

UM-PAC Sexual Wellness/PrEP Clinic

Description/Need

Miami Beach is facing an epidemic of new HIV infections. Since 2011, new HIV infections on South Beach (33139) have risen 71%. South Beach's HIV rate of 5% exceeds sub-Saharan Africa and all but thirteen African countries. Miami Beach's HIV rate (2.9%) is 97 times the national average; South Beach's is 167 times. Miami-Dade County, meanwhile, has historically led the nation in new HIV infections. 26,000 people live with HIV in Miami-Dade County alone, 2,910 of them in Miami Beach.

Seeking to combat this rise in new infections, the University of Miami (UM) Medical School and Prevention Access Campaign (PAC), in partnership with The Gaythering Hotel, are seeking to open a twice-weekly evening sexual wellness/PrEP clinic to reduce new HIV infections on Miami Beach. PrEP, a daily pill that reduces the risk of HIV infection by 99 percent, has been cited in the dramatic reduction of HIV infections in London, New York and San Francisco. After its widespread adoption in San Francisco, new HIV diagnoses dropped 17%. The San Francisco AIDS Foundation PrEP Clinic, which has enrolled 1,200 people, has not seen any new infections since 2014.¹ Meanwhile, in London, the city's busiest sexual health clinic attributed a 40% reduction in new HIV cases to PrEP.²

The UM-PAC Clinic will be overseen by UM Associate Professor Dr. Susanne Doblecki-Lewis, an infectious disease specialist who opened Miami's first full-time PrEP clinic downtown with the Miami-Dade Department of Health in 2016. It will operate with guidance from UM Chief of Infectious Disease, Dr. Mario Stevenson and PAC Executive Director John Byrne. Dr. Stevenson leads the AIDS Research Division at the UM Miller School of Medicine; Byrne, a community advocate for PrEP and Miami entrepreneur, founded PAC in 2015. Space for the clinic would be provided pro bono by The Gaythering Hotel, Miami Beach's only gay hotel and a popular meeting space for gay and bisexual men. PAC, a nonprofit, will donate time and marketing resources to promote the clinic across Miami Beach and Miami-Dade County.

Objective

The UM-PAC Clinic would seek to enroll 250 candidates for PrEP in its first year, with a goal of keeping 200 individuals (80%) adherent for six months and 175 (70%) adherent after a full year, with adherence monitored by appointment compliance and continued prescriptions. Non-adherent patients would be replaced by new patients after a two-month lapse in care.

The UM-PAC Clinic will be a game-changer, providing easy and free access to PrEP in a non-clinical setting.³ The challenge for Miami residents now in obtaining this life-changing medication is

¹ Highleyman, Liz. "AIDS 2016: No New HIV Infections Seen in San Francisco's Strut PrEP Program." *HIVandHepatitis.com*, Aug. 8, 2016. (<http://bit.ly/2aSMt7M>)

² "PrEP Contributes to 40% Decline in HIV Diagnoses at UK's Busiest Sexual Health Clinic." *National AIDS Trust*, Dec. 23, 2016. (<http://bit.ly/2qp20os>)

³ Ard, Kevin MD and Mayer, Kenneth H. MD, et al. "Best Practices in HIV Prevention: Translating Innovation into Action." *National LGBT Health Education Center*, Apr. 2014. (<http://bit.ly/2pDL28L>)

threefold – few access points for those who are uninsured; anxiety about clinical or HIV-focused settings; and few locations accessible to those who work during the day. The UM-PAC Clinic would be open in the evening, 6 – 10pm, two nights a week. This will allow those with daytime employment to see a medical provider without missing work. It will also be situated in a popular gay venue, rather than a HIV-focused medical center, using a discreet text-message based appointment structure. This allows a comfortable access point for individuals to discuss their sexual health without worrying about “being seen.”

Following its first full-year, the clinic will aim to be self-sufficient. UM will apply to the Health Department for 340b status – a process by which the University receives subsidized drugs for uninsured patients, allowing it to fund labs and provider time. We believe the clinic can be self-sufficient by fall 2018. UM already has 340b status for HIV-positive patients.

