

FLORIDA CONSORTIUM FOR HIV/AIDS RESEARCH (FCHAR)
INVENTORY OF HIV/AIDS RESEARCH IN FLORIDA

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**FLORIDA CONSORTIUM FOR HIV/AIDS RESEARCH (FCHAR)
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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
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Clinical Trials

Community AIDS Resource, Inc. (Care Resource)
3510 Biscayne Boulevard, Suite 300
Miami, FL 33137

<p>MEDICATION TRIALS: Treatment Naïve – No PAST USE OF ANTIRETROVIRAL THERAPY</p>	<p><i>ViiV HealthCare/Pfizer - A4001095: A multicenter, randomized, double-blind, comparative trial of Maraviroc+Darunavir /Ritonavir versus Emtricitabine/Tenofovir + Darunavir /Ritonavir for the treatment of antiretroviral-naïve HIV infected patients with CCR5 Tropic HIV-1</i></p>	<p>PI: Steven Santiago, M.D Contacts for further information: Leandro Pisani 305/576-1234 ext 276 lpisani@careresource.org or Milagros Rodriguez 305/576-1234 ext 244 mrodriguez@careresource.org</p>	<p>Recruitment Begins 9/15/2011</p>	<p>MEDICATION TRIALS: Treatment Naïve – No PAST USE OF ANTIRETROVIRAL THERAPY ELIGIBILITY : Men and women ≥ 18 yrs of age who have never taken antiretroviral drugs and have a viral load > 1000 copies/ml and CD4 > 100 cells/mm3</p>
<p>MEDICATION TRIALS: Treatment Naïve – No PAST USE OF ANTIRETROVIRAL THERAPY</p>	<p><i>Tobira Therapeutics -652-2-202: A phase 2b, multicenter, double blind comparative study to evaluate the efficacy, safety and tolerability of Cenicriviroc in HIV-1 infected, antiretroviral treatment-naïve patients with only CCR5-tropic virus. Participants will receive either once-daily 100 mg or 200 mg doses of Cenicriviroc in combination with Truvada or once-daily Sustiva plus Truvada.</i></p>	<p>PI: Steven Santiago, M.D Contacts for further information: Leandro Pisani 305/576-1234 ext 276 lpisani@careresource.org or Milagros Rodriguez 305/576-1234 ext 244 mrodriguez@careresource.org</p>	<p>Recruitment Begins 8/20/2011</p>	<p>MEDICATION TRIALS: Treatment Naïve – No PAST USE OF ANTIRETROVIRAL THERAPY Eligibility: Men and women > 18 years of age with CCR5-tropic virus by GT and Trofile-ES who have never taken antiretroviral drugs; viral load > 5,000 copies/ml and CD4 > 250 cells/mm3</p>

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<p>MEDICATION TRIALS: Treatment Naïve – No PAST USE OF ANTIRETROVIRAL THERAPY</p>	<p><i>Viiv HealthCare/ Pfizer - A4001098: A multi-center, randomized, blinded, placebo-controlled study to evaluate the safety of Maraviroc in combination with other antiretroviral agents in HIV-1-infected subjects co-infected with Hepatitis C and/or Hepatitis B virus.</i></p>	<p>PI: Luis Saenz D.O</p> <p>Contacts for further information: Leandro Pisani 305/576-1234 ext 276 lpisani@careresource.org or Milagros Rodriguez 305/576-1234 ext 244 mrodriguez@careresource.org</p>	<p>Enrollment Open</p>	<p>MEDICATION TRIALS: Treatment Naïve – No PAST USE OF ANTIRETROVIRAL THERAPY</p> <p>Eligibility: ≥ 18 yrs of age co-infected with Hepatitis C or B and not receiving treatment. for Hepatitis B or C. Undetectable viral load for at least 3 months. No prior treatment with Maraviroc or another CCR5</p>
<p>MEDICATION TRIALS: Treatment Naïve – No PAST USE OF ANTIRETROVIRAL THERAPY</p>	<p><i>EPZ113734 - A Prospective, Randomized, Multicenter, Open-Label Study to Compare the Efficacy and Safety of Simplifying from a Regimen of Atazanavir + Ritonavir + Tenofovir/Emtricitabine to Atazanavir + Abacavir/Lamivudine Without Ritonavir for 48</i></p>	<p>PI: Steven Santiago, M.D. Luis Saenz D.O.</p> <p>Contacts for further information: Milagros Rodriguez 305/576-1234 ext 244 mrodriguez@careresource.org</p>		<p>MEDICATION TRIALS: Treatment Naïve – No PAST USE OF ANTIRETROVIRAL THERAPY</p>
<p>MEDICATION TRIALS: Treatment experienced (history of Current or Past Use of Antiretroviral Therapy)</p>	<p>GlaxoSmithKline -EPZ113734: <i>A prospective, randomized, multicenter, open-label study to compare the efficacy and safety of simplifying from a regimen of Atazanavir + Ritonavir/Tenofovir/ Emtricitabine to Atazanavir + Abacavir/ Lamivudine without Ritonovir for 48 weeks in virologically suppressed, HIV-</i></p>	<p>PI: Steven Santiago, M.D.</p> <p>Contacts for further information: Leandro Pisani 305/576-1234 ext 276 lpisani@careresource.org or Milagros Rodriguez 305/576-1234 ext 244 mrodriguez@careresource</p>	<p>Enrollment Open</p>	<p>MEDICATION TRIALS: Treatment experienced (history of Current or Past Use of Antiretroviral Therapy)</p> <p>Eligibility: 18 yrs of age who have been undetectable for more than 3 months and receiving a regimen of ATV/RTV (300mg/100 mg) +TDF/FTC (300mg/200 mg) as initial or first and only switch regimen for at least 6 months.</p>

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	<i>infected HLA-B 5701 negative subjects</i>	<i>.org</i>		
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UNIVERSITY OF CENTRAL FLORIDA Presenter: Alexander M. Cole, Ph.D.				
CLINICAL TRIAL	<i>Contract with HIV Vaccine Trials Network (HVTN) and Fred Hutchinson Cancer Research Center to process specimens for study# HVTN505</i>	Alexander M. Cole, Ph.D. (PI of lab contract); Edwin DeJesus, M.D. (PI of clinical contract)	Microbiology and Molecular Biology	cGLP laboratory processing for clinical trial
NOVA SOUTHEASTERN UNIVERSITY –6 Studies Presenter: Isa Fernandez, Ph.D.				
CLINICAL TRIAL	<i>Young Hispanic Men – Entre Culturas: Navigating Culture, Identity and HIV Risk</i>	Maria Isabel Fernandez, Ph.D. G. Stephen Bowen, M.D.	College of Osteopathic Medicine	HIV prevention among young Hispanic/Latino MSM
CLINICAL TRIAL	<i>Project POWER: A Health Promotion and HIV Risk Reduction Intervention for Black Men.</i>	Maria Isabel Fernandez, Ph.D	College of Osteopathic Medicine	HIV prevention among black men who have sex with men and women
CLINICAL TRIAL	<i>Adolescent Trials Network for HIV interventions</i>	Maria Isabel Fernandez, Ph.D. G.	College of Osteopathic Medicine	HIV and adolescents (both infected and at risk for HIV)
CLINICAL TRIAL	<i>Risk Reduction for Urban Substance Using MSM</i>	Steven P. Kurtz, Ron Stall, Hilary L. Surratt	Division of Applied Interdisciplinary Studies	HIV, MSM, drug use National Institute on Drug Abuse Grant # DA024579
CLINICAL TRIAL	<i>A Self-Assessment Intervention for Young Adult Polydrug Users at Risk for HIV</i>	Steven P. Kurtz, Hilary L. Surratt	Division of Applied Interdisciplinary Studies	HIV, young adults, drug use National Institute on Drug Abuse Grant # DA019048
CLINICAL TRIAL	<i>Case Management Alternatives for African American Women at High Risk for HIV</i>	Hilary L. Surratt, Gladys Ibanez	Division of Applied Interdisciplinary Studies	HIV, women, drug use National Institute on Drug Abuse Grant # DA013131

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University of Miami Department of Medicine, Division of Infectious Diseases
Jackson Medical Towers, 8th Floor East
1500 NW 12th Avenue
Miami, FL 33136

MEDICATION TRIALS: Treatment Naïve – No PAST USE OF ANTIRETROVIRAL THERAPY	<i>ViiV HealthCare/Pfizer - A4001095–1019: A multicenter, randomized, double-blind trial comparing Maraviroc + Darunavir/ Ritonavir vs. Emtricitabine/Tenofovir + Darunavir/Ritonavir for the treatment of antiretroviral naïve HIV-infected patients with CCR5-tropic HIV-1</i>	P.I.: Dushyantha Jayaweera, M.D. Contact for further information: Tom Tanner, R.N. 305/243-5621 TTanner@med.miami.edu	Waiting for IRB approval	MEDICATION TRIALS: Treatment Naïve – No PAST USE OF ANTIRETROVIRAL THERAPY Eligibility: Men and women > 18 years of age with CCR5-tropic HIV-1 who have never taken antiretroviral drugs and have a viral load > 1,000 copies/ml and CD4 > 100 cells/mm3
MEDICATION TRIALS: Treatment Naïve – No PAST USE OF ANTIRETROVIRAL THERAPY	<i>Tobira Therapeutics -652: A phase IIb, multicenter, double blind comparative study to evaluate the efficacy, safety and tolerability of Cenicriviroc in HIV-1 infected, antiretroviral treatment naïve patients with only CCR5-tropic virus. Participants will receive either once-daily 100 mg or 200 mg doses of Cenicriviroc in combination with Truvada or once-daily Sustiva plus Truvada</i>	P.I.: Dushyantha Jayaweera, M.D. Contact for further information: Tom Tanner, R.N. 305/243-5621 TTanner@med.miami.edu	Begins 9/1/2011	MEDICATION TRIALS: Treatment Naïve – No PAST USE OF ANTIRETROVIRAL THERAPY Eligibility: Men and women > 18 years of age with CCR5 tropic virus who have never taken antiretroviral drugs; BMI < 35 kg/m2, viral load > 5,000 copies/ml and CD4 > 250 cells/mm3
MEDICATION TRIALS: Treatment Naïve – No PAST USE OF ANTIRETROVIRAL THERAPY	<i>University of Minnesota/Insight: Strategic Timing of Anti-Retroviral Treatment (START): A</i>	P.I.: Michael Kolber, M.D. Contact for further information:	Begins 9/15/2011	MEDICATION TRIALS: Treatment Naïve – No PAST USE OF ANTIRETROVIRAL THERAPY

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
	<i>multicenter study of the International Network for Strategic Initiatives in Global HIV Trials (INSIGHT)</i>	Tom Tanner, R.N. 305/243-5621 TTanner@med.miami.edu		Eligibility: Healthy HIV infected men and women > 18 years of age who have never taken antiretroviral drugs or interleukin-2 and have CD4 > 500 cells/mm ³
MEDICATION TRIALS: Treatment experienced (history of Current or Past Use of Antiretroviral Therapy)	Merck and Co. 35835: <i>A prospective, open-label, single-center pilot study to evaluate the addition of Raltegravir to established suppressive antiretroviral therapy while monitoring changes in markers of immune activation among HIV-1 infected individuals without adequate immune restoration.</i>	P.I.: Rafael Campo, M.D. Contact for further information: Tom Tanner, R.N. 305/243-5621 TTanner@med.miami.edu	Enrollment open	MEDICATION TRIALS: Treatment experienced (history of Current or Past Use of Antiretroviral Therapy) Eligibility: Men and women > 18 years of age with HIV-1. CD4 count < 350 cells/mm ³ at time of enrollment
MEDICATION TRIALS: Treatment experienced (history of Current or Past Use of Antiretroviral Therapy)	Viiv HealthCare/Pfizer - A4001098-1021: <i>A multicenter, randomized, blinded, placebo-controlled study to evaluate the safety of Maraviroc in combination with other antiretroviral agents in HIV-1 infected subjects co-infected with Hepatitis C and/or Hepatitis B virus.</i>	P.I.: Dushyantha Jayaweera, M.D. Contact for further information: Tom Tanner, R.N. 305/243-5621 TTanner@med.miami.edu	Begins 9/15/2011	MEDICATION TRIALS: Treatment experienced (history of Current or Past Use of Antiretroviral Therapy) Eligibility: Men and women > 18 years of age who are available for 148 weeks. Undetectable viral load, detectable HCV RNA and/or Hepatitis B positive. Treatment with antiretroviral therapy excluding Ritonavir.
MEDICATION TRIALS: Treatment experienced (history of Current or Past Use of Antiretroviral Therapy)	University of Miami Developmental Center for AIDS Research: <i>Recovery of latent reservoirs after treatment for lymphoma in HIV infected patients (Pilot Study).</i>	P.I.s: Luis Espinoza, M.D./Michael Kolber, M.D. Contact for further information: Tom Tanner, R.N. 305/243-5621 TTanner@med.miami.edu	Enrollment Open	MEDICATION TRIALS: Treatment experienced (history of Current or Past Use of Antiretroviral Therapy) Eligibility: Men and women > 18 years of age. HIV+ lymphoma. On highly active antiretroviral therapy. Non- detectable viral load <50.

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<p>MEDICATION TRIALS: Treatment experienced (history of Current or Past Use of Antiretroviral Therapy)</p>	<p><i>Vitamin Study – Double-Blind, randomized, placebo controlled study of Livethesource® daily multi-vitamin (MVI) compared with standard MVI in patients infected with HIV-1</i></p>	<p>P.I.: Dushyantha Jayaweera, MD</p> <p>Contact for further information: Tom Tanner, R.N. 305/243-5621 TTanner@med.miami.edu</p>	<p>Waiting UM IRB approval</p>	<p>MEDICATION TRIALS: Treatment experienced (history of Current or Past Use of Antiretroviral Therapy)</p> <p>Eligibility: HIV-1 infected men and women > 18 yrs of age. On stable highly active antiretroviral therapy. CD4 <500 cells/mm³</p>
<p>University of Miami Department of Pediatrics, Division of Infectious Diseases and Immunology Batchelor Children’s Institute, 1580 NW 10 Avenue Suite 287 Miami, Fl 33136</p>				
<p>CLINICAL TRIAL</p>	<p><i>International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) – PROMISE Study: The study will determine if women who receive highly active antiretroviral therapy (HAART) during pregnancy and continue their regimen after delivery will have less morbidity and mortality than those who only receive HAART during pregnancy and stop after delivery. The study also will evaluate the likelihood of developing resistance to HIV meds in women who stop compared with those who continue HAART after delivery. The study will supply antiretroviral medications.</i></p>	<p>P.I.: Gwendolyn Scott, M.D.</p> <p>Contact for further information: Patricia Bryan, R.N. 305/243-4447 PBryan@med.miami.edu</p>	<p>Enrollment open</p>	<p>MEDICATION TRIALS:</p> <p>Eligibility: Pregnant women who have only taken antiretroviral therapy in pregnancy and have CD4 cells of 400 or higher.</p>

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
University of Miami AIDS HIV Women’s Program (Dept. Obstetrics and Gynecology) Clinical Research Building 1120 NW 14th Street, 7th Floor Miami, FL 33136				
MEDICATION TRIALS: Treatment Naïve – No PAST USE OF ANTIRETROVIRAL THERAPY	<i>Tibotec. A single arm open label study to assess the pharmacokinetics of Rilpivirine in HIV-1 pregnant women.</i>	P.I.: Salih Yasin, M.D. Contact for further information: Yvette Rivero 305/243-2169 YRivero@med.miami.edu	Enrollment open	MEDICATION TRIALS: Treatment Naïve – No PAST USE OF ANTIRETROVIRAL THERAPY Eligibility: Women ≥ 18 years of age who have never taken antiretroviral drugs and are between 18-24 weeks pregnant.
MEDICATION TRIALS: Treatment experienced (history of Current or Past Use of Antiretroviral Therapy)	<i>Tibotec. A single arm open label study to assess the pharmacokinetics of Darunavir/Ritonavir and/or Etravirine in HIV-1 pregnant women</i>	P.I.: Salih Yasin, M.D. Contact for further information: Yvette Rivero 305/243-2169 YRivero@med.miami.edu	Enrollment open	MEDICATION TRIALS: Treatment experienced (history of Current or Past Use of Antiretroviral Therapy) Eligibility: Women ≥ 18 years of age, with a history of taking antiretroviral drugs, who are between 18-24 weeks pregnant.
Wohlfeiler, Piperato & Associates, LLC 1613 Alton Road Miami Beach, FL 33139				
MEDICATION TRIALS: Treatment Naïve – No PAST USE OF ANTIRETROVIRAL THERAPY	Sangamo Biosciences <i>(selected as site – details pending)</i>	P.I.: Michael Wohlfeiler, M.D. Contact for further information:	Selected as a site – waiting for contract approval	MEDICATION TRIALS: Treatment Naïve – No PAST USE OF ANTIRETROVIRAL THERAPY Eligibility:

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
		Daniel Guzman, CRC 305/538-1400 ext: 222 danielguzmanwpa@aol.com		Men and women > 18 years of age never taken antiretroviral drugs and have a viral load > 2,500 copies/ml and CD4 > 500 cells/mm ³
MEDICATION TRIALS: Treatment Naïve – No PAST USE OF ANTIRETROVIRAL THERAPY	Sangamo Biosciences <i>(selected as site – details pending)</i>	P.I.: Michael Wohlfeiler, M.D. Contact for further information: Daniel Guzman, CRC 305/538-1400 ext: 222 danielguzmanwpa@aol.com	Selected as a site – waiting for contract approval	MEDICATION TRIALS: Treatment Naïve – No PAST USE OF ANTIRETROVIRAL THERAPY Eligibility: Men and women > 18 years of age never taken antiretroviral drugs and have a viral load > 2,500 copies/ml and CD4 > 500 cells/mm ³
MEDICATION TRIALS: Treatment Naïve – No PAST USE OF ANTIRETROVIRAL THERAPY	Gilead Sciences – GS-0118: <i>A phase III trial to characterize the effect of Cobicistat-based regimens in patients with mild to moderate renal impairment.</i>	P.I.: Michael Wohlfeiler, M.D. Contact for further information: Daniel Guzman, CRC 305/538-1400 ext: 222 danielguzmanwpa@aol.com	Enrollment Open	MEDICATION TRIALS: Treatment Naïve – No PAST USE OF ANTIRETROVIRAL THERAPY Eligibility: HIV infected men and women > 18 years of age who have never taken antiretroviral drugs, have a viral load > 1,000 copies, and have mild to moderate renal impairment.
MEDICATION TRIALS: Treatment experienced (history of Current or Past Use of Antiretroviral Therapy)	ViiV Healthcare –111762: <i>A multicenter, randomized, double-blind study of the safety and efficacy of GSK 1349572 (50 mg. once daily) versus Raltegravir (400 mg. twice daily) added to an optimized background regimen.</i>	P.I.: Michael Wohlfeiler, M.D. Contact for further information: Daniel Guzman, CRC 305/538-1400 ext: 222 danielguzmanwpa@aol.com	Enrollment Open	MEDICATION TRIALS: Treatment experienced (history of Current or Past Use of Antiretroviral Therapy) Eligibility: HIV-infected men and women > 18 years of age who are antiretroviral experienced and are integrase inhibitor naïve.

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<p>MEDICATION TRIALS: Treatment experienced (history of Current or Past Use of Antiretroviral Therapy)</p>	<p>ViiV Healthcare – ASSURE: <i>A randomized phase 4 switch study designed to compare the efficacy and safety of simplifying therapy from a regimen of atazanavir (ATV) + ritonavir (RTV) + tenofovir/emtricitabine (TDF/FTC) to a regimen of ATV + abacavir sulfate/lamivudine (ABC/3TC) without RTV in virologically suppressed, HIV-1 infected subjects.</i></p>	<p>P.I.: Michael Wohlfeiler, M.D.</p> <p>Contact for further information: Daniel Guzman, CRC 305/538-1400 ext: 222 danielguzmanwpa@aol.com</p>	<p>Enrollment Open</p>	<p>MEDICATION TRIALS: Treatment experienced (history of Current or Past Use of Antiretroviral Therapy)</p> <p>Eligibility: Men and women > 18 years of age. 1) TDF/3TC + ATV/r (300/100 mg) must be patient’s initial antiretroviral regimen or the first or second switch regimen, 2) virologically suppressed on TDF/FTC + ATV/r, 3) must be HLA-B*5701 negative.</p>
<p>Trials for HIV-Associated Conditions</p>	<p>Salix Pharmaceuticals – CFHD3092: <i>This study is being conducted to evaluate the safety and tolerability of cfofelemer 125 mg twice a day, taken orally, over 48 weeks of therapy in human immunodeficiency virus-positive (HIV+) subjects with diarrhea.</i></p>	<p>P.I.: Michael Wohlfeiler, M.D.</p> <p>Contact for further information: Daniel Guzman, CRC 305/538-1400 ext: 222 danielguzmanwpa@aol.com</p>	<p>Enrollment open</p>	<p>Trials for HIV-Associated Conditions</p> <p>Eligibility: HIV-infected adults who have been on antiretroviral therapy for at least 4 weeks prior to screening with self-reported presence of diarrhea</p>
<p>Miami Beach Community Health Center, Inc. 710 Alton Road Miami Beach, FL 33139</p>				
<p>Trials for HIV-Associated Conditions</p>	<p>KOWA Research Institute – NK-104-4.05US: <i>A study comparing Pitavastatin (4 mg.) vs. Pravastatin (40 mg.) in HIV-infected subjects with dyslipidemia.</i></p>	<p>P.I.: Mark Keller, M.D.</p> <p>Contact for further information: Alice Lopez 305/866-8915</p>	<p>Enrollment open</p>	<p>Trials for HIV-Associated Conditions</p> <p>Eligibility: HIV-infected men and women, ages 18-70, who have taken antiretroviral drugs for at least 6 months. LDL > 130 mg. and < 220 mg. and triglyceride levels < 400.</p>

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University of Miami, AIDS Clinical Research Unit Elliot Building, Room 2016 1800 NW 10th Avenue, Miami FL 33136				
MEDICATION TRIALS: Treatment Naïve – No PAST USE OF ANTIRETROVIRAL THERAPY	AIDS Clinical Trials Group – 5303: <i>A phase-IIIb trial to evaluate bone, immunologic, virologic and neuro-cognitive effects of Maraviroc-containing antiretroviral therapy regimen in patients infected with CCR5 tropic HIV-1</i>	P.I.: Margaret Fischl, M.D. Contacts for further information: Juan Casuso 305/243-3838 jcasuso@med.miami.edu	Expect to begin enrolling 9/2011	MEDICATION TRIALS: Treatment Naïve – No PAST USE OF ANTIRETROVIRAL THERAPY Eligibility: Men and women > 18 years of age with documented CCR5 only virus. Excludes those who are Hep-B+, pregnant, weigh > 300 lbs., have bone fractures related to osteoporosis or bone fragility, or active drug or alcohol abuse.
MEDICATION TRIALS: Treatment Naïve – No PAST USE OF ANTIRETROVIRAL THERAPY	ViiV Healthcare/Pfizer UK-427: <i>A comparative study of Maraviroc/ Darunavir/Ritonavir vs. Truvada/Darunavir/ Ritonavir in ARV-naïve individuals with CCR5 tropic HIV-1 infection</i>	P.I.: Margaret Fischl, M.D. Contacts for further information: Juan Casuso 305/243-3838 jcasuso@med.miami.edu	Enrollment Open	MEDICATION TRIALS: Treatment Naïve – No PAST USE OF ANTIRETROVIRAL THERAPY Eligibility: Men and women > 18 years of age with CCR5 tropic HIV-1 infection. Excludes pregnant women and those with acute hepatitis or pancreatitis, renal insufficiency, HepB+ or CXCR4 HIV-virus.
Trials for HIV-Associated Conditions	AIDS Clinical Trials Group – A-5279: <i>A phase-III trial of short course Rifapentine/ Isoniazid for the prevention of active tuberculosis (TB) in HIV-infected individuals with latent TB infection.</i>	P.I.: Margaret Fischl, M.D. Contacts for further information: Juan Casuso 305/243-3838 jcasuso@med.miami.edu	Expected to begin 9/2011	Trials for HIV-Associated Conditions Eligibility: HIV-1 infection, positive TB test prior to study entry. Excludes those with current pregnancy, active TB within 2 years of study entry, on P.I.-based or Raltegravir – regimen; liver cirrhosis, acute hepatitis.
Trials for HIV-Associated Conditions	AIDS Clinical Trials Group - A5247: <i>A phase II clinical trial to evaluate the safety, tolerability and immune</i>	P.I.: Margaret Fischl, M.D. Contacts for further information:	Enrollment open	Trials for HIV-Associated Conditions Eligibility: Men and women ≥ 18 yrs of age with a history of shingles (herpes zoster in the

