

**Pfizer Independent Grant for Learning & Change Letter of Intent**  
**“The VaccineLink Project” / “La Salud Conexión”**

**I. Title:** **VaccineLink / La Salud Conexión:** Utilizing Bilingual, Bicultural, Community-Based Participatory Methods to Link Community Pharmacy and Health Providers to Increase Adult Vaccination Uptake among Hispanics and African Americans.

**II. Goal:** To identify current barriers to immunization among Hispanic and African American adults in Florida as to forge sustainable links between pharmacy and health care providers as to close current gaps in vaccine preventable morbidity.

**III. Objectives:**

- 1) To increase absolute number of pneumococcal, influenza, and Tdap vaccine uptakes among Hispanic and African American adults by linking existing trusted, local community-based pharmacy supply chains with trusted, local health care clinics as to expand the reach of an efficient, sustainable vaccine delivery system to underserved populations and to close current vaccination delivery gaps.
- 2) To deploy community based participatory research strategies including mixed method quantitative cross sectional surveys and bilingual qualitative opinion interviews with local, trusted opinion leaders and community participants as to identify community-specific barriers to vaccine uptake (i.e. accessibility, affordability, language) and to determine how to best target a sustainable, culturally beneficial vaccine delivery strategy to minority communities.
- 3) To create sustainable system changes for coordinated, long term vaccine delivery in the community by expanding the current pediatric state-wide vaccination registry system (FloridaShots) to include adult populations for the first time with the VaccineLink initiative. (<http://www.flshots.com>)

**IV. Assessment of the Need for the Intervention:**

Florida with population of 19.3 million currently has the third highest Hispanic community in the nation with a 23.2% Hispanic and 16.6% African American distribution.<sup>1</sup> Hillsborough and Polk counties Florida (total population 1.9 million) have experienced a recent increase in combined influenza and pneumococcal mortality from 7.4 (2005-2007) to 9.4 (2010-2012) per 100,000 population in Hillsborough county, which is higher than the general Florida rate of 8.8 per 100,000 population (2010-2012). Further, neighboring Polk county has also seen a mortality increase from 11.8 (2008) to 12.5 (2010-2012) per 100,000 population.<sup>2</sup>

Adults in these counties are majority non-Medicare eligible (28.0% are between the ages of 25-44, and 25.8% are between the ages of 45-64),<sup>3</sup> and thus a large adult population without a reliable network of vaccination screening and delivery presents a formidable public health challenge in need of a systemic solution. A recent pertussis outbreak has underscored the need for improved, coordinated adult vaccination delivery uptake, especially among minority Hispanic and African American populations.

<sup>1</sup> <http://quickfacts.census.gov/qfd/states/12000.html>

<sup>2</sup> [http://www.floridacharts.com/charts/mapp\\_report.aspx](http://www.floridacharts.com/charts/mapp_report.aspx)

<sup>3</sup> <http://quickfacts.census.gov/qfd/states/12/12057.html>

## **V. Intervention Design and Methods**

The VaccineLink Project / La Salud Conexión will engage a population size of 1.9 million persons with approximately 25.6% of Hispanic origin and 17.4% of African American origin in Hillsborough and Polk counties, Florida.

### **A) Objective 1 Methods:** *Link Providers and Patients to Local Pharmacies*

- Identify and engage pharmacies in high density Hispanic and African American population areas to partner with community health providers for vaccination delivery;
- Provide medical expertise as required by the state of Florida as to enable and empower local pharmacists to offer vaccination coverage to minority community populations who are currently undervaccinated;
- Engage local community health providers in minority areas restate current vaccination practices and to couple with pharmacies as viable option for patient vaccination, especially for health care providers who do not currently carry or offer vaccines due to cost and maintenance issues;
- Organize community outreach vaccination publicity and delivery fairs in partnerships with local pharmacies and providers including venues such as community cultural festivals, church-based events, and sporting events;

### **B) Objective 2 Methods:** *Community-Based Participatory Research*

- Initiate project by harnessing established community-academic partnerships with minority community-based opinion leaders and stakeholders including church-based ministry leaders, local business leaders, local political leaders to establish community participatory research protocol to decrease gaps in current vaccination provisions in a culturally acceptable format. Project will be vetted in advance by community leaders to ensure successful implementation.
- Develop a concise, bilingual cross sectional survey using the Qualtrics survey system to assess current attitudes and barriers to vaccination among high percentage Hispanic and African American clients;
- Data will be analyzed using STATA IC12 and implemented to reduce identified barriers to vaccination procurement;
- Bilingual qualitative interviews will be conducted with selected clients and health care providers in underserved areas as to assess barriers to vaccination procurement and analyzed using Atlas.ti.

### **C) Objective 3 Methods:** *Start FloridaShots Registry for Adult Vaccinations*

- Coordinate with professional societies of physicians, nurse practitioners, and pharmacists to raise awareness of entering adult vaccinations into FloridaShots statewide vaccine registry as to avoid duplicated vaccine administration and to confirm timing of needed revaccination
- Expand Florida's successful Vaccines for Children Program to establish a new "Vaccines for Adults Program" also included in the FloridaShots registry;
- Update existing department of public health laboratory and electronic record infrastructures as to link automatically with FloridaShots adult vaccination registry.

## **VI. Innovation**

The VaccineLink Project / “La Salud Conexión” introduces innovation to Hispanic and African American communities as no other program has been this extensive or comprehensive in our local area.

### **A) Objective 1:**

- Builds upon the successful corporate pharmacy vaccine delivery model and expands for the first time to local pharmacies in underserved minority areas;
- Creates new vaccine delivery networks for non-Medicare and non-Medicaid eligible adults who are not covered by local health departments and who may not be able to receive vaccines in Federally Qualified Health Centers.

### **B) Objective 2:**

- Builds upon past successful NIH-funded USF School of Public Health community based initiatives as to increase vaccine knowledge and self-efficacy among minority populations; builds capacity in the community specifically around vaccine literacy using the CDC’s social marketing approach;
- Introduces the concept of “vaccine health navigators” and lay advisors to populations at risk, creating sustainable health attitude change;
- Use of innovative mixed quantitative and qualitative methodology.

### **C) Objective 3:**

- First time creation of a sustainable adult vaccine registry to avoid vaccination duplication and clinical clarity on clients needed vaccination updates.

## **VII. Design of Outcomes Evaluation**

- 1) Determine success in closing the vaccine delivery gap by analyzing absolute number of vaccines delivered at each partnered pharmacy as well as absolute numbers of vaccinations, by neighborhood and demographics, over the 18 month implementation period as registered on FloridaShots.
- 2) Determine success in identifying barriers to vaccination by pre and post cross-sectional surveys in selected clients and providers.

## **VIII. Project Timeline:** (abbreviated)

<b>Months</b>	<b>0-1</b>	<b>2-6</b>	<b>6-8</b>	<b>8-12</b>	<b>12-14</b>	<b>14-16</b>	<b>16-18</b>
Hispanic and African American community partner engagement							
FloridaShots registry campaign launch							
Qualtrics iPad survey development							
Qualitative interviews							
Provider and pharmacy coordination							
Data analysis / program evaluation							
Manuscript preparation							

**IX. Requested Budget:** Total Requested is \$475,000; details available upon request.

**X. Additional Information:** (Please see Organizational Detail in following attachment.)

**Pfizer Independent Grant for Learning & Change Full Proposal**  
**“The VaccineLink Project” / “La Salud Conexión”**

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## **A. Main Section**

### **1. Overall Goal & Objectives:**

**Title:** VaccineLink / La Salud Conexión: Utilizing bilingual, bicultural, community-based participatory methods to link community pharmacy and health providers to increase adult vaccination uptake among Hispanics and African Americans.

**Goal:** To identify current barriers to immunization among Hispanic and African American and other underserved adults in Florida as to forge sustainable links between pharmacy and health care providers as to close current gaps in vaccine preventable morbidity and mortality.

#### **Objectives:**

- 1) To increase absolute number of pneumococcal, influenza, and Tdap vaccine uptake among Hispanic and African American and other underserved adults by 35% by linking existing trusted, local pharmacy supply chains with trusted, local health care clinics in order to forge an efficient, sustainable vaccine delivery system in underserved populations and to close current vaccination delivery gaps.
- 2) To deploy community-based participatory research strategies with local, trusted opinion leaders and community participants as to identify community-specific barriers to vaccine uptake (i.e. accessibility, affordability, language, beliefs) and to determine how to best target a sustainable vaccine delivery strategy to minority communities.
- 3) To centralize, modernize, and expand current state-wide vaccine registry system (FloridaShots) for pneumonia, flu and Tdap vaccinations through the use of mobile tablet and QR scanning technologies.

### **2. Technical Approach:**

The state of Florida contains one of the largest vaccine eligible populations nationally with 3.52 million people (18.2%) over the age of 65 [1]. With a population of 19.3 million, Florida is one of the four most ethnically diverse states in the nation, with a 23.2% Hispanic and 16.6% African American distribution [1]. Florida's Hillsborough and Polk counties with a combined total population of 1.9 million have experienced a recent increase in combined influenza and pneumococcal mortality. In Hillsborough, mortality increased from 7.4 to 9.4 per 100,000 population in 2005-2012, which is higher than the general Florida rate of 8.8 per 100,000 population. Further, neighboring Polk county has also seen a mortality increase from 11.8 to 12.5 per 100,000 population [2].