Program Activities

Maintaining 250 PrEP patients in care will require regular medical appointments and quarterly laboratory work. It will also necessitate a part-time director and PrEP navigators, who help acquire the drugs for those who don't have insurance through patient assistance programs and monitor patient adherence. Because of the manufacturer's generous assistance programs, anyone making less than \$58,000 per year who doesn't have insurance can get the pills for free, provided they see a provider and keep up with lab work. Each PrEP prescription requires initial testing for HIV, kidney function and Hepatitis B and C, as well as sexually transmitted infections. For subsequent visits, HIV, kidney and STI tests are repeated.

The clinic will operate out of the Gaythering Hotel, conveniently located on Lincoln Road next to dining, shopping and the Regal movie theater. The hotel will promote the clinic to its client base of several hundred gay men through bar coasters, posters, emails, and announcements during weekly events. PAC will market the clinic externally through dating apps, events and advertisements.

Expected Outcomes/Impact

We expect that none of those who remain adherent to PrEP will acquire HIV, and anticipate a year-long adherence rate of 70%. This means the program will protect at least 175 PrEP patients from HIV. It also means that none of the partners of those 175 people will acquire HIV from our patients.

We also anticipate the clinic will increase community interest in PrEP, as the project will be holistically integrated into Hotel Gaythering's program activities. PAC will produce marketing materials for the clinic, hotel, nearby gay establishments, events and other health centers, including posters, bar coasters and brochures. Through other grants, PAC will also promote the clinic on gay dating apps using peer educators around Miami-Dade.

In line with the end of the first year, the UM-PAC Clinic will draw on 340b funding to support its activities for uninsured patients for the 2018-2019 year, ensuring a permanent site for biomedical HIV prevention on Miami Beach. With 340b funding, we also hope to be able to provide STI treatment on site, creating the first after-hours STI treatment site on Miami Beach.

Title of Grant: Sexual Wellness Clinic
PI Name: Mario Stevenson
Project Period Start Date: 10/01/17
Project Period End Date: 09/30/18

FOA: 0
Agency Name: 0
IDC Rate: 10.00%
Escalation Factor: 1.03

InfoEd# [REDACTED]
M# [REDACTED]
DIVISION Infectious Diseases

COMMENTS:

BUDGET SUMMARY

PERSONNEL	Year 1	Year 2	Year 3	Year 4	Year 5	Total
ALL PERSONNEL SALARY	145,639	0	0	0	0	\$ 145,639
ALL PERSONNEL FRINGE	48,988	0	0	0	0	\$ 48,988
	194,626	0	0	0	0	\$ 194,626

MATERIALS & SUPPLIES	Year 1	Year 2	Year 3	Year 4	Year 5	Total
3225 TECHNICAL SUPPLIES	6,139					\$ 6,139
3225 LAB SUPPLIES FOR PHLEBOTOMY	6,250					\$ 6,250
3225 LABORATORY TESTS	20,625					\$ 20,625
	33,014	0	0	0	0	\$ 33,014

OTHER DIRECTS	Year 1	Year 2	Year 3	Year 4	Year 5	Total
PRINTING OF MATERIALS	459	0	0	0	0	\$ 459
PILLBOXES	1,250	0	0	0	0	\$ 1,250
	1,709	0	0	0	0	\$ 1,709

	Year 1	Year 2	Year 3	Year 4	Year 5	Total (All Years)
DIRECT COSTS - Subject to Facilities & Admin. Rate:	229,349	0	0	0	0	\$ 229,349
DIRECT COSTS - <i>NOT</i> Subject to Facilities & Admin. Rate:	0	0	0	0	0	\$ -
0.100 F&A COSTS**	22,935	0	0	0	0	\$ 22,935
TOTAL AGENCY FUNDS REQUESTED	252,284	0	0	0	0	\$ 252,284

Title of Grant: Sexual Wellness Clinic

FOA:

PI Name: Mario Stevenson

Agency Name:

Budget Period Start Date: 08/01/17

Activity Code:

Budget Period End Date: 7/31/18

IDC Rate: 10.0%

COMMENTS:

Escalation Factor		Months - Split base on UM FY	
1st Half	2nd Half	1st Half	2nd Half
1.00	1.03	10.00	2.00