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	<i>response of ZOSTAVAX® (Zoster Vaccine Live) in HIV-1-infected adults on combination ART.</i>	Juan Casuso 305/243-3838 jcasuso@med.miami.edu		past one year) who are taking combination ARV therapy and have a viral load < 50 copies/ml and CD4 cell count ≥ 200

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UNIVERSITY OF MIAMI – 51 Studies Presenter: Savita Pahwa, M.D.				
CLINICAL TRIAL	<i>Adolescent Medicine Trials Network for HIV/AIDS Interventions, aka ATN (longstanding collaborative NIH research consortium continually funded here since 2001 following previous 1994-2001 award for REACH Protocol)</i>	Lawrence B Friedman, MD (PI)	Pediatrics/Division of Adolescent Medicine	Youth 13-24 y/o with HIV infection or high-risk attributes (numerous therapeutic, behavioral, and community studies that continuously are introduced, implemented and completed). No drug or treatment protocols are open presently.
CLINICAL TRIAL	<i>International Maternal Pediatric Adolescent AIDS Clinical Trials Group</i>	Charles Mitchell, Gwendolyn Scott	Microbiology and Immunology, Pediatrics	U01
CLINICAL TRIAL	<i>Miami HIV/AIDS Clinical Therapeutic and Vaccine Trial Unit</i>	Margaret Fischl	Medicine	NIAID
CLINICAL TRIAL	<i>Atherosclerotic Risk and Response to Exercise Intervention in HIV+ Children</i>	Tracie L. Miller	Pediatrics	NHLBI
CLINICAL TRIAL	<i>DIETARY INTAKES AND PATTERNS, BIOMARKERS, AND MATERNAL AND INFANT OUTCOMES IN HIV</i>	Tracie L. Miller	Pediatrics	NICHD
CLINICAL TRIAL	<i>University of Miami Pediatric Perinatal HIV/AIDS Clinical Trails Unit</i>	Gwendolyn B. Scott	Pediatrics	NIAID
CLINICAL TRIAL	<i>Florida Node Alliance of the Drug Abuse Clinic Trials Network</i>	Jose Szapocznik	Epidemiology & Pub. Health Med.	NIDA
CLINICAL TRIAL	<i>AIDS Malignancy Consortium University of Miami Core Site</i>	Juan Carlos Ramos	Therapeutics Research	NCI
CLINICAL TRIAL	<i>NIAID IRAC: combination influenza treatment in high risk and low risk patients with acute influenza</i>	Margaret Fischl Hector Bolivar Jose Castro Michelle Morris	Therapeutics Research	NIAID

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CLINICAL TRIAL BASIC SCIENCE/VIROLOGY	<i>Effect of Raltegravir on immune activation, immune reconstitution and gut microbial translocation in patients with chronic HIV infection</i>	Rafael Campo Savita Pahwa Mario Stevenson	Novel therapeutics and pathogenesis	Merck
CLINICAL TRIAL	<i>P1066: Phase I/II Multicenter, Open-Label, Noncomparative Study of the International Maternal, Pediatric, Adolescent AIDS Clinical Trials Group to Evaluate the Safety, Tolerability, Pharmacokinetics, and Antiretroviral Activity of Raltegravir (MK-0518) in HIV-1 Infected Children and Adolescents</i>		IMPAACT Studies	
CLINICAL TRIAL	<i>P1077HS:HAART Standard Version of the PROMISE Study: Promoting Maternal and Infant Survival Everywhere P1083: A Phase II/III Trial of Lopinavir/Ritonavir Dosed According to The WHO Pediatric Weight band Dosing Guidelines</i>		IMPAACT Studies	The purpose of this study is to see if pregnant women receiving highly active antiretroviral treatment (HAART) to prevent mother-to-child transmission of HIV will be healthier if, after delivery, they continue or stop HAART.
CLINICAL TRIAL	<i>P1093: Phase I/II, Multi-Center, Open-Label Pharmacokinetic, Safety, Tolerability and Antiviral Activity of GSK1349572, a Novel Integrase Inhibitor, in Combination Regimens in HIV-1 Infected Infants, Children and Adolescents</i>		IMPAACT Studies	
CLINICAL TRIAL	<i>P1090 A Phase I/II Open Label Trial to evaluate safety, tolerability, PK, and antiviral</i>		IMPAACT Studies	

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
	<i>activity of ETR in ARV experienced infants and children (pending)</i>			
CLINICAL TRIAL	<i>P1065, A Phase I/II Study of the Safety and Immunogenicity of Quadrivalent Meningococcal Conjugate Vaccine in HIV-Infected Youth</i>		IMPAACT Studies	
CLINICAL TRIAL	<i>P1096 Phase 1 Study to Determine the Safety, Infectivity, Immunogenicity and Tolerability of Live Attenuated Recombinant Cold-passaged 45 Human Parainfluenza Type 3 Virus Vaccine</i>		IMPAACT Studies	
CLINICAL TRIAL	<i>A5240: A Phase II Study to Evaluate the Immunogenicity and safety of a Quadrivalent Human Papillomavirus Vaccine in HIV-1 Infected Females.</i>		IMPAACT Studies	
CLINICAL TRIAL	<i>ATN 063: Randomized, Double-Blind, Placebo-Controlled Trial of the Safety/ Effectiveness of Vitamin D to Improve Tubular Reabsorption of Phosphate and Decrease Bone Turnover in Adolescents with HIV Infection Treated with ART Containing Tenofovir Compared to ART not Containing Tenofovir</i>		ATN Clinical Studies	
CLINICAL TRIAL	<i>ATN 064: Immunogenicity, safety, behavioral consequences of Quadrivalent Human Papillomavirus Vaccine in HIV-infected young women</i>		ATN Clinical Studies	

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
CLINICAL TRIAL	<i>CTN 0032: HIV Testing and Counseling in Drug Abuse Treatment Clinics in the U.S.</i>	Lisa Metsch, PI	NIDA Clinical Trials Network (CTN)	
CLINICAL TRIAL BEHAVIORAL/EPIDEMIOLOGICAL	<i>CTN 0049: Project HOPE: Hospital Visit is an Opportunity for Prevention and Engagement</i>	Lisa Metsch, PI	NIDA Clinical Trials Network (CTN)	
CLINICAL TRIAL	<i>058: Companion Protocol To Evaluate Anogenital HPV Infection And Anogenital Squamous Intraepithelial Lesions (ASIL) In Patients Participating In AMC Clinical Trials</i>		AMC Studies	
CLINICAL TRIAL	<i>070: Phase I/II Study of Lenalidomide in Patients with AIDS-Associated Kaposi's Sarcoma</i>		AMC Studies	
CLINICAL TRIAL	<i>075: Sequential Phase I/Randomized Phase II Trial of Vorinostat and Risk-Adapted Chemotherapy with Rituximab in HIV-Related B-cell Non-Hodgkin's Lymphoma</i>		AMC Studies	
CLINICAL TRIAL	<i>072: Protective Effect of quadrivalent vaccine in young HIV-positive males who have sex with males (pending)</i>		AMC Studies	
CLINICAL TRIAL	<i>A5257: A Phase III Comparative Study of Three Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI)-Sparing Antiretroviral Regimens for Treatment-Naïve HIV-1-Infected Volunteers</i>		ACTG studies	
CLINICAL TRIAL	<i>A5286: Pilot Study of Rifaximin</i>		ACTG studies	

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
	<i>as a Modulator of Gut Translocation and Systemic Immune Activation in HIV-Infected Individuals with Incomplete CD4+ T-cell Recovery on Antiretroviral Therapy</i>			
CLINICAL TRIAL	<i>A5298: A Randomized, Double-Blinded, Placebo-Controlled, Phase III Trial of the Quadrivalent HPV Vaccine to Prevent Anal Human Papillomavirus Infection in HIV-Infected Men</i>		ACTG studies	
CLINICAL TRIAL	<i>A5305: A Phase II Study of the Safety, Tolerability, and Adherence of Maraviroc + Emtricitabine (MVC+FTC) Compared to Tenofovir + Emtricitabine (TDF+FTC) For Pre-Exposure Prophylaxis (PrEP) To Prevent HIV Transmission in At-Risk Men Who Have Sex with Men</i>		ACTG studies	
CLINICAL TRIAL	<i>A5295: A Randomized, Placebo Controlled Phase 1 Study to Assess the Safety, PK, and Antiviral Efficacy of Subcutaneous Ibalizumab, an anti-CD4 Monoclonal Antibody, in HIV-1 Infected Patients</i>		ACTG studies	
CLINICAL TRIAL	<i>A5301: Administration of an Anti-PD-1 Antibody for Reducing the Latent Reservoir: A Pilot Study</i>		ACTG studies	
CLINICAL TRIAL	<i>A Phase IIb/III randomized,</i>		ACTG studies	

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
	<i>controlled study of Interleukin-7 in HIV-infected patients who have responded to ART and have a plasma HIV-1 RNA \leq 50 copies/ml and a CD4 cell count \leq 350 cells/mm³ after at least 18 months of ART (pending)</i>			
CLINICAL TRIAL	<i>A4001095: Multicenter, randomized, double-blind, comparative trial of Maraviroc with darunavir/ritonavir versus emtricitabine/ tenofovir with darunavir/ritonavir for the treatment of antiretroviral-naïve-HIV-infected patients with CCR5-tropic HIV</i>		Industry Studies	
CLINICAL TRIAL	<i>A012: Pilot study of raltegravir + darunavir/ritonavir vs. raltegravir + emtricitabine/tenofovir with secondary randomization to Maraviroc to assess effect on peripheral and mucosal viremia and biomarkers of immune activation</i>		Industry Studies	
CLINICAL TRIAL	<i>GS-US-236-0102 - A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of Elvitegravir/Emtricitabine/Tenofovir Disoproxil Fumarate/GS-9350 Vs Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate in HIV-1 Infected, Antiretroviral</i>	Rafael Campo On-Going	Medicine	Treatment comparison

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
CLINICAL TRIAL	<i>Treatment-Naïve Adults.</i> <i>GS-US-216-0114: A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of GS-9350-boosted Atazanavir Versus Ritonavir-boosted Atazanavir Each Administered with Emtricitabine/Tenofovir Disoproxil Fumarate in HIV-1 Infected, Antiretroviral Treatment-Naïve Adults</i>	Rafael Campo On-Going	Medicine	Naive
CLINICAL TRIAL	<i>GS-US-264-0106-A Phase 3 Randomized Open-Label Study to Evaluate Switching from Regimens Consisting of a Ritonavir-boosted Protease Inhibitor and Two Nucleoside Reverse Transcriptase Inhibitors to Emtricitabine /Rilpivirine/ Tenofovir Disoproxil Fumarate (FTC/RPV/TDF) Fixed-dose Regimen in Virologically -Suppressed, HIV-1 Infected Patients</i>	Rafael Campo New-Enrolling soon	Medicine	Clinical Efficacy
CLINICAL TRIAL	<i>A4001067 - An International, Multi-center, Prospective Observational Study of the safety of Maraviroc used with Optimized Background Therapy in Treatment-Experienced HIV-1 Infected Patients.</i>	Jose Castro On-Going	Medicine	Clinical Efficacy
CLINICAL TRIAL	<i>MIDAS - Maraviroc Plus Darunavir/ritonavir Study for treatment-Naïve Patients</i>	Jose Castro	Medicine	Clinical Efficacy

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
	<i>Infected with R5 tropic HIV-1 based on Enhanced Sensitivity Trofile</i>	On-Going		
CLINICAL TRIAL	<i>A4001098 – 1021 - A MULTICENTER, RANDOMIZED, BLINDED, PLACEBO-CONTROLLED STUDY TO EVALUATE THE SAFETY OF MARAVIROC IN COMBINATION WITH OTHER ANTIRETROVIRAL AGENTS IN HIV-1-INFECTED SUBJECTS CO-INFECTED WITH HEPATITIS C AND/OR HEPATITIS B VIRUS</i>	Dushyantha Jayaweera New – Enrolling soon	Medicine	Clinical Efficacy
CLINICAL TRIAL	<i>A0081244 – 1029 - A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, PARALLEL-GROUP, MULTICENTER TRIAL OF PREGABALIN VERSUS PLACEBO IN THE TREATMENT OF NEUROPATHIC PAIN ASSOCIATED WITH HIV NEUROPATHY (PREGABALIN A0081244)</i>	Jose Castro Enrolling	Medicine	Clinical Efficacy
CLINICAL TRIAL	<i>A0081251 – 1029 - AN OPEN-LABEL, EXTENSION SAFETY TRIAL OF PREGABALIN IN SUBJECTS WITH NEUROPATHIC PAIN ASSOCIATED WITH HIV NEUROPATHY.</i>	Jose Castro Enrolling	Medicine	Clinical Efficacy
CLINICAL TRIAL	<i>TMC278-TiDP6-C215: A Phase III, randomized, double-blind trial of TMC278 25 mg q.d. versus efavirenz 600 mg q.d. in</i>	Jose Castro	Medicine	Clinical Efficacy

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
	<i>combination with a background regimen containing 2 nucleoside/nucleotide reverse transcriptase inhibitors in antiretroviral-naïve HIV-1 infected subjects</i>			
CLINICAL TRIAL	<i>TMC-278-TiDP6-C222 - An open-label trial with TMC278 25 mg q.d. in combination with a background regimen containing 2 nucleoside/nucleotide reverse transcriptase inhibitors in HIV-1 infected subjects, who participated in TMC278 clinical trials.</i>	Jose Castro New-Roll-over for C215	Medicine	Clinical Efficacy
CLINICAL TRIAL	<i>A4001078 – 1045 - Pilot Study of Novel Combination of Maraviroc + Atazanavir/ Ritonavir Vs. Atazanavir/ Ritonavir + Emtricitabine/ Tenofovir For The Treatment Of Treatment Naïve HIV-Infected Patients With R5 HIV-1</i>	Dushyantha Jayaweera On-Going	Medicine	Clinical Efficacy
CLINICAL TRIAL	<i>A4001095 – 1019 - A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, COMPARATIVE TRIAL OF MARAVIROC + DARUNAVIR/RITONAVIR VERSUS EMTRICITABINE/TENOFOVIR + DARUNAVIR/RITONAVIR FOR THE TREATMENT OF ANTIRETROVIRAL-NAÏVE HIV-INFECTED PATIENTS WITH CCR5-TROPIC HIV-1</i>	Dushyantha Jayaweera New – On-Hold Per Sponsor	Medicine	Clinical Efficacy
CLINICAL TRIAL	<i>Protocol VX08-950-110: A Phase</i>			Clinical Efficacy

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
	<i>2A, 2-Part, Randomized, Double Blind, Placebo Controlled, Parallel Group, Multicenter Study of Telaprevir in Combination with Peginterferon Alfa-2a (Pegasys®) and Ribavirin (Copegus®) in Subjects who Have Chronic HCV-1/HIV-1 Co-Infection and are Treatment-Naïve for Hepatitis C</i>	Dushyantha Jayaweera On-Going	Medicine	
CLINICAL TRIAL	<i>A Phase 2b Randomized, Double-Blind, Double-Dummy Trial of 100 or 200 mg Once-Daily Doses of Cenicriviroc (CVC, TBR-652) or Once-Daily EFV, Each With Open-Label FTC/TDF in HIV-1-Infected, Antiretroviral Treatment-Naïve, Adult Patients with Only CCR5-Tropic Virus</i>	Dushyantha Jayaweera New – Enrolling soon	Medicine	Clinical Efficacy
CLINICAL TRIAL	<i>Recovery of Latent Reservoirs After Treatment for Lymphoma in HIV Infected Patients: A Pilot Study</i>	Luis Espinoza/Michael Kolber Enrolling	Medicine	Viral reservoirs
CLINICAL TRIAL	<i>Strategic Timing of Anti-Retroviral Treatment (START) - A Multicenter Study of the International Network for Strategic Initiatives in Global HIV Trials (INSIGHT)</i>	Michael Kolber New – Enrolling soon	Medicine	INSIGHT –multicenter
CLINICAL TRIAL	<i>Retaining HIV Positive Patients in Medical Care: Test for Intervention Strategies for HIV Clinics (Phase II)</i>	Allan Rodriguez On-Going	Medicine	CDC retention in care

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STUDY CATEGORY PROJECT TITLE INVESTIGATORS DEPARTMENT SCIENTIFIC AREA

**UNIVERSITY OF SOUTH FLORIDA – 25 Studies
Presenter: John W. Sleasman, M.D.**

CLINICAL TRIAL	<i>Pfizer- A40001031. Phase I/II trial on the use of maraviroc in HIV infected children and adolescents</i>	Carina Rodriguez, MD (site PI), John Sleasman, MD, Patricia Emmanuel, MD, Jorge Lujan, MD, Alicia Marion, ARNP, Kenneth Kavanagh, ARNP (Co-Investigators)	Pediatric Infectious Diseases	CCR5 inhibitor for HIV treatment in HIV infected children and adolescents
CLINICAL TRIAL	<i>NO1-HD-8-0001NIH/NICHD Pediatric AIDS Clinical Trials Group (IMPAACT).</i>	Patricia Emmanuel, MD (PI), Carina Rodriguez, MD, John Sleasman, MD Jorge Lujan, MD, Alicia Marion, ARNP, Kenneth Kavanagh, ARNP (Co-Investigators)	Pediatric Infectious Diseases	Multicenter clinical trial related to therapy, HIV related complications, vaccines, and perinatal transmission.
CLINICAL TRIAL	<i>U01 HD040497-06 NIH, Adolescent Trials Network</i>	Patricia Emmanuel, MD (PI), Diane Straub, MD, John Sleasman, MD, Carina Rodriguez, MD, Jorge Lujan, MD, Alicia Marion, ARNP, Kenneth Kavanagh, ARNP (Co-Investigators)	Pediatric Infectious Diseases	ATN is a national, multicenter research network, to conduct research to explore behavioral, microbicidal, prophylactic, therapeutic, and vaccine modalities in HIV-infected and HIV at-risk adolescents, age 12 through 24
CLINICAL TRIAL	<i>Changes in the B cell repertoire following vaccination with novel H1N1 inactivated influenza vaccine in immune deficient adolescents and young adults chronically infected with HIV</i>	Carina Rodriguez, MD (PI), John Sleasman, MD, Li Yin, PhD, Maureen Goodenow, PhD	Pediatric Infectious Diseases, Allergy and Immunology (USF) and Pathology (UF)	Immunologic responses to H1N1 inactivated influenza vaccine in HIV-infected adolescents and young adults
CLINICAL TRIAL	<i>Treatment De-intensification and Residual HIV-1 in Youth. (ATN 081)</i>	John Sleasman	Allergy and Immunology, USF	Effects of early treatment followed by treatment deintensification. Sponsor: NICHD
CLINICAL TRIAL	<i>Preservation & Expansion of T-cell Subsets Following HAART</i>	John Sleasman	Allergy and Immunology, USF	Early treatment of HIV during deintensification to ATV/r.

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
	<i>De-intensification to Atazanavir/ritonavir (ATN 061)</i>			Sponsor: NICHD
CLINICAL TRIAL	<i>Longitudinal changes in cardiovascular risk markers among adolescents newly infected with HIV (ATN 083)</i>	John Sleasman	Allergy and Immunology, USF	Cardiovascular risks in HIV-infected adolescents. Sponsor: NICHD
CLINICAL TRIAL	<i>Assessment of inflammatory Markers Associated with Neurocognitive impairment in HIV-infected Adolescents (ATN 101)</i>	John Sleasman	Allergy and Immunology, USF	Neurocognitive impairment in HIV. Sponsor: NICHD
CLINICAL TRIAL	<i>A randomized placebo controlled trial of probiotics to lower microbial translocation & immune activation in HIV-infected adolescents</i>	John Sleasman	Allergy and Immunology, USF	LPS levels and immunity preservation. Sponsor: NICHD
CLINICAL TRIAL	<i>ATN 081/083 Processing Contracts – ATN Coordinating Center</i>	John Sleasman (PI)	Pediatrics	
CLINICAL TRIAL	<i>Leadership Group for Adolescent Medicine Trials Network</i>	John Sleasman (PI)	Pediatrics	
CLINICAL TRIAL	<i>Protocol #Hizentra Transition Study</i>	John Sleasman (PI)	Pediatrics	
CLINICAL TRIAL	<i>Impact of HIV-1 Genotype on Therapy Response in Children</i>	John Sleasman (PI)	Pediatrics	
CLINICAL TRIAL	<i>Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Study to Assess the Efficacy and Safety of Crofelemer 125 mg, 250 mg and 500 mg Orally Twice Daily for the Treatment of HIV-Associated Diarrhea (ADVENT Trial)</i>	Beata Casanas (PI)	Internal Medicine	Complications, therapy GI: diarrhea
CLINICAL TRIAL	<i>A Phase III, randomized, double-blind trial of TMC278 75 mg q.d.</i>	Beata Casanas (PI)	Internal Medicine	primary therapy

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
	<i>versus efavirenz 600 mg q.d. in combination with a fixed background regimen consisting of tenofovir disoproxil fumarate and emtricitabine in antiretroviral-naïve HIV-1 infected subjects</i>			
CLINICAL TRIAL	<i>A Phase IIb randomized, partially blinded, dose-finding trial of TMC278 in antiretroviral naïve HIV-1 infected subjects</i>	Beata Casanas (PI)	Internal Medicine	primary therapy
CLINICAL TRIAL	<i>An Open-label, Multicenter, Multiple-dose Pharmacokinetic and 48-week Safety and Efficacy Trial of Maraviroc in Combination with Optimized Background Therapy for the Treatment of Antiretroviral-Experienced CCR5-Tropic HIV-1 Infected Children 2-18 Years</i>	Carina Rodriguez (PI)	Pediatrics	Primary therapy
CLINICAL TRIAL	<i>A Phase 1B Study of the Safety and Pharmacokinetics of Ritonavir-Boosted Elvitegravir (EVG/r) Plus a Background Regimen (BR) in HIV-1 Infected, Antiretroviral Treatment-Experienced Adolescents</i>	Patricia Emmanuel (PI)	Pediatrics	pharmacokinetics, HIV therapy
CLINICAL TRIAL	<i>International Maternal Pediatric Adolescent AIDS Clinical Trials Group</i>	Patricia Emmanuel (PI)	Pediatrics	Prevention of maternal to child transmission, pediatric treatment studies
CLINICAL TRIAL	<i>Adolescent Medicine Trials Network II</i>	Patricia Emmanuel (PI)	Pediatrics	Multicenter trials group, prevention and treatment studies in HIV at risk and infected youth
CLINICAL TRIAL	<i>Efficacy and Safety of Vicriviroc in HIV-Infected Treatment-Naïve Subjects</i>	Chararut Somboonwit (PI)		primary therapy

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
CLINICAL TRIAL	<i>A Phase II randomized, double-blind, placebo-controlled trial to investigate the efficacy, tolerability and safety of TMC125 as part of an ART including TMC114/RTV and an investigator-selected OBR in HIV-1 infected subjects</i>	Todd Wills (PI)	Internal Medicine	HIV therapy
CLINICAL TRIAL	<i>A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of GS-3950-boosted Atazanavir Versus Ritonavir-boosted Atazanavir Each Administered with Emtricitabine/Tenofovir Disoproxil Fumarate in HIV-1 Infected, Antiretroviral Treatment Naive Adults</i>	Todd Wills (PI)	Internal Medicine	HIV therapy
CLINICAL TRIAL	<i>A Phase 3, Open-Label, Multicenter Study of the Safety of Ritonavir-Boosted GS-9137 (GS-9173/r) Administered in Combination with Other Antiretroviral Agents for the Treatment of HIV-1 Infected Subjects</i>	Todd Wills (PI)	Internal Medicine	HIV therapy
CLINICAL TRIAL	<i>A Phase 3, Randomizes, Double-Blind, Study to Evaluate the Safety and Efficacy of Elivitegravir/Emtricitabine/Tenofovir disoproxil Fumarate-GS-9350 Versus Efavirenz/Emtriciitabane/Tenofovir Disoproxil Fumarate in HIV-1 Infected, Antiretroviral Treatment-Naïve Adults</i>	Todd Wills (PI)	Internal Medicine	primary therapy