Overall population vaccination coverage in Florida is currently inadequate, and vaccination delivery systems are poor in terms of reaching at-risk, underserved populations. Socio-economically disadvantaged patients are unable to obtain needed vaccinations at medical offices due to insurance or logistical constraints. The state-wide FloridaShots database, originally intended for pediatric vaccine registration, is currently incomplete for adult vaccinations, and thus the total vaccination rates for Florida are unclear.

The majority of adults in Hillsborough and Polk counties are non-Medicare eligible (28.0% are between the ages of 25-44, and 25.8% are between the ages of 45-64) [3], and thus a large adult population without a reliable network of vaccination screening and delivery presents a formidable public health challenge in need of a systemic solution. A recent pertussis outbreak of 257 cases from 2010 to 2013 in both Hillsborough and Polk counties has

underscored the need for improved, coordinated adult vaccination delivery uptake and documentation, especially among minority Hispanic and African American populations [4].

Current literature suggests that African American and Hispanic groups receive fewer recommended vaccinations than Caucasian counterparts and have higher logistical and financial barriers to vaccine completion [5-7]. Further, the socio-economically disadvantaged in general show the same patterns of vaccine underutilization. This “vaccination gap” leads to greater morbidity and mortality from vaccine preventable diseases in these populations [8].

#### **a) Current Assessment of Need in Target Area:**

In order to provide an objective vaccine needs assessment, Florida vaccination rates for influenza, pneumonia, and Tdap for Hillsborough and Polk counties were queried through FloridaShots in Tallahassee. Data were stratified by age and race/ethnicity and revealed 187,342 such vaccinations in both counties for 2012 with striking underrepresentation of minority populations. Of all vaccinations reported, only 20.4% of African Americans and 10.7% of Hispanics were registered. Further, populations above age 65 were also underrepresented at 6.7% of total vaccinations.

Vaccination rates for the main Hillsborough County Health Department clinic in 2012 revealed a total of 4482 influenza, 2550 pneumonia, and 4850 Tdap vaccines administered. For 2013, this included 5291 total vaccine encounters with 3222 vaccine doses to ages 20 to 49, 1404 doses to ages 50-64, and 665 doses to ages 65+. Specifically, this included 1679 influenza and 947 Tdap vaccinations.

The Polk County Health Department reported 2761 influenza vaccines and 2930 Tdap vaccines within a similar one year period in 2013. Age groups greater than 65 were also underrepresented for vaccine delivery for both counties. Pneumonia vaccine reporting for Polk county was inconsistent and incomplete.

We observed substantial vaccine delivery gaps in minority communities as evidenced by low vaccine uptake percentages when compared to total county population. Further, this database represented those vaccinations only reported by current health care providers and was not an exhaustive sample. We recognized that current influenza, Tdap, and especially pneumonia vaccination estimates in Florida are incomplete as not all participating vaccine providers input data into the state-wide FloridaShots vaccine registry. Hospital inpatient vaccinations also are not routinely registered, and this creates problems for under or duplicated vaccinations during hospital visits.

Thus, there exists in Florida a vaccine system gap reflecting poor uptake in minority and underserved communities and inadequate vaccination registry documentation in need of project VaccineLink.

#### **Primary Intervention Audience**

The primary audience of this intervention will include African American and Hispanic communities in Hillsborough and Polk counties who are currently undervaccinated and thus at disproportionate risk for developing morbidity and mortality for flu, invasive pneumonia, and tetanus/pertussis. Specifically, communities of color are disproportionately impacted by vaccine preventable outbreaks such as the recent pertussis outbreak. Further, other

undervaccinated racial/ethnic groups in these geographical areas will also be included in this outreach as to maximize vaccination delivery outcomes.

Of these communities, non-Medicare and non-Medicaid eligible adults who are not covered by local health departments and who may not be able to receive vaccines in Federally Qualified Health Centers will thus also be a natural fit for the intervention.

#### **b) Intervention Design and Methods:**

The VaccineLink Project / La Salud Conexión will engage a population of 1.9 million persons in Hillsborough and Polk counties, Florida for a projected 35% increase in vaccination rates for influenza, pneumonia, and Tdap combined. Our goal in disseminating vaccination coverage is to link to primary care centers in a bilingual and bicultural framework as to increase trust and close gaps between community members and vaccine providers. In so doing, we aim to create a sustainable and stronger link for intervention counties to deliver and document vaccination administration, especially to high-risk population groups.

A research infrastructure specifically tailored for this intervention will be created to accomplish the following specific project aims:

**Aim 1:** Increase absolute number of pneumococcal, influenza, and Tdap vaccine uptake among Hispanic and African American and other underserved adults by 35% by linking existing trusted, local pharmacy supply chains with trusted, local health care clinics in order to forge an efficient, sustainable vaccine delivery system in underserved populations and to close current vaccination delivery gaps.

**Aim 2:** Deploy community-based participatory research strategies with local, trusted opinion leaders and community participants in order to identify community-specific barriers to vaccine uptake (i.e. accessibility, affordability, language, beliefs) and to determine how to best target a sustainable vaccine delivery strategy to minority communities.

**Aim 3:** Centralize, modernize, and expand current state-wide vaccine registry system (FloridaShots) for pneumonia, flu and Tdap vaccinations through the use of mobile tablet and QR scanning technologies.

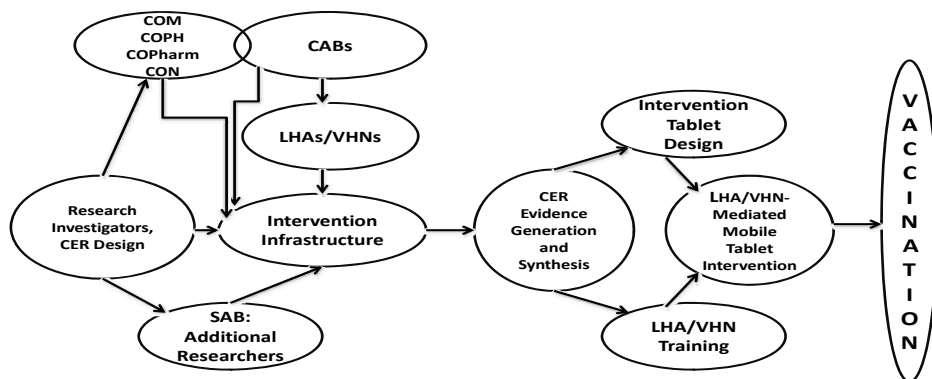
#### **Infrastructure Development Plan: Community-Based Participatory Research (CBPR)**

The project activities will be guided by using the principles of community-based participatory research (CBPR). CBPR has been defined as a systematic inquiry with the collaboration of those affected by the issue being studied and is defined by the following principles: [a] community participation to investigate shared, lived experiences; [b] community stakeholders participate as equals; [c] co-learning as a group process between community and researchers; [d] community descriptions of the local social context and real world constraints; [e] community congruence between the project and the local reality [13-15]. In adherence with these principles, the principal investigators will secure the resources and research expertise at the USF Morsani College of Medicine, USF College of Public Health, USF College of Pharmacy, USF College of Nursing, and the NIH-funded USF Health-Moffitt Collaborative Transdisciplinary Center to Address Cancer Health Disparities, and the Hillsborough and Polk County Health Departments in order to create a Scientific Advisory Board.

This Scientific Advisory Board (SAB) will include senior researchers/faculty with expertise in evidence-based medicine, community-based participatory research, community outreach,

and health disparities research. Further, the board will provide scientific oversight, and the primary investigators will report to its members the progress on project objectives. Relations will be formalized with the Hispanic American and African American Community Advisory Boards (CABs). These are local boards whose 12 members often work collaboratively and regularly provide assistance to USF scientists (including one of the PIs, Dr. Dawood Sultan) to enhance research conduct among local minority populations.

In addition to the principal and co-principal investigators, a computer software and applications developer from USF Health, graduate research assistants, a project coordinator, undergraduate interns, specialized Lay Health Advisors / Vaccine Health Navigators (LHAs/VHNs) will be recruited and brought together to establish an intervention infrastructure to conduct activities to increase vaccine uptake among local African American, Hispanic, and underserved populations and to conduct research on informed decision making (IDM) in vaccination. Consultative activities within this structure will generate evidence which will determine [a] the technical and substantive capabilities of the project intervention modalities [b] ideal and culturally appropriate survey and educational instruments, [c] community venues with the least bias for participant recruitment and data collection, [d] ideal community interventional promotional materials, [e] which LHAs/VHNs to employ for the intervention, [f] specific training for LHAs/VHNs as to prepare for field intervention and interview work, and [g] the scientific integrity of the intervention program. This approach will differentiate this project from all previous projects which attempted to increase vaccine uptake among local African American, Hispanic, and underserved populations.



**Figure 1:** Community-Based Participatory Research (CBPR) Infrastructure Development Plan

First, members of the African American and Hispanic American CABs will be approached by the investigators for partnership and for recommendations of community members who could serve as LHAs/VHNs. Once selected, the LHAs/VHNs and primary research team members will travel to the zip code areas with high percentages of minority populations to map out local businesses, pharmacies, churches, community centers, and local government agencies contained in each area. These venues will be categorized, and each will be assigned a random number. All business owners, pharmacists, and the leaders of the other community venues will



be met by the investigators and LHAs/VHNs in the order in which their facilities were listed. During these meetings, the primary research team members will introduce the LHAs/VHNs, explain the intervention program, and solicit participation in the program.