KEY PERSONNEL												
OBJ.	NAME	TITLE	Effort	CM	BASE	ADJ.BASE	%F/B	Salary Request	Fringe Benefits	Salary & Fringe		
	Mario Stevenson	PI	1%	0.12		\$ -	24.2%	-	-	-		
	Susan Doblecki-Lewis	Medical Director	10%	1.20	\$ 164,000	\$ 164,820	20.6%	16,482	3,395	19,877		
SENIOR PERSONNEL TOTAL								16,482.00	3,395.29	19,877.29		
OTHER NON-KEY PERSONNEL												
OBJ.	NAME	TITLE	Effort	CM	BASE	ADJ.BASE	%F/B	Salary Request	Fringe Benefits	Salary & Fringe		
	TBA	ARNP	20%	2.4	\$ 95,000	\$ 95,475	35.3%	19,095	6,741	25,836		
	TBA	Program Coordinator	25%	3	\$ 55,000	\$ 55,275	35.3%	13,819	4,878	18,697		
	TBA	Prep Navigator	100%	12	\$ 50,013	\$ 50,013	35.3%	50,013	17,655	67,668		
	TBA	Prep Counselor	100%	12	\$ 40,000	\$ 40,200	35.3%	40,200	14,191	54,391		
	TBA	Courier	20%	2.4	\$ 30,000	\$ 30,150	35.3%	6,030	2,129	8,159		
OTHER PERSONNEL TOTAL								129,157	45,592	174,749		
ALL PERSONNEL TOTAL								\$ 145,639	\$ 48,988	\$ 194,626		
MATERIALS & SUPPLIES												
	TECHNICAL SUPPLIES		6,139		0	-		0	-			
	PHLEBOTOMY SUPPLIES		6,250		0	-		0	-			
	LABORATORY TESTS		20,625		0	-		0	-			
	0		-		0	-		0	-	\$ 33,014		
OTHER DIRECT COSTS												
	PRINTING OF MATERIALS		459		0	-		-	-			
	PILLBOXES		1,250		0	-		-	-			
	0		-		0	-		-	-	\$ 1,709		
To use with NIH	NIH Total Direct Costs	\$	229,349							DIRECT COSTS - Subject to Facilities & Admin. Rate: \$		229,349
	Consortium IDC	\$	-							DIRECT COSTS - NOT Subject to Facilities & Admin. Rate:		-
	TOTAL IDC	\$	22,935							Facilities & Administrative Costs (IDC):		22,935
	TOTAL COSTS	\$	252,284							TOTAL AGENCY FUNDS REQUESTED: \$		252,284

UM-PAC Sexual Wellness/PrEP Clinic Budget

Personnel

Program Directors: Mario Stevenson, PhD, John Byrne: 0% FTE

- Oversee administrative aspects of clinic operations

Program Administrator: TBA (.25 FTE)

- Monitor overall patient load, recordkeeping, compliance and adherence
- Produce monthly reporting on progress
- Analyze outcome data under supervision of the PD and Medical Director to create reports summarizing outcomes to further optimize implementation
- Provides quarterly reporting to Miami Beach City Commissioners

Medical Director: Susanne Doblecki-Lewis, MD: (0.1 FTE)

- Create/adapt PrEP clinical protocols to clinic venue
- Train staff in PrEP provision per CDC protocols
- Oversee clinical activities
- Oversee clinic outcome tracking
- Provide STD testing and treatment

Nurse Practitioner (ARNP) (.2 FTE)

- Provide prescriptions and medical services to PrEP patients
- Provide STI testing
- Provide STI treatment

PrEP Navigator/HIV Tester: TBA (1 FTE)

- Provide assessment for PrEP appropriateness and HIV prevention counseling
- Certified HIV testing counselor; will provide pre- and post-test counseling as needed and rapid HIV test results
- Acquire drugs for uninsured patients through drug assistance programs
- Monitor patient adherence (after first week, month and quarterly)
- Oversee medical recordkeeping
- Engage in community outreach and planning with Prevention Access Campaign

PrEP Counselor/Lab Technician: TBA (1 FTE)

- Conduct phlebotomy for STD, HIV and lab tests
- Provide assessments for PrEP appropriateness and PrEP counseling
- Support Navigator in drug acquisition/prior authorization/insurance work
- Certified HIV testing counselor
-

Courier: TBA (.2 FTE)

- Transport lab specimens to Health Department and LabCorp

Non-Personnel Expenses

Laboratory Tests

Health Department Laboratory Tests: \$0. Includes tests supplied by the Health Department for sexually transmitted infections. These tests include rapid HIV tests, 4th generation HIV blood and confirmatory tests; syphilis blood tests (RPR); and gonorrhea and chlamydia tests (C/G) including urine, oral, and rectal swabs.

