HIV Cure News

UCSF Awarded $20 Million to Research HIV Cure

On World AIDS Day, amfAR, The Foundation for AIDS Research, announced an award of $20 million to University of California San Francisco (UCSF) researchers and collaborating partners for the newly established amfAR Institute for HIV Cure Research.

The goal of the Institute will be to build the “scientific foundation” for an HIV cure by the year 2020, said Kevin Frost, CEO of amfAR, at an HIV cure symposium held at UCSF on December 1. The team will be led by principal investigator Paul Volberding, MD, a renowned AIDS treatment specialist who helped found Ward 86 at San Francisco General Hospital in the early days of the epidemic.

The Institute is organized around four smaller teams that will each address one of the primary challenges to curing HIV, explained Rowena Johnston, PhD, the chief scientist at amfAR. Successful antiretroviral therapy lowers the level of HIV in a person’s body to undetectable levels, yet doesn’t eliminate HIV from the body because HIV persists in an inactive—latent—state in “reservoirs” throughout the body.

“We need to understand: Where are these reservoirs? We need to understand how do those reservoirs come to be there, and how do they persist? We need to know how much of that virus is there. And obviously, ultimately, we want to be able to eliminate those reservoirs. And that’s what this institute is going to do,” said Johnston. Read more about the HIV cure research that will be conducted at UCSF on BETA at: http://bit.ly/10AqAdE

Clinical Research Opportunities

Studies are listed with brief descriptions only. Additional inclusion and exclusion criteria may apply. For more information, please contact the study site directly.

Bridge HIV
San Francisco Department of Public Health
25 Van Ness, Suite 100
San Francisco, CA 94102

• Pre-Exposure Prophylaxis (PrEP) study for women: Study testing a vaginal ring containing 2 different HIV meds. Vaginal rings that slowly release HIV meds could be an effective alternative to oral PrEP or vaginal gels. Participants wear the vaginal ring for 28 days with 13 visits over 5 weeks. Must be female, HIV negative, ages 18–45. Compensation up to $250/visit. Visit www.joinprep.org or call 415-437-7485.

• Pre-exposure prophylaxis (PrEP) study: Study testing the safety of a pill and a long-acting injectable (a shot). Must be HIV negative, healthy and age 18–50. May be male, female, or transgender. Compensation is $50–$75/visit. Visit www.sfsready.org or call 415-437-7485.

• HIV vaccine study: Study evaluating the safety and dosage of HIV vaccines. Must be HIV negative, healthy and age 18–50. May be male, female, or transgender. Compensation is $50–$75/visit. Visit www.sfsready.org or call 415-437-7485. You cannot get HIV from the study vaccine.

• Bridge HIV is seeking participants for interviews and focus groups to help develop a new sexual health mobile app. Study visits will take place in Oakland and San Francisco and will last 1.5 - 2 hours. You may be eligible if you’re Black, male-identified, ages 18-29 and have sex with men. Compensation is up to $50 per visit. Call or text us at 415-385-3973 or visit HelpFightHIV.org to enroll. All information is kept strictly confidential.

ABBREVIATIONS

| NS | New study, or changes to an existing study |
| ARV | Antiretroviral |
| > | Greater than |
| < | Less than |
| VL | Viral Load |
| PI | Protease Inhibitor |
| INI | Integrase Inhibitor |
| NRTI | Nucleoside/Nucleotide Analog |
| NNRTI | Non-nucleoside Analog |

Get involved, make a difference with Bridgemen

Bridgemen is for gay, bi and trans guys who are looking to give back to the San Francisco community. The group organizes service projects and social events such as Ocean Beach clean-ups, Habitat for Humanity projects, meal service at Glide Memorial, outings to local art openings, and more!

The group’s goal is to have fun, build friendships and make San Francisco a safe and happy place for everyone. Want to get involved? Meet the Bridgemen every third Wednesday of the month for fun, free food and camaraderie at Lookout in the Castro (3600 16th Street). Find out about other upcoming events at bridgemen.org.
MK-1439A-024. Study to evaluate a switch to MK-1439A in HIV+ people virologically suppressed on a ritonavir-boosted PI and two NRTIs. $75/visit.