Prior to the start of participant recruitment and intervention activities, four focus groups (two with self-identified Hispanic Americans and two with self-identified African Americans) will be created. Each of the intervention counties will have one Hispanic and one African American focus group. The focus groups will review and assess the content, graphic and pictorial presentation, and cultural and linguistic relevance of a number of vaccine education and vaccine IDM tools as well as the iPad survey instrument, which will be used for survey data collection. Content analysis of the formative evaluations by focus group members will provide evidence which will allow for an initial determination of the graphic, linguistic, and cultural content of the tools to be used in the intervention arm of this project. During this time, graduate research assistants and undergraduate interns will complete training in [a] systematic literature reviews, [b] comparative effectiveness research (CER) methodologies in vaccine uptake, [c] linguistic and cultural competency in community-based vaccine uptake interventions, [d] LHA skill clusters and competencies training modalities, [e] IDM in vaccination, and [f] CER research translation. Afterwards the principal investigators, research scientist, and research assistants will reassess the initial determination of the contents of the intervention tools which was made following focus group evaluations.

Consequently, the software and applications developer and database architect will be able to start assembling the study intervention tools and survey instruments on the latest iPad technology platform to create a vaccination patient decision aid (VPtDA). The VPtDA which will be used in this project will be an information technology based psychoeducational intervention on vaccinations. It will be developed as an application for iPad tablets. In its final form it will contain bilingual and bicultural audiovisual videos which will provide in both English and Spanish a discussion of the three major vaccines: pneumonia, influenza, and tetanus/pertussis. The videos will be linked to pre-post viewing questionnaires which will use validated instruments measuring [a] vaccine health knowledge, [b] vaccination decisional conflict, [c] vaccination decisional self efficacy, and [d] vaccination decision control preference. The videos and bilingual printed materials on vaccine health will constitute the study intervention tool. The survey questionnaire on “knowledge”, “decisional conflict”, “decisional efficacy”, and “decision control preference” will be linked to the videos and will solicit responses to identical questions in order to yield information will be used to determine whether or not changes have occurred in the four vaccine IDM domains. All survey participants will be offered vaccination if clinically needed with a free vaccine voucher paid for by either existing medical insurance, Health Department supply, or participating local pharmacies.

Innovative iPad tablet applications and survey instruments as well as complimentary Quick Response “QR” barcode scanning will be developed and piloted. Further literature reviews will be conducted to develop a curriculum and modules to train LHAs/VHNs specifically for this project. Development of the modules will be informed by the health belief model [16-19], research findings on the core roles and competences of community health workers [20-22], and scientific research findings on the behaviors, attitudes, psychological predispositions, and interests of African Americans and Hispanics in vaccine health and vaccine IDM. Substantive lectures and interactive hands-on instruction on the use of mobile tablets will be delivered to

the LHAs/VHNs. These lectures will be designed specifically to enable a detailed understanding of the craft of social science and population-based research and the importance of research neutrality, protection of human research subjects [23], health and vaccine health outcomes disparities [24-28], social interaction and emotional intelligence [29,30], community socioeconomic and demographic profiles, and use of internet-enabled iPad tablets [31,32]. Feedback from LHAs/VHNs at the end of the training sessions will be used to make further adjustments to the functionality of the VPtDA. Once all adjustments and LHAs/VHNs training are completed, field intervention and data collection will be started. In the process, African Americans and Hispanics who agreed to participate in the project will be enabled to directly interface with the project mobile tablet. The LHAs/VHNs will provide help to participants who are not accustomed to navigating mobile tablets.

Hillsborough and Polk counties have a combined total population numbering approximately 1.9 million persons (1.23 million in Hillsborough and 0.6 million in Polk). Hillsborough county is comprised of 24.9% (n=306,635) Hispanic and 16.7% (n=205,073) African American individuals; Polk county is comprised of 17.7% (n=106,532) Hispanic and 14.8% (n=88,833) African American individuals. Intervention areas of need are zip codes within Hillsborough and Polk counties, Florida with disproportionately high numbers of African American and Hispanic individuals, many of whom are above the age of 65. There are 17 zip codes in Hillsborough county and 26 zip codes in Polk counties that fit these racial/ethnic concentration criteria and thus will be considered intervention areas.

The purposive method used to identify these areas gives us a major advantage: increased odds of exposing to the intervention larger numbers of African American and Hispanic residents than if randomly selected zip codes contained below county average numbers of Hispanics and African Americans. However, this method introduces a degree of selection bias in the proposed study. To minimize bias, we will randomize at the individual levels within each zip code area. At venue level, pharmacies, churches, community centers, barbershops, beauty salons, other local businesses, and local government agencies that are located in each area will be geomapped. These venues will be categorized, and each will be assigned a random number generated by SAS. From each category, 50% of its venues will be randomly selected using the random numbers generated by SAS. Selected venue owners/leaders will then be met by the investigators and LHAs/VHNs in the order in which their facilities were listed. During these meetings, the primary research team members will [a] introduce the LHAs/VHNs [b], explain the intervention program, and [c] solicit participation in the grant program. If participation is refused, the venue will be replaced by randomly selecting from the remaining members within its sample category. If participation is secured, the research team will record the location address and obtain information on weekly adult client flow into the venue. On the basis of information from community-based, NIH-funded research conducted by Dr. Sultan in Hillsborough, Pinellas, and Pasco counties, weekly client flow in minority zip code businesses and other venues averages between 60 and 70 individuals [9]. We will randomly select 100 clients over the intervention period for intervention for survey, to assess for vaccine readiness, and to offer free vaccination via voucher. This will yield a sample size of 4,300 persons with a potential increase of more than 3000 new vaccinations.

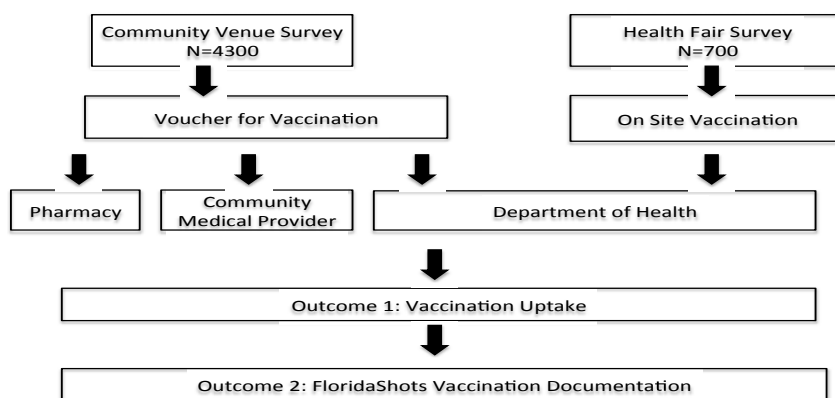
To further minimize sampling bias, a second intervention venue will be deployed in the form of vaccination health fairs in grouped intervention zip code areas. The same iPad pre- and

post-survey assessments and intervention materials will be distributed but in an intensive, day-long event with offering of free vaccinations sponsored by the Department of Public Health on site. Four such health fairs over one year will be held in collaboration with the Hillsborough and Polk Departments of Public Health, the USF Morsani College of Medicine, and the USF College of Nursing. The advantage of this intervention is that it is complementary to the community sample venues and is an excellent forum to further promote vaccine uptake in the community and to strengthen ties between vaccine providers and community members. We anticipate attracting an additional 700 participants. This will increase our total sample survey assessment size to 5,000 individuals.

Incentives for survey completion for all participants will include a \$10 gift card to defray the opportunity cost of the time spent reviewing educational materials and answering survey questions. All participants will have the opportunity for free vaccination, with the cost covered by either current insurance (Medicaid, Hillsborough Health Plan, Clear Health, etc.), the local health department, or donations by pharmacy providers utilizing a voucher system. Health fair participants will be offered free vaccination on site.

Permission from the Institutional Review Boards of the University of South Florida as well as both Hillsborough and Polk County Departments of Health will be obtained prior to the beginning of the study. This will ensure the protection of all human subjects in the intervention.

To further contribute to vaccine health and intervention capacity building, this project will be open to USF Health graduate and undergraduate students as a Vaccine Health Intervention internship activity and research site. The various colleges in the USF Health system require field experiences for the completion of graduate education and integrate in research and field interventions. Opening this project to students is a novel approach which will increase (at no cost) the project's human resources. Students with good academic standing and willingness to commit one year to internship research activities will be trained in intervention methods and vaccine health research. Students who demonstrate significant research capabilities will be encouraged to get involved in manuscript preparation as coauthors.



**Figure 2:** Vaccination Uptake and Documentation Study Design

### Control Group

A control group will be utilized in this study to provide a comparison group. We are in contact with the Director of Health in neighboring Pinellas County as to be able to analyze

vaccination rates and documentation into FloridaShots within five county zip code areas that are similarly socio-economically disadvantaged and have concentrations of minority populations. Effectiveness of the intervention over the control group will be assessed by total number of vaccination uptake rate in the state-wide database.