Non-Health Department Laboratory Tests: \$20,625. Includes all tests not supplied by the Health Department. These include kidney function tests and CBC, Hepatitis B and C, pregnancy, and other tests as required.

Supplies

Technical Supplies: \$6,139. For estimated 250 patients seen in first 12 months of operation. Including medical supplies such as gauze, Band-Aids, condoms and lubricant, specimen collector cups, refrigerator, injectable and oral treatments for sexually transmitted infections. Note that this specifically excludes PrEP medication, which will be obtained outside of this contract through available assistance programs and insurance.

Phlebotomy Supplies: \$6,250 (250 patients with average 4 visits / year @ \$6.25 /visit): phlebotomy tubes and needles for phlebotomy, alcohol pads, tourniquets.

Other

Educational Materials: \$459. Printing of educational brochures and materials for distribution to PrEP clients to provide information regarding PrEP, the importance of adherence, and clinic protocols and follow-up.

Adherence Tools: \$1,250. Pillboxes and pill holders (\$5 each item for 250 patients) – provided to patients to support adherence with PrEP medication.



INTERNAL – NOT FOR PUBLICATION

HIV PREVALENCE IN MIAMI BEACH, FL

	HIV cases	Population	HIV Prevalence
33139	1,916	38,035	5.0%
33140	299	23,381	0.1%
33141	695	38,244	1.8%
33109	*	602	**
Total	2,910	99,660**	2.9%

From 2010 – 2014, 766 people were diagnosed with HIV in these zip codes.

- South Beach’s (33139) HIV prevalence exceeds that of Sub-Saharan Africa (4.9%).
- South Beach’s (33139) HIV prevalence exceeds that of all but thirteen African countries.
- South Beach’s HIV prevalence exceeds that of Cameroon (4.8%), Central African Republic (4.3%), Gabon (3.9%) and Rwanda (2.8%).
- Miami Beach’s combined HIV prevalence exceeds that of Republic of the Congo (2.8%), South Sudan (2.7%), Chad (2.5%), Angola (2.2%) and Haiti (1.9%).
- The US HIV rate overall is .03%. Miami Beach’s HIV rate is **97 times** the national average.
- South Beach’s HIV rate is **167 times** the national average.

HIV INCIDENCE IN SOUTH BEACH 33139 (RESIDENTS) - NEW DIAGNOSES PER YEAR

Year	Total
2011	59
2012	68
2013	71
2014	78
2015	101

*Sources: Miami-Dade County Department of Health, CDC, Afri-Dev.Info, UNAIDS Report on the Global AIDS Epidemic 2012. HIV Case data as of June 30, 2016. Population as of 2015. * Health Department withholds data for privacy due to small population. ** Fisher Island excluded; no HIV data available.*

July 7, 2017

Dear Commissioner Malakoff:

I write to enthusiastically endorse the PrEP Clinic being proposed by the University of Miami and Prevention Access Campaign that will operate out of the Gaythering Hotel on South Beach. In my time as Executive Director at SAVE (Safeguarding American Values for Everyone), I've worked with both Dr. Mario Stevenson, Director of the Miami Center for AIDS Research at the University of Miami Miller School of Medicine, and John Byrne, Executive Director of Prevention Access Campaign, in educating the greater Miami community about HIV and PrEP for HIV prevention.

In January, Mario and I hosted an event on the quest for an HIV cure, which brought leading HIV researchers to Miami to discuss their research and what the future looks like for HIV/AIDS. I know Mario to be a committed warrior in the HIV/AIDS epidemic and a tireless advocate for improving the lives of those living with HIV and HIV prevention in Miami.

I believe a PrEP clinic on South Beach, which suffers from the worst HIV rates in Miami-Dade County, will go a long way toward reducing the spread of new HIV infections. The Gaythering is a central location with a built-in gay clientele, and offers a non-clinical setting that will be welcoming for those who are uncomfortable with a medical or HIV-focused health center. Moreover, its evening hours will allow those with daytime employment access to STD testing and treatment. I am excited about their plan to broaden access to this life-changing medication, and am pleased it will be made available to those with or without insurance. As you know, Miami residents struggle to buy and keep health insurance, and improving health outcomes for all residents is a value we can all agree on.

