to perform epidemiologic and clinical research studies on transfusion safety. Studies will focus on infectious, immunologic and hematologic complications of transfusion, and will involve both blood donors and transfusion recipients.

OPP1071295 (Co-Investigator) 2013 - 2016
Gates Foundation/Carlos Slim Foundation
Fighting Infections through Research, Science and Technology (FIRST) Phase 1 and 2: Creating a Partnership to Fight Neglected Infectious Disease in Mesoamerica BSRI's role is to identify biomarkers that allow assessment of response to new therapeutic interventions for Chagas' disease and establish a repository of samples that can be used to validate novel markers discovered by other groups.

R44AI098567 (Co-Investigator) 2014 - 2017
NIH/NIAID
Rapid Test for Recent HIV Infection
Goals are to complete development and validate an innovative rapid test for HIV incidence and complete collection and commercialization of plasma panels for evaluating HIV incidence tests.

R44HL127698 (Co-Investigator) 2015 - 2018
NIH/NHLBI
Babesia Antigen Detection Assay for Blood Screening
Develop, validate and optimize novel diagnostics and antigen-based blood donor screening assays.

11492 (Co-Investigator) 2016 - 2019
amfAR
amfAR Institute for HIV Cure Institute
Goals are to address the four barriers to an HIV cure as described by amfAR in its CURE (Chart, Understand, Record, Eliminate) paradigm: 1) Chart: determine the cellular and tissue locations of persistent reservoirs of HIV; 2) Understand: characterize the mechanisms maintaining HIV persistence despite ART and immune responses; 3) Record: develop assays to measure levels of persistent virus that can be used in the context of clinical trials as well as clinical practice (patient monitoring); and 4) Eliminate: test strategies to safely eliminate or control viral reservoirs.

HHSF223201510149C (Co-Investigator) 2015 – 2019
FDA
Transfusion-Transmissible Infections Monitoring System (TTIMS) Laboratory and Risk Factor Coordinating Center (LRCC)

PENDING:

Pending R01 (Co-Investigator) 2016 - 2021
NIH
Determinants of HIV Persistence on the Central Nervous System

Pending R01 (Co-Investigator) 2016 – 2021
NIH/NIAID
Multiplex Treatment-Outcomes Test for Chagas Disease

COMPLETED RESEARCH STUDIES:

1. N01-HB-97074 (Principal Investigator, UCSF / IMBC sub) 1984 - 1996
   NIH / NHLBI
   Transfusion Safety Study (TSS)

2. P01-36589, Program Project Grant (co-Principal Investigator, IMBC sub) 1986 - 1991
   NIH / NHLBI
   Transfusion-Related Viral Infections and Immune Response

3. 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

4. N01-HB-9-7024 (Principal Investigator, IMBC sub) 1986 - 1993
   NIH / NHLBI
   Effectiveness of HIV-1 Screening

5. 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)

6. U62-CCU-902947 (Principal Investigator, IMBC) 1987 - 1992
   CDC
   Epidemiologic Study of Heterosexual Transmission of HIV from Persons with Transfusion-Associated Infections ("Partner Study").

7. 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.

8. R01-HL-41361 (Co-Investigator, UCSF; Princ. Investigator, IMBC sub) 1988 - 1991
   NIH / NHLBI
   Removal/Inactivation of Viruses in Blood

9. 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);

10. no number assigned (Principal Investigator, IMBC) 1989 - 1990
UCSF AIDS Clinical Research Center
HIV Proviral Load: Prognostic Value and Pathogenic Relevance

11. 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.

12. 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

13. 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

14. 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

15. R01-HL-48367 (Principal Investigator, UCSF / IMBC) 1992 - 1996
NIH / NHLBI
HIV Diversity/Pathogenesis in Donor/Recipient Clusters

16. 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

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 (Principal Investigator, IMBC) 1993 - 1995
Becton Dickinson Immunocytometry Systems, Inc. (BDIS

Retrospective Correlative Studies of Immune Activation and AIDS Progression" (2 studies)

20. 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

21. 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. leukocreduced 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.