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
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<p>ORANGE COUNTY HEALTH DEPARTMENT – 2 Studies Presenter: Gerald Horton, Jr. M.D.</p>
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CLINICAL TRIAL	<i>INSIGHT PROTOCOL001- Strategic Timing of AntiRetroviral Treatment (START); Version2. (Not Yet Started)</i>	Dr. Gerald Horton (PI), Dr. Richard Solero and Dr. Nila Desai (CoPIs)	HugMe Immunology Clinic	HIV Adults Sponsor: NIH, University of Minnesota, Washington DC International Coordinating Center (ICC)
CLINICAL TRIAL	<i>Protocol AI424403: An open-label, randomized study evaluating a switch from a regimen of two nucleoside reverse transcriptase inhibitors plus any third agent to either a regimen of Atazanavir/Ritonavir once daily & Raltegravir twice daily or to a regimen of Atazanavir/Ritonavir once daily & Tenofovir/Emtricitabine once daily in virologically suppressed HIV-1 infected subjects with safety and/or tolerability issues on their present treatment regimen (Not Yet Started)</i>	Dr. Nila Desai (PI) and Dr. Richard Solero/ Dr. Lynn Hopkins (CoPIs)	Central Immunology Clinic	HIV Adults Sponsor: Bristol-Myers Squibb

<p>UNIVERSITY OF FLORIDA Presenter: Maureen Goodenow, Ph.D.</p>
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CLINICAL TRIAL	<i>Pharmacotherapy to reduce hazardous drinking in HIV-Infected women</i>	Robert L. Cook (PI)	Epidemiology	Alcohol
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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
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**FLORIDA INTERNATIONAL UNIVERSITY – 3 Studies
Presenter: Mario De La Rosa, Ph.D.**

CLINICAL TRIAL	<i>Micronutrient Therapy in HIV+ Adults in Botswana.</i>	Marianna Baum (PI) and Adriana Campa, Co-PI	Robert Stempel College of Public Health and Social Work (Recently Completed Studies)	A seven-year clinical trial of micronutrient rplementation in collaboration with the Harvard School of Public Health and the Botswana-Harvard Partnership. Funded by NIDA
CLINICAL TRIAL	<i>Zinc Therapy in Zinc Deficient HIV+ Drug Users Supplements to this project: Effect of Zinc Supplementation on Cytokine Modulation, HIV-HCV Coinfection and Antioxidant Status</i>	Marianna Baum, PI, and Adriana Campa, Co-PI	Robert Stempel College of Public Health and Social Work (Recently Completed Studies)	A seven-year clinical trial that compared the effects of zinc /placebo supplementation on HIV disease progression, and extended its research objectives by funded supplemental research into the effects of zinc in modulating cytokine responses and decreasing oxidative stress in HIV/HCV co-infection Funded by NIDA
CLINICAL TRIAL	<i>"HIV-Risk Reduction for Teens in Alcohol Treatment."</i>	Jonathan Tubman (PI)	Robert Stempel College of Public Health and Social Work (Recently Completed Studies)	Randomized, clinical trial to evaluate the efficacy of clinic-based HIV-risk reduction intervention for multi-ethnic youth undergoing outpatient treatment for alcohol and other drug abuse problems; Funded by NIAAA

**VACCINE & GENE THERAPY INSTITUTE – FLORIDA – 3 Studies
Presenters: Rafick Pierre Sékaly, Ph.D. & Lydie Trautmann, Ph.D.**

CLINICAL TRIAL	<i>A Pilot Study Evaluating the Addition of Raltegravir to Established Suppressive Antiretroviral Therapy while</i>	Dr Campo, Dr Stevenson, Dr Dr. Pahwa, Dr. Chomont	Microbiology and Immunology and University of Miami (dcFAR)	HIV reservoirs
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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
	<i>Monitoring Changes in Markers of Immune Activation among HIV-1 Infected Individuals Without Adequate Immune Restoration</i>			
CLINICAL TRIAL	<i>Recovery of latent reservoirs after treatment for lymphoma in HIV infected patients: A Pilot Study</i>	Dr. Espinoza, Dr. Kolber and Dr. Ramos, Dr. Sekaly, Dr. Chomont	Microbiology and Immunology and University of Miami (dcFAR)	HIV reservoirs
CLINICAL TRIAL	<i>Evaluation of HAART initiation during acute HIV infection on HIV reservoir persistence</i>	Dr. Ananworanich, Dr. Kim, Dr. Chomont, Dr. Sekaly	VGTI and US Military HIV Research Program	HIV reservoirs
University of Florida Center for HIV/AIDS Research Education and Service (UF CARES) – 15 Studies Presented by Mobeen Rathore, M.D.				
CLINICAL TRIAL	<i>Efficacy of an Accelerated, High-Dose, Hepatitis B Immunization Series in HIV-Infected Patients</i>	Levonne Mitchell-Samon, MD (PI) Sub-Investigators: Michael Sands, MD, MPH & TM Nilmarie Guzman, MD Christina L. Bailey, MD	Infectious Diseases Division and Department of Health Boulevard Comprehensive Care Center	Hepatitis B Vaccination scheduling and dosing in HIV-Infected Patients
CLINICAL TRIAL	<i>Strategic Timing of AntiRetroviral Treatment (START)</i>	Michael Sands, MD, MPH & TM Sub-Investigators: Nilmarie Guzman, MD Christina L. Bailey, MD Mobeen Rathore, MD	Infectious Diseases Division	HIV and initiation of ART
CLINICAL TRIAL	<i>A Phase I/II, Multicenter, Open-Label, Noncomparative Study of the International Maternal, Pediatric, Adolescent AIDS Clinical Trials (IMPACT) Group to Evaluate the Safety, Tolerability, Pharmacokinetics, and Antiretroviral Activity of</i>	Mobeen Rathore, MD	Pediatrics	Keywords: HIV, Raltegravir in HIV-infected children, teens

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
	<i>Raltegravir (Isentress™, MK-0518) in HIV-1 Infected Children and Adolescents IMPAACT P1066</i>			
CLINICAL TRIAL	<i>A Phase II Safety and Immunogenicity Study of Quadrivalent Human Papilloma Virus [TYPES 6, 11, 16, 18] L1 Virus-Like Particle [VLP] Vaccine (GARDASIL®) in HIV-Infected Children (greater or equal to) 7 to < 12 Years of Age P1047 Ver. 1.0</i>	Mobeen Rathore, MD	Pediatrics	HIV, HPV Vaccine
CLINICAL TRIAL	<i>A5240: A Phase II Study to Evaluate the Immunogenicity and Safety of a Quadrivalent Human Papillomavirus Vaccine in HIV-1-Infected Females</i>	Mobeen Rathore, MD	Pediatrics	HIV, HPV Vaccine
CLINICAL TRIAL	<i>A5257: A Phase III Comparative Study of Three Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI)-Sparing Antiretroviral Regimens for Treatment-Naïve HIV-1-Infected Volunteers (The ARDENT Study: Atazanavir, Raltegravir, or Darunavir with Emtricitabine- Tenofovir for Naïve Treatment)</i>	Mobeen Rathore, MD	Pediatrics	HIV infected women; HIV medication study
CLINICAL TRIAL	<i>An Open-label, Multicenter, Multiple-dose Pharmacokinetic & 48-week Safety & Efficacy Trial of Maraviroc in Combination with Optimized Background Therapy for the Treatment of Antiretroviral-experienced CCR5-tropic HIV-1 Infected Children 2-</i>	Mobeen Rathore, MD	Pediatrics	HIV, maraviroc

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
	<i>18 Years of Age (A4001031)</i>			
CLINICAL TRIAL	<i>IMPAACT P1065: Phase I/II, Study of Safety and Immunogenicity of Quadrivalent Meningococcal Conjugate Vaccine (MCV-4) In HIV-Infected Children and Youth</i>	Mobeen Rathore, MD	Pediatrics	HIV, meningococcal conjugate vaccine, children, youth
CLINICAL TRIAL	<i>IMPAACT P1086 A Phase II Study to Assess the Safety & Immunogenicity of an Inactivated A(H1N1) 2009 Monovalent Vaccine in HIV-1 Infected Pregnant Women</i>	Mobeen Rathore, MD	Pediatrics	HIV-infected pregnant women, H1N1 influenza vaccine
CLINICAL TRIAL	<i>IMPAACT P1088: A Phase II Study to Assess the Safety & Immunogenicity of an Inactivated Influenza A (H1N1) 2009 Monovalent Vaccine in HIV-1 Perinatally Infected Children & Youth</i>	Mobeen Rathore, MD	Pediatrics	HIV and H1N1
CLINICAL TRIAL	<i>Phase III, Randomized Trial of the Safety & Efficacy of Three Neonatal Antiretroviral Regimens for the Prevention of Intrapartum HIV-1 Transmission (NICHD/HPTN 040/P1043)</i>	Mobeen Rathore, MD	Pediatrics	
CLINICAL TRIAL	<i>A5257: A Phase III Comparative Study of Three Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI)-Sparing Antiretroviral Regimens for Treatment-Naïve HIV-1-Infected Volunteers (The ARDENT Study: Atazanavir, Raltegravir, or Darunavir with Emtricitabine/Tenofovir for Naïve Treatment)</i>	Mobeen Rathore, MD	Pediatrics	HIV infected women; HIV medication study

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CLINICAL TRIAL	<i>An International, Multicenter, Prospective Observational Study of the Safety of Maraviroc used with Optimized Background Therapy in Treatment-Experienced HIV-1 Infected Patients (POEM)</i>	Nilmarie Guzman, MD (PI) Sub-Investigators: Michael Sands, MD, MPH & TM, Christina L. Bailey, MD, Levonne Mitchell-Samon, MD Catherine Rogers, PA-C Ne'Tosha Dopson, PA-C	Infectious Diseases Division	HIV-1; maraviroc safety in long-term use
CLINICAL TRIAL	<i>IMPACCT 1077 HS: HAART Standard Version of the PROMISE Study (Promoting Maternal and Infant Survival Everywhere), Version 1.0</i>	Mobeen Rathore, MD	Pediatrics	HIV, post partum
CLINICAL TRIAL	<i>Pharmacotherapy for Hazardous Drinking in HIV Infected Women: Randomized Trial</i>	Robert Cook, MD, MPH and Mobeen Rathore, MD	Pediatrics	Hazardous Drinking Behavior, HIV, alcohol, naltrexone
BROWARD CHILDREN'S DIAGNOSTIC & TREATMENT CENTER - 12 Studies Presented by Ana Puga, M.D.				
CLINICAL TRIAL	<i>ATN 061: Preservation and Expansion of T-cell Subsets Following Highly Active Antiretroviral Therapy (HAART) De-intensification to Atazanavir/ritonavir (ATV/r) in Adolescents and Young Adults with CD4 + T Cells > 350 and HIV RNA < 100,000 Initiating HAART (on-going)</i>	Ana Puga, MD Barbara Moscicki	CFAP Research	Antiretroviral Therapy (ART) in adolescents
CLINICAL TRIAL	<i>ATN 064: Immunogenicity, Safety, Tolerability, and Behavioral Consequences of an HPV-6,-11,-16,-18 Vaccine in HIV-Infected Young Women (closed)</i>	Ana Puga, MD	CFAP Research	Human Papilloma Virus (HPV) vaccine in adolescents
CLINICAL TRIAL	<i>Campbell Study: HPV Infections and Associated Morbidity in</i>	Ana Puga, MD	CFAP Research	HPV in Perinatally Infected Children/Youth

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
	<i>Children and Adolescents Perinatally Infected with HIV</i>			
CLINICAL TRIAL	<i>IMPAACT 1077HS: HAART Standard Version of the PROMISE Study (Promoting Maternal and Infant Survival Everywhere) (recruiting)</i>	Ana Puga, MD	CFAP Research	HIV and Pregnancy Postpartum Antiretroviral Treatment Strategy
CLINICAL TRIAL	<i>IMPAACT 1058A: Intensive Pharmacokinetic Studies of New Classes of Antiretroviral Drug combinations in Children, Adolescents and Young Adults (recruiting)</i>	Ana Puga, MD	CFAP Research	Pharmacokinetics of Newer Agents in Children/Youth.
CLINICAL TRIAL	<i>IMPAACT 1066: A Phase I/II, Multicenter, Open-Label, Noncomparative Study of the International Maternal, Pediatric, Adolescent AIDS Clinical Trials (IMPAACT) Group to Evaluate the Safety, Tolerability, Pharmacokinetics, and Antiretroviral Activity of Raltegravir (MK-0518) in HIV-1 Infected Children and Adolescents (recruiting)</i>	Ana Puga, MD	CFAP Research	Raltegravir in Children Pharmacokinetics
CLINICAL TRIAL	<i>IMPAACT A5240: A Phase II Study to Evaluate the Immunogenicity and Safety of a Quadrivalent Human Papillomavirus Vaccine in HIV-1 Infected Females (recruiting)</i>	Ana Puga, MD	CFAP Research	HPV in Adult HIV positive females
CLINICAL TRIAL	<i>IMPAACT A5241: The Optimized Treatment that Includes or Omits NRTIs (OPTIONS) Trial: A Randomized Strategy Study for</i>	Ana Puga, MD	CFAP Research	Salvage Antiretroviral Therapy (ART)

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
	<i>HIV-1 Infected Treatment-Experience Subjects Using the cPss to Select an Effective Regimen (recruiting)</i>			
CLINICAL TRIAL	<i>IMPAACT A5257: A Phase III Comparative Study of Three Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI)-Sparing Antiretroviral Regimens for Treatment-Naïve HIV-1 Infected Volunteers (recruiting)</i>	Ana Puga, MD	CFAP Research	Antiretroviral Therapy Strategy
CLINICAL TRIAL	<i>IMPAACT P1063: Phase I/II Safety and Efficacy Investigation of Atorvastatin for Treatment of Increased LDL Cholesterol In HIV-Infected Children, Adolescents, and Young Adults (recruiting)</i>	Ana Puga, MD	CFAP Research	Pharmacokinetics Cholesterol treatment for children/youth
CLINICAL TRIAL	<i>IMPAACT P1093: A Phase I/II, Multi-Center, Open-Label Pharmacokinetic, Safety, Tolerability and Antiviral Activity of GSK1349572, A Novel Integrase Inhibitor, in Combination Regimens in HIV-1 Infected Infants, Children and Adolescents. 2/9/2011 - Present (recruiting)</i>	Ana Puga, MD	CFAP Research	Novel Integrase in children Pharmacokinetics
CLINICAL TRIAL	<i>IMPAACT P1096: A Companion Protocol to CIR Protocol Number: CIR255 Phase 1 Study to Determine the Safety, Infectivity, Immunogenicity and Tolerability of 2 Doses of Live Attenuated Recombinant Cold-passaged (cp) 45 Human Parainfluenza Type 3 Virus Vaccine, rHPIV3cp45, Lot</i>	Ana Puga, MD	CFAP Research	Human Parainfluenza Vaccine in HIV negative Children

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
	<i>PIV3#102A, Delivered as Nose Drops to HPIV3-Seronegative Infants and Children 6 to 36 Months of Age, at a 6 Month Interval (recruiting)</i>			
ClinicalTrials.gov Website Studies – 39 Additional Studies				
CLINICAL TRIAL	<i>Sleep Quality and Presence of Sleep Disordered Breathing In An Inner City African American HIV Infected Population Aged 50 Years and Older</i>	Supriya Mannepalli, MD, Akram Khan, MD	University of Florida	
CLINICAL TRIAL	<i>A Phase 2B Multicenter, Randomized, Comparative Trial Of UK-453,061 Versus Etravirine In Combination With Darunavir/Ritonavir And A Nucleos(t)Ide Reverse Transcriptase Inhibitor For The Treatment Of Antiretroviral Experienced HIV-1 Infected Subjects With Evidence Of NNRTI Resistant HIV-1</i>	Study Director: Pfizer CT.gov Call Center		Percentage of subjects with HIV-1 RNA <50 copies/mL at 24 weeks.; The percentage of subjects with HIV-1 RNA <50 copies/mL and <400 copies/mL at various time points; The change from baseline in log10 transformed HIV 1 RNA levels; Assessment of Genotypic and phenotypic resistance at various time points; The time-averaged difference (TAD) in log10 transformed HIV 1 RNA levels at various time points.; The percentage of subjects with virologic response at different time points.; Change from baseline in CD4+ cell counts (absolute and percentage).; Safety and tolerability as measured by spontaneous adverse event reports, serious adverse events and safety laboratory tests.; Pharmacokinetic (PK) and pharmacokinetic/pharmacodynamic (PK/PD) analyses (to be reported separately). Sponsor: Pfizer
CLINICAL TRIAL	<i>A Study to Assess the Pharmacokinetics (Blood Levels) of TMC114 (Darunavir) Taken With TMC114r (Ritonavir), and TMC125 (Etravirine) in HIV-1 Infected Pregnant Women NCT00855335</i>	Tibotec, Inc. Clinical Trial Recruiting: Daytona Beach, Miami, Pensacola, Port St. Lucie, West Palm Beach, Florida		To assess the influence of pregnancy on the pharmacokinetics of darunavir/ritonavir (darunavir/r) and/or etravirine during the second and third trimesters of gestation, as well as postpartum; Changes in anti-viral activity and safety and tolerability of darunavir/r and/or etravirine-based antiretroviral regimens during gestation and postpartum; compare darunavir/r and/or etravirine concentrations between serum and cord blood; pregnancy outcome
CLINICAL TRIAL	<i>Optimizing Treatment for Treatment-Experienced, HIV-infected People</i>	National Institute of Allergy and Infectious Diseases AIDS Clinical Trials Group Karen T. Tashima, MD, Brown University; Richard H. Haubrich, MD, Division of Infectious Diseases, UCSD Antiviral Research Center		Time to regimen failure; Toxicity, as defined as time to first Grade 3 or higher (and one grade higher than baseline) signs/symptom or laboratory abnormality; Tolerability, as defined as time to first dose modification, time to permanent discontinuation of all study drugs; Time to abandoning randomized NRTI strategy; Time to virological failure, as defined by the protocol; Binary variable indication if viral load is less than 50 copies/ml; Change in viral load; Binary variable indicating acquisition of drug resistance mutations to any of the study agents; Change in summarized quality of life score; Binomial indicator of "perfect"

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				adherence to assigned ARVs; Change in cardiovascular risk score and fasting lipid values; Change in CD4 count; Time to serious non-AIDS events; Change in virus coreceptor tropism among those with R5-only tropic virus in Step 1; HIV-1 co-receptor tropism; Binary indicator of undetectable CSF HIV-1 RNA; Summarized continuous neuro-cognitive performance Z-scores; Binary variable indicating whether CSF ARV drug concentrations are above the population median; CPE score (CNS penetration effectiveness)
CLINICAL TRIAL	<i>TMC125-TiDP2-C238: An Exploratory Pharmacokinetics, Safety and Anti-HIV Activity Study of Etravirine (ETR) When Given With Boosted Atazanavir (ATV/Rtv) at Two Different Doses and 1 Nucleoside Reverse Transcriptase Inhibitor (NRTI) in Treatment Experienced HIV Patients</i>	Tibotec Pharmaceuticals Clinical Trial, IRELAND Recruiting: Orlando, Tampa, Vero Beach, West Palm Beach		PK interaction between ETR and ATV/rtv at 2 different doses; safety & tolerability of ETR in combination with ATV/rtv and 1 NRTI over 48 weeks.; Assessing the impact of cytochrome P450 (CYP) 2C9 and 2C19 genotypes on ETR PK; Evaluating safety and tolerability of ETR in combination with ATV/r and 1 NRTI over 48 weeks; Evaluating the antiviral activity of ETR and ATV/r with 1 NRTI over 48 weeks; Evaluating the immunologic changes (as measured by CD4 cells) with ETR and ATV/r with 1 NRTI over 48 weeks; Evaluating changes in viral genotype and drug susceptibility
CLINICAL TRIAL	<i>Study to Evaluate the Safety and Efficacy of a Single Tablet Regimen of Emtricitabine/Rilpivirine/Tenofovir Disoproxil Fumarate Compared With a Single Tablet Regimen of Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate in HIV-1 Infected, Antiretroviral Treatment-Naïve Adults.</i>	Alena Jandourek, M.D. Gilead Sciences		The primary efficacy endpoint is the proportion of subjects who achieve HIV 1 RNA < 50 copies/mL at week 48; The change from baseline in CD4 count in each treatment arm at week 48; The change from baseline in CD4 count in each treatment arm at week 96
CLINICAL TRIAL BEHAVIORAL/EPIDEMIOLOGICAL	<i>Safety of and Immune Response to an H1N1 Influenza Vaccine in HIV Infected Pregnant Women</i>	NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID) Sharon Nachman, MD, State University of New York at Stony Brook Pfizer CT.gov Call Center		Adverse events (AEs) of all grades; AEs of all grades attributed to the study vaccine; Withholding of second vaccine dose due to adverse reactions attributed to first dose; Immunologic response, defined as hemagglutination inhibition (HAI) titer of at least 1:40; Maternal immunologic response, defined as HAI of at least 1:40; Infant HAI of at least 1:40; Maternal geometric mean titers (GMT) of antibodies HAI; Infant GMT of antibodies HAI; Maternal cell-mediated immunity (CMI) responses, as measured by B-cell and T-cell enzyme-linked immunosorbent spot (ELISPOT) assay values; CD4 count; HIV RNA copies/ml; Response to seasonal trivalent influenza vaccine (TIV); Exploration of factors related to HIV and its treatment that might affect the response to H1N1 vaccinations
CLINICAL TRIAL BEHAVIORAL/EPIDEMIOLOGICAL	<i>Safety of and Immune Response to the Human Papillomavirus (HPV) Vaccine in HIV-Infected Women</i>	NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID); NATIONAL		Type-specific HPV antibody development from the seronegative status at baseline to seropositive status a month after the completion of HPV vaccination series (Week 28) for HPV types 6, 11, 16, and 18;

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		INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH (NIDCR) Erna Milunka Kojic, MD, Department of Immunology/Infectious Disease, The Miriam Hospital, Brown University; Susan Cu-Uvin, MD, Obstetrics-Gynecology and Medicine, The Miriam Hospital, Brown University		Occurrence of Grade 3 or greater adverse events; HPV antibody titers to types 6, 11, 16, 18; Longitudinal changes in HIV viral load; Nadir and baseline CD4 count; Baseline HIV viral load; Cellular immune response assay data from the subset of U.S. participants; Longitudinal changes in CD4+ cell count from baseline
CLINICAL TRIAL	<i>An Open Label Pharmacokinetic, Safety And Efficacy Study Of Maraviroc In Combination With Background Therapy For The Treatment Of HIV-1 Infected, CCR5 - Tropic Children</i>	VIIV Healthcare Pfizer CT.gov Call Center Recruiting: Jacksonville, Miami, St. Petersburg, Tampa		To determine the safety and tolerability of maraviroc in HIV-infected children and adolescents.; To determine the pharmacokinetic profile(s) and dosing schedule(s) for maraviroc in treatment experienced HIV-infected children and adolescents on different background therapies;; Describe the efficacy of multiple dose administration of maraviroc in treatment experienced children infected with CCR5 tropic HIV-1;; Describe tropism changes over time.
CLINICAL TRIAL BASIC SCIENCE/VIROLOGY	<i>Safety and Effectiveness of Raltegravir (MK-0518) in Treatment-Experienced, HIV-Infected Children and Adolescents</i>	NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID) Sharon A. Nachman, MD, State University of New York at Stony Brook, Health Science Center; Andrew Wiznia, MD, Jacobi Medical Center, Albert Einstein College of Medicine		Termination from treatment due to suspected drug reaction attributable to the study medication; Grade 3 or 4 adverse events; Pharmacokinetic parameters; HIV viral load; CD4 count and percentage; Genotypic and phenotypic resistance measures Recruiting: Jacksonville, Miami, Ft. Lauderdale, Tampa
CLINICAL TRIAL	<i>The TMC125-C214 Study Provides Early Access to TMC125 for HIV-1 Infected Patients Who Have Failed Multiple Antiretroviral Regimens and Will Also Gather Information on the Long-term Safety and Tolerability of TMC125 Combined With Other Antiretroviral Drugs.</i>	Study Director, Tibotec Pharmaceuticals Clinical Trial Tibotec Pharmaceutical Limited and IREL		The purpose of this study is to provide early access of TMC125 to HIV-1 infected patients who have failed multiple antiretroviral (ARV) regimens. Information on safety and tolerability aspects of TMC125 in combination with other ARVs in treatment-experienced HIV-1 patients with limited treatment options will be assessed. Available data regarding the effectiveness of the drug will also be collected. To be eligible, patients should be failing their current ARV regimen or be on a treatment interruption, should have previously received 2 different protease inhibitor (PI) containing regimens and be at least 3-class experienced (protease inhibitors [PI], nucleoside/tide reverse transcriptase inhibitors [N[t]RTIs] and non-nucleoside reverse transcriptase inhibitors [NNRTIs]) or at least 2-class experienced (PIs and N[t]RTIs) with primary NNRTI resistance. TMC125 will