• GS-US-380-1489: A phase 3, randomized, double-blind study to evaluate the safety and efficacy of GS-9883/emtricitabine/tenofovir alafenamide versus abacavir/dolutegravir/lamivudine in HIV-1 infected, antiretroviral treatment-naïve adults. $75/visit. NS

• GS-US-380-1490: A phase 3, randomized, double-blind study to evaluate the safety and efficacy of GS-9883/emtricitabine/tenofovir alafenamide versus dolutegravir+emtricitabine/tenofovir alafenamide in HIV-1 infected, antiretroviral treatment-naïve adults. $75/visit. NS

Kaiser Permanente, San Leandro
2500 Merced Street, Suite 206
San Leandro, CA 94577
510-454-2703; kenneette.yoshimura@kp.org or korenna.sinn@kp.org.

• MK-1439A-024: Evaluates switch from ritonavir-boosted PI and two NRTIs to MK-1439A in virologically suppressed HIV+ people. Study will last at least 55 wks with 9 visits. $75/visit.

• GS-US-380-1489: Evaluates a fixed dose containing GS-9883/FTC/TAF versus abacavir/dolutegravir/lamivudine in HIV+ adults who have not been treated with ARVs. $75/visit. NS

• GS-US-380-1490: Evaluates a fixed dose containing GS-9883/FTC/TAF versus dolutegravir plus a fixed-dose of FTC/TAF in HIV+ adults who have not been treated with ARVs. $75/visit. NS

• GS-US-380-1484: Evaluates a switch from a regimen of dolutegravir and ABC/3TC or a fixed-dose of abacavir/dolutegravir/lamivudine to GS-9883/FTC/TAF versus continuing dolutegravir and abacavir/lamivudine as abacavir/dolutegravir/lamivudine in HIV+ adults who are virologically suppressed. $75/visit. NS

• GS-US-380-1878: Evaluates a switch to a fixed-dose of GS-9883/FTC/TAF versus a regimen of boosted atazanavir or darunavir plus either FTC/TDF or abacavir/lamivudine in HIV+ adults who are virologically suppressed. $75/visit. NS

• Contact kenneette.yoshimura@kp.org or korenna.sinn@kp.org at 510-454-2703.

Kaiser Clinical Trials Unit
4141 Geary Boulevard, Suite 219
San Francisco, CA 94118
Miki.mettinger@kp.org, 415-833-3223

• MK-1439-024. Study to evaluate a switch to MK-1439A in HIV+ people virologically suppressed on a ritonavir-boosted PI and two NRTIs. $75/visit.

• GS-US-380-1489: A phase 3, randomized, double-blind study to evaluate the safety and efficacy of GS-9883/emtricitabine/tenofovir alafenamide versus abacavir/dolutegravir/lamivudine in HIV-1 infected, antiretroviral treatment-naïve adults. $75/visit. NS

• GS-US-380-1490: A phase 3, randomized, double-blind study to evaluate the safety and efficacy of GS-9883/emtricitabine/tenofovir alafenamide versus dolutegravir + emtricitabine/tenofovir alafenamide in HIV-1 infected, antiretroviral treatment-naïve adults. $75/visit. NS

East Bay AIDS Center (EBAC)
3100 Summit Street, 2nd Floor
Oakland, CA 94609
www.altabates.com/clinical/aids_scvs.html
510-863-0021

• Connecting Resources for Urban Sexual Health (CRUSH): For people age 18-29 to review (and treat) sexual health needs. Provides either PEP or PrEP to HIV-negative participants if they need it. For HIV+ or HIV-negative men who have sex with men, trans men or women, or with a known HIV+ partner. A small stipend for completing a questionnaire four times and STD testing and treatment provided.

• GS-US-380-1489: A phase 3, randomized, double-blind study to evaluate the safety and efficacy of GS-9883/emtricitabine/tenofovir alafenamide versus abacavir/dolutegravir/lamivudine in HIV-1 infected, antiretroviral treatment-naïve adults. NS

• GS-US-380-1490: A phase 3, randomized, double-blind study to evaluate the safety and efficacy of GS-9883/emtricitabine/tenofovir alafenamide versus dolutegravir + emtricitabine/tenofovir alafenamide in HIV-1 infected, antiretroviral treatment-naïve adults. NS

Optimus Medical Group
870 Market Street, Suite 600
San Francisco, CA 94102
Shannon (415-423-4055), Scott (415-518-1292), or 415-397-0700

• GS-US-1490: New Gilead phase 3 treatment study comparing current tenofovir versus reformulated tenofovir, no placebo. For HIV-infected, treatment naive adults over 18 who have received either no treatment or 10 days or less of ART. Study is 92 weeks with automatic extension.