### **Innovation**

The VaccineLink Project / “La Salud Conexión” introduces multiple areas of innovation for vaccine delivery and documentation in a systemic fashion and forges sustainable, bilingual and bicultural networks as to close vaccination delivery and documentation gaps within underserved regions in Florida. In particular, this represents the first official program to reach out to predominately Hispanic and African American communities for vaccination uptake using iPad and QR scanning technologies in Florida.

First, up to date, culturally and bilingual vaccination materials will be available not only on Health Department websites, but also via innovative QR scanning and iPhone application technologies that will serve as “take-home” electronic informational bundles for further consideration of vaccine uptake for families and communities. This electronic venue is low cost and more easily disseminated than traditional paper pamphlets or posters.

Second, iPad technology enables access to up to date bilingual audio-visual and internet materials but also provides a more efficient and complete survey methodology. Furthermore, use of tablet-based questionnaire and educational materials eliminates variance messaging and improves accuracy of data analysis and correlates of vaccination uptake.

Third, integrating local vaccine providers with the state-wide FloridaShots database enables for the first time a clear determination of exact number of vaccines administered as well as the ability to identify geographical inadequacies in vaccine delivery. This project also will build upon the successful corporate pharmacy vaccine delivery model and expands for the first time to local pharmacies in underserved minority areas. This innovation will also give the advantage of avoiding re-vaccination among high risk groups as to better allocate community resources. Especially relevant for the pneumonia vaccine, this project will represent the first attempt to standardize and document pneumonia vaccine administration in the community.

Fourth, the Community-based participatory research framework is an innovative concept in organizing vaccine delivery interventions as it allows for greater acceptance of the community for vaccination uptake. This approach also sustainably trains individuals from local communities to improve long term public health capacity and has been shown to be more effective than traditional health informational brochure or poster notices [10-12].

Fifth, results from this study will enable the development of an interactive vaccine concept map on iPad platform to provide an evidence-based education and vaccine delivery program that could be used nation-wide. Such a program provides deeper understanding of vaccine health and the need for vaccination. This project builds upon past successful NIH-funded USF School of Public Health community-based initiatives as to increase vaccine self-efficacy among minority populations and builds capacity in the community.

### **c. Evaluation Design:**

We predict a 35% increased absolute uptake in vaccine delivery with a 35% increase in provider state reporting. We also anticipate a sustainable positive effect in overall vaccine

readiness through the intervention counties. We will aim to determine the success in closing the vaccine delivery gap by analyzing absolute numbers of vaccines delivered at each partnered pharmacy as well as absolute numbers of vaccinations, by neighborhood and demographics, over the implementation period as registered on FloridaShots.

The three study objectives will be assessed by three main methodologies: 1) patient level survey data analysis for correlates of vaccine readiness and uptake, 2) qualitative interviews with community-based advisory boards as to barriers to vaccination, and 3) data analysis of total net increase in vaccination documentation into FloridaShots for the two intervention counties as compared to the control county.

First, iPad enabled pre and post-intervention patient surveys will capture data relevant to age, gender, race/ethnicity, socio-economic variables, and zip-code to identify baseline vaccine readiness, barriers to vaccination, and ultimately vaccine uptake. Captured data will enable assessments of [1] vaccine health knowledge, [2] vaccination decisional conflict, [3] vaccination decisional self-efficacy, and [4] vaccination decision control preferences. Specifically, iPad survey data will be designed using the Qualtrics interface and will allow for greater data accuracy as data will be directly exported to the STATA/SAS statistical platforms for further logistical regression analysis for correlates of the above outcomes. Vaccine delivery gap will be assessed by the absolute numbers of survey participants who complete the needed vaccinations during the study period.

Second, interviews with community advisory boards (CAB's) as well as a selection of survey participants will be qualitatively assessed to give further insight into vaccine readiness, barriers to vaccination, and determinants of vaccine uptake among the community. Such interviews will employ Atlas.ti to categorize themes in order to further inform the interpretation of the quantitative results.

Third, the total net increase in vaccinations in intervention zip codes will be analyzed using the FloridaShots database, which can confirm individual vaccine completion, zip code origin, age, and race/ethnicity.

The control group for this study includes neighboring Pinellas county, which has similar demographics to intervention counties. As we envision a favorable "spill-over" effect within the intervention zip codes areas due to successful project promotion and delivery, a separate county such as Pinellas within the FloridaShots database system would serve as an ideal control. We anticipate less vaccine uptake and documentation within the control county over this intervention period.

### **Target Audience Engagement**

We will determine if the target audience was fully engaged in the intervention by the following assessments: 1) high level of engagement and support by African American and Hispanic community advisory boards as well as venue owners and community leaders 2) post-survey responses as to vaccine readiness 3) absolute vaccine uptake at health fair and community venues 4) absolute increase in FloridaShots vaccination statistics within intervention zip codes as compared to controls in Pinellas county.

Project outcomes and deliverables will be disseminated sustainably through the following methods. First, developed vaccination surveys and iPad and QR educational tools will be made available through the Hillsborough and Polk county websites for free downloading for any interested county health department nationwide. Second, total vaccination uptake results and correlations of successful vaccine delivery will be communicated to the community and scientific advisory boards and departments of health in a final publication report format as to implement sustained policy changes in vaccine delivery and documentation. Third, information on successful implementation will be published in the scientific literature and briefed with well-timed media reports and scientific conferences. Fourth, connections between community and local vaccination providers (pharmacies, federally qualified health care clinics, and local medical providers) are anticipated to be strengthened with increased vaccine readiness in the community in the future.

### **Quantitative Evaluation Design**

Pre-intervention (pre-test) and post-intervention (post-test) survey questionnaires will be administered to obtain responses to identical questions at two different points in time (immediately prior to and immediately after the intervention) to determine whether or not the intervention has caused change in the four vaccination IDM domains. Responses on the four IDM will be numerically scaled to yield mean values. As such paired t-Tests will be appropriate for the data and will be used as analysis tools. Also, to understand within group variations, mean responses on the four IDM domains will be assessed in terms of a number of respondent socioeconomic and demographic characteristic variables which include educational level, income, marital status and age. Effect size statistics will be calculated to determine relative size of mean differences. Furthermore, the Kolmogorov-Smirnov two sample K-S test will be performed to assess the empirical cumulative distribution functions of the two (pre and post-test) samples, and the folded F-test for homogeneity to determine whether or not the assumption of normality is reasonable. We hypothesize that the test results will be nonsignificant, with P values greater than 0.05 ( $P > 0.05$ ) to indicate that the respondent samples were drawn from the same distribution and that distribution normality is not violated.

In addition, responses on domain questions will be dichotomized into low/high (0,1) risk categories. We will run multivariate logistic regression models to obtain estimates of independent socioeconomic and demographic variable effects on the mean values of each of the four vaccination IDM domains. In its primary form, the logistic model to be fitted to the data takes the following form:  $\ln(P/1-P) = \beta_0 + \beta_1 X_1 + \beta_i X_i + e$ ; where P is the probability of a vaccination IDM domain mean value,  $X_1 \dots X_i$ ,  $i=1,2,\dots,N$ , are explanatory variables,  $\beta_0$  is a constant,  $\beta_1$  and  $\beta_i$ ;  $i=1,2,\dots,N$ , are coefficients (logits) denoting the effect of a unit change in the explanatory variables on the log-odds of IDM domain mean value, and e is the error term which accounts for the amount of variation not explained by the independent variables. Statistical analyses of data will be conducted by the Statistical Analysis Software (SAS) version 9.2. and STATA IC12 (both of which are available for use by the PIs and the Database Architect).

### **Qualitative Evaluation**

Interviews with community advisory boards (CAB's) as well as a selection of 25 consented survey participants will be qualitatively assessed using transcription and input into

Atlas.ti. Standard methods of theme-based analysis will be employed to provide more insight into quantitative responses and correlations. This will represent one of the first times that such qualitative analysis is applied to vaccine uptake behaviors among underserved populations.

### **3. Detailed Work Plan and Deliverables Schedule:**

VaccineLink / La Salud Conexión will unfold in three separate phases over a total of 18 months.

**Phase I** (Months 1-3): Current qualitative and quantitative needs assessment will be launched in intervention zip code areas in conjunction with community partnerships. A formalized literature review will inform training materials for LHAs/VHNs. iPad survey materials will be developed using Qualtrics and piloted before being launched into the community. Promotional materials for community and health fair events will be developed and circulated with preliminary qualitative findings publicized.

**Phase II** (Months 4-12): Intensive implementation phase of vaccination patient decision aid (VPtDA) surveys at community and health fair venues. Survey data will be entered in real time to the database with feedback to community boards and vaccination providers. Individual and county-wide vaccination uptake documentation will be assessed.

**Phase III** (Months 13-18): Assessment, analysis, and dissemination of findings in meetings with community and scientific advisory boards, local pharmacy vaccine providers, and medical providers, all with coordination with the departments of public health in intervention areas. Complete data analysis will be completed.