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				be administered in combination with an investigator-selected background of additional ARVs from the list of allowed medications.
CLINICAL TRIAL	<i>A Simplification Study of Unboosted Reyataz With Epzicom (ASSURE)</i>	GSK Clinical Trials and VIIV Healthcare		To determine the proportion of subjects who maintain HIV-1 RNA <50 copies/mL through Week 24; Number of patients with adverse events as a measure of safety and tolerability in each treatment arm; To assess change from baseline in HIV-1 RNA and CD4+ cell count in each arm; To compare change from baseline in fasting lipid parameters (triglycerides, total cholesterol, LDL- and HDL-cholesterol)
CLINICAL TRIAL BEHAVIORAL/EPIDEMIOLOGICAL	<i>Pharmacokinetic Study of Anti-HIV Drugs During Pregnancy</i>	NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID); EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT (NICHD) Mark Mirochnick, MD, Boston Medical Center		The purpose of this study is to determine what doses of anti-HIV medications are appropriate for pregnant women. Anti-HIV medication taken during pregnancy may control a woman's viral load and reduce the chance that the baby will become infected with HIV. Pregnant women may require different doses of anti-HIV drugs than women who are not pregnant. This study will use pharmacokinetic (PK) sampling to determine what doses of anti-HIV medications are best for HIV-infected pregnant women and their infants.
CLINICAL TRIAL	<i>Study to Evaluate Switching From Regimens Consisting of Ritonavir-boosted Protease Inhibitor (PI) and Two Nucleoside Reverse Transcriptase Inhibitors (NRTIs) to a Fixed Dose Tablet Containing Emtricitabine/Rilpivirine/Tenofovir DF</i>	John Flaherty, PharmD, Gilead Sciences		The purpose of this study is to evaluate the non-inferiority of FTC/RPV/TDF fixed dose regimen (FDR) relative to regimens consisting of a ritonavir-boosted protease inhibitor (PI/r) and two nucleoside reverse transcriptase inhibitors (NRTIs). The FDR could offer an attractive treatment option to patients who wish to simplify dosing by reducing pill burden or to improve the tolerability of their treatment.
CLINICAL TRIAL	<i>Pregabalin Versus Placebo In The Treatment Of Neuropathic Pain Associated With HIV Neuropathy</i>	Pfizer CT.gov Call Center		The purpose of this study is to evaluate the efficacy of pregabalin compared to placebo in reducing neuropathic pain associated with HIV neuropathy.
CLINICAL TRIAL BEHAVIORAL/EPIDEMIOLOGICAL	<i>An Open-Label, Extension Safety Trial Of Pregabalin In Subjects With Neuropathic Pain Associated With HIV Neuropathy (Pregabalin A0081251)</i>	Pfizer CT.gov Call Center		This study examines the safety of pregabalin over a 6 month period in patients with neuropathic pain associated with HIV infection as an extension of another trial that tests the efficacy of pregabalin.
CLINICAL TRIAL	<i>A Randomized, Double-blind Study of the Safety and Efficacy of GSK1349572 50 mg Once Daily Versus Raltegravir 400 mg Twice Daily, Both Administered With an Investigator-selected Background Regimen Over</i>	Sherene Min, Project Physician Lead GSK Clinical Trials SHIONOGI VIIV HEALTHCARE		ING111762 is a 48 week, randomized, double-blind, active-controlled, multicenter, parallel group, non-inferiority study. The study will be conducted in at least 688 HIV-1 infected antiretroviral experienced, integrase-naïve subjects. Subjects will be randomized 1:1 to receive GSK1349572 50 mg once daily or raltegravir (RAL) 400 mg twice daily, each added to an investigator selected background regimen consisting of at least

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	<i>48 Weeks in HIV-1 Infected, Integrase Inhibitor-Naive, Antiretroviral-Experienced Adults</i>			one fully active agent plus no more than one second single agent which may or may not be active. Antiviral activity, safety, pharmacokinetics (PK), and development of viral resistance will be evaluated
CLINICAL TRIAL BEHAVIORAL/EPIDEMIOLOGICAL	<i>High Dose Chemotherapy With Autologous Stem Cell Rescue for Aggressive B Cell Lymphoma and Hodgkin Lymphoma in HIV-infected Patients (BMT CTN 0803)</i>	Joseph Alvarnas, MD, City of Hope National Medical Center Richard Ambinder, MD, Johns Hopkins Medical Institution NATIONAL HEART, LUNG, AND BLOOD INSTITUTE (NHLBI); NATIONAL CANCER INSTITUTE (NCI); BLOOD AND MARROW TRANSPLANT CLINICAL TRIALS NETWORK		This study is a Phase II, multicenter trial assessing overall survival after autologous hematopoietic stem cell transplantation using a BEAM transplant regimen in lymphoma patients with HIV.
CLINICAL TRIAL BEHAVIORAL/EPIDEMIOLOGICAL	<i>Perinatal Core Protocol (Prenatal and Postnatal Studies of Interventions for Prevention of Mother-To-Child Transmission)</i>	Ruth Tuomala, MD, Director of Obstetrics and Gynecology, Brigham and Women's Hospital; Gwen Scott, MD, Pediatric Infectious Diseases, University of Miami School of Medicine INTERNATIONAL MATERNAL PEDIATRIC ADOLESCENT AIDS CLINICAL TRIALS GROUP; NAT'L INST. OF ALLERGY AND INFECTIOUS DISEASES (NIAID); EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT (NICHD)		The purpose of this study is to collect and study clinical and laboratory information about a pregnant or new mother and her medical care that will increase our knowledge of the best care for HIV-infected pregnant women and their children. The rate of transmission of HIV from mothers to their infants has gone down. Specific U.S. Public Health Service guidelines recommend that HIV-infected pregnant women be treated with anti-HIV therapies; but the effectiveness of treatment and safety for the mother and her infant have not been fully examined. This study will monitor the health of women and their infants while they receive anti-HIV therapy. Also, this study will provide information that may be used for future studies.
CLINICAL TRIAL	<i>Emergency Use Program for Highly Treatment-Experienced HIV+ Patients (Emergency Use Program for HTE HIV+ Patients Who Need Tipranavir Treatment)</i>	Boehringer Ingelheim Pharmaceuticals		To provide early access to tipranavir and evaluate the safety and tolerance of tipranavir combined with low dose of ritonavir in patients with progressive, HIV-1 disease who have failed or are intolerant to currently approved treatments for HIV infection, who are unable to participate in another tipranavir controlled clinical trial and have an urgent need for anti-HIV treatment.
CLINICAL TRIAL	<i>Connect To Protect® Partnerships for Youth Prevention Interventions: Phase III</i>	EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT (NICHD); NATIONAL INSTITUTE ON		Connect to Protect (C2P): Partnerships for Youth Prevention Interventions is a multi-site, three-phase project developed by the Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN). The overall goal of the project is to ultimately reduce HIV incidence and prevalence in youth 12-24 years old through a community mobilization intervention. This protocol (ATN

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		DRUG ABUSE (NIDA); NATIONAL INSTITUTE OF MENTAL HEALTH (NIMH); NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM (NIAAA) Jonathan Ellen, MD, Johns Hopkins University Hospital		040) describes part one of Phase III. Part two of Phase III will be submitted as a separate protocol (ATN 041).
CLINICAL TRIAL	<i>A Phase 1/2, Open Label, Single Infusion Study of Autologous T-Cells Genetically Modified at the CCR5 Gene by Zinc Finger Nucleases (SB-728-T) in HIV Infected Subjects NCT01252641</i>	SANGAMO Biosciences Winson Tang, M.D., Sangamo BioSciences, Inc.		This research study is being carried out to study a new way to possibly treat human immunodeficiency virus (HIV). The agent is called SB-728-T which are CD4+ T-cells obtained from an individual that are genetically modified at the CCR5 gene by Zinc Finger Nucleases. The CCR5 gene is required for certain types of HIV to enter into and infect T-cells. T cells are one of the white blood cells used by the body to fight HIV. The most important of these are called "CD4+ T-cells" Some people are born without the CCR5 gene on their T-Cells. These people remain healthy and are resistant to infection with HIV. Other people have a low number of CCR5 genes on their T-cells and their HIV disease is less severe and is slower to cause disease (AIDS). The purpose of this research study is to find out whether SB-728-T is safe to give to humans and find out how this affects HIV.
CLINICAL TRIAL	<i>A Phase 2B Open Label Pilot Study to Evaluate Switching From a Regimen Consisting of a Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate (EFV/FTC/TDF) Single Tablet Regimen (STR) to Emtricitabine/Rilpivirine/Tenofovir Disoproxil Fumarate (FTC/RPV/TDF) STR in Virologically Suppressed, HIV 1 Infected Subjects NCT01286740</i>	Alena Jandourek, MD, Gilead Sciences		The purpose of this pilot study is to evaluate the efficacy and safety of FTC/RPV/TDF STR after switching from EFV/FTC/TDF at baseline in maintaining HIV-1 RNA < 50 copies/mL at week 12. HIV-infected patients who have been receiving EFV/FTC/TDF for greater than or equal to 3 months and are experiencing safety or tolerability concerns (in particular, efavirenz-related intolerance) may wish to change to an alternate, better tolerated regimen.
CLINICAL TRIAL BASIC SCIENCE/VIROLOGY	<i>Pilot Assessment of Lopinavir/Ritonavir and Maraviroc in Experienced Patients NCT00981318</i>	Abbott, Barry M. Rodwick, M. D.		This is a study to assess the response of lopinavir/ritonavir plus maraviroc (with no nucleoside medications) in HIV patients failing their initial antiviral therapy.
CLINICAL TRIAL	<i>Intensive Pharmacokinetic Studies of New Classes of Antiretroviral Drug Combinations in Children, Adolescents</i>	Jennifer R. King, Pharm. D., U of A at Birmingham; Ram Yogev, MD,		This study will examine drug and body interactions in children receiving anti-HIV treatment regimens using new medications. Drug regimens to be examined will feature the medications raltegravir (RAL), maraviroc (MVC),

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
	<i>and Young Adults</i> NCT00977756	Northwestern University Feinberg School of Medicine INTERNATIONAL MATERNAL PEDIATRIC ADOLESCENT AIDS CLINICAL TRIALS GROUP NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID)		and etravirine (ETV). These drugs will not be provided through the study.
CLINICAL TRIAL	<i>A Multicenter, Single Arm, Open-Label Study of the Once Daily Combination of Etravirine and Darunavir/Ritonavir As Dual Therapy in Early Treatment-Experienced Patients</i> NCT01199939	Tibotec, Inc. Clinical Trial		This study is a Phase II single arm, open-label, multicenter, study of 50 human immunodeficiency virus-1 (HIV) infected adult patients, all of whom will receive etravirine (ETR) 400mg and DRV/r 800/100mg each given orally once daily. This trial is designed to evaluate the efficacy of the aforementioned ARV regimen, as measured by the percentage of patients with HIV RNA <50 copies/mL at 48 weeks, in early treatment-experienced HIV-infected patients. In addition to general safety parameter measurements, this trial will also assess changes in metabolic, inflammatory, immune restoration, and bone markers. Screening will occur over a 6-week period. The primary endpoint will be assessed at Week 48, and the treatment period is 48 weeks. The end of study endpoint will be met by either completing the Week 48 visit, or by early termination from the study for any reason.
CLINICAL TRIAL	<i>A 12-Week, Randomized, Double-Blind, Active-Controlled, Parallel-Group Study Comparing Pitavastatin 4 mg vs. Pravastatin 40 mg in HIV-Infected Subjects With Dyslipidemia, Followed by a 40-Week Safety Extension Study</i> NCT01301066	KOWA RESEARCH INSTITUTE, INC. Roger E Morgan, MD, FACS		A 12-Week, Randomized, Double-Blind, Active-Controlled, Parallel-Group Study.
CLINICAL TRIAL BASIC SCIENCE/VIROLOGY	<i>Safety and Immunogenicity of GlaxoSmithKline Biologicals' Herpes Zoster Vaccine 1437173A in Adult HIV-infected Subjects</i> NCT01165203	GSK Clinical Trials 877-379-3718 GSKClinicalSupportHD@gsk.com 877-379-3718		This observer-blind study will evaluate the safety and immunogenicity of GlaxoSmithKline (GSK) Biologicals' investigational Herpes Zoster (HZ) vaccine GSK1437173A in Human Immunodeficiency Virus (HIV) infected subjects, firstly enrolling subjects treated with antiretroviral therapy (ART) and with high CD4 T cell counts, and subsequently ART-treated subjects with low CD4 T cell counts, and ART-naïve subjects with high CD4 T cell counts. This Protocol Posting has been updated following Amendment 1 of the Protocol, August 2010. The impacted section is exclusion criteria.

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CLINICAL TRIAL BEHAVIORAL/EPIDEMIOLOGICAL	<i>Maraviroc Plus Darunavir/Ritonavir Study for Treatment-Naive Patients Infected With R5-tropic HIV-1 Based on Enhanced Sensitivity Profile</i> NCT00993148	Principal Investigator: Jose Castro, M.D. (U of Miami); Babafemi Taiwo, MD, Northwestern University PFIZER TIBOTEC, INC		The objective of this study is to evaluate the safety and efficacy of a novel combination antiretroviral therapy regimen consisting of maraviroc plus darunavir/ritonavir in treatment-naive patients infected with R5-tropic HIV-1. The hypothesis is that in treatment-naive subjects infected with R5-tropic HIV-1, combination antiretroviral therapy with maraviroc plus darunavir/ritonavir is well tolerated and efficacious.
CLINICAL TRIAL	<i>An Observer- and Subject-Blinded, Randomized, Placebo-Controlled, Single Dose Escalation Study to Investigate the Safety, Tolerability and Pharmacokinetics of Intramuscular and Subcutaneous Long Acting GSK1265744 in Healthy Subjects</i> NCT01215006	GSK Investigational Site, Daytona Beach, Florida VIIV Healthcare – Study Sponsor		A single dose escalation study to determine the safety, tolerability, and pharmacokinetic profile of intramuscular and subcutaneous injections of GSK1265744 long acting parenteral (LAP) in healthy subjects. This study consists of a screening visit, a single injection, and follow-up evaluations for a minimum of 12 weeks following the injection.
CLINICAL TRIAL BEHAVIORAL/EPIDEMIOLOGICAL	<i>A Phase II Trial of Response-Adapted Therapy of Stage III-IV Hodgkin Lymphoma Using Early Interim FDG-PET Imaging</i> NCT00822120	M.D. Anderson Cancer Center at Orlando Recruiting Orlando, FL Contact: Julio J. Hajdenberg, M.D. 321-841-7219 Southwest Oncology Group National Cancer Institute (NCI)		RATIONALE: Drugs used in chemotherapy work in different ways to stop the growth of cancer cells, either by killing the cells or by stopping them from dividing. Giving more than one drug (combination chemotherapy) may kill more cancer cells. G-CSF may help lessen the side effects in patients receiving chemotherapy. Imaging procedures, such as fludeoxyglucose F 18-PET/CT imaging, may help doctors predict how patients will respond to treatment. PURPOSE: This phase II trial is studying fludeoxyglucose F 18-PET/CT imaging to see how well it works in assessing response to combination chemotherapy and allow doctors to plan better additional further treatment in treating patients with stage III or stage IV Hodgkin lymphoma.
CLINICAL TRIAL	<i>A Randomized, Double Blind, Placebo-Controlled, Parallel-Group, Multicenter Trial of An Investigational Medication VS. Placebo in The Treatment of Neuropathic Pain Associated With HIV Neuropathy</i>	Email: cahlstrom@southfloridamedicalresearch.com Cheryl Ahlstrom, Patient Liaison/Recruitment South Florida Medical Research 21150 Biscayne Blvd , Suite 300 Aventura, FL 33180 Phone: 305-931-8080 Fax: 305-931-8088		The study is being done to find out the good and bad effects of an investigational drug that is not approved for sale to treat peripheral neuropathic pain associated with HIV. The purpose is to see if the study drug relieves peripheral neuropathic pain associated with HIV. The study will also evaluate any side effects and whether or not they might be related to the study drug. Lastly, the study will assess whether patients will experience improvement in sleep , general health, and on symptoms of anxiety and depression. There will be about 422 people in this study. You will be in the study for about 127 days.
CLINICAL TRIAL	<i>HIV-Neuropathy Study- Phase three trial which lasts for 5 months with 12 visits for patients who suffer from</i>	Email:cahlstrom@southfloridamedicalresearch.com Cheryl Ahlstrom, Patient Liaison		Men or women 18 years or older with documented evidence of HIV-1 infection who have distal symmetrical polyneuropathy with subjective sensory symptom of pain. (physician rated)

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	<i>neuropathic pain associated with HIV. Phase 3B, randomized, double-blind, placebo-controlled, parallel group, study of drug vs. a placebo in the treatment of neuropathic pain associated with HIV-1 infection. It is a 5 month, 12 visit study to compare the effects of the study medication to placebo.</i>	South Florida Medical Research 21150 Biscayne Blvd, Suite 300 Aventura, FL 33180 Phone: 305-931-8080 Fax: 305-931-8088	Pain started in the feet Must have moderate to severe neuropathy symptoms in the feet for at least 3 months due to HIV neuropathy Pain is constant every day HIV treatment is stable	
CLINICAL TRIAL BEHAVIORAL/EPIDEMIOLOGICAL	<i>An International Observational Study to Characterize Adults Who Are Hospitalized With Complications of Influenza A – Pandemic H1N1 (H1N1v); NCT01056185</i>	UNIVERSITY OF MINNESOTA – CLINICAL AND TRANSLATIONAL SCIENCE INSTITUTE NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID) NATIONAL INSTITUTES OF HEALTH (NIH) Infectious Diseases Associates NW FL, PA Pensacola, Florida , United States, 32504 Contact: Barbara He Wade, MD, FACP 850-476-3131 bwade@infectioncenter.com Principal Investigator: Barbara He Wade, MD, FACP	The “flu” is a common disease and usually mild, but severe disease and death may occur. There are several types of flu viruses and they change over time. Recently, a new influenza A virus known commonly as swine flu or H1N1v has emerged. This flu has spread rapidly around the world. It is important to understand the course of illness for those who have H1N1v and the characteristics of people who do not do well. The investigators will also try to learn more about how different treatments and prior vaccination for the flu affects the course of the illness. Approximately 1,000 individuals will be enrolled in several countries around the world. The results of this study will be used to advise on the management of patients who are hospitalized with the flu.	
CLINICAL TRIAL BEHAVIORAL/EPIDEMIOLOGICAL	<i>INSIGHT H1N1v Outpatient Study (FLU 002) Official Title: An International Observational Study to Characterize Adults With Influenza A – Pandemic H1N1 (H1N1v); NCT01056354</i>	UNIVERSITY OF MINNESOTA - CLINICAL AND TRANSLATIONAL SCIENCE INSTITUTE; NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID) NATIONAL INSTITUTES OF HEALTH (NIH) Infectious Diseases Associates NW FL, PA Not yet recruiting Pensacola, FL P.I.: Barbara Wade, M.D. Contact Barbara Wade, MD 850-476-3131	The “flu” is a common disease and usually mild but severe disease and deaths may occur. There are several types of flu viruses and they change over time. Recently, a new influenza A virus known commonly as swine flu or H1N1v has emerged. This flu has spread rapidly around the world. It is important to understand the course of illness for those who have H1N1v and the characteristics of people who do not do well. The investigators will also try to learn more about how different treatments and prior vaccination for the flu affect the course of the illness. Approximately 5,000 individuals with swine flu will be enrolled in several countries around the world.	

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
		bwade@infectioncenter.com		
CLINICAL TRIAL	<i>A Blinded, Randomized, Placebo-controlled, Dose Ranging Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Antiviral Activity of Multiple Doses of ABT-450 With Ritonavir (ABT-450/r), ABT-333 or ABT-072 Each Administered Alone and in Combination With Peginterferon α-2a and Ribavirin (PegIFN/RBV) in Treatment-Naïve Subjects With Genotype 1 Chronic Hepatitis C Virus (HCV) Infection NCT01074008</i>	ABBOTT Contact: Christian Naylor (847) 935-2492 christian.naylor@abbott.com Contact: Victoria M Mullally 847-935-1406 tori.mullally@abbott.com Orlando area		A 12-week study of combination direct-acting antiviral agent (DAA) and pegIFN/RBV in subjects with chronic HCV.
CLINICAL TRIAL	<i>A Study of Danoprevir Boosted With Low Dose Ritonavir in Combination With Pegasys and Copegus in Treatment-Naïve Patients With Chronic Hepatitis C Virus Infection NCT01220947</i>	HOFFMANN-LA ROCHE Recruiting Orlando and South Miami, FL Study ID #: NV22776 888-662-6728 (U.S. only) Genentechclinicaltrials@druginfo.com		This randomized, open-label, active-controlled, parallel-group study will evaluate the sustained virological response of danoprevir boosted with low dose ritonavir in combination with Pegasys (peginterferon alfa-2a) and Copegus versus Pegasys and Copegus alone in treatment-naïve patients with chronic Hepatitis C
CLINICAL TRIAL BEHAVIORAL/EPIDEMIOLOGICAL	<i>Isotretinoin With or Without Monoclonal Antibody, Interleukin-2, and Sargramostim Following Stem Cell Transplantation in Treating Patients With Neuroblastoma</i> <i>Official Title: Phase III Randomized Study Of Chimeric Antibody 14.18 (CH14.18) In High Risk Neuroblastoma Following Myeloablative Therapy And Autologous Stem Cell Rescue NCT00026312</i>	Numerous locations throughout Florida CHILDREN'S ONCOLOGYGROUP; NATIONAL CANCER INSTITUTE (NCI) Under 30 yrs old Study Chair: Alice L. Yu, M.D., Ph.D. UC at San Diego		RATIONALE: Drugs used in chemotherapy work in different ways to stop tumor cells from dividing so they stop growing or die. Monoclonal antibodies can locate tumor cells and either kill them or deliver tumor-killing substances to them without harming normal cells. Interleukin-2 and sargramostim may stimulate a person's white blood cells to kill cancer cells. It is not yet known if chemotherapy is more effective with or without monoclonal antibody therapy, interleukin-2, and sargramostim following stem cell transplantation in treating neuroblastoma. PURPOSE: Randomized phase III trial to compare the effectiveness of chemotherapy with or without monoclonal antibody, interleukin-2, and sargramostim following stem cell transplantation in treating patients who have neuroblastoma
CLINICAL TRIAL	<i>Study on The Combination of RO5024048 And Ritonavir-Boosted Danoprevir With And Without Copegus (Ribavirin) in Interferon-</i>	HOFFMAN-LA ROCHE Will be recruiting in Orlando, FL		This multicenter, randomized, double-blind, parallel group study will evaluate the safety and efficacy of the combination RO5024048 and ritonavir-boosted danoprevir with and without Copegus (ribavirin) in patients with chronic hepatitis C genotype 1 who are treatment-naïve for interferons.