Studies provide free blood work-up, study drugs, and compensation between $500-$750.

• Herpes Zoster: Patients having a episode of shingles will be randomized to either standard of care with valacyclovir 3x/day for 10 days or an investigational drug given once or twice only. Follow up for complications of shingles for 52 weeks. NS

• Sword: Switch study to a “nuc-sparing” regimen, containing Tivicay® and Edurant®, once a day. People with HIV qualify, if they are on their first or second HIV treatment and have an undetectable viral load. Compensation is $75 per study visit, this study will be ongoing for three years and provide HIV medications.

• TMC114FD3013: Switch study for people with HIV and undetectable viral load on a boosted protease inhibitor regimen (i.e.Prevista®/Norvir® or Reyataz®/Norvir®) and Truvada®. People will be randomized to either switch to an investigational one-tablet-a-day regimen containing darunavir, cobicistat, emtricitabine and tenofovir alafenamide (TAF) or go on darunavir/cobicistat and Truvada. Compensation is $75 per study visit.

• TMC114FD3013: People with HIV, but never been treated (“treatment-naïve”) and detectable viral load will start with an HIV regimen of Reyataz®/Norvir®, and Truvada® or an investigational one-tablet-a-day regimen containing darunavir, cobicistat, emtricitabine and tenofovir alafenamide (TAF). Compensation is $75 per study visit.

• Striving: A switch study for people with undetectable viral load to Triumeq® (one tablet containing dolutegravir/abacavir/lamivudine). Participants need to be on their first or second HIV regimen in order to qualify. 48 week study. Compensation is $75 per study visit.
until drug is FDA approved. $50 per visit, up to $50 for travel. Free labs, treatment and medical care from a leading private practice HIV doctor. NS

- A5332: Study to see if pitavastatin can prevent heart disease and related deaths. Participants must be HIV+, 40 - 75 years old, on ARVs for at least 6 months, CD4 >100, no history of cardiovascular disease, and not currently using a statin drug. Free labs, treatment and medical care from a leading private practice HIV doctor. NS

- City of Hope: A pilot study to evaluate the feasibility, safety and engrafment of Zinc Finger Nucleases (ZFN) CCR5 modified CD34+ stem cells in HIV+ subjects with CD4 between 200 and 500.

- MK-1439: A phase 3 study for people who have never used ART before, testing MK-1439 versus ritonavir-boosted darunavir, in combination with a backbone therapy of Truvada or Epzicom. 2 yrs, 14 visits. $50/visit for a total of $650.

- A study of suppression of HIV following substitution of ARVs with a monoclonal CCR5 antibody for 12 weeks. Participants must have never had a CD4 <200. Must have a current HIV viral load <100 copies/ml and CD4 >350. $2,000 for the entire study.

- M14-004: A phase 2/3 study for the treatment of genotype 1 hep C in patients also with HIV. Treated with three antiviral agents (DAAs), ABT-450/r/ABT-267 + ABT-333, plus ribavirin for either 12 or 24 weeks; no placebo. $50 per visit.

- HIV gene therapy study of modified stem cells. Must be HIV+ and age 18–65, with a history of ART and a CD4 count >600. Sponsored by Calimmune, Inc.

- “Zinc finger nuclease” (ZFN) study: CD4 cells are extracted from participants’ blood and genetically modified by ZFNs to resist HIV infection. More modified cells are then made and re-infused back into participants.

- Study of the safety and immunogenicity of MVA-BN smallpox vaccine when increasing the number of injections compared to the standard regimen in immunocompromised people with HIV.

- Lipid-lowering drug study for people with high LDL levels who are HIV+ and > 40 years. CD4 counts must be ≥350, LDL levels ≥70 with a cardiovascular risk factor. Pays up to $1,100 for the entire study. Ten visits over a span of 58 weeks total. Contact Cooper at 415-353-0800 or cooper@questclinical.com.

- Stanford Clinical Trials Unit

  1000 Welch Road, Suite 202
  Palo Alto, CA 94304
  650-723-2804
  http://actu.stanford.edu

  Compensation is provided for travel and meals for most studies.