### **Project Timeline:**

	<b>Phase I</b>		<b>Phase II</b>		<b>Phase III</b>	
<b>Months</b>	<b>0-1</b>	<b>2-3</b>	<b>4-8</b>	<b>8-12</b>	<b>13-15</b>	<b>16-18</b>
Literature review and training of LHAs/VHNs						
Community and local pharmacy engagement						
Qualtrics iPad survey and QR development						
FloridaShots registry campaign launch						
Qualitative assessments						
Vaccine health fair events						
Qualitative assessments						
Program evaluation and community feedback						
Quantitative data analysis						
Manuscript preparation						
Conference/Media promotion of results						

**B. Organizational Detail:** (maximum 3 pages)

**1. Leadership and Organizational Capacity:**

The University of South Florida Health network (USF Health), is one of the premier clinical research institutions in Central Florida and encompasses an extensively integrated academic network of health care delivery experts, physicians, scientists, and experienced public health advocates with extensive NIH-supported track records of partnering with local communities for sustainable community-based change innovations.

The USF College of Public Health recently was granted over \$200 million in total federal funding for key research initiatives. The USF Health faculty have extensive research experience in collaborating with existing community providers to improve health delivery outcomes. The USF-Moffitt Center for Equal Health is an NIH funded center for excellence in health disparities research and elimination practice. Center researchers work collaboratively with COPH researchers. The COPH office of research administration has successfully administered more than \$100 million per year of research grants. The USF Morsani College of Medicine successfully garnered \$81.8 million in awarded grant projects in FY 2012-13.

The Hillsborough County Health Department is home to the state-wide database FloridaShots and also is a key provider of vaccinations in the county. With a budget of \$48 million dollars with 90,217 client visits in 2009, it continues to be a substantial vaccine provider. The Polk County Health Department is an integral health provider with 29,000 patients seen yearly and has been responsible for administering 37,111 vaccines over the past year.

**2. Staff Capacity:**

**Jamie P. Morano, MD, MPH, Principal Investigator:** PI Dr. Jamie P. Morano will share with Dr. Dawood H. Sultan, Ph.D., the responsibilities of overall leadership of the grant program. Dr. Morano will provide overall leadership, direction, and supervision for all activities and initiatives of the grant program. Dr. Morano will serve as point of contact for Pfizer and will assure compliance with all Pfizer grant-related policies, ensure that all research activities undertaken within the grant program receive approval of the USF Institutional Review Board (IRB), and oversee all Pfizer reporting requirements. Dr. Morano will ensure the successful implementation of the grant program. She will also be responsible for project evaluation. Dr. Morano brings multiple years in the field as well as formal training in biostatistics. Along with Dr. Sultan, she will lead and mentor research investigators in survey design and execution. She will participate and instruct in the analysis of data generated by the grant program. She will also contribute to the development of manuscript and conference presentations based on grant program data and will contribute to the reporting and disseminating of data analysis findings.

**Dawood H. Sultan, Ph.D., Principal Investigator:** PI Dr. Sultan will share with Dr. Jamie P. Morano the responsibilities of overall leadership of the grant program. Dr. Sultan will provide overall leadership, direction, and supervision for all activities and initiatives of the grant program. He brings to this project experiences as Co-PI in an NIH P20-funded interdisciplinary center for excellence in health disparities where he co-led the center's Research Training and Education Core. He also brings to this project additional experience as Co-Investigator in an NIH ARA-funded LHA-mediated intervention in prostate cancer IDM in minority communities in Hillsborough, Pinellas and Pasco counties of Florida. He trained the program LHAs. Dr. Sultan will be responsible for the human capital development for this project and will coordinate the



recruitment of program staff. Dr. Sultan will also be responsible for designing key training modules implementing training activities for the LHAs/VHNs, research assistants and program coordinator. He will also lead and participate in the analysis of data generated by the grant program, contribute to the development of manuscript and conference presentations based on grant program data, and will contribute to the reporting and disseminating of the findings of data analysis.

**Meghan E. Borysova, Ph.D., Co-Principal Investigator:** Co-PI Dr. Borysova will serve as the research scientist for this grant program. Dr. Borysova has a unique scientific background as both a classically trained molecular biologist/geneticist as well as having extensive postdoctoral training directly in health disparities/health equity research. Dr. Borysova's background brings to the research program of this grant a unique perspective on immunity, disease etiologies, vaccinations and vaccine-related scientific discovery. In addition to a proven record of work as a bench scientist, Dr. Borysova has spent several years working on NIH-funded comparative effectiveness research activities to eliminate cancer disparities and has served as the Principal Investigator on a Department of Defense grant to investigate the health and health care needs of underserved members of society. Her experiences bring added insights into health disparities and scientific discovery. Dr. Borysova will be responsible for vaccine-related participant recruitment and retention. She will be directing the development of vaccine-related survey instruments and for determining the scientific input required for communicating vaccine information to study participants. Dr. Borysova will also be responsible for determining the scientific efficacy of vaccine-related electronic and audiovisual materials including QR scanning applications used in this study for communicating with the Community Advisory Boards, study participants, and the wider study community. Dr. Borysova will be jointly responsible for data analysis, manuscript preparation and dissemination, presentations at seminars and conferences.

**Software Developer:** TBA. The software developer will be a highly experienced USF Health/USF-Affiliate Information Systems expert with knowledge in software development life cycle, database systems design implementation, and administration, User Interface (UI) systems design, application testbed design, knowledge and technical architecture design, technical support, GIS, image processing, enterprise-level software solutions, and concept mapping. The software developer will be responsible for the development of all computer-based applications (including iPhone and iPad applications) used in this project and in the development of Vaccine Concept Maps (VCMs). The software developer will also be responsible timely troubleshooting and resolution of all software-related problems. The software developer will report to the two Principal Investigators and grant program coordinator.

**April Schenck, B.S., M.B.A., Grant Program Coordinator:** Ms. April Schenck will serve as Grant Program Coordinator. Ms. Schenck was trained by Dr. Sultan (PI in this grant application) to serve as LHA in an NIH grant which supported an iPad 2-mediated intervention on prostate cancer IDM among African American men in Hillsborough, Pinellas and Pasco counties of Florida. Ms. Schenck received training in LHA competencies, community engagement, interpersonal relations, interviewing techniques, research methodologies and IRB human subject protection requirements and iPad 2 use in research intervention. Over the grant life-cycle, she twice took and passed USF IRB human research subjects protection certification CITI exams. She liaised with the local Hispanic American and African American CABs, local

businesses and community organizations and successfully recruited research participants in the research counties. She conducted field intervention and interviews using an iPad 2 mobile tablet with cloud computing capabilities. After the successful completion of her field duties, Ms. Schenck served as Project Coordinator. She was responsible for reporting activities and management of project finances. Ms. Schenck earned an MBA, currently works as financial analyst at CitiGroup, and has graduate education in Public Health. She will bring to this project significant capabilities which will ensure the successful completion of all project activities.

**Lay Health Advisors/Vaccine Health Navigators (2):** Two full-time LHAs/VHNs [*one Spanish-Speaking, one with African American non-Hispanic identification*] will be brought into this grant project to receive training on providing effective messaging and empowering local African American and Spanish-speaking communities in informed decision making (IDM) about vaccination. They will assist in liaising with local African American and Hispanic American Community Boards and in the recruitment of African American and Latino study participants. The LHAs/VHNs will also assist research assistants with participant recruitment and retention. The LHAs/VHNs will deliver the program information and research materials to the study community study participants. They will also collect “additional”/intelligence information from the study participants and community to further assist in the development of better substantive interpretations of collected research data and vaccine concept maps.

**Graduate Research Assistant:** A graduate research assistant (*preferably Spanish language proficient*) already trained in research methods and statistics will provide assistance with participant recruitment tasks. S/he will also be responsible for maintaining all follow-up appointments. The graduate research assistant will also be responsible for literature mining and preparation of research manuscripts and conference presentations. S/he will also be responsible for assisting with data management and research-related tasks. S/he will work under the direction of the two PIs and will also report to the grant program coordinator.

**Jay Wolfson, Dr.P.H., J.D. (5% FTE in-Kind):** Dr. Wolfson will be responsible for coordinating with influential departments within USF to facilitate project aims. As Director of the Florida Health Information Center, he also brings a valuable perspective to feasibility of research design and implementation into the larger Florida community and will contribute legal counsel.

**Douglas A. Holt, MD, FACP (5% FTE in-Kind):** Dr. Holt currently serves as the Director of Hillsborough County Health Department as well as the Division Chief of the University of South Florida Department of Infectious Disease and International Medicine. He has agreed to promote and advance the project’s goals in his jurisdiction as well as to promote survey data and information in the health department clinics to facilitate client recruitment. Further, Dr. Holt has agreed to support outreach with local pharmacies to promote community vaccine uptake and data capturing by central vaccination databases.

**Ulyee Choe, DO (5% FTE in-Kind):** Dr. Choe currently serves as Director of Polk County Health Department as well as continues to serve as Assistant Professor of USF Morsani School of Medicine. He has agreed to promote the project’s aims through dissemination of educational materials (internet and mobile device platforms) as well as to coordinate vaccination entry into the database system.

**Charurut Samboonwit, MD, FACP (1% FTE in-Kind):** Dr. Samboonwit serves as Assistant Professor in Infectious Diseases at the USF Morsani School of Medicine and will be responsible for promoting project generated surveys and informational materials during clinic hours.