22. *number not available* (non-funded Consultant to SFSU researcher) 1995 - 1998
NIH Academic Research Enhancement Award program
Transcriptional Processivity in HIV-1 Latency

23. P50-HL-54476 (Principal Investigator, BCP/BRSI sub-contract) 1996 - 2006
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.

24. R01-HL-062235 (co-Principal Investigator, UCSF; Principal Investigator, BSRI)
NIH / NHLBI 1999 - 2009
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.

25. U01-AI-41531 (Principal Investigator, BCP/BSRI sub-contract) 2002 - 2007
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.

26. R01-HL-076902 (Principal Investigator) 2003 - 2010
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.

27. R01-CI-000214 (PI) 2004 - 2008
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.

28. N01-HB-47174 (co-PI, UCSF; co-PI, BCP sub) 2004 - 2009
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.

29. R01-DA-016159 (PI, BSRI sub) 2004 - 2008
(succeded 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.

30. N01-HB-57181 (co-PI, UCSF; PI, BSRI sub) 2005 - 2011
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.

HHSN268200417175C (PI, BSRI subcontract) 2006 - 2012
NIH / NHLBI
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.

31. HHSN268200417175C (Principal Investigator) 2006 - 2012
NIH / NHLBI
Retrovirus Epidemiology Donor Study, - Part II (REDS-II) - International Component
Compilation of extensive blood donor/donation data/specimens; 4 projects on critical Transfusion Medicine issues in Latin America.

32. R01-HL-088388 (Principal Investigator, BSRI) 2006 - 2011
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.

33. R01-DA-021550 (prime, SUNY; formerly Weill/Cornell) (PI, BSRI sub) 2008 - 2013
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.

34. R01-AI-084109 (KI, UCSF, PI, BSRI sub) 2009 - 2013
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.

35. U19-AI-067854 (Principal Investigator, BSRI) 2009 - 2010
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.

36. RC2-HL-101632 (Principal Investigator) 2009 - 2011
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.

37. RC2HL101632 (PI-Busch) 2009 – 2013
NIH / NHLBI, Viral/Immune Parameters of Dengue and WNV in Donors: Blood Safety Implications"
Characterization of WNV+ and Dengue+ blood donations and establishment of a repository for pathogenesis research.

38. 1R01-AI-090677 (KI, UCSF: PI, BSRI sub) 2010 - 2014
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.

39. R01-AI-087145 (PI, BSRI sub) 2010 - 2011
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).

40. OPP1017716 (Murphy) 2011 – 2014
Bill and Melinda Gates Foundation, Development of specimen repository and evaluation of assays for identification of recent HIV infection and estimation of HIV incidence. The goals of this project are to evaluate and compare currently available assays for use in the measurement of
recent HIV infection using a common set of specimens collected for this purpose and to assess the ability of the assays, alone or in combination, to accurately estimate HIV incidence in populations.
Role: Co-investigator

41. HHSN268201200067C (Levin) 2012 – 2014
NIH/NIAID, Screening and Confirmatory Testing for Human Babesia-SBIR Phase II, Topic 56

This project is aimed at development of an enzyme immunoassay (ELISA) for screening blood for antibodies to Babesia microti.
Role: Co-Investigator

42. OPP1062806 (Pilcher) 2012 – 2015
The Bill and Melinda Gates Foundation
HIV Incidence Testing using Multiple Biological Specimens (CEPHIA II)
BSRI will receive and assemble specimen sets collected under the CEPHIA-II project, distributing to collaborating researchers, and maintaining the specimens in storage. Additionally, BSRI will assist as required in assay evaluations or in characterization of CEPHIA II specimens on existing laboratory testing as determined by the CEPHIA leadership.

43. 200-2014 M-59495 (Busch) 2014 – 2015
CDC
Chikungunya Seroprevalence Study in Puerto Rico Following a 2014 Outbreak
The purpose of this project is to conduct a Chikungunya seroprevalence study using blood donor samples collected from Puerto Rico.

For publications, please see separate file.