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	<p><i>Naïve Patients With Chronic Hepatitis C Genotype 1 (INFORM-SVR) Official Title: INFORM-SVR: A Randomized, Multi-Center Study of Interferon-Free Treatment With a Combination of a Polymerase Inhibitor (RO5024048) and a Ritonavir Boosted HCV Protease Inhibitor (RO5190591/r, DNV/r) With or Without Copegus® in Interferon Naïve HCV Genotype 1 Infected Patients NCT01278134</i></p>	<p>Please reference Study ID # PP25213 888-662-6728 genentechclinicaltrials@druginfo.com</p>	<p>Patients will receive 1000 mg RO5024048 orally twice daily and 100 mg danoprevir with 100 mg ritonavir orally twice daily plus either Copegus (1000 mg or 1200 mg orally daily) or placebo for 12 weeks. Depending on viral response, the assigned treatment will be continued for a further 12 weeks. The anticipated time on study treatment is up to 24 weeks plus a 24-week follow-up</p>	
<p>COMMUNITY AIDS NETWORK, SARASOTA, FL TANYA SCHREIBMAN, M.D., MEDICAL DIRECTOR</p>				
<p>CLINICAL TRIAL</p>	<p><i>Title: A pilot randomized, open-label study comparing the safety and efficacy of a Raltegravir based NRTI sparing regimens "No Nukes Study".</i></p>	<p>Site Investigator: Tanya Schreibman, M.D. (PI is Yale based: Michael Kozal, MD) Community AIDS Network 941-366-0134</p>	<p>Study primary site is Yale University with our site (Community AIDS Network/Comprehensive Care Clinic) as a satellite site</p>	<p>HIV, antiretroviral therapy</p>
<p>ORLANDO IMMUNOLOGY CENTER, ORLANDO, FL EDWIN DEJESUS, M.D., MEDICAL DIRECTOR</p>				
<p>CLINICAL TRIAL</p>	<p><i>Title: Evolution of L74V or K65R Mutations in Vremic Subjects on TDF or ABC (EVITA)</i></p>	<p>Study Director: Edwin Dejesus, MD, FACP (407) 647-3960</p>	<p>This is a multicenter, open-label, non-randomized, dual-arm pilot study to investigate the prevalence of the reverse transcriptase (RT) resistance mutations, K65R/x or L74V/x, in HIV-1 plasma from subjects experiencing confirmed first-time incomplete virologic suppression during treatment with an initial antiretroviral (ARV) regimen consisting of at least 12 weeks of TDF or ABC + emtricitabine (FTC) or lamivudine (3TC) + non-nucleoside reverse transcriptase inhibitor (NNRTI) or protease inhibitor (PI). Subjects will be followed until a substantial loss of virologic or immunologic control requires a treatment switch. Confirmed first-time incomplete virologic suppression is defined as an initial plasma HIV-1 RNA response < 400 copies/mL, and subsequent virologic rebound > 400 copies/mL measured at two consecutive times.</p>	

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				<p>Subjects will have a screening genotype to establish adherence to their non-suppressive TDF- or ABC-containing regimen by the presence of M184V (or other treatment-related primary) mutation and to demonstrate that the evolution of treatment-emergent RT mutations can be characterized.</p> <p>Twenty subjects (a maximum of 10 per arm) will be enrolled at 10-20 United States (U.S.) sites. If fewer than 20 subjects can be enrolled, the study may be discontinued early by the sponsor. Equal numbers of subjects on Arm A versus Arm B will be a goal.</p>

TOTAL NUMBER OF CLINICAL TRIAL STUDIES LISTED AS OF 9/12/11 = 184

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
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BEHAVIORAL/EPIDEMIOLOGICAL STUDIES

UNIVERSITY OF CENTRAL FLORIDA
Presenter: Alexander M. Cole, Ph.D.

BEHAVIORAL/EPIDEMIOLOGICAL	<i>HIV Prevention for Criminal Justice-involved Individuals (grant through Nehemiah Educational & Economic Development, Inc.)</i>	Roberto Potter, Ph.D.	Clinical Justice	HIV Prevention
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NOVA SOUTHEASTERN UNIVERSITY – 4 Studies
Presenter: Isa Fernandez, Ph.D.

BEHAVIORAL/EPIDEMIOLOGICAL	<i>Cyber Mentors: A Sustainable Model for Developing Minority HIV Researchers</i>	Maria Isabel Fernandez, Ph.D. John Anderson, Ph.D.	College of Osteopathic Medicine	Mentoring and faculty development in HIV prevention
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Proyecto SOL: A Risk Reduction Intervention for Hispanic MSM Recently Completed</i>	Maria Isabel Fernandez, Ph.D.; G. Stephen Bowen, M.D., M.P.H.	College of Osteopathic Medicine	HIV prevention among Latino/Hispanic MSM
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Understanding the Scope and Magnitude of Prescription Drug Diversion</i>	Steven P. Kurtz, Theodore J. Cicero, Hilary L. Surratt	Division of Applied Interdisciplinary Studies	HIV, drug use, diversion National Institute on Drug Abuse Grant # DA021330
BEHAVIORAL/EPIDEMIOLOGICAL	<i>The Diversion of Antiretroviral Medications to Street Markets</i>	Hilary L. Surratt, Gladys Ibanez, Steven P. Kurtz	Division of Applied Interdisciplinary Studies	HIV, diversion, ARV medications, drug use National Institute on Drug Abuse Grant # DA023157

FLORIDA STATE UNIVERSITY
Presenter: Neil Abell, Ph.D., L.C.S.W. – 11 Studies

BEHAVIORAL/EPIDEMIOLOGICAL	<i>Promoting Male Involvement to Improve Prevention of Mother-to-Child Transmission Uptake and Reduce Antenatal Infection</i>	Deborah Jones (PI), Karl Peltzer, Stephen Weiss, Olga Villar.	Psychiatry Micro and Immunol.	HIV and women.
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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Expression and impact of HIV/AIDS provider stigma in the West Indies: Examining the context of testing, treatment, and care</i>	Rutledge, S.E., and Abell, N., Padmore, J., & McCann, T.	College of Social Work and UNIVERSITY OF THE WEST INDIES, ST. AUGUSTINE, TRINIDAD & TOBAGO; ST. GEORGE'S UNIVERSITY, GRENADA	HIV/AIDS Provider Stigma; International
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Social work and HIV/AIDS in Northern India</i>	Abell, N., & Thomas, G., & associates	College of Social Work and INDIRA GHANDI NATIONAL OPEN UNIVERSITY	Prevention, education, & outreach; International; Curriculum development
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Validation of the HIV/AIDS Provider Stigma Inventory (HAPSI)</i>	Abell, N., Rutledge, S.E., Whyte, IV, J., Brown, K., & Cesnales, N.	College of Social Work, College of Nursing and TEMPLE UNIVERSITY	HIV/AIDS provider stigma; Psychometrics
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Awareness/Acceptance/Action Model (AAAM): Mindfulness and Stigma</i>	Abell, N., & Rutledge, S.E.	College of Social Work and TEMPLE UNIVERSITY	HIV/AIDS provider stigma; Intervention modeling
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Assessing capacity for self-care among HIV heads of household: Bilingual validation of the Parental Self-Care Scale</i>	Abell, N., Ryan, S., & Kamata, A.	College of Social Work, College of Education	Prevention; Intervention; Psychometrics
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Bilingual validation of the Family Responsibility Scale: Assessing stress among HIV+ heads of household</i>	Abell, N., Ryan, S., & Kamata, A.	College of Social Work, College of Education	Prevention; Intervention; Psychometrics
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Development and evaluation of the Adherence Attitudes Inventory</i>	Lewis, S., & Abell, N.	College of Social Work	Treatment; Psychometrics
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Assessing willingness to care for persons with AIDS</i>	Abell, N.	College of Social Work, College of Education	Caregiving; Psychometrics
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Cultivating Compassion: Recognizing and Interrupting</i>	Abell, N., Garland, E., Whyte, IV, J., Eccles, D., &	College of Social Work and TEMPLE	HIV/AIDS provider stigma; Intervention

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	<i>Unconscious Stigmatizing Responses in HIV/AIDS Health Care and Social Service Provision (Proposed)</i>	Rutledge, S.E.	UNIVERSITY	
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Health Relationships for Women with HIV</i>	Stephanie Marhefka, Robert Gleukhauf	FSU College of Medicine and DPH, Medical Humanities and Social Science	Behavioral intervention for women with HIV
UNIVERSITY OF MIAMI – 29 Studies Presenter: Savita Pahwa, M.D.				
BEHAVIORAL/EPIDEMIOLOGICAL BASIC SCIENCE/VIROLOGY	<i>Longitudinal analysis of a high risk HIV negative cohort</i>	Derek Dykxhoorn (Human Genetics, Microbiology and Immunology, DCFAR), Lisa Metsch (Epidemiology and Public Health, DCFAR), Jose Castro (Medicine, DCFAR), Savita Pahwa (Microbiology and Immunology, DCFAR), Margaret Fischl (Medicine, DCFAR), Rafick Sekaly (VGTI-Florida, DCFAR), Lydie Trautmann (VGTI-FL, DCFAR)	Human Genetics, Microbiology and Immunology, Epidemiology and Public Health, Medicine, VGTI-FL, Developmental Center for AIDS Research (DCFAR)	Genetics and Genomics of HIV infection, Acute HIV infection (AHI)
BEHAVIORAL/EPIDEMIOLOGICAL	<i>The impact of early antiretroviral therapy on HIV persistence and inflammation</i>	Mario Stevenson, Stevens Deeks UCSF (PI)	Medicine	To evaluate whether early intervention can improve treatment responses in HIV infected individuals.
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Promoting Male Involvement to Improve Prevention of Mother-To-Child Transmission Uptake and Reduce Antenatal Infection</i>	Deborah Jones, Karl Peltzer, Stephen Weiss, Olga Villar	Psychiatry Micro and Immunology	HIV and women Sponsor: PEPFAR
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Implementing HIV Risk Reduction Zambia</i>	Deborah L. Jones Weiss	Psychiatry & Behavioral Sciences	NICHD

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BEHAVIORAL/EPIDEMIOLOGICAL	<i>Enhancing HIV Medication Adherence in India</i>	Deborah L. Jones Weiss	Psychiatry & Behavioral Sciences	NINR
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Longitudinal Dyadic Analysis of HIV-positive Substance Users with Trauma History</i>	Deborah Jones Weiss	Psychiatry & Behavioral Sciences	NIDA
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Juvenile Offender HIV Prevention and Drug Abuse Services</i>	Howard Liddle	Epidemiology & Pub. Health Med.	NIDA
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Center for Implementing Juvenile Justice Drug Abuse & HIV Systems Interventions</i>	Howard Liddle	Epidemiology & Pub. Health Med.	NIDA
BEHAVIORAL/EPIDEMIOLOGICAL	<i>HIV Testing and Counseling in STD Clinics: an Adaptation of CTN 0032</i>	Lisa R. Metsch	Epidemiology & Pub. Health Med.	NIDA
BEHAVIORAL/EPIDEMIOLOGICAL	<i>HIV Testing in Dental Care Settings</i>	Lisa R. Metsch	Epidemiology & Pub. Health Med.	NIDCR
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Enhancing Oral Health Care Use by HIV-Positives</i>	Lisa R. Metsch	Epidemiology & Pub. Health Med.	NIDCR
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Prevention Among HIV+ Crack Users in the Hospital</i>	Lisa R. Metsch	Epidemiology & Pub. Health Med.	NIDA
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Familias Unidas State III Study: Preventing Substance Abuse in Hispanic Youth</i>	Guillermo Prado	Epidemiology & Pub. Health Med.	NIDA
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Preventing Drug Abuse & HIV in Hispanic First Offenders</i>	Guillermo Prado	Epidemiology & Pub. Health Med.	NIDA
BEHAVIORAL/EPIDEMIOLOGICAL	<i>PS07-003, Minority HIV/AIDS</i>	Guillermo Prado	Epidemiology & Pub.	OTHER

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	<i>Research Initiative (MARI)</i>		Health Med.	
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Long-term Outcomes and Economic Impact of the Detention to Community Model</i>	Cynthia Rowe	Epidemiology & Pub. Health Med.	NIDA
BEHAVIORAL/EPIDEMIOLOGICAL	<i>The Role of Culture in Thriving and Risk Behavior in Hispanic Adolescents</i>	Seth J. Schwartz	Epidemiology & Pub. Health Med.	NIDA
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Sex and gender influences on addiction and health</i>	Bandstra, E.	Drug Abuse	NIDA
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Family intervention for teen drinking and alcohol-related crises in the ER</i>	Rowe, C.	Drug Abuse	NIAAA
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Culturally informed family based treatment of adolescents: A randomized trial</i>	Santisteban, D.	Drug Abuse	NIDA
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Identity and context in HIV prevention for Hispanic youth</i>	Schwartz, S.	Drug Abuse	NIDA
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Alcohol and HIV in Latin America</i>	Shor-Posner, G.	Drug Abuse	NIAAA
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Longitudinal Dyadic Analysis of HIV-positive Substance Users with Trauma History</i>	Deborah Jones	Behavioral Research	NIDA
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Health literacy, cognitive and social determinants of HIV appointment attendance</i>	Drenna Waldrop-Valverde	Behavioral Research	NIMH
BEHAVIORAL/EPIDEMIOLOGICAL	<i>A targeted decision and to improve minority participation in clinical trials</i>	Margaret Byrne	Behavioral Research	NCMHD

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
BEHAVIORAL/EPIDEMIOLOGICAL	<i>HAART associated cardiotoxicity in HIV-infected children</i>	Steven Lipshultz	Pediatric Metabolic/ Pathogenesis Research	NHLBI
BEHAVIORAL/EPIDEMIOLOGICAL	<i>PHACS (Pediatric HIV/AIDS Study)</i>	Gwendolyn Scott	Pediatric Metabolic/ Pathogenesis Research	NICHHD
CLINICAL TRIAL BEHAVIORAL/EPIDEMIOLOGICAL	<i>CTN 0049: Project HOPE: Hospital Visit is an Opportunity for Prevention and Engagement</i>	Lisa Metsch, PI	NIDA Clinical Trials Network (CTN)	
BEHAVIORAL/EPIDEMIOLOGICAL	<i>CTN 0047: SMART ED SBIRT* in the Emergency Dept. *screening, brief interventions, referral and treatment</i>		NIDA Clinical Trials Network (CTN)	
DUVAL COUNTY HEALTH DEPARTMENT Presenter: M. Maximillion Wilson, Ph.D. – 2 Studies				
BEHAVIORAL/EPIDEMIOLOGICAL	<i>The Interdiction Project</i>	M. Maximillion Wilson, Ph.D. (PI), Samuel Frimpong, M.D., M.P.H. (co-PI)	Prevention Unit, Area 4 AIDS Program Office	Behavioral Intervention, Prevention-for-Positives
BEHAVIORAL/EPIDEMIOLOGICAL	<i>HIV Mapping: Understanding Service Gaps through use of GIS</i>	M. Maximillion Wilson, Ph.D. (PI), David L. Andress	Prevention Unit, Area 4 AIDS Program Office.	Public Health Program Evaluation
UNIVERSITY OF SOUTH FLORIDA – 17 Studies Presenter: John W. Sleasman, M.D.				
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Novel dissemination of a group intervention for HIV+ women via web conferencing</i>	Marhefka, Stephanie (PI) Baldwin, Julie Buhi, Eric	Community and Family Health	Behavioral Science, HIV+ Women, Prevention, MTCT Intervention Dissemination Sponsor: NIMH
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Florida/Carribbean AIDS Education and Training Center</i>	Jeff Beal	Mental Health Law & Policy	Provider training, Educational materials

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BEHAVIORAL/EPIDEMIOLOGICAL	<i>Perinatal HIV Transmission Prevention Project</i>	Michael Knox (PI)	Mental Health Law & Policy	Provider training, Educational materials
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Environmental Factors in HIV Transmission Among Suburban IDUs</i>	Wilson Palacios (PI)	Criminology	Prevention, IVDU
BEHAVIORAL/EPIDEMIOLOGICAL	<i>A Randomized Controlled Trial of Family-Based HIV Prevention for Latino Youth</i>	Celia Lescano (PI)	Mental Health Law & Policy	prevention intervention, Latinos, disparities
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Evaluation of Pinellas County Adult Treatment Drug Court</i>	Kathleen Moore (PI)		
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Medication Assisted Drug Court Treatment (MADCT) Program</i>	Kathleen Moore (PI)		
BEHAVIORAL/EPIDEMIOLOGICAL	<i>New Faculty Recruitment to Enhance Co-Morbidity Research in Justice Settings</i>	Roger Peters (PI)		
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Conference: Advances in Translational Research in AIDS/HIV in India</i>	Shyam Mohapatra (PI)	Internal Medicine	basic and translational research in HIV; collaborative projects
BEHAVIORAL/EPIDEMIOLOGICAL	<i>ATN 096: Identifying Undiagnosed Asymptomatic HIV Infection in Hispanic/Latino Adolescents and Young Adults</i>	Diane Straub and Patricia Emmanuel	Pediatrics	HIV testing, linkage to care, Latino
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Program in Adolescent HIV/AIDS Research Training (PAHRT) – Fogarty AITRP</i>	Patricia Emmanuel (PI)	Pediatrics	prevention, treatment and natural history studies in Gujarat India
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Ryan White Care Act Title IV Adolescent Initiative</i>	PATRICIA EMMANUEL (PI)	PEDIATRICS	HIV TESTING, OUTREACH AND CARE FOR YOUTH
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Brief Intervention for Drug Use</i>	Richard Dembo (PI)		Prevention; Drug Use

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	<i>and HIV/STD Risk Prevention Among Truants</i>			
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Statistical Methods for Long-Term HIV Dynamic Modeling and Design</i>	Brian Giunta (PI)	Psychiatry and Neurosciences	
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Statistical Methods for Long-Term HIV Dynamic Modeling and Design</i>	Yangxin Huang (PI)		
BEHAVIORAL/EPIDEMIOLOGICAL	<i>A Randomized Controlled Trial of Family-Based HIV Prevention</i>	Celia Lescano (PI)		
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Enhancing NIH Supported health Research in Gujarat, India</i>	Tiffany Ann Chenneville (PI)	Pediatrics	
ORANGE COUNTY HEALTH DEPARTMENT – 2 Studies Presenter: Gerald Horton, Jr. M.D.				
BEHAVIORAL/EPIDEMIOLOGICAL	<i>SIHLE A study seeking to determine the effectiveness of the SIHLE model to reduce sexual health and relationship-related disparities in the Orange County zip codes: 32808, 32811, 3281 and increase self-efficacy, self-esteem, communication and condom negotiation skills in females, ages 14 -18 years.</i>	(PD)- Karen Wint, MPA Ronessa Strickland-Roberts, MPH (Project Coord)		
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Multimedia WILLOW Program Outcome Study: A study to test the effectiveness of a multimedia version of a HIV/AIDS Prevention Program Archive (HAPPA) program and</i>	Dr. Carmela Lomonaco (PD) and Alelia Munroe, MPH (Sub-PD, OCHD)	Immunology Clinics	HIV Behavioral Intervention and Awareness African American Female, Age18-50 SPONSOR: NIH, and SOCIOMETRICS Corp.

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
	<i>provide clients with additional HIV management tools and techniques.</i>			
UNIVERSITY OF FLORIDA Presenter: Maureen Goodenow, Ph.D. - 8 studies				
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Natural History of HPV Infection in Men (HIM) Study</i>	Anna Giuliano (PI) Moffitt Cancer Center, Maureen Goodenow (Co-PI), Li, Yin (Co-I)	Pathology	HPV in a multinational cohort of men
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Smoking cessation and the natural history of HIV-Induced Emphysema</i>	Thomas Clanton (PI)	Exercise and Sports Sciences	Pathogenesis
BEHAVIORAL/EPIDEMIOLOGICAL	<i>A breath-based medication adherence monitoring system for HIV-AIDS therapies (specific AIM2-Food Interference)</i>	Timothy Morey (PI), Donn M. Dennis (Co-PI), Susan P. McGorray (PI)	Anesthesiology Health Outcomes and Policy	Adherence
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Multiple behavior SBIRT Model of drug abuse among emerging adults in primary</i>	Dennis Thombs (PI)	Behavioral Science and Comm Health	Drug Abuse
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Florida AIDS Education Training Centers</i>	Robert M. Lawrence (PI), Charles E. Stewart (CO-PI)	Pediatrics	Education
BEHAVIORAL/EPIDEMIOLOGICAL	<i>HIV risk among racially-diverse, minority youth and partner selection</i>	Stephanie Staras (PI)	Medicine	Behavior
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Pharmacotherapy for Hazardous Drinking in HIV-infected women</i>	Robert L. Cook (PI), Bridgett Rahim-Williams, Mobeen Rathore, WHAT-IF study investigators	Epidemiology, Medicine, Peds, Social & Behavioral Health Sciences	Alcohol and HIV Randomized clinical trial
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Molecular epidemiology of HIV infection in Morocco</i>	Robert L. Cook (PI), Marco Salemi, Andy Tatem, Maureen Goodenow, Glenn Morris, Moroccan Co-	Epidemiology Pathology Geography	Contextual and behavioral factors associated with HIV spread

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
Investigators				
FLORIDA INTERNATIONAL UNIVERSITY – 35 Studies Presenter: Mario De La Rosa, Ph.D.				
BEHAVIORAL/EPIDEMIOLOGICAL	<i>The Impact of HIV/AIDS among Latina/o Suicide Victims (completed)</i>	Dr. Ramiro Martinez (PI)	School of Criminology	HIV/AIDS and Latina/o Suicide Victims Funding Source: NIMHD
BEHAVIORAL/EPIDEMIOLOGICAL	<i>HIV and Substance Abuse Risk Behaviors Among Hispanic Youth of Florida (completed)</i>	Dr. WayWay M. Hlaing (PI)	School of Social Work	HIV, Substance Abuse, Risk Behaviors, and Hispanic Youth of Florida Funding Source: NIMHD
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Impact of 2005 Hurricane Season on HIV/ AIDS Health Services in Miami Dade County (Completed)</i>	Dr. Sukumar Ganapati	School of Social Work	2005 Hurricane Season, HIV/ AIDS, and Health Services in Miami Dade County Funding Source: NIMHD
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Latino Minority Drug Abuse Research Center: Women Study (Completed)</i>	Dr. Mario De La Rosa (PI), Dr. Patria Rojas	School of Social Work	intergenerational transmission of drug use, Risky sexual behaviors, Latino women (mother-daughter dyads Funding Source: NIDA
BEHAVIORAL/EPIDEMIOLOGICAL	<i>HIV Infection and Risk of Fatal Drug Overdose in Miami Communities: An Individual and Community Level Analysis (Completed)</i>	Dr. Ramiro Martinez	CRUSADA	HIV Infection, Risk of Fatal Drug Overdose in Miami Communities Funding Source: NIMHD
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Clusters and Trends of Sexual, Substance Use, and Other Health Risks among Hispanic and Non-Hispanic Adolescents (Completed)</i>	WayWay Hlaing, Sunny Kim, Mario De La Rosa	CRUSADA	Clusters and Trends of Sexual, Substance Use, and Other Health Risks and Hispanic and Non-Hispanic Adolescents Funding Source: NIMHD
BEHAVIORAL/EPIDEMIOLOGICAL	<i>HIV Risk Reduction In High Risk Hispanic Migrant Workers In South Florida (Completed)</i>	Dr. Jesus Sanchez	CRUSADA	HIV Risk Reduction and Risk Hispanic Migrant Workers In South Florida Funding Source: NIMHD
BEHAVIORAL/EPIDEMIOLOGICAL	<i>HIV Risk Behavior and Substance Abuse among Recent Latino Immigrants (ongoing)</i>	Mario De La Rosa (PI), Patria Rojas	CRUSADA	HIV Risk Behavior and Substance Abuse, recent Latino Immigrants Funding Source: NIMHD