Thank you for allowing me the chance to write in support of this project.

Sincerely,



Tony Lima
Executive Director
tony@save.lgbt

MIAMI BEACH

LGBTQ Advisory Committee

Committee Chair, Robin Schwartz

Committee Members

Craig Garmendia
Dale Stine
David Lancz
David Leeds
Edison Farrow
Elizabeth Schwartz
Gayle Durham
George Neary
Heriberto Sosa
Jorge Richa
Mark Wylie
Michael Bath
Stephen Fox, Jr.

Dear Mayor and Commissioners:

The LGBTQ Advisory Committee for the City of Miami Beach is writing this letter in support of a PrEP Clinic in Miami Beach.

Miami Beach's current high HIV rates and the high rates of new infections are particularly alarming. Current health care providers have left a gap when it comes to utilizing the benefits of PrEP as a way to reduce new rates of HIV infection and making it readily accessible. Efforts in other cities have shown that the implementation of PrEP has led to reductions in the rates of new HIV infections.

A PrEP clinic could be a vital step in decreasing the rate of new HIV infections. It is important the clinics be in areas where statistics show the rates of new infections remain high. Miami Beach is one of these areas and thus it is vital we have a clinic to provide PrEP.

Thank you for your consideration of this project.

Sincerely,



Robin Schwartz
Committee Chair



1130 Washington Ave.
1st Floor North
Miami Beach, FL 33139
EMAIL: info@gaybizmiami.com
WEB: www.gaybizmiami.com
OFFICE: 305-673-4440
FAX: 305-673-8883

A Not -For-Profit Corporation

July 7, 2017

Commissioner Joy Malakoff
City of Miami Beach
1700 Convention Center Drive
Miami Beach, FL 33139

RE: PrEP Clinic on South Beach

Dear Commissioner Malakoff:

I am writing this letter in support of the PrEP Clinic/Sexual Wellness project being put forth by the University of Miami, under the direction of Dr. Mario Stevenson, the Director of the Institute of AIDS and Emerging Infectious Diseases at the University of Miami Leonard M. Miller School of Medicine, and by John Byrne, President of the Prevention Access Campaign.

Miami Beach's current high HIV rates and the high rates of new infections are particularly alarming. Current health care providers have left a gap when it comes to utilizing the benefits of PrEP as a way to reduce new rates of HIV infection and making it readily accessible.

I would like to offer my endorsement of the proposal for the PrEP clinic that the University of Miami and the Prevention Access Campaign are proposing. The University of Miami's deep history and leadership in working with HIV/AIDS and the largest provider of care to HIV positive patients in South Florida, its team of doctors focusing on HIV, its work in doing the research trials for PrEP and its fiscal oversight of this program make it an excellent fit to provide this service. The grass roots promotion being proposed by the Prevention Access Campaign should enable people to learn about the clinic and that people in need of this service find it. Furthermore, the University of Miami is already experienced in operating another South Florida PrEP clinic on the Jackson/UM Hospital campus.

Please contact me if I can be of further assistance.

Sincerely,


Steve Adkins
President/CEO

LATINOS SALUD

PRIDE, COMMUNITY, SUPPORT

2330 Wilton Drive
Wilton Manors, FL 33305
(954) 765-6239

925 Arthur Godfrey Road, Ste 200
Miami Beach, FL 33139
(305) 397-8967

9580 SW 107th Avenue, Ste 202
Kendall, FL 33176
(783) 801-1803

www.PrideCommunitySupport.org

www.latinossalud.org

RE: Community PrEP Clinic

July 10th, 2017

Dear Commissioner Malakoff:

I am pleased to support the University of Miami and Prevention Access Campaign's proposal to open a PrEP Clinic, with a proposed operation site at the popular Gaythering Hotel on South Beach. This innovative proposal seeks to reach at-risk community members and their partners who might not otherwise seek out an important tool in HIV-prevention, pre-exposure prophylaxis (PrEP).

Latinos Salud is a non-profit community-based HIV/AIDS prevention, screening and service agency, with 30 employees in three South Florida locations. Opened in 2008 in Broward County, the agency added its Miami Beach location in 2014, and its Kendall location at the start of 2016. These three locations provide over 2,000 targeted HIV tests each year, with nearly 2% of our tests resulting in a new HIV infection, and many of our 1,000 annual STD tests also resulting in diagnoses of syphilis, gonorrhea and chlamydia. With culturally competent HIV risk reduction education, condoms, and access to PrEP, we could virtually eradicate new infections in the area, and the ongoing STD screening required to maintain PrEP treatment could help break the chain of transmission by asymptomatic individuals.