**APPENDIX A**  
**Detailed Budget**

## 2013 BUDGET TEMPLATE

**Itemized Budget (please complete in US \$)**

Direct Costs	US \$	Description	Notes
Direct Labor Costs			<b>Direct Labor Costs :</b> Please itemize requested budget amount for Initiative Lead and other staff involved in initiative conduct.
Dawood Sultan, PhD	\$48,275.00	PI	
Jamie Morano, MD	\$32,293.00	PI	
Meghan Borysova, PhD	\$46,228.00	Co-PI	
April Schenck	\$84,540.00	Grant Coord	
TBD - (2) Community Health Workers	\$95,238.00	LHA/VHN	
Graduate Assistant	\$5,706.00	LHA/VHN	
Direct Initiative Costs			<b>Direct Initiative Costs:</b> Please itemize costs such as data management and analysis, web development, layouts, etc.
Travel - Mileage	\$4,450.00	Travel to sites	
Tuition	\$2,364.00	GA tuition costs	
Ipads	\$2,000.00	5 iPads	
Participant Incentives	\$50,000.00	5000 participants	
<b>Subtotal</b>	<b>\$371,094.00</b>		
<b>Institutional Overhead/Indirect Costs</b>			<b>Institutional Overhead Costs:</b> Costs to the institution for the support of your initiative. Examples include human resources department costs, payroll processing and accounting costs, janitorial services, utilities, property taxes, property and liability insurance, and building maintenance. Please note: Pfizer does not provide funding for capital equipment. Indirect Costs: Please itemize additional initiative expenses such as costs for publication, IRB / IEC review fees, software licence fees, and travel. Please note: Pfizer does not provide funding for capital equipment.
Institutional Overhead/Indirect Costs	\$103,906	28% TDC	
<b>Subtotal</b>	<b>\$103,906.00</b>		
<b>Total Initiative Budget</b>	<b>\$475,000.00</b>		
<b>Total Funding Requested</b>	<b>\$475,000.00</b>		

## **Budget Justification**

### **Program Personnel:**

1. **Jamie P. Morano, MD, MPH, Principal Investigator (35% FTE):** PI Dr. Jamie P. Morano will share with Dr. Dawood H. Sultan, Ph.D., the responsibilities of overall leadership of the grant program. Dr. Morano will provide overall leadership, direction, and supervision for all activities and initiatives of the grant program. Dr. Morano will serve as point of contact for Pfizer and will assure compliance with all Pfizer grant-related policies, ensure that all research activities undertaken within the grant program receive approval of the USF Institutional Review Board (IRB), and oversee all Pfizer reporting requirements. Dr. Morano will ensure the successful implementation of the grant program. She will also be responsible for project evaluation. Dr. Morano brings multiple years in the field as well as formal training in biostatistics. Along with Dr. Sultan, she will lead and mentor research investigators in survey design and execution. She will participate and instruct in the analysis of data generated by the grant program. She will also contribute to the development of manuscript and conference presentations based on grant program data and will contribute to the reporting and disseminating of data analysis findings.
2. **Dawood H. Sultan, Ph.D., Principal Investigator (20% FTE):** PI Dr. Sultan will share with Dr. Jamie P. Morano the responsibilities of overall leadership of the grant program. Dr. Sultan will provide overall leadership, direction, and supervision for all activities and initiatives of the grant program. Dr. Sultan will ensure successful implementation of the grant program. He brings to this project experiences as Co-PI in the NIH P20-funded USF Health-Moffitt Cancer Center and Research Institute's interdisciplinary center for excellence in health disparities where he co-led the center's Research Training and Education Core. He also brings to this project additional experience as Co-Investigator in an NIH ARA-funded LHA-mediated intervention in prostate cancer IDM in minority communities in Hillsborough, Pinellas and Pasco counties of Florida. He was responsible for training the program LHAs. Dr. Sultan will be responsible for the human capital development for this project. He will coordinate the recruitment of graduate and undergraduate research assistants, grant program coordinator, LHAs/VHNs, and software developer. Dr. Sultan will also be responsible for designing key training modules on community-based participatory research strategies, research methods and interviewing techniques and implementing training activities for the LHAs/VHNs, research assistants and program coordinator. Dr. Sultan will also lead and participate in the analysis of data generated by the grant program, contribute to the development of manuscript and conference presentations based on grant program data, and will contribute to the reporting and disseminating of the findings of data analysis.

3. **Meghan E. Borysova, Ph.D., Co-Principal Investigator (40%FTE):** Co-PI Dr. Borysova will serve as the research scientist for this grant program. Dr. Borysova has a unique scientific background as both a classically trained molecular biologist/geneticist as well as having extensive postdoctoral training directly in health disparities/health equity research. Dr. Borysova's background brings to the research program of this grant a unique perspective on immunity, disease etiologies, vaccinations and vaccine-related scientific discovery. In addition to a proven record of work as a bench scientist, Dr. Borysova has spent several years working on NIH-funded comparative effectiveness research activities to eliminate cancer disparities and has served as the Principal Investigator on a Department of Defense grant to investigate the health and health care needs of underserved members of society. Her experiences bring added insights into health disparities and scientific discovery. Dr. Borysova will be responsible for vaccine-related participant recruitment and retention. She will be directing the development of vaccine-related survey instruments and for determining the scientific input required for communicating vaccine information to study participants. Dr. Borysova will also be responsible for determining the scientific efficacy of vaccine-related electronic and audiovisual materials including QR scanning applications used in this study for communicating with the Community Advisory Boards, study participants, and the wider study community. Dr. Borysova will be jointly responsible for data analysis, manuscript preparation and dissemination, presentations at seminars and conferences.
4. **April Schenck, B.S., M.B.A., Grant Program Coordinator (100% FTE):** Salary support is requested for a Grant Program Coordinator position. The coordinator will serve as the overall grant program coordinator. The coordinator will be responsible for day-to-day supervision of graduate and undergraduate research assistants, LHAs/VHNs, software developer, and will be responsible for managing all grant-related business involving USF Human Resource Management and the offices of Research Administration at the USF College of Medicine and College of Public Health. The coordinator will be responsible for supervising the activities of the assistant coordinator, undergraduate and graduate research assistant and the CHWs. The coordinator will be responsible for working with the two Principal Investigators on developing community outreach and engagement strategies, and will liaison with local African American and Hispanic Community Advisory Boards for evaluations and implementation of the strategies. The coordinator will also closely monitor accrual and retention of grant program study participants and ensure that all follow-up are conducted by the research assistants in accordance with study design parameters. The coordinator will also be responsible for working closely with the Principal Investigators to ensure the time completion of program evaluations and evaluation reports. The coordinator will have graduate-level education in public health

and financial management and training in community interventions designed to reduce health outcome disparities.

5. **Lay Health Advisors/Vaccine Health Navigators (2):** Two full-time LHAs/VHNs [*one Spanish-Speaking, one with African American non-Hispanic identification*] will be brought into this grant project to receive training on providing effective messaging and empowering local African American and Spanish-speaking communities in informed decision making (IDM) about vaccination. They will constitute the intervention arm of this program by directly communicating with community members and identifying potential study participants. The LHAs/VHNs will assist the grant program coordinator and assistant coordinator in liaising with local African American and Hispanic American Community Boards and in the recruitment of African American and Latino study participants. The LHAs/VHNs will also assist undergraduate and graduate research assistants with participant recruitment and retention. The LHAs/VHNs will deliver the program information and research materials to the study community study participants. The LHAs/VHNs will also be responsible for collecting “additional”/intelligence information from the study participants and community to further assist in the development of better substantive interpretations of collected research data and vaccine concept maps.
6. **Graduate Research Assistant (50% FTE) :** One information systems graduate research assistant (*preferably Spanish language proficient*) already trained in software development life cycle, database systems design implementation, and administration, User Interface (UI) systems design, application testbed design, knowledge and technical architecture design, technical support, GIS, image processing, enterprise-level software solutions, and concept mapping will be hired. S/he will be responsible for the development of all computer-based applications (including iPhone and iPad applications) used in this project and in the development of Vaccine Concept Maps (VCMs). S/he will also be responsible for timely troubleshooting and resolution of all software-related problems. The graduate research assistant will have training in the creation, maintenance and statistical analysis of multivariate data in large databases and will also have hands-on knowledge in relational database design and relational database statistical analysis. S/he will design data warehousing methods and will streamline data transmission and management. S/he will also have formal graduate-level training in Statistics/Biostatistics. S/he will be responsible for working with the LHAs/VHNs in study participant recruitment and retention. S/he will also be responsible for maintaining all follow-up appointments. The graduate research assistants will also be responsible for literature mining and preparation of research manuscripts and conference presentations. S/he will work under the direction of the two Principal Investigators and will also have to report to the grant program coordinator.
7. **Jay Wolfson, Dr.P.H., J.D. (2% FTE in-kind):** Dr. Wolfson will be responsible for coordinating with influential departments within USF to facilitate project aims. As Director of the Florida Health Information Center, he also brings a valuable perspective

to feasibility of research design and implementation into the larger Florida community and will contribute legal counsel.