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
BEHAVIORAL/EPIDEMIOLOGICAL	<i>A Longitudinal Study of Substance Abuse and HIV Risk Among Adult Latina Mother-Daughter (ongoing)</i>	Mario De La Rosa (PI), Patria Rojas, Frank Dillon	CRUSADA	Substance use, HIV risk behavior trajectories, Latina mothers and daughters Funding Source: NINR
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Retrospective cohort study to estimate the contribution of socioeconomic status, segregation and rural residence on racial disparities in HIV survival, Florida</i>	Mary Jo Trepka (PI), Theophile Niyonsenga, Spencer Lieb, Lorene Maddox	Epidemiology and Biostatistics (and FDOH)	To estimate the effect of community-level deprivation and rural residence on racial disparities in HIV survival over time To estimate the effect of racial segregation on HIV survival To characterize changes in community-level socioeconomic status between the time of AIDS diagnosis and death To compare the degree of community racial segregation between the time of AIDS diagnosis and death To characterize patterns and predictors of rural to urban migration between AIDS diagnosis and death Funded by The NCMHHD
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Impact of 2005 Hurricane and HIV Risk among Latino Father-Son Dyads (Planned)</i>	Mario De La Rosa (PI), Frank Dillon, Patria Rojas	CRUSADA Social Work	2005 Substance Use, HIV/AIDS, Health Services, Miami-Dade County Funding Source: NIMHD
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Serotonin and Brain Derived Neurotrophic Factor Roles on HIV Risk Behaviors on Latino Mother-Adolescent Dyads (Planned)</i>	Investigators: Maria Jose Miguez (PI), Mario De La Rosa, Robert Malow, Patria Rojas, Changwon Yoo	CRUSADA	Serotonin and Brain Derived Neurotrophic, HIV Risk Behaviors, Latino Mother-Adolescent Dyads Funding Source: NINR
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Alcohol Use and the Immune-Cardiovascular-Brain Loop in HIV Positives (Planned)</i>	Maria Jose Miguez (PI), Deshratan Asthana, Ximena Burbano, Mario De La Rosa, Mehmet Dorak	College of Public Health	Alcohol Use, Immune-Cardiovascular-Brain Loop, HIV Positives Funding Source: NIAAA
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Development of an Intervention Package to Reduce Alcohol and</i>	Robert Malow (PI), Maria Jose Miguez, Jessy	College of Public Health	Alcohol Use, Immune-Cardiovascular-Brain Loop, HIV Positives

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
	<i>Sexual Risks (Planned)</i>	Devieux		Funding Source: NIAAA
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Multi-level HIV Prevention for Pregnant Drug Abusers</i>	Robert Malow (PI), Jessy Devieux, Michele Jean-Gilles, Brenda Lerner, Rhonda Rosenberg	Robert Stempel College of Public Health and Social Work	This study of Pregnant Drug Abusers in treatment is a randomized trial of Enhanced- Behavioral Skills Training (E-BST) compared to a time- and attention-matched Health Promotion Comparison (HPC) condition. It responds to the NIH priority on translational research to adapt effective research-based intervention strategies to 'real world' conditions. If successful, this research will offer a realizable HIV intervention strategy, bridging research and practice, that can be implemented for pregnant drug abusers within their communities. Funded by NIDA
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Intervening with HIV+ Alcohol Abusers: Influence of Neuro-Behavioral Factors</i>	Robert Malow (PI), Jessy Devieux, Michele Jean-Gilles, Brenda Lerner, Rhonda Rosenberg, Madhavan Nair	Robert Stempel College of Public Health and Social Work	To reduce HIV sexual transmission risk and substance use, increase the utilization of primary HIV care services, and improve psychosocial health among alcohol abusing, HIV+ individuals. The study evaluates memory, information processing, executive functioning and genetic factors of participants to discern factors with treatment effects, and to identify individual characteristics that may contribute to specific reductions in risky behaviors. Funded by NIAAA
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Intervening with Haitian HIV+ Alcohol Abusers: An environmental Psychosocial Framework</i>	Robert Malow (PI), Jessy Devieux, Michele Jean-Gilles, Rhonda Rosenberg	Robert Stempel College of Public Health and Social Work	To address the problem of health disparities in HIV risks and to adapt "effective" interventions to reach this population in Haiti. The project also responds to the NIH priority on bridging clinical research and practice into community settings in a manner adaptable

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
				to "real world" conditions. Funded by NIAAA
BEHAVIORAL/EPIDEMIOLOGICAL	<i>A longitudinal Study of Drug Abuse & HIV Risk among Latina Mother-Daughter Dyads</i>	Mario De La Rosa (PI), Patria Rojas, Frank Dillon	Robert Stempel College of Public Health and Social Work	To determine the influence of cultural and social determinants on trajectories of change for substance use and HIV risk behaviors among a community-based sample of Latina mothers and daughters. To determine the influence of mother-daughter attachment on trajectories of change for substance use and HIV risk behaviors. To determine the moderating role of mother-daughter attachment on associations between experiences of detrimental social determinants and trajectories of change for substance use and HIV risk behaviors. Funded by NINR
BEHAVIORAL/EPIDEMIOLOGICAL	<i>HIV Risk Reduction in Migrant Workers</i>	H. Virginia McCoy, (PI); Robert Malow, Co-PI; Jessy G. Dévieux, Co-Investigator; Theophile Niyonsenga, Biostatistician	Robert Stempel College of Public Health and Social Work	A randomized community trial to reduce HIV risk and to promote healthy behaviors among alcohol and other drug (AOD)-using Migrant Workers
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Curriculum Development Institute</i>	Richard Beaulaurier (PI)	Robert Stempel College of Public Health and Social Work	To explore the perspective of social workers who treat or work with older Latinos who are HIV+, including the language, techniques and approaches employed to discuss issues of sex, sexuality and the risk of HIV infection with their Latino patients and clients; Funded by The John A. Hartford Foundation
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Center for Substance Use and AIDS Research on Latinos in the United States (CRUSADA)</i>	Mario de la Rosa (PI), Jesus Sanchez, Frank Dillon, Robert Malow, Changwon Yoo, Richard	Robert Stempel College of Public Health and Social Work	To explore behavioral and social factors contributing to or influencing minority health and health disparities To translate research findings into

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
		Beaulaurier		<p>interventions for improving minority health or eliminating health disparities</p> <p>To explore the efficacy of a range of health promotion and information dissemination approaches for improving minority health or eliminating health disparities</p> <p>To establish innovative partnerships between academic and community entities</p> <p>To increase the number of researchers and professionals committed to eliminate health disparities</p> <p>Funded by NCMHD: P-20 Center Grant</p>
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Tanzanian Drug Treatment as AIDS Prevention - Reliability and Validity Study</i>	Mark Williams (PI)	Robert Stempel College of Public Health and Social Work	<p>To develop culturally appropriate measures of psychological functioning, social functioning, treatment motivation, addiction severity, and readiness for treatment</p> <p>To assess IDUs' understanding and relevancy of the measures of psychological functioning, social functioning, treatment motivation, addiction severity, and readiness for treatment</p> <p>To test the reliability and validity of the D-TAPP Questionnaire</p> <p>Funded by NIDA</p>
BEHAVIORAL/EPIDEMIOLOGICAL	<i>HIV Risk Behavior and Substance Abuse among Recent Latino Immigrants</i>	Mario De La Rosa (PI), Patria Rojas	Robert Stempel College of Public Health and Social Work	<p>To study HIV Risk Behaviors and Substance Abuse in recent Latino Immigrants</p> <p>Funded by NCMHD</p>
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Community Mobilization for HIV Prevention—Racial and Ethnic Approaches to Community Health (REACH) 2010 in Broward County.</i>	William W. Darrow, PI and Project Leader	Robert Stempel College of Public Health and Social Work (Recently Completed Studies)	<p>Eliminate disparities in HIV infection among Black and Hispanic 18-39 year-old residents of 12 high AIDS-prevalence ZIP-code areas of Broward County; Funded by CDC</p>

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
BEHAVIORAL/EPIDEMIOLOGICAL	<i>The Impact of HIV/AIDS among Latina/o Suicide Victims</i>	Dr. Ramiro Martinez (PI)	School of Criminology (Recently Completed Studies)	HIV/AIDS and Latina/o Suicide Victims. Funded by NCMHD
BEHAVIORAL/EPIDEMIOLOGICAL	<i>HIV and Substance Abuse Risk Behaviors Among Hispanic Youth of Florida</i>	Dr. WayWay M. Hlaing (PI)	Robert Stempel College of Public Health and Social Work (Recently Completed Studies)	HIV, Substance Abuse, Risk Behaviors, and Hispanic Youth of Florida Funded by NCMHD
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Impact of 2005 Hurricane Season on HIV/ AIDS Health Services in Miami Dade County</i>	Sukumar Ganapati	Robert Stempel College of Public Health and Social Work (Recently Completed Studies)	2005 Hurricane Season, HIV/ AIDS, and Health Services in Miami Dade County Funded by NCMHD
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Latino Minority Drug Abuse Research Center: Women Study</i>	Mario De La Rosa (PI), Dr. Patria Rojas	Robert Stempel College of Public Health and Social Work (Recently Completed Studies)	Intergenerational transmission of drug use, Risky sexual behaviors, Latino women (mother-daughter dyads). Funded by NIDA
BEHAVIORAL/EPIDEMIOLOGICAL	<i>HIV Infection and Risk of Fatal Drug Overdose in Miami Communities: An Individual and Community Level Analysis</i>	Ramiro Martinez (PI)	Robert Stempel College of Public Health and Social Work (Recently Completed Studies)	HIV Infection, Risk of Fatal Drug Overdose in Miami Communities. Funded by NCMHD
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Clusters and Trends of Sexual, Substance Use, and Other Health Risks among Hispanic and Non-Hispanic Adolescents</i>	WayWay Hlaing, Sunny Kim, Mario De La Rosa	Robert Stempel College of Public Health and Social Work (Recently Completed Studies)	Clusters and Trends of Sexual, Substance Use, and Other Health Risks and Hispanic and Non-Hispanic Adolescents Funded by NCMHD
BEHAVIORAL/EPIDEMIOLOGICAL	<i>HIV Risk Reduction In High Risk Hispanic Migrant Workers In South Florida</i>	Jesus Sanchez (PI)	Robert Stempel College of Public Health and Social Work (Recently Completed Studies)	HIV Risk Reduction and Risk Hispanic Migrant Workers In South Florida. Funded by NCMHD
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Older Latina Perspectives on Sex, Sexuality and Risk of AIDS</i>	Richard L. Beaulaurier: PI	Robert Stempel College of Public Health and Social Work (Recently Completed Studies)	To document culturally-relevant interpersonal and intrapsychic scripts To classify respondents into discrete groups based on behavioral indicators of risk for HIV exposure. The study uses a mixed methods design with qualitative and quantitative components. Funding

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
				Agency: NIGMS
BEHAVIORAL/EPIDEMIOLOGICAL	<i>NIH NIAAA 3RO1AA017405-0251 MJM Gender Differences in an HIV intervention</i>	Míguez and Malow	Florida International University	The main task of this study is to identify gender differences in cognitive tasks and genetic polymorphisms that can explain differential responses to brief alcohol interventions. The study evaluates memory, information processing, executive functioning and genetic factors of participants to discern factors with treatment effects, and to identify individual characteristics that may contribute to specific reductions in risky behaviors
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Research Core, C-SALUD: Center for Substance Use and AIDS Research on Latinos in the United States</i>	Robert Malow (Research Core PI)	AIDS Prevention Program, Department of Health Promotion & Disease Prevention and Stempel College of Public Health and Social Work	The Research Core is aimed at designing and implementing long-term infrastructure support to facilitate and guide interdisciplinary research initiatives at Florida International University (FIU), directed towards eliminating health disparities and assisting investigators of the FIU center called CRUSADA (Center for Research on US Latinos HIV/AIDS and Drug Abuse), which was created under a grant awarded by the NIH National Center on Minority Health and Health Disparities for 2007-2012 to Mario De La Rosa (PI, and Director) under the title, "C-SALUD: Center for Substance Use and AIDS Research on Latinos in the USA." Two full research projects and four pilot projects are proposed as part of the core. All these projects focus on the social and cultural factors underlying the twin epidemics of HIV/AIDS and substance abuse among

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				Latino populations, the theme of the Center of Excellence; NCMHD, Research Core, 2010-2011
BEHAVIORAL/EPIDEMIOLOGICAL	<i>HIV Prevention Groups for AOD Using SMI Women</i>	Robert Malow (PI), Jessy Dévieux (Co-PI), Mark MacGowan (Co-Inv), Amy Paul Ward (Co-Inv), Michèle Jean-Gilles (Inv), Brenda Lerner (Project Director)	AIDS Prevention Program, Department of Health Promotion & Disease Prevention and Stempel College of Public Health and Social Work	Consists of an R01 randomized controlled trial of an adapted intervention, "Let's Chat: A Brief Behavioral Skills Intervention (BBSI) to Prevent HIV Infection Among Chronic Mentally Ill Adults," strengthened to be gender and culturally appropriate for a target population of alcohol and other drug (AOD) using, seriously mentally ill (SMI) women in outpatient treatment; The analytical and therapeutic foreground of the study is group process and its role as a putative change mechanism. NIDA (Primary), NIAAA, 2004-2009
BUREAU OF HIV/AIDS – 9 Studies Presenters: Spencer Lieb, M.P.H. & Marlene LaLota, M.P.H.				
BEHAVIORAL/EPIDEMIOLOGICAL	<i>HIV Prevalence Rates Among Men Who Have Sex with Men in the Southern United States: Population-Based Estimates by Race/Ethnicity</i>	Lieb S, MPH, Fallon S, PhD, Friedman S, PhD, Thompson D, MPH, Gates G, PhD, Liberti T, BS, and Malow R, PhD	Public Health Reports 2011	MSM and HIV
BEHAVIORAL/EPIDEMIOLOGICAL	<i>HIV Prevalence Rates Among Men Who Have Sex with Men in the Southern United States: Population-Based Estimates by Race/Ethnicity</i>	Spencer Lieb, Joseph Prejean, Daniel R. Thompson, Stephen J. Fallon, Hannah Cooper, Gary J. Gates, Thomas M. Liberti, Samuel R. Friedman and Robert M. Malow	AIDS and Behavior 2010	MSM and HIV
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Estimated HIV Incidence, Prevalence, and Mortality Rates Among Racial/Ethnic Populations of Men Who Have</i>	Lieb, Spencer MPH; White, Stefanie MPH; Grigg, Becky L PhD; Thompson, Daniel R MPH; Liberti, Thomas M	Journal of Acquired Immune Deficiency Syndromes 2010	MSM and HIV

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
	<i>Sex with Men, Florida</i>	BS; Fallon, Stephen J PhD		
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Estimating Populations of Men Who Have Sex with Men in the Southern United States</i>	Lieb S, Thompson D, Misra S, Gates G, Duffus W, Fallon S, Liberti T, Foust E, Malow R, and the Southern AIDS Coalition Team	Journal of Urban Health 2009	MSM and HIV
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Men Who Have Sex with Men: Racial/ethnic Disparities in Estimated HIV/AIDS Prevalence at the State and County Level, Florida</i>	Lieb S, Thompson D, Santana A, Liberti T, Maddox M, Bush T, Fallon S	AIDS and Behavior 2009	MSM and HIV
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Men Who Have Sex With Men: Estimated Population Sizes and Mortality Rates by Race/Ethnicity, Miami-Dade County, Florida</i>	Lieb S, Trepka MJ, Thompson D, Arons P, Liberti T, Maddox L, Metsch L, LaLota M, Fallon S	Journal of Acquired Immune Deficiency Syndromes 2007	MSM and HIV
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Medical Monitoring Project</i>	Grigg, Becky L PhD	Supplemental HIV/AIDS Surveillance	Persons receiving HIV medical care in public and private facilities in Florida.
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Protocol Title: TLC-Plus: A Study to Evaluate the Feasibility of an Enhanced Test, Link to Care, Plus Treat Approach for HIV Prevention in the United States</i>	PI: Becky Grigg, PH.D, Florida Dept. of Health, Bureau of HIV/AIDS, Surveillance		Funded By: Fred Hutchinson Cancer Research Center, Plus 0000698642 National Institute of Child Health and Human Development (NICHD)
BEHAVIORAL/EPIDEMIOLOGICAL	<i>National HIV Behavioral Surveillance (Miami-Dade County site)</i>	Marlene LaLota, Lisa Metsch, David Forrest, Dano Beck	Behavioral studies	Behavioral surveillance among high-risk populations (i.e., MSM, IDUs, and heterosexuals at increased risk for infection). This ongoing study was first implemented in 2004. Each population is sampled approximately once every three years; two study cycles have been completed among each population. The study provides data on 1) trends in sexual and drug-use risk behaviors, 2) HIV

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
				prevalence and incidence, 3) HIV testing patterns, and 4) the use and impact of prevention services. The overarching goal of NHBS is to help evaluate and direct local and national prevention efforts
University of Florida Center for HIV/AIDS Research Education and Service (UF CARES) – 11 Studies Presented by Mobeen Rathore, M.D.				
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Calcium, Vitamin D and bone mineral density in HIV infected children compared to normal age and sex matched subjects (planning ongoing)</i>	Saran Valdez- Johnson MD, Ayesha Mirza MD	Pediatrics	HIV and children and adolescents
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Dyslipidemia in HIV infected children on HAART (ongoing)</i>	Ayesha Mirza, Peter Wludyka, Mobeen Rathore	Pediatrics	Metabolic complications in HIV and children
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Analysis of perinatal HIV transmission in Florida 2002-2009 (completed)</i>	Ayesha Mirza, N Harrell, M Lalota, L Maddox, Mobeen Rathore	UF Pediatrics and DOH, Bureau of HIV/AIDS	Perinatal HIV transmission
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Longitudinal Epidemiologic Study to Gain Insight Into HIV/AIDS In Children & Youth (legacy)</i>	Mobeen Rathore, MD	Pediatrics	HIV
BEHAVIORAL/EPIDEMIOLOGICAL	<i>P1074: A Prospective Surveillance Study of Long-Term Outcomes in HIV-infected Infants, Children & Adolescents, Version 1.0 dated February 2, 2009 The IRB has determined the risk/benefit for this study is consistent with 45 CFR 45.404</i>	Mobeen Rathore, MD	Pediatrics	HIV, long-term outcomes, chart review
BEHAVIORAL/EPIDEMIOLOGICAL	<i>PACTG P1055: Psychiatric Co-Morbidity in Perinatally HIV-Infected Children & Adolescents</i>	Mobeen Rathore, MD	Pediatrics	HIV, children, Psychiatric

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Evaluation of Lipid Profiles on HIV Infected Patients on HAART</i>	Mobeen Rathore, MD	Pediatrics	Lipid disorders, HIV infection, serum cholesterol
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Improving Hepatitis C testing compliance among infants born to Hepatitis C and HIV infected mothers</i>	Mobeen Rathore, MD	Pediatrics	
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Perinatal Core Protocol, PACTG 1025 Includes Substudy: IMPAACT P1026s: Pharmacokinetic Properties of Antiretroviral Drugs During Pregnancy</i>	Mobeen Rathore, MD	Pediatrics	HIV
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Surveillance Monitoring for ART Toxicities Study in HIV-uninfected Children Born to HIV-infected Women (SMARTT study) (PH100)</i>	Mobeen Rathore, MD	Pediatrics	HIV
BEHAVIORAL/EPIDEMIOLOGICAL	<i>The Antiretroviral Pregnancy Registry</i>	Isaac Delke, MD	Pediatrics	HIV, antiretrovirals
BROWARD CHILDREN'S DIAGNOSTIC & TREATMENT CENTER - 13 Studies Presented by Ana Puga, M.D.				
BEHAVIORAL/EPIDEMIOLOGICAL	<i>ATN 071/101: Neurocognitive Assessment in Youth Initiating Highly Active Antiretroviral Therapy (HAART)(recruiting 101 only)</i>	Ana Puga, MD Doyle Patton, PhD	CFAP Research	Neurocognitive impact of HIV in youth
BEHAVIORAL/EPIDEMIOLOGICAL	<i>ATN 078: A Pilot Study Using Cell Phone Interactions to Improve Medication Adherence in Adolescents Who Have Previously Failed Antiretroviral therapy due to Non-Adherence. (on-going)</i>	Ana Puga, MD	CFAP Research	Adherence in youth
BEHAVIORAL/EPIDEMIOLOGICAL	<i>ATN 093: Evaluation of Strategic Multisite Initiative for the</i>	Ana Puga, MD Marie Hayes, MSW	CFAP Research	Youth Linkage to Care Study

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
	<i>Identification, Linkage, and Engagement (SMILE) in Care of Youth (recruiting)</i>			
BEHAVIORAL/EPIDEMIOLOGICAL	<i>ATN 096: Identifying Undiagnosed Asymptomatic HIV Infection in Hispanic/Latino Adolescentn and Young Adults (recruiting)</i>	Ana Puga, MD	CFAP Research	HIV Testing
BEHAVIORAL/EPIDEMIOLOGICAL	<i>IMPAACT 1074: A Prospective Surveillance Study of Long-Term Outcomes in HIV-Infected Infants, Children and Adolescents (recruiting)</i>	Ana Puga, MD	CFAP Research	Prospective long term follow-up of Children/Youth on Highly Active Antiretroviral Therapy (HAART)
BEHAVIORAL/EPIDEMIOLOGICAL	<i>IMPAACT P1080: A Pilot Study of Psychiatric and Antiretroviral Medication Concentrations in HIV-1 Infected and Uninfected Children and Adolescents (recruiting)</i>	Ana Puga, MD	CFAP Research	Psychiatric medications and antiretroviral medication pharmacokinetics
BEHAVIORAL/EPIDEMIOLOGICAL BASIC SCIENCE/VIROLOGY	<i>IMPAACT P1085 : Duration of Human Papilloma Virus (HPV) Type-Specific Antibody After Administration of Quadrivalent HPV Vaccine to HIV-1 Infected Children Preciously Enrolled in IMPAACT P1047 (recruiting)</i>	Ana Puga, MD	CFAP Research	Duration of HPV antibodies post-vaccination
BEHAVIORAL/EPIDEMIOLOGICAL	<i>PACTG 1025: Perinatal Core Protocol (recruiting)</i>	Ana Puga, MD	CFAP Research	Perinatal Observational Study
BEHAVIORAL/EPIDEMIOLOGICAL	<i>PH 201 AMP Memory Study: Memory Functioning in Children and Adolescents with Perinatal HIV Infection (recruiting)</i>	Ana Puga, MD	CFAP Research	Neuropsychology and HIV in Children
BEHAVIORAL/EPIDEMIOLOGICAL	<i>PH100 SMARTT: PHACS 100: Surveillance Monitoring for ART Toxicities in HIV-uninfected</i>	Ana Puga, MD	CFAP Research	Antiretroviral (ART) toxicity monitoring in HIV exposed and infected infants

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
	<i>Children Born to HIV-infected Women (SMARTT Study). Version change includes SMARTT Reference Cohort Sub Study and SMARTT Nutrition Sub Study (recruiting)</i>			
BEHAVIORAL/EPIDEMIOLOGICAL	<i>PH100 SMARTT REFERENCE: A Study of the Effect of Maternal Health in Pregnancy on Health and Development of Infants and Children (recruiting)</i>	Ana Puga, MD	CFAP Research	Unexposed control cohort for SMARTT
BEHAVIORAL/EPIDEMIOLOGICAL	<i>PH200 AMP: PHACS 200: Adolescent Master Protocol (AMP). (recruiting)</i>	Ana Puga, MD	CFAP Research	Long term follow-up of perinatally infected youth and perinatally HIV exposed youth
BEHAVIORAL/EPIDEMIOLOGICAL	<i>SMARTT NUTRITION: SMARTT Nutrition Component (recruiting)</i>	Ana Puga, MD	CFAP Research	Nutrition for HIV positive pregnant women