Latinos Salud offers free walk-in testing and education services 50 hours each week, with additional late night outreach efforts on the beach and at other venues throughout the county. Our staff members also provide education and navigation to PrEP intake. However, our surveys find that community members are confused about how (and even whether) PrEP works. Among those who do learn about PrEP's protective benefits, the steps to initiate PrEP are cumbersome; lab work is expensive; and appointments are too limited.

For the past two years, I've shared in productive conversations with John Byrne, Executive Director of Prevention Access Campaign, on improving education and increasing access to PrEP. We provided Spanish translation for the PAC's first PrEP brochures, and still offer these at our HIV testing sites. Mr. Byrne also worked with the National Gay and Lesbian Task Force to create PrEP rallies to accompany their annual events, and supported our own "DiversiSafe" town halls, each drawing hundreds of participants. John has traveled the

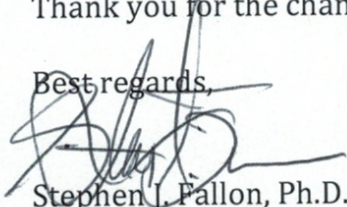
country in hopes of identifying best practices in PrEP deployment – including trips to San Francisco and Chicago – and is a regular face at health and HIV-related conferences. I've enjoyed working with him and am confident he will help make this clinic a success.

Miami-Dade County, and Miami Beach in particular, is in dire need of easy and welcoming access points for PrEP and STI treatment, especially as it suffers from exceptionally high HIV rates. This clinic is an exciting opportunity to turn the tide on the growing HIV epidemic in Miami Beach among young Latino gay and bisexual men.

The University of Miami and the Prevention Access Campaign are proposing a welcoming free PrEP clinic that will operate in evening hours, aligning dovetail with our own hours at our Miami Beach location where we conduct HIV prevention counseling and testing. We look forward to bringing our clients to the PrEP clinic, and fully support the proposal.

Thank you for the chance to write in support of this project.

Best regards,

A handwritten signature in black ink, appearing to read 'Stephen J. Fallon', with a large, stylized flourish extending to the right.

Stephen J. Fallon, Ph.D.

Executive Director

sfallon@latinossalud.org



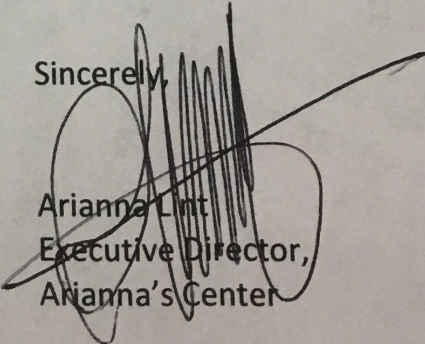
Dear Commissioner Malakoff:

I am delighted to support the PrEP (Pre-Exposure Prophylaxis) Clinic the University of Miami and Prevention Access Campaign are proposing at the Gaythering Hotel on South Beach. I have enjoyed working with John in introducing PrEP to the transgender community of Miami/Ft. Lauderdale, and his support for our events and mission. As you may know, transgender individuals face a higher HIV infection risk than any other demographic group, and my client base is primarily HIV positive.

I have also enjoyed working with Prevention Access Campaign in providing support for transgender women recently released from prison and Immigration and Customs Enforcement (ICE) detention centers. John helped us in writing a grant proposal, which will support 30 recently released transgender women. I look forward to working with him to continue advancing trans women's health issues.

By way of background, Arianna's Center is a service-focused nonprofit that provides a panoply of services to those who identify as transgender. Specifically, we engage in trans advocacy, education and training; healthcare linkage; case management for recently incarcerated transwomen (HIV-positive and non-HIV clients); and small support groups. Serving 250 people annually, Arianna's Center has 40 active clients, and is the only agency directly addressing the underserved trans community in Fort Lauderdale. Our clients include sex workers, those on the street, those recently jailed, those living temporarily in Florida, and victims of domestic violence.

Sincerely,



Arianna Lint
Executive Director,
Arianna's Center