8. **Douglas A. Holt, MD, FACP (2% FTE in-kind):** Dr. Holt currently serves as the Director of Hillsborough County Health Department as well as the Division Chief of the University of South Florida Department of Infectious Disease and International Medicine. He has agreed to promote and advance the project's goals in his jurisdiction as well as to promote survey data and information in the health department clinics to facilitate client recruitment. Further, Dr. Holt has agreed to support outreach with local pharmacies to promote community vaccine uptake and data capturing by central vaccination databases.
9. **Ulyee Choe, DO (2% FTE in-kind):** Dr. Choe currently serves as Director of Polk County Health Department as well as continues to serve as Assistant Professor of USF Morsani School of Medicine. He has agreed to promote the project's aims through dissemination of educational materials (internet and mobile device platforms) as well as to coordinate vaccination entry into the database system.
10. **Charurut Samboonwit, MD, FACP (2% FTE in-kind):** Dr. Samboonwit serves as Assistant Professor in Infectious Diseases at the USF Morsani School of Medicine and will be responsible for promoting project generated surveys and informational materials during clinic hours.

#### **Direct Initiative Costs:**

1. **Mileage Expenses for CHWs:** Average 10,000 miles travel distance is expected to be covered by each CHW in one year. The CHW will travel through both Hillsborough and Polk counties during the recruitment, intervention/interviewing phase of this project. \$0.445 per mile for 10,000 miles are requested for each of the CHWs.
2. **Tuition:** Tuition is requested for the graduate student for one semester. Tuition is calculated at \$263 per credit hour for 9 credit hours.
3. **iPad2 Tablets:** iPad2 mobile tablets are requested for this intervention. The mobile tablets are of fundamental importance to the implementation and success of this project. They will be reconfigured to house the project survey instruments, instructional materials for participants, project concept maps and training modules. They will enable the project LHAs/VHNs to wirelessly access the internet and to communicate with potential participants. They will also enable the recording of recruitment information and the secure transmission of research data to the project Database. Wireless service expenses are also requested.
4. **Participant Incentives:** Each participant will be offered \$10 in a gift card to defray the opportunity cost of the time they spend reviewing educational materials and answering survey questions. A total of \$50,000 will be requested to purchase gift cards.
5. **Institutional Overhead (at 28%):** F&A is calculated at 28% on all direct costs.



**APPENDIX "**  
**Staff Biosketches**

## NIH BIOGRAPHICAL SKETCH

NAME: Morano, Jamie Patricia	POSITION TITLE: Assistant Professor of Medicine, University of South Florida, Morsani School of Medicine		
eRA COMMONS USER NAME: jpmorano			
EDUCATION/TRAINING:			
INSTITUTION AND LOCATION	DEGREE (if applicable)	MM/YY	FIELD OF STUDY
Princeton University	B.A.	06/98	Politics, East Asian Studies
University of Tennessee, Memphis	M.D.	05/03	Medicine
Harvard University	M.P.H.	05/04	Epidemiology/Biostatistics
Dartmouth-Hitchcock Medical Center	Residency	06/07	Internal Medicine
Yale University	Fellowship	06/13	Infectious Diseases

### A. Personal Statement

I, **Jamie P. Morano, MD, MPH**, am a trained infectious disease physician and epidemiologist with a specific interest in harnessing the power of community-based implementation science to collaborate with public health, academic, and business communities as reach a sustainable, multi-faceted approach to test, treat, and prevent infectious diseases in the community. The Southeastern United States continues to have an underfunded, fractured health care system in which disadvantaged groups lack access and ability to preventative vaccinations and continue to have disproportionate morbidity and mortality across nearly all health outcome indicators. My research and personal mission is to continue to work in this geographical area as to effect systemic change to improve health outcomes.

Bringing extensive experience with survey design, implementation, and analysis from field experience from New Haven, CT, to Hangzhou, China, I look forward to working on a multi-disciplinary team to improve our health care delivery systems and to link at-risk populations to sustainable infectious disease prevention services as to have a stronger and more vibrant Florida. My experience testing and treating for Hepatitis C and HIV in a medical delivery model can be readily translated to the community screening and vaccination campaigns outlined in this project.

Options such as enhanced community outreach using mobile and innovative technologies have enhanced our linkage to care protocols and serve to protect not only our general Florida population but also our minority and marginalized communities that have unique infectious disease risk factors and affect the entire population's health at large.

With advanced, formal language training in both Spanish and Mandarin Chinese as well as extensive grassroots clinical experience at multiple, innovative training sites nationally and internationally, I am uniquely poised to tackle the difficult health questions concerning Florida's minority and underserved populations as well as able to contribute vaccine delivery and documentation innovations to benefit all sectors of Florida's vaccine infrastructure.

### B. Positions and Honors

#### Research Positions:

1996	Research Scholar, Zhejiang University Mandarin Studies and Hangzhou College of Traditional Medicine, Hangzhou, People's Republic of China
1998-1999	Fulbright Scholar, University of Hong Kong, School of Public Health & Epidemiology, with Dr. T.H. Lam and Dr. Anthony Hedley
2000	Research Scholar, Judicial-Medical-Pharmacy Health Policy Fellowship with Tennessee Bureau of Investigations, Nashville, TN
2000-2003	Investigator, "Mama Informativa, Bebé Sano: Instrucción Prenatal," Longitudinal Community Research Project with Hispanic Community at University of Tennessee School of Medicine
2003	Research Intern, Centers for Disease Control and Prevention, Atlanta, GA, Mercury in Hispanic

2004 Populations, Emergency Operations Center on SARS Epidemic, with Dr. Alyssa Easton  
Thesis Research, Harvard School of Public Health, Department of Biostatistics, Public Health Preparedness, with Dr. Marcia Testa

2006-2007 Research Assistant, Dartmouth-Hitchcock Medical Center, Evidence Based Medicine (EBM) Decision Support Tool Project, with Dr. Jonathan Ross

2009-2010 Instructor/Lecturer, Clinical Attending, Yale New Haven Hospital Internal Medicine Division

2010-2013 Epidemiologist and Investigator, Yale University School of Medicine, The Latent Tuberculosis Determinant and Treatment Adherence Project (LTBDATA), with Dr. Frederick Altice

2010-2013 Program Manager, Epidemiologist, and Investigator, The HepHome Project: First Mobile Rapid Hepatitis C Testing and Linkage to Care Initiative, with Dr. Frederick Altice and Connecticut Department of Viral Hepatitis

2010-2013 Instructor and Attending, Yale School of Medicine, HIV in Prisons Program

2013 - Visiting Fogarty Lecturer on HIV, Hepatitis C, and Bioethics, Changsha School of Medicine, Hunan Province, Yale University School of Public Health, with Dr. Kaveh Khoshnood

2013 - Associate and Advisor, Yale Center for Interdisciplinary Research on AIDS (CIRA)

2013 - Assistant Professor, University of South Florida, Morsani School of Medicine

#### **Other Experience and Professional Memberships:**

1994 Exchange Student, Madrid, Spain

1996-1998 Spanish Translator, Guatemalan Refugee Clinic, Princeton Medical Center, Princeton, NJ

1997 Scholarship Recipient, Princeton in Beijing, Beijing Normal University, Intermediate Mandarin

1997-1998 Reviewer, Princeton University, Princeton Pacific Asian Review

1999-2003 Member and Secretary, Honor Council Executive, University of Tennessee School of Medicine

2001-2002 National Health Policy Action Committee Coordinator, American Medical Student Association, Local Chapter Vice-President of Programming

2002-2003 Board of Trustees, American Medical Student Association, Southeastern Region VII Chapter

2002 Coordinator and Participant, National Political Leadership Institute, American Student Medical Association

2002-2003 Medical Spanish Translator, University of Tennessee College of Medicine Clinical Rotations

2003- Member, American Medical Association; AMPAC Workshop (2007)

2003 Intern and Translator, International Children's Heart Foundation, Shanghai, Nanjing, PR China

2003-2004 Founder, Health Policy Forum, Harvard School of Public Health; Harvard Medical International Conference invited lecturer, 2004

2007-2009 Key Legislative Contact and Congressional Contact, American College of Physicians

2007-2009 Internal Medicine Physician Attending and Community Medicine Instructor, Rockville, Maryland

2008-2009 Board of Trustees, Fulbright Association, National Capital Area Chapter

2009- Member and Academic Contributor, Yale-China Association

2010-2012 Clinician, Ryan White HIV Clinic, St. Raphael's Hospital Haelen Center, New Haven, Connecticut

2010-2013 Participant, Yale University School of Medicine Investigative Medicine Program

2010-2013 Member, Harvard Club of Eastern Connecticut, former Schools Committee Interviewer; Princeton Alumni Association of Eastern Connecticut, former Schools Committee Interviewer; Volunteer Global Health and Medicine Mentor to Princeton Club of New York

2011-2012 Fellow Representative, Graduate Medical Education Council, Selected from Section of Infectious Diseases, Yale School of Medicine

2011-2013 Hepatitis C Clinical Consultant, Educator, Protocol Developer, and Surveillance Coordinator, Yale School of Medicine, Yale Community Health Care Van Mobile Clinic

2012-2013 Member, Yale University School of Medicine – Connecticut Department of Public Health Hepatitis C Working Group, with Dr. Frederick Altice and Dr. Joseph Lim

2012-2013 Ad-hoc medical contributor, The China Center at Yale Law School seminar series, including Reb Law Public Interest Conference 2013