ClinicalTrials.gov Website Studies – 18 Additional Studies

BEHAVIORAL/EPIDEMIOLOGICAL	<i>Identifying Undiagnosed Asymptomatic HIV Infection in Hispanic/Latino Adolescents and Young Adults (Effectiveness of AVT strategy with SS NIT; Facilitators & barriers to HIV testing; Sub-group differences)</i>	Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) National Institute on Drug Abuse (NIDA) National Institute of Mental Health (NIMH) Cherrie B. Boyer, Ph.D., Jonathan M. Ellen, M.D., Adolescent Trials Network	The proposed research will include adolescent and young adult Hispanic/Latino men who have sex with men (MSM) and heterosexual men and women, aged 13-24 years, and will be based at 13 ATN Adolescent Medicine Trial Units (AMTUs) that provide clinical care and psychosocial services to the target group. In 10 of the 13 sites, comparisons will be made between alternative venue-based testing (AVT) and social and sexual network-based interviewing and HIV testing (SSNIT) strategies to assess which, among these approaches, is the most effective means for identifying undiagnosed human immunodeficiency virus (HIV) in young, at-risk Hispanics/Latinos. Three of the sites will focus solely on use of SSNIT for identifying undiagnosed HIV in our target group of adolescents and young adults. All study participants will complete an audio computer-assisted self-interview (ACASI) and undergo HIV screening. Participants with presumptive HIV positive screening results will be referred to the local AMTU for confirmatory testing, post-test counseling and referrals for linkage to HIV medical care. Linkage to care for ATN 096 study participants will be conducted in accordance with the Strategic Multisite Initiative for the Identification, Linkage, and Engagement in Care of Youth with Undiagnosed HIV Infection (SMILE in CARING for YOUTH) Program (ATN 093), a collaboration of the CDC and NICHD/ATN, to ensure that youth who test positive for HIV as part of this	
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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
			protocol are linked with treatment and care.	
<p>CLINICAL TRIAL BEHAVIORAL/EPIDEMIOLOGICAL</p>	<p><i>Safety of and Immune Response to an H1N1 Influenza Vaccine in HIV Infected Pregnant Women</i></p>	<p>NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID) Sharon Nachman, MD, State University of New York at Stony Brook Pfizer CT.gov Call Center</p>		<p>Adverse events (AEs) of all grades; AEs of all grades attributed to the study vaccine; Withholding of second vaccine dose due to adverse reactions attributed to first dose; Immunologic response, defined as hemagglutination inhibition (HAI) titer of at least 1:40; Maternal immunologic response, defined as HAI of at least 1:40; Infant HAI of at least 1:40; Maternal geometric mean titers (GMT) of antibodies HAI; Infant GMT of antibodies HAI; Maternal cell-mediated immunity (CMI) responses, as measured by B-cell and T-cell enzyme-linked immunosorbent spot (ELISPOT) assay values; CD4 count; HIV RNA copies/ml; Response to seasonal trivalent influenza vaccine (TIV); Exploration of factors related to HIV and its treatment that might affect the response to H1N1 vaccinations</p>
<p>CLINICAL TRIAL BEHAVIORAL/EPIDEMIOLOGICAL</p>	<p><i>Safety of and Immune Response to the Human Papillomavirus (HPV) Vaccine in HIV-Infected Women</i></p>	<p>National Institute of Allergy and Infectious Diseases (NIAID); National Institute of Dental and Craniofacial Research (NIDCR) Erna Milunka Kojic, MD, Department of Immunology/Infectious Disease, The Miriam Hospital, Brown University; Susan Cu-Uvin, MD, Obstetrics-Gynecology and Medicine, The Miriam Hospital, Brown University</p>		<p>Type-specific HPV antibody development from the seronegative status at baseline to seropositive status a month after the completion of HPV vaccination series (Week 28) for HPV types 6, 11, 16, and 18; Occurrence of Grade 3 or greater adverse events; HPV antibody titers to types 6, 11, 16, 18; Longitudinal changes in HIV viral load; Nadir and baseline CD4 count; Baseline HIV viral load; Cellular immune response assay data from the subset of U.S. participants; Longitudinal changes in CD4+ cell count from baseline</p>
<p>BEHAVIORAL/EPIDEMIOLOGICAL</p>	<p><i>Efficacy and Safety of GSK Biologicals HIV Vaccine in Antiretroviral Therapy (ART)-naive HIV-1 Infected Persons</i></p>	<p>GSK Clinical Trials</p>		<p>This study is designed to determine whether administration of the GSK Biologicals HIV vaccine 732462 can lead to a reduction in viral load, and impact on the course of human immunodeficiency virus type 1 (HIV-1) infection. In HIV-1 infected persons who have not yet started antiretroviral therapy (ART), such a vaccine would potentially lead to a delay in the initiation of treatment.</p>
<p>CLINICAL TRIAL BEHAVIORAL/EPIDEMIOLOGICAL</p>	<p><i>Pharmacokinetic Study of Anti-HIV Drugs During Pregnancy</i></p>	<p>National Institute of Allergy and Infectious Diseases (NIAID); Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) Mark Mirochnick, MD,</p>		<p>The purpose of this study is to determine what doses of anti-HIV medications are appropriate for pregnant women. Anti-HIV medication taken during pregnancy may control a woman's viral load and reduce the chance that the baby will become infected with HIV. Pregnant women may require different doses of anti-HIV drugs than women who are not pregnant. This study will use pharmacokinetic (PK) sampling to determine what doses of anti-HIV medications are best for HIV-infected pregnant women and</p>

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
		Boston Medical Center	their infants.	
BEHAVIORAL/EPIDEMIOLOGICAL	<i>A Phase 2b Open-Label Rollover Study For Subjects Discontinuing From UK-453,061 Studies For The Treatment Of HIV-1 Infected Subjects</i>	Pfizer CT.gov Call Center		The purpose of the protocol is to assess long-term safety and tolerability of subjects who discontinue for any reason from UK-453,061 qualifying studies.
CLINICAL TRIAL BEHAVIORAL/EPIDEMIOLOGICAL	<i>An Open-Label, Extension Safety Trial Of Pregabalin In Subjects With Neuropathic Pain Associated With HIV Neuropathy (Pregabalin A0081251)</i>	Pfizer CT.gov Call Center		This study examines the safety of pregabalin over a 6 month period in patients with neuropathic pain associated with HIV infection as an extension of another trial that tests the efficacy of pregabalin.
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Strategic Timing of Antiretroviral Treatment (START)</i>	University of Minnesota - Clinical and Translational Science Institute		To find out if the chance of developing a serious illness or of getting AIDS is less if patients start taking HIV medicines at a time when their CD4+ cell count is still fairly high, instead of waiting until the CD4+ count is at the level where there is good evidence for starting medicines. To learn more about how a strategy of starting HIV medicines early might affect other aspects of care, such as the chances of developing other illnesses or resistance to HIV medicines, the frequency of doctor visits, the cost of medical care, and general health and satisfaction.
CLINICAL TRIAL BEHAVIORAL/EPIDEMIOLOGICAL	<i>High Dose Chemotherapy With Autologous Stem Cell Rescue for Aggressive B Cell Lymphoma and Hodgkin Lymphoma in HIV-infected Patients (BMT CTN 0803)</i>	Joseph Alvarnas, MD, City of Hope National Medical Center Richard Ambinder, MD, Johns Hopkins Medical Institution National Heart, Lung, and Blood Institute (NHLBI); National Cancer Institute (NCI); Blood and Marrow Transplant Clinical Trials Network		This study is a Phase II, multicenter trial assessing overall survival after autologous hematopoietic stem cell transplantation using a BEAM transplant regimen in lymphoma patients with HIV.
CLINICAL TRIAL BEHAVIORAL/EPIDEMIOLOGICAL	<i>Perinatal Core Protocol (Prenatal and Postnatal Studies of Interventions for Prevention of Mother-To-Child Transmission)</i>	Ruth Tuomala, MD, Director of Obstetrics and Gynecology, Brigham and Women's Hospital; Gwen Scott, MD, Pediatric Infectious Diseases, University of Miami School of Medicine International Maternal		The purpose of this study is to collect and study clinical and laboratory information about a pregnant or new mother and her medical care that will increase our knowledge of the best care for HIV-infected pregnant women and their children. The rate of transmission of HIV from mothers to their infants has gone down. Specific U.S. Public Health Service guidelines recommend that HIV-infected pregnant women be treated with anti-HIV therapies; but the effectiveness of treatment and safety for the mother and her infant have not been fully examined. This study will monitor the health of women and their infants while

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		Pediatric Adolescent AIDS Clinical Trials Group; Nat'l Inst. of Allergy and Infectious Diseases (NIAID); Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)		they receive anti-HIV therapy. Also, this study will provide information that may be used for future studies.
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Phase I/II Safety and Efficacy Investigation of Atorvastatin for Treatment of PI-Associated Increased LDL Cholesterol in HIV-Infected Children and Adolescents</i>	Ann Melvin, MD, Seattle Children's Hospital; John Farley, MD, University of Maryland at Baltimore International Maternal Pediatric Adolescent AIDS Clinical Trials Group; National Institute of Allergy and Infectious Diseases (NIAID); Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)		Treatment of HIV with antiretroviral regimens that include protease inhibitors (PIs) frequently results in the suppression of HIV viral load, significant immune recovery, and delayed disease progression. However, treatment with PIs has been associated with significant increases in cholesterol and triglycerides in HIV infected adults and children. The purpose of this study is to evaluate the safety and effectiveness of escalating doses of atorvastatin, a FDA-approved drug which lowers cholesterol and triglyceride levels, in HIV infected children receiving antiretroviral regimens containing at least one PI.
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Computer-Delivered Motivational Intervention to Prevent Adherence Problems Among Youth Newly Recommended for HIV Medications: Project MESA (Motivational Enhancement System for Adherence)</i>	Sylvie Naar- King, PhD, Adolescent Trials Network Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD); National Institute on Drug Abuse (NIDA); National Institute of Mental Health (NIMH)		This is a two-phase study, consisting of the following plan: Phase I - This is a pre-test of the feasibility and acceptability of the beta version of a computer-delivered intervention, Motivational Enhancement System for Adherence (MESA), as well as the control intervention Motivational Enhancement System for Health (MESH) at three selected AMTUs. Following analysis of the responses in Phase I and further modification of the intervention, Phase II will be initiated. Phase II - This is a pilot, randomized, controlled trial (RCT) testing a two-session computer-delivered intervention, MESA, designed to increase motivation for adherence to Highly Active Antiretroviral Therapy (HAART) among youth newly recommended to begin medications, as well as an attention control, MESH, matched for dose and delivery format. Phase II is open to all 15 AMTUs.
CLINICAL TRIAL BEHAVIORAL/EPIDEMIOLOGICAL	<i>Maraviroc Plus Darunavir/Ritonavir Study for Treatment-Naïve Patients Infected With R5-tropic HIV-1 Based on Enhanced Sensitivity Profile</i>	Principal Investigator: Jose Castro, M.D. (U of Miami); Babafemi Taiwo, MD, Northwestern University		The objective of this study is to evaluate the safety and efficacy of a novel combination antiretroviral therapy regimen consisting of maraviroc plus darunavir/ritonavir in treatment-naïve patients infected with R5-tropic HIV-1. The hypothesis is that in treatment-naïve subjects infected with R5-tropic HIV-1,

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	<i>NCT00993148</i>	Pfizer Tibotec, Inc		combination antiretroviral therapy with maraviroc plus darunavir/ritonavir is well tolerated and efficacious.
BEHAVIORAL/EPIDEMIOLOGICAL	<i>Study to Test Meta-intervention to Increase Retention in HIV Prevention Counseling (This may be a duplication – see Duval CHD on page 14 ±)</i>	University of Illinois at Urbana-Champaign Collaborators: Duval County Health Department Dolores Albarracin, PhD William Livingood, PhD, Duval CHD		Unfortunately, people most at risk for HIV are the least likely to enroll and remain in prevention programs. In our past work, we have learned how to increase enrollment in such programs among this group. We have identified and addressed previously ignored gender-specific and client self-validation issues that conventional interventions often leave not only uncontrolled, but often biased against participation. The present work will extend these methods from enrollment to retention. We intend to recruit a sample of 656 at-risk participants through our collaboration with the Duval County, FL Health Department for our randomized, double-blind trial. Our study will investigate if a meta-intervention video designed for empowering participants as agents of their own change can increase the number of attended sessions relative to a control condition without such a video. This trial will also determine if a meta-intervention video addressing various emotional/social and instrumental benefits of an HIV-prevention-counseling intervention can also increase the number of attended sessions. These two factors will be crossed, and their effects on retention will be estimated for different genders and ethnicities. Effects on clients' attention to the return sessions as reported by the counselor will also be explored among participants who return. We will also conduct mediator analyses for investigating if the meta-intervention has mediating influences on corresponding expectations about the return counseling session. As the inclusion of meta-cognitive measures can alter the efficacy of the intervention, half of the sample will receive measures immediately (0-10 minutes) after exposure to the meta-intervention, before attendance to the next session is registered. The other half will not complete these measures
CLINICAL TRIAL BEHAVIORAL/EPIDEMIOLOGICAL	<i>A Phase II Trial of Response-Adapted Therapy of Stage III-IV Hodgkin Lymphoma Using Early Interim FDG-PET Imaging</i> <i>NCT00822120</i>	M.D. Anderson Cancer Center at Orlando Recruiting Orlando, Florida Contact: Julio J. Hajdenberg, MD 321-841-7219 Southwest Oncology Group National Cancer Institute (NCI)		RATIONALE: Drugs used in chemotherapy work in different ways to stop the growth of cancer cells, either by killing the cells or by stopping them from dividing. Giving more than one drug (combination chemotherapy) may kill more cancer cells. G-CSF may help lessen the side effects in patients receiving chemotherapy. Imaging procedures, such as fludeoxyglucose F 18-PET/CT imaging, may help doctors predict how patients will respond to treatment. PURPOSE: This phase II trial is studying fludeoxyglucose F 18-PET/CT imaging to see how well it works in assessing response to combination chemotherapy and allow doctors to plan better additional further treatment in treating patients with stage III or stage IV Hodgkin lymphoma.

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
<p>CLINICAL TRIAL BEHAVIORAL/EPIDEMIOLOGICAL</p>	<p><i>An International Observational Study to Characterize Adults Who Are Hospitalized With Complications of Influenza A – Pandemic H1N1 (H1N1v); NCT01056185</i></p>	<p>University of Minnesota – Clinical and Translational Science Institute National Institute of Allergy and Infectious Diseases (NIAID) National Institutes of Health (NIH) Infectious Diseases Associates NW FL, PA Pensacola, Florida, United States, 32504 Contact: Barbara He Wade, MD, FACP bwade@infectioncenter.com 850-476-3131 Principal Investigator: Barbara He Wade, MD, FACP</p>		<p>The “flu” is a common disease and usually mild, but severe disease and death may occur. There are several types of flu viruses and they change over time. Recently, a new influenza A virus known commonly as swine flu or H1N1v has emerged. This flu has spread rapidly around the world. It is important to understand the course of illness for those who have H1N1v and the characteristics of people who do not do well. The investigators will also try to learn more about how different treatments and prior vaccination for the flu affects the course of the illness. Approximately 1,000 individuals will be enrolled in several countries around the world. The results of this study will be used to advise on the management of patients who are hospitalized with the flu.</p>
<p>CLINICAL TRIAL BEHAVIORAL/EPIDEMIOLOGICAL</p>	<p><i>INSIGHT H1N1v Outpatient Study (FLU 002) Official Title: An International Observational Study to Characterize Adults With Influenza A – Pandemic H1N1 (H1N1v); NCT01056354</i></p>	<p>University of Minnesota – Clinical and Translational Science Institute National Institute of Allergy and Infectious Diseases (NIAID) National Institutes of Health (NIH) Infectious Diseases Associates NW FL, PA Pensacola, Florida, United States, 32504 Contact: Barbara He Wade, MD, FACP bwade@infectioncenter.com 850-476-3131 Principal Investigator: Barbara He Wade, MD, FACP</p>		<p>The "flu" is a common disease and usually mild but severe disease and deaths may occur. There are several types of flu viruses and they change over time. Recently, a new influenza A virus known commonly as swine flu or H1N1v has emerged. This flu has spread rapidly around the world. It is important to understand the course of illness for those who have H1N1v and the characteristics of people who do not do well. The investigators will also try to learn more about how different treatments and prior vaccination for the flu affect the course of the illness. Approximately 5,000 individuals with swine flu will be enrolled in several countries around the world.</p>

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<p>CLINICAL TRIAL BEHAVIORAL/EPIDEMIOLOGICAL</p>	<p><i>Isotretinoin With or Without Monoclonal Antibody, Interleukin-2, and Sargramostim Following Stem Cell Transplantation in Treating Patients With Neuroblastoma</i></p> <p><i>Official Title: Phase III Randomized Study Of Chimeric Antibody 14.18 (CH14.18) In High Risk Neuroblastoma Following Myeloablative Therapy And Autologous Stem Cell Rescue</i> <i>NCT00026312</i></p>	<p>Numerous locations throughout Florida CHILDREN'S ONCOLOGYGROUP ; NATIONAL CANCER INSTITUTE (NCI) Under 30 yrs old</p> <p>Study Chair: Alice L. Yu, MD, PHD UC at San Diego</p>		<p>RATIONALE: Drugs used in chemotherapy work in different ways to stop tumor cells from dividing so they stop growing or die. Monoclonal antibodies can locate tumor cells and either kill them or deliver tumor-killing substances to them without harming normal cells. Interleukin-2 and sargramostim may stimulate a person's white blood cells to kill cancer cells. It is not yet known if chemotherapy is more effective with or without monoclonal antibody therapy, interleukin-2, and sargramostim following stem cell transplantation in treating neuroblastoma.</p> <p>PURPOSE: Randomized phase III trial to compare the effectiveness of chemotherapy with or without monoclonal antibody, interleukin-2, and sargramostim following stem cell transplantation in treating patients who have neuroblastoma</p>

TOTAL NUMBER OF BEHAVIORAL STUDIES LISTED AS OF 9/13/11 = 160

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BASIC SCIENCE

UNIVERSITY OF CENTRAL FLORIDA – 4 Studies

Presenter: Alexander M. Cole, Ph.D.

BASIC SCIENCE/VIROLOGY	<i>Retrocyclins: circular defensins active against HIV-1 (NIH R01 grant AI052017)</i>	Alexander M. Cole, Ph.D. (PI)	Microbiology and Molecular Biology	Topical microbicides to prevent HIV-1 transmission
BASIC SCIENCE/VIROLOGY	<i>Project 2. Development of RC-101 as an intravaginal topical microbicide. (NIH U19 grant AI082623)</i>	Alexander M. Cole, Ph.D. (PD of Project 2); Phalguni Gupta, Ph.D. (PI; PD of Project 3; U. Pitt); other project and core directors	Microbiology and Molecular Biology	Topical microbicides to prevent HIV-1 transmission
BASIC SCIENCE/VIROLOGY	<i>Aminoglycoside microbicides restore natural anti-HIV-1 retrocyclins (NIH R21 grant AI082693)</i>	Alexander M. Cole, Ph.D. (PI)	Microbiology and Molecular Biology	Innate host defense against HIV-1
BASIC SCIENCE/VIROLOGY	<i>Reawakening retrocyclins to prevent mucosal STIs (Gates Grand Challenges Explorations Award)</i>	Alexander M. Cole, Ph.D. (PI)	Microbiology and Molecular Biology	Innate host defense against STIs, including HIV

UNIVERSITY OF MIAMI – 36 Studies

Presenter: Savita Pahwa, M.D.

BASIC SCIENCE/VIROLOGY	<i>Targeted siRNA delivery as an anti-HIV microbicide</i>	Derek Dykxhoorn	Dr. John T. Macdonald Foundation Department of Human Genetics and the Department of Microbiology and Immunology	Microbicide development
BEHAVIORAL/EPIDEMIOLOGICAL BASIC SCIENCE/VIROLOGY	<i>Longitudinal analysis of a high risk HIV negative cohort</i>	Derek Dykxhoorn (Human Genetics, Microbiology and Immunology, DCFAR), Lisa Metsch (Epidemiology and	Human Genetics, Microbiology and Immunology, Epidemiology and Public	Genetics and Genomics of HIV infection, Acute HIV infection (AHI)

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
		Public Health, DCFAR), Jose Castro (Medicine, DCFAR), Savita Pahwa (Microbiology and Immunology, DCFAR), Margaret Fischl (Medicine, DCFAR), Rafick Sekaly (VGTI-Florida, DCFAR), Lydie Trautmann (VGTI-FL, DCFAR)	Health, Medicine, VGTI-FL, Developmental Center for AIDS Research (DCFAR)	
BASIC SCIENCE/VIROLOGY	<i>Identification of genetic variations associated with viral set point control in long term non-progressors</i>	Derek Dykxhoorn (Human Genetics, Microbiology and Immunology, DCFAR), Hector Bolivar (Medicine, DCFAR), William Scott (Human Genetics, DCFAR)	Human Genetics, Microbiology and Immunology, Medicine, VGTI-FL, Developmental Center for AIDS Research (DCFAR)	Genetics of HIV infection
BASIC SCIENCE/VIROLOGY	<i>Activation of CD40 by HIV and Role in AIDS Dementia</i>	Mario Stevenson (PI)	Medicine	Identify mechanism by which HIV induces neuronal destruction in AIDS dementia
BASIC SCIENCE/VIROLOGY	<i>Role of Monocytotropism in HIV/SIV Pathogenicity</i>	Mario Stevenson (PI) Keith Mansfield (Harvard)	Medicine	Examine the role of myeloid lineage cells in the persistence & pathogenicity of HIV/SIV
BASIC SCIENCE/VIROLOGY	<i>Cellular Co-Factors of HIV-1 Infection</i>	Mario Stevenson (PI)	Medicine	Identify cellular factors that are commandeered by HIV in its replication cycle. The goal is to identify new targets for therapeutic intervention
BASIC SCIENCE/VIROLOGY	<i>Preclinical Development of HIV-1 Vif Antagonists</i>	Mario Stevenson (PI) Tariq Rana (Burnham), Keith Mansfield (Harvard), Brigitte Beer (Bioqual)	Medicine	Undertake preclinical development of a lead molecule that interferes with the action of the HIV Vif protein.
BASIC SCIENCE/VIROLOGY	<i>Molecular characterization of cryptic HIV-1 replication during HAART (Project 1)</i>	Mario Stevenson (PI) Tim Schacker (U. Minnesota)	Medicine	To identify the viral reservoirs that persist in the face of antiretroviral therapy. Our analysis focuses on the role of the gut lymphoid tissue in viral persistence.
BASIC SCIENCE/VIROLOGY	<i>Pharmacokinetics of HIV-1 with the integrase inhibitor Raltegravir</i>	Mario Stevenson, Rafael Campo (PI)	Medicine	To evaluate whether intensification of ART with Raltegravir reduces the extent of aberrant immune activation and improves on-treatment CD4 gains in HIV infection individuals

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
BASIC SCIENCE/VIROLOGY	<i>The Role of Myeloid Cells in Viral Replication, Persistence and Neuroinvasion</i>	Mario Stevenson (PI)	Medicine	To determine whether macrophage are a source of persistent virus in patients on ART & to develop a strategy to remove infected macrophage reservoirs using agents that promote macrophage apoptosis
BASIC SCIENCE/VIROLOGY	<i>HIV Exposed Uninfected: Adaptive Immunity</i>	Jose Castro, Margaret Fischl, Rafick Sekaly	Microbiology and Immunology, Medicine, VGTI	Pathogenesis, Mucosal Immunity
BASIC SCIENCE/VIROLOGY	<i>UM Developmental Center For AIDS Research Int'l AIDS Malignancy Initiative Program</i>	Enrique Mesri	Microbiology and Immunology	NCI
BASIC SCIENCE/VIROLOGY	<i>DCFAR- SCCC International Collaborations in AIDS-Malignancies</i>	Enrique Mesri, Gail Shor-Posner, Juan Carlos Ramos	Microbiology and Immunology, Medicine, Pediatrics	AIDS Malignancies Projects in Brazil and Argentina NIH
BASIC SCIENCE/VIROLOGY	<i>International Maternal Pediatric Adolescents AIDS Clinical Trials Group Immunology Laboratory</i>	Savita Pahwa,	Microbiology and Immunology	NIAID
BASIC SCIENCE/VIROLOGY	<i>Role of IL21 in HIV infection</i>	Savita Pahwa	Microbiology and Immunology	NIAID
BASIC SCIENCE/VIROLOGY	<i>Effect of Raltegravir on immune activation, immune reconstitution and gut microbial translocation in patients with chronic HIV infection</i>	Savita Pahwa	Microbiology and Immunology	Merck
BASIC SCIENCE/VIROLOGY	<i>Induction of mucosal SIV immunity in non human primates by secreted Hsp-Gp96</i>	Eckhard Podack, Savita Pahwa	Microbiology and Immunology	NIAID
BASIC SCIENCE/VIROLOGY	<i>HIV Exposed Uninfected: Innate Immunology</i>	Lydie Trautmann, Margaret Fischl, Rafick Sekaly	Microbiology and Immunology, Medicine, VGTI	Pathogenesis, Mucosal Immunity
BASIC SCIENCE/VIROLOGY	<i>Targeted therapy for Burkitt Lymphoma in Resource Poor Settings</i>	Barber Glen	Medicine	NCI
BASIC SCIENCE/VIROLOGY	<i>Targeting of EBV Latency in</i>	Juan Carlos Ramos	Medicine	NCI