- A5332: The main purpose of this clinical trial is to see if pitavastatin can prevent heart disease and heart disease-related deaths in people with HIV infection who are taking HIV medications. Participants must be HIV infected, between the ages of 40 and 75 years, on ARVs for at least 6 months, CD4>100, no history of cardiovascular disease, and not currently using a statin drug. NS

- Anal cancer rates are rising among people living with HIV. The ANCHOR study’s goal is to find the best way to prevent anal cancer among HIV+ men and women ≥ 35 years old. Study visits are every 6 months for at least 5 years. Participants are compensated $100 per visit. For more info go to anchorstudy.org or call 415-353-7443.

- UCSD School of Nursing

  Austin Nation, austin90621@gmail.com, 714-401-6913

  - Study to understand substance use, sexual risk and HIV risk for young black men. Please share your unique story during an interview lasting no longer than 2 hours. For young black men ages 13 - 29 who have had sex with another man and have used drugs and/ or alcohol. Volunteers receive a $20 gift card for each interview. All personal information kept strictly confidential.

- UCSD/San Francisco General Hospital

  1001 Potrero Ave, Building 5, Rom SG1
  San Francisco, CA 94110
  danny.lii@ucsf.edu / bernard.weigel@ucsf.edu
  415-206-5801 and 415-206-5461

  - Clinical trial to see the impact of canakinumab on inflammation reduction and improvement in heart health in people ≥40 with HIV. This medication has been used safely in people with inflammatory diseases for 4 years in the U.S. Seeking HIV+ men & women with undetectable viral load, CD4 >400, and documented cardiovascular disease or at least one risk factor. Study is 9 months with 12 visits. $25 - $100 per study procedure.

  - B-HIVE Study: clinical trial to evaluate the impact of bococizumab on cholesterol-lowering in people ≥40 with HIV. Bococizumab is part of the new class of lipid-lowering drugs known as PCSK9 inhibitors, which have been well-tolerated and shown to drastically lower LDL-C in the non-HIV population. Seeking HIV+ men & women with undetectable viral load, CD4 >50, and documented cardiovascular disease or at least one risk factor. Study is 58 weeks with 10 visits and involves bi-weekly self-injections of study drug. $1250 total reimbursement. NS
• HIV
• A5327: Acute HCV treatment study in Coinfected and monoinfected HCV
• A5337: Evaluation of sirolimus to reduce HIV persistence in the body. Multiple visits to measure HIV viral reservoirs; may include blood draws, leukapheresis, and tissue biopsies. Enrolling newly infected and/or treatment-naive ART suppressed >1 years. Compensation provided. Call 415-476-4082, x139, x144; email Rebecca.Hoh@ucsf.edu or Marian.Kerbleski@ucsf.edu.

• DARE: A study to identify how & where HIV persists in the body. Multiple visits to measure HIV viral reservoirs; may include blood draws, leukapheresis, and tissue biopsies. Enrolling newly infected and/or treatment-naive or continually ART suppressed >10 years. Compensation provided. Call 415-476-4082, x139, x144; email Rebecca.Hoh@ucsf.edu or Marian.Kerbleski@ucsf.edu.

• Fecal Microbial Transplantation: To determine if the transfer of intestinal microbial communities is safe & can improve immune function and reduce inflammation in HIV+ patients on ART. Must have CD4 count >200, undetectable VL. Compensation provided. Montha Pao at 415-476-4082 x140 or montha.pao@ucsf.edu.

• RADL: To assess ARV levels in lymphoid tissues by drug regimen and if ARV drug levels are associated with amount of HIV in the body. 2-3 visits with questionnaires, blood draws, flexible sigmoidoscopy or colonoscopy procedure and optional lymph node biopsy procedure. Must be on first & only ARV regimen of Truvada OR Epzicom plus Isentress OR Reyataz and Norvir OR Prezista and Norvir. On ART for >1 year with undetectable VL. Compensation provided. Call 415-476-4082 x139; Rebecca.Hoh@ucsf.edu or rebecca.hoh@ucsf.edu.

• SCOPE Study: Study recruiting: (1) elite controllers (HIV+ with VL <200 copies/mL & not taking ARVs), (2) individuals with no prior ART, (3) long-term non-progressors (HIV+ for >10 years with a CD4 count >500 cells/mm3 with no ARVs), and (4) HIV-negative controls. Study involves interviews & blood draws every 2–4 mos. Compensation provided. Call 415-476-4082 x139 or x144, Rebecca.Hoh@ucsf.edu or Marian.Kerbleski@ucsf.edu.

• Observational SCOPE study assessing immune response to flu vaccine. 3 visits for blood draw and questionnaire. Can either be 1) HIV+, age 40-65 years with documented undetectable VL & >3 years on continuous ART or 2) HIV-negative, age 40-80. Flu vaccine not provided. Compensation provided. Call 415-476-4082 x330 or x139, Mollie.Hudson@ucsf.edu or Rebecca.Hoh@ucsf.edu.

• A5332 “REPREVIE” Study: Study to see if pitavastatin can prevent heart disease and related deaths. Participants must be HIV+, 40-75 years, on ARVs for at least 6 months, CD4 >100, no history of cardiovascular disease, and not currently using a statin drug.

• A5314: Study to evaluate the effect of low dose methotrexate on markers of cardiovascular disease and inflammation. Participants must be >40 years on ART, HIV undetectable at baseline, CD4 >400, with cardiovascular disease risk.

• A5325: Study to evaluate Isotretinoin on immune activation. Participants must be HIV+, on ART therapy for >2 years, HIV undetectable, CD4 <350, no active hepatitis B or C infection.

• A5315: Safety and tolerability study of Romidepsin for people taking ARVs with an undetectable viral load. Participants must be taking ART that includes raltegravir, dolutegravir, or efavirenz-based regimen, viral load <50 for past 12 months, CD4 >300, men and non-pregnant women >18 years.

• A5337: Evaluation of sirolimus to reduce inflammation and the HIV latent reservoir. HIV+ people, with CD4 >400 & HIV 75 or less for at least 24 months, will receive 20 weeks of open label, oral sirolimus, an inhibitor of T cell activation that has been used as an antirejection drug in organ transplantation. Cannot be on an ART regimen containing an HIV protease inhibitor or cobicistat. Active hepatitis C or B prohibited.

• A5327: Acute HCV treatment study in Coinfected and monoinfected HCV genotype-1 & genotype-3 patients who have failed prior sofosbuvir and/or NS5a-based therapy, contact our site for details.

• Hepatitis B observational study recruiting HIV/HBV coinfected patients for an observational longitudinal study of natural history of HBV/HIV coinfection. Must be willing to undergo a one-time liver biopsy at baseline (provided by the study if not indicated as part of patient care).

• Multiple other HIV studies and hep C treatment studies available, including interferon-sparing regimens enrolling hep C monoinfected and HIV/HCV coinfected and HCV. Call 415-476-4082 x358 to see what is currently available and if you may qualify.

• A5346: Januvia (Sitagliptin) to reduce inflammation and immune activation in HIV infection: This phase II, randomized double blinded placebo controlled trial will enroll HIV+ individuals with CD4 cell counts of >100 and on ART >48 weeks, and randomize to 16 weeks of Januvia vs placebo.

• A5353: Dolutegravir/lamivudine for HIV treatment naive patients (ACTG 5353). Single arm open label, non-randomized Phase II study of dolutegravir/lamivudine for treatment naive HIV infected patients with resistance genotyping without evidence of major NRTI, PR, or integrase mutations. Active hepatitis B or C are exclusionary.

• A5329: All oral, interferon-free triple therapy with Viekira Pak for HIV/HCV coinfected patients with hep C genotype 1. Will enroll both treatment naive and experienced (including prior sofosbuvir failures). Liver biopsy not required. ART permitted includes darunavir/r, atazanavir/r, dolutegravir, raltegravir, with tenofovir, abacavir, 3TC/FTC.

• Coinfected and monoinfected HCV genotype-1 & genotype-3 patients who have failed prior sofosbuvir and/or NS5a-based therapy, contact our site for details.

• Hepatitis B observational study recruiting HIV/HBV coinfected patients for an observational longitudinal study of natural history of HBV/HIV coinfection. Must be willing to undergo a one-time liver biopsy at baseline (provided by the study if not indicated as part of patient care).

UCSF Memory and Aging Center HIV Research Group
675 Nelson Rising Lane
San Francisco, CA 94158
415-476-1688
HIVOver60@memory.ucsf.edu

• UCSF HIV Elders Study: A study examining Mindfulness Based Stress Reduction (MBSR) to alleviate symptoms of attention, executive functioning, stress, and anxiety in people > age 60 with HIV. Study includes an 8-week MBSR course, cognitive testing, blood draw, and MRI; follow-up for 1 year. Must demonstrate mild-moderate cognitive impairment & controlled viral load. Other criteria apply. Compensation is $15-$50 per study visit. Visit our website at www.hivelders.weebly.com.