2010-2013 Member, Harvard Club of Eastern Connecticut, former Schools Committee Interviewer; Princeton Alumni Association of Eastern Connecticut, former Schools Committee Interviewer; Volunteer Global Health and Medicine Mentor to Princeton Club of New York

2010- Lifetime Member, International Fulbright Association; Member, Infectious Disease Society of

2011- America (IDSA), HIV Medical Association (HIVMA); International AIDS Society (IAS-USA)  
 2011- Member, American Society of Tropical Medicine and Hygiene  
 2013- Member, National Viral Hepatitis Roundtable  
 Ad-hoc reviewer for *Journal of Immigrant and Minority Health*, *Journal of HIV/AIDS and Infectious Diseases (JAID)*. *The Clinical Respiratory Journal*, *Tropical Medicine & Surgery*

#### **Honors:**

1997 Princeton University, Christine M. Picard '87 Award, outstanding thesis proposal  
 1998 Princeton Mandarin Chinese Elocution Award for best non-native extemporaneous speaking  
 2001 Charlotte M. Kennedy Award, excellence in cross-cultural medical education (University of TN)  
 2002 IMHOTEP Leadership in Medicine Award (University of TN)  
 2007 Medical Teaching and Mentorship Excellence Award, Dartmouth Hitchcock Medical Center  
 2008 Nomination for Physician R.I.S.E.S Award (Respect, Integrity, Service, Excellence, and Stewardship); Rockville, MD  
 2012 Fellow Travel Scholarship to 2012 Conference, Infectious Disease Society of America, for HIV/HCV Co-infection Oral Presentation

#### **C. Selected Peer-reviewed Publications**

1. **Morano J**, Gibson B, Altice F. The burgeoning HIV/HCV syndemic in the urban northeast: HCV, HIV, and HIV/HCV coinfection in an urban setting. *PLoS One*. 2013;8(3):e64321. PMID: 23691197; PMCID: 3653872.
2. **Morano J**, Walton M, Zelenev A, Bruce R, Altice F. Latent tuberculosis infection: screening and treatment in an urban setting. *J Community Health*. Jun 1, 2013;[Epub ahead of print]. PMID: 23728822; PMCID: In process.
3. Manzoli L, Di Giovanni P, Dragani V, Ferrandino MGF, **Morano J**, Rauti I, Schioppa F, Romano F, Staniscia T. Smoking behaviour, cessation attempts and parental smoking influence in older adult women: a cross-sectional analysis from Italy. *Public Health*. 2005 Aug; 119 (8):6708. PMID: 15893347.
4. Savoia E, **Morano J**, Cote D, Rampal S, Villa D, and Testa M. Public Health Preparedness Evaluation and Measurement. *Italian Journal of Public Health*. 2004;1(1-2):56.
5. **Morano, J**. Medical and Legal Analysis for the Primary Care Physician: Sexual Abuse of the Mentally Retarded Patient. *The Primary Care Companion to The Journal of Clinical Psychiatry*. Vol 3, No 3, 2001:126-135. PMCID: PMC181173.

#### **D. Research Support**

<b>NIH NIAID 2 T32 AI 007517-11</b>	Fikrig (PI)	08/01/11 - 07/31/12
<b>NIH NIAID 5 T32 AI 007517-12</b>	Kazmierczak (PI)	08/01/12 - 07/31/13

Yale University School of Medicine: Infectious Diseases Fellowship Training Grant

This project gave salary and research support to the two main fellowship projects on the mobile Yale Community Health Care Van that included a retrospective analysis of approximately 23,000 visits that elucidated the two most pressing infectious disease syndemics among urban populations 1) HIV/HCV coinfection among marginalized and underserved, urban minority populations and 2) latent tuberculosis among foreign-born and Hispanic immigrant populations.

**Vertex Pharmaceuticals** (no number) Altice (PI), Morano (co-PI) 02/1/12 - 03/31/13  
Hepatitis C Circle of Care Grant

This two-year competitive national grant project launched the first national, mobile rapid Hepatitis C testing campaign as well as enhanced surveillance and linkage to care protocols for marginalized, urban populations in coordination with the Connecticut Department of Public Health. First mobile treatment protocol also developed in coordination and educational collaborations with Yale Gastroenterology and Yale Liver Center.

**NIH FIC 5-R25 TW007700 03** Khoshnood (PI) 06/01/11 - 05/31/16

Research Ethics Training and Curriculum Development Program with China

This project in conjunction with South Central University, Xiangya School of Medicine, in Changsha, Hunan Province, serves to protect and strengthen the capacity of Institutional Review Boards at Xiangya School of Medicine in conjunction with Yale University. Collaborations forged with Chinese counterparts in HIV and Hepatitis for practice-based interventions and future academic initiatives.

### BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.  
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Sultan, Dawood H.	POSITION TITLE Assistant Professor of Health Policy and Management		
eRA COMMONS USER NAME (credential, e.g., agency login)			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	MM/YY	FIELD OF STUDY
University of Gezira, Sudan	B.Sc. (HONORS)	12/84	Economics & Rural Development
University of East Anglia, United Kingdom	M.A.	07/8796	Development Studies
Louisiana State University, Baton Rouge	Ph.D.	08/96	Sociology

#### A. Personal Statement

The goal of the proposed program aims to increase vaccine uptake among socioeconomically disadvantaged populations in Hillsborough and Polk counties in Florida through an intervention using Lay Health Advisors (LHAs) as Vaccine Health Navigators (VHNs). The program will provide instruction to LHAs/VHNs in the links between economic status and health outcomes, minority health profiles and health disparities, with special focus on vaccinations and training in the use of iPad mobile tablets in community settings to affect improvement in vaccination informed decision making (IDM). I have broad training in community development, community development planning and individual health outcomes and have actively participated in community development work. I have also published and presented research work and taught on socioeconomically disadvantaged populations, minority groups and communities, minority health profiles and ethnic health outcome disparities. I have completed NIH-funded community-based interventions using mobile computer technology and LHAs to improve IDM in prostate cancer screening among local African American men. I have also been responsible for implementing NIH-funded programs to train and increase the numbers of minority graduate-level researchers in the field of health disparities and minority LHAs.

#### B. Positions and Honors

##### Positions and Employment

From May 7, 2009	<b>Assistant Professor of Health Policy and Management</b> , Department of Health Policy and Management, College of Public Health, University of South Florida, Tampa, Florida.
August 2007-May 6, 2009	<b>Joint Assistant Professor of Africana Studies and Health Policy and Management</b> , Department of Africana Studies (College of Arts and Sciences) and the Department of Health Policy and Management (College of Public Health), University of South Florida, Tampa, Florida.
August 2003 - June 2007	<b>Assistant Professor of Sociology</b> , Department of Sociology, Anthropology, Social Work and Criminal Justice, The University of Tennessee at Martin, Martin, Tennessee.
August 2001 - May 2003	<b>Assistant Director of International Development</b> . Office of International Programs, Louisiana State University, Baton Rouge, Louisiana.
August 1998 - May 2003	<b>Full-time Instructor</b> . Department of Sociology, Louisiana State University, Baton Rouge, Louisiana.

### Other Experience and Professional Memberships

July 2010 – December 2013	<b>CO-PI, Co-Leader of Comparative Effectiveness Research to Eliminate Health Disparities (CERED)</b> , USF Health- Moffitt interdisciplinary Center for Equal Health, University of South Florida & Moffitt Cancer Center and Research Institute, Tampa, Florida.
March 2010 – Dec 2012	<b>CO-PI-Co-Leader of Research Training and Education Core</b> , USF Health- Moffitt interdisciplinary Center for Equal Health, University of South Florida & Moffitt Cancer Center and Research Institute, Tampa, Florida.
From November 2012	<b>Advisor</b> , Our Humanity In the Balance. <a href="http://www.ourhumanityinthebalance.org/index.cfm/do/home.about">http://www.ourhumanityinthebalance.org/index.cfm/do/home.about</a>
July 2010-September 2012	<b>Member, Board of Directors</b> , Our Humanity In the Balance. <a href="http://www.ourhumanityinthebalance.org/index.cfm/do/home.about">http://www.ourhumanityinthebalance.org/index.cfm/do/home.about</a>
June 3-July 3, 2011	<b>Consultant</b> , JBS International. Assessment of USAID/HED-funded <b>Leadership Initiative for Public Health in East Africa (LIPHEA)</b> grant program in Uganda, Kenya, Tanzania, Ethiopia, Democratic Republic of Congo and Rwanda.
From September 2010	<b>Member, Board of Directors</b> , John Harvey Lowery Foundation, Inc. <a href="http://www.jhlowery.org">http://www.jhlowery.org</a>
From January 2010	<b>Member, Editorial Board</b> , <i>Journal of Social and Behavioral Sciences</i> .
From January 2010	<b>Member, Board of Directors</b> , Peercorps Trust Fund, Tanzania. Website: <a href="http://www.peercorpstrust.org">http://www.peercorpstrust.org</a>
From January 2010	<b>Director</b> , Centre for Education and Youth Development, Peercorps Trust Fund, Tanzania. Website: <a href="http://www.peercorpstrust.org">http://www.peercorpstrust.org</a>
2009-2010	<b>Member, International Volunteer Staff</b> , Peercorps Trust Fund, Tanzania. Website