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
	<i>Burkitt's Lymphoma</i>			
BASIC SCIENCE/VIROLOGY	<i>Biochemical Mechanisms of Drug Resistance in HIV RT</i>	Walter A. Scott	Biochemistry & Molecular Biology	NIAID
BASIC SCIENCE/VIROLOGY	<i>Mitochondrial determinations metabolic disease in HIV-infected children</i>	Tracie Miller	Pediatric Metabolic/ Pathogenesis Research	NINR
BASIC SCIENCE/VIROLOGY	<i>Ologonucleotide aptamer ligands to reverse T cell anergy HIV-infected patients</i>	Eli Gilboa	Novel therapeutics and pathogenesis	NIAID
CLINICAL TRIAL BASIC SCIENCE/VIROLOGY	<i>Effect of Raltegravir on immune activation, immune reconstitution and gut microbial translocation in patients with chronic HIV infection</i>	Rafael Campo Savita Pahwa Mario Stevenson	Novel therapeutics and pathogenesis	Merck
BASIC SCIENCE/VIROLOGY	<i>HIV-1 C clade progression and neuroaids</i>	Mahendra Kumar	Pathogenesis	NINDS
BASIC SCIENCE/VIROLOGY	<i>Gp96-Ig HIV and SIV vaccines; HPV based HIV vaccines</i>	Podack, E. R; Franchini, G (NCI); Haddad, E (VGTI); Sekaly, R. (VGTI) Pahwa, S; Altman, N	Vaccine Research	R21, R33 funded; PO1, UO1 pending (NIAID)
BASIC SCIENCE/VIROLOGY	<i>Novel adjuvants</i>	Stone, G.	Vaccine Research	R21, K22, R21 pending NIAID
BASIC SCIENCE/VIROLOGY	<i>TL1A and LMP1</i>	Strbo, N; Stone, G.	Vaccine Research	DCFAR/ NIAID Supplements
BASIC SCIENCE/VIROLOGY	<i>Hu-mice for HIV vaccine research</i>	Gonzales, L; Strbo, N; Podack E.R.	Vaccine Research	Predoctoral stipend from HIV training grant (NIMH)
BASIC SCIENCE/VIROLOGY	<i>Host Defense Regulation and Viral Oncogenesis</i>	Glen Barber	AIDS Malignancies	NCI
BASIC SCIENCE/VIROLOGY	<i>Role of RAC and Reactive Oxygen Species in Kaposi's Sarcoma Viral Oncogenesis</i>	Enrique Mesri P Goldschmidt	AIDS Malignancies	NCI
BASIC SCIENCE/VIROLOGY	<i>Biology of KSHV/HHV8 G Protein Coupled Receptor</i>	Enrique Mesri	AIDS Malignancies	NCI

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
BASIC SCIENCE/VIROLOGY	<i>A Prospective, Open-Label, Double-Arm, Crossover, Single-Center Pilot Study to Evaluate the Addition of Raltegravir to Established Suppressive Antiretroviral Therapy while Monitoring Changes in Markers of Immune Activation among HIV-1 Infected Individuals Without Adequate Immune Restoration. (35835)</i>	Rafael Campo	Medicine	Immune reconstitution
BASIC SCIENCE/VIROLOGY	<i>140 - Clinical Evaluation of the Xpert® CT/NG Assay</i>	Jose Castro New – enrolling soon	Medicine	Efficacy
BASIC SCIENCE/VIROLOGY	<i>73B - Evaluation of the Xpert® CT/NG Assay</i>	Jose Castro New Enrolling soon	Medicine	Efficacy
BASIC SCIENCE/VIROLOGY	<i>Effect of Raltegravir on immune activation, immune reconstitution and gut microbial translocation in patients with chronic HIV infection</i>		Industry Studies	Immune reconstitution
UNIVERSITY OF SOUTH FLORIDA – 13 Studies Presenter: John W. Sleasman, M.D.				
BASIC SCIENCE/VIROLOGY	<i>R01 AI47723-04A1; NIAID. Impact of HIV-1 Genotype on Therapy Response in Children</i>	John Sleasman, MD (PI), Carina Rodriguez, MD, Soichi Haraguchi, PhD, Patricia Emmanuel, MD (Co-Investigators)	Allergy and Immunology	Impact of HIV resistance in immunologic and viral responses in HIV-1 infected children and adolescents
BASIC SCIENCE/VIROLOGY	<i>Defective immunoglobulin somatic hypermutation results in pneumococcal vaccination hyporesponsiveness in HIV infected children. Center for</i>	Carina Rodriguez, MD (PI), John Sleasman, MD, Li Yin, PhD, Maureen Goodenow, PhD.	Pediatric Infectious Diseases, Allergy and Immunology (USF) and Pathology (UF)	Impact of HIV infection on B cell repertoire and somatic mutation and the role of vaccine response

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
	<i>Florida AIDS Research</i>			
BASIC SCIENCE/VIROLOGY	<i>Do children with HIV have dysregulated amyloid loads in their blood?</i>	Brian Giunta, MD (PI), Carina Rodriguez, MD, Patricia Emmanuel, MD, John Sleasman, MD, Jaime Fernandez, MD, Frank Fernandez, MD	Psychiatry and Pediatric Infectious Diseases	Changing levels of amyloid beta in peripheral blood and HIV viral infection. Basic/translational, immune response
BASIC SCIENCE/VIROLOGY	<i>Substance use and immunity function in HIV+ adolescents by systems biology</i>	Maureen Goodenow, John Sleasman	Pathology, UF Allergy and Immunology, USF	Substance use and immunity function in HIV adolescents Sponsor: NIDA
BASIC SCIENCE/VIROLOGY	<i>Impact of HIV-1 Genotype on Therapy Response in Children.</i>	Maureen Goodenow, John Sleasman	Pathology, UF Allergy and Immunology, USF	Structure function relationships between HIV-1 protease and p7NC. Sponsor: NIAID
BASIC SCIENCE/VIROLOGY	<i>Role of HIV-1 Env Diversity in Cellular Tropism</i>	Maureen Goodenow, John Sleasman	Pathology, UF Allergy and Immunology, USF	HIV-1 envelope and CD4 target cells. Sponsor: NICHD
BASIC SCIENCE/VIROLOGY	<i>Studies of Ocular Complications of AIDS (SOCA)</i>	Peter Pavan (PI)	Ophthalmology	Complications, ocular diseases, AIDS, CMV
BASIC SCIENCE/VIROLOGY	<i>Defective immunoglobulin somatic hypermutation results in pneumococcal vaccination hyporesponsiveness in HIV infected children</i>	Carina Rodriguez (PI)	Pediatrics	basic/translational, immune response
BASIC SCIENCE/VIROLOGY	<i>Changes in the B cell repertoire following vaccination with novel H1N1 inactivated influenza vaccine in immune deficient adolescents and young adults chronically infected with HIV</i>	Carina Rodriguez (PI)	Pediatrics	basic/translational, immune response
BASIC SCIENCE/VIROLOGY	<i>The Role of HIV-TAT in Alzheimer's Disease</i>	Richard Dembo (PI)	Psychiatry and Neurosciences	Prevention; Drug Use
BASIC SCIENCE/VIROLOGY	<i>Uncovering Co-stimulatory T Cell Help Defects in Common Variable Immunodeficiency</i>	Elena Perez (PI)	Pediatrics	
BASIC SCIENCE/VIROLOGY	<i>Green Tea Derived EGCG Opposes AIDS Dementia-Like</i>	Jun Tan (PI)	Psychiatry and Neurosciences	

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
	<i>Neuronal Damage</i>			
BASIC SCIENCE/VIROLOGY	<i>Role of Cannabinoid 2 Receptors in B Lymphocyte Function</i>	Catherin Patterson (PI)	Biochemistry	
UNIVERSITY OF FLORIDA Presenter: Maureen Goodenow, Ph.D. - 14 studies				
BASIC SCIENCE/VIROLOGY	<i>Substance use and immunity in HIV+ infected adolescents by systems biology</i>	Maureen Goodenow (PI), Li Yin (Co-PI), Mark Wallet; John W. Sleasman, USF, co PI; Sharon Nichols, University of California, San Diego	Pathology	HIV and adolescents
BASIC SCIENCE/VIROLOGY	<i>Human Immunodeficiency Virus Proteinase</i>	Ben Dunn (PI), Maureen Goodenow (Co-I)	Pathology	Mechanisms of HIV drug resistance to protease inhibitors
BASIC SCIENCE/VIROLOGY	<i>Role of HIV-1 Env Diversity in Cellular Tropism</i>	Maureen Goodenow (PI), Li Yin (Co-PI); John W. Sleasman, co-PI USF	Pathology	Mechanisms of HIV-1 entry into macrophages and genetic determinants in envelope that modulate macrophage infection; deep pyrosequencing of HIV-1 variants in longitudinal study
BASIC SCIENCE/VIROLOGY	<i>Impact of HIV-1 Genotype on Therapy Response in Children</i>	John Sleasman (PI), USF, Maureen Goodenow (Co-PI)	Pathology	Mechanisms of HIV-1 genotype and therapy outcome in children
BASIC SCIENCE/VIROLOGY	<i>Characterization of novel polyreactive anti-HIV antibodies in autoimmunity</i>	Maureen Goodenow (PI), Li Yin (Co-I), Mark Wallet; John W. Sleasman, co-PI USF	Pathology	HIV vaccine; deep pyrosequencing of human immunoglobulin repertoire and novel phage display library from autoimmune individuals to identify broadly neutralizing antibodies against HIV-1
BASIC SCIENCE/VIROLOGY	<i>Molecular mechanisms of skeletal muscle loss in HIV-infected older persons</i>	Marco Pahor (PI), Christiaan Leeuwenburgh, Maureen Goodenow, Todd Manini, Bradley Bender, Madhuri Sankuratri, Kevin Yarasheski, Martin Rhee	Geriatrics and Aging Research; Pathology	Effects of HIV-1 on strength and fatigue in older infected individuals; peripheral blood biomarkers of inflammation and innate immune activation
BASIC SCIENCE/VIROLOGY	<i>Viral evolution in peripheral</i>	Marco Salemi (PI),	Pathology	Viral dynamics of neuroAIDS in macaque

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
	<i>macrophages and brain during progression to AIDS</i>	Maureen Goodenow (Co-I), Rebecca Gray		model
BASIC SCIENCE/VIROLOGY	<i>Alveolar Macrophage Proteomics in HIV-Induced Emphysema</i>	Thomas Clanton (PI)	Exercise and Sports Sciences	Pathogenesis
BASIC SCIENCE/VIROLOGY	<i>Rational design of HIV fusion inhibitors targeting GP 41</i>	Alan R. Katritzky (PI)	Chemistry	Drug Design
BASIC SCIENCE/VIROLOGY	<i>Human Immunodeficiency Virus Proteinase</i>	Ben M. Dunn (PI), Maureen Goodenow (Co-PI)	Biochemistry and Molecular Biology	Drug Therapy
BASIC SCIENCE/VIROLOGY	<i>Combination of CCR5 32 and SIRTAS targeting HIV</i>	Lung-Ji Chang	Molecular Genetics & Micro	Gene Therapy
BASIC SCIENCE/VIROLOGY	<i>Analysis of HIV sequence data</i>	Marco Salemi (PI)	Pathology	Molecular Epidemiology
BASIC SCIENCE/VIROLOGY	<i>Foamy virus vector for Immunodeficiency viruses therapy</i>	Ayalew Mergia (PI)	Pathobiology	Gene Therapy
BASIC SCIENCE/VIROLOGY	<i>Protective CMI mechanisms of a dual subtype FIV Vaccine</i>	Janet K. Yamamoto (PI)	Pathobiology	Vaccine

STATE BUREAU OF LABORATORIES – 5 Studies

Presenter: Berry Bennett, M.P.H.

BASIC SCIENCE/VIROLOGY	<i>(Planned) Implementation of a 4th Generation HIV-1/2 Ag/Ab Screening assay and a Non-Traditional Confirmatory Process</i>	B. Bennett (PI), D. Willis, M. Salfinger, M. Diamante	Retrovirology, Jacksonville & Miami	Laboratory/Patient Care – HIV-1 acute infection detection and the implementation of a new HIV diagnostic algorithm
BASIC SCIENCE/VIROLOGY	<i>Correlation on the Use of a Reactive Signal to Cutoff Threshold Value in a 3rd Generation HIV-1/2 Antibody Immunoassay to Expedite Supplemental Testing and Reduce Screening Costs. Poster, 2010 HIV Diagnostic Conference, March 2010, Orlando</i>	Bennett B (PI), Fordan S, Diamante M, et.al.	Retrovirology, Jacksonville & Miami	Laboratory

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
BASIC SCIENCE/VIROLOGY	<i>Performance of the Aptima HIV-1 RNA Qualitative Assay with 16- and 32-Member Specimen Pools. Journal of Clinical Microbiology, Vol. 48, No. 9, Sept. 2010, p. 3343-3345</i>	Ethridge S (PI), Bennett, B, Stephens, P, et.al.	Retrovirology, Jacksonville & Albany; CDC and NYDOH LABORATORY	Laboratory
BASIC SCIENCE/VIROLOGY	<i>Cost-Effectiveness of Pooled Nucleic Acid Amplification Testing for Acute HIV Infection after Third-Generation HIV Antibody Screening and Rapid Testing in the United States: A Comparison of Three Public Health Settings. PLoS Medicine, Vol. 7, Issue 9, Sept. 2010, e1000342</i>	Hutchinson A (PI), Bennett B, et.al.	Retrovirology, Jacksonville & Albany; CDC and NYDOH LABORATORY	Laboratory
BASIC SCIENCE/VIROLOGY	<i>Detecting Acute Human Immunodeficiency Virus Infection Using 3 Different Screening Immunoassays and Nucleic Acid Amplification Testing for Human Immunodeficiency Virus RNA, 2006-2008, Archives of Internal Medicine, Vol 170 (#1), Jan. 11, 2010</i>	Patel P (PI), Bennett B, Lalota M, Simmons P, et.al.	Retrovirology, Jacksonville & Albany; Prevention Program; CDC and NY LABORATORY	Laboratory/Prevention

FLORIDA INTERNATIONAL UNIVERSITY – 6 Studies

Presenter: Mario De La Rosa, Ph.D.

BASIC SCIENCE/VIROLOGY	<i>Platelets Mediating Alcohol and HIV Damage</i>	Maria-Jose Miguez (PI)	Robert Stempel College of Public Health and Social Work	To evaluate platelets, platelet associated factors, immune and cognitive function in four groups: hazardous and non-hazardous alcohol consuming HIV-infected subjects and hazardous and non-hazardous alcohol consuming HIV sero-negative subjects
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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
				Funded by NIAAA
BASIC SCIENCE/VIROLOGY	<i>Polydrug Nanocarrier to Treat Opiate Addiction and HIV Disease</i>	Madhavan Nair (PI), Zainulabedin Saiyed	Herbert Wertheim College of Medicine	To use state-of-the-art nanotechnology for HIV drug targeting to brain affected by Neuro-AIDS through the following specific aims: To develop a magnetoliposome based multifunctional nanocarrier bound to CTOP, BDNF and AZTTP To test the developed formulation in vitro for its ability to transigrate across BBB. To evaluate the in vivo efficacy of the developed nanocarrier in an HIVE SCID morphine mouse model; Funded by NIDA
BASIC SCIENCE/VIROLOGY	<i>Mechanisms of Neuro-AIDS by HIV1B and C Clades</i>	Madhavan Nair (PI), Robert Malow, Zainulabedin Saiyed	Herbert Wertheim College of Medicine	To investigate the molecular mechanisms of clade-specific neuronal dysfunctions associated with clade-specific HIV infections, and to suggest novel anti-HIV therapeutic research strategies to alleviate the HIV induced neuronal dysfunctions in HIV infected subjects; Funded by NIDA
BASIC SCIENCE/VIROLOGY	<i>Cytokines An Underlying Cause Of Health Disparities In Tobacco Related Diseases</i>	Maria Jose Míguez-Burbano, MD, PhD (PI)	Florida International University	The principal tasks of this five-year longitudinal translational study, which builds upon our previous work, are to examine the immunological and behavioral mechanisms underlying health disparities in tobacco related diseases in PLWH and PLWOH. Specifically, we propose to search for disparities in the gene expression and cytokine production patterns. Funding: James and Esther King Florida Health Department
BASIC SCIENCE/VIROLOGY	<i>NIH NIAAA 1R01AA018095-01 Title: Platelets Mediating Alcohol and HIV Damage</i>	Miguez, Malow, Nair	Florida International University	The first aim of this 5 years longitudinal study is to confirm an inverse relationship between alcohol use and platelet counts and explore putative mediating immune

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
				mechanisms. Building on our previous findings and published data, our second aim is to investigate the relationship between platelet counts and levels of platelet associated factors (PAF, BDNF, serotonin) and neuropsychological function in PLWH.
BASIC SCIENCE/VIROLOGY	<i>NIH NIAAA 1R01AA018095-01 Platelets and the Blood Brain Barrier</i>	Miguez, Nair	Florida International University	The main task of this project is to explore the plausible role of platelets in the disruption of the blood brain barrier among PLWH and identify if factors released from apoptotic platelets may be underpinning the damage
VACCINE & GENE THERAPY INSTITUTE – FLORIDA – 7 Studies Presenters: Rafick Pierre Sékaly, Ph.D. & Lydie Trautmann, Ph.D.				
BASIC SCIENCE/VIROLOGY	<i>Investigating the impact of homeostatic proliferation on HIV persistence</i>	Dr. Sekaly, Dr. Chomont, Dr. Cameron, Dr. Wilkinson	N/A	HIV reservoirs
BASIC SCIENCE/VIROLOGY	<i>The role of negative regulators of T cell activation in the maintenance of viral latency</i>	Dr Chomont, Dr Sekaly	N/A	HIV reservoirs
BASIC SCIENCE/VIROLOGY	<i>Identifying the antigen specificity of the latent reservoir: A rationale for the development of vaccine aimed at activating HIV-specific CD4 T cell</i>	Dr Chomont		HIV reservoirs
BASIC SCIENCE/VIROLOGY	<i>Understanding the first immunological events in acute HIV infection.</i>	Dr. Trautmann, Dr Sekaly, Dr MBitikon-Kobo	VGTI-FL	Acute HIV infection
BASIC SCIENCE/VIROLOGY	<i>Systems biology approaches to identify innate and adaptive mucosal immune correlates of protection from HIV infection</i>	Dr. Trautmann, Dr. MBitikon-Kobo, Dr. Fischl, Dr. Castro and Dr. Pahwa	VGTI-FL, University of Miami School of Medicine	Mucosal immunity and HIV

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
BASIC SCIENCE/VIROLOGY	<i>Screening of small molecules aimed at reactivating HIV from its latent reservoirs</i>	Dr Chomont, Dr. Sekaly	VGTI and Merck	HIV reservoirs
BASIC SCIENCE/VIROLOGY	<i>Evasion of the innate immune response by HIV-1</i>	John Hiscott	VGTI Microbiology & Immunology and McGill University	Antiviral signaling is inhibited in HIV-1 infection by a protease-mediated sequestration of RIG-I (Solis et al, J. Virol. 85:1224-1236, 2011)
BROWARD CHILDREN'S DIAGNOSTIC & TREATMENT CENTER - 2 Studies Presented by Ana Puga, M.D.				
BASIC SCIENCE/VIROLOGY	<i>ATN 081: Treatment De-intensification and Residual HIV-1 in Adolescents and Young Adults (on-going)</i>	Ana Puga, MD	CFAP Research	Residual Viral Load in patients in Highly Active Antiretroviral Therapy (HAART) deintensification
BEHAVIORAL/EPIDEMIOLOGICAL BASIC SCIENCE/VIROLOGY	<i>IMPAACT P1085 : Duration of Human Papilloma Virus (HPV) Type-Specific Antibody After Administration of Quadrivalent HPV Vaccine to HIV-1 Infected Children Previously Enrolled in IMPAACT P1047 (recruiting)</i>	Ana Puga, MD	CFAP Research	Duration of HPV antibodies post-vaccination
ClinicalTrials.gov Website Studies – 4 Additional Studies				
CLINICAL TRIAL BASIC SCIENCE/VIROLOGY	<i>Safety and Effectiveness of Raltegravir (MK-0518) in Treatment-Experienced, HIV-Infected Children and Adolescents</i>	NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID) Sharon A. Nachman, MD, State University of New York at Stony Brook, Health Science Center; Andrew Wiznia, MD, Jacobi Medical Center, Albert Einstein College of Medicine	Termination from treatment due to suspected drug reaction attributable to the study medication; Grade 3 or 4 adverse events; Pharmacokinetic parameters; HIV viral load; CD4 count and percentage; Genotypic and phenotypic resistance measures Recruiting: Jacksonville, Miami, Ft. Lauderdale, Tampa	
CLINICAL TRIAL BASIC SCIENCE/VIROLOGY	<i>Pilot Assessment of Lopinavir/Ritonavir and Maraviroc in Experienced Patients NCT00981318</i>	Abbott, Barry M. Rodwick, M. D.	This is a study to assess the response of lopinavir/ritonavir plus maraviroc (with no nucleoside medications) in HIV patients failing their initial antiviral therapy.	

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STUDY CATEGORY	PROJECT TITLE	INVESTIGATORS	DEPARTMENT	SCIENTIFIC AREA
BASIC SCIENCE/VIROLOGY	<i>Phase 2, Randomized, Placebo-controlled Trial to Evaluate the Safety and Effect on Post-HIV Acquisition Viremia of a Multiclade HIV-1 DNA Plasmid Vaccine Followed by a Multiclade HIV-1 Recombinant Adenoviral Vector Vaccine in HIV-Uninfected, Adenovirus Type 5 Neutralizing Antibody Negative, Circumcised Men and Male-to-Female (MTF) Transgender Persons, Who Have Sex With Men NCT00865566</i>	Scott Hammer, Magdalena Sobieszczyk, Michael Yin – Columbia University; Orlando Immunology Center HVTN CRS - Jeffrey Dinsmore, RN NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID), HIV VACCINE TRIALS NETWORK		The purpose of this study is to determine the safety and efficacy of a VRC DNA/rAd5 vaccine regimen in healthy, circumcised men and male-to-female (MTF) transgender persons who have sex with men.
CLINICAL TRIAL BASIC SCIENCE/VIROLOGY	<i>Safety and Immunogenicity of GlaxoSmithKline Biologicals' Herpes Zoster Vaccine 1437173A in Adult HIV-infected Subjects NCT01165203</i>	GSK Clinical Trials 877-379-3718 GSKClinicalSupportHD@gsk.com 877-379-3718		This observer-blind study will evaluate the safety and immunogenicity of GlaxoSmithKline (GSK) Biologicals' investigational Herpes Zoster (HZ) vaccine GSK1437173A in Human Immunodeficiency Virus (HIV) infected subjects, firstly enrolling subjects treated with antiretroviral therapy (ART) and with high CD4 T cell counts, and subsequently ART-treated subjects with low CD4 T cell counts, and ART-naïve subjects with high CD4 T cell counts. This Protocol Posting has been updated following Amendment 1 of the Protocol, August 2010. The impacted section is exclusion criteria.

TOTAL NUMBER OF BASIC SCIENCE STUDIES LISTED AS OF 9/13/11 = 91

GRAND TOTAL NUMBER OF STUDIES LISTED AS OF 9/13/11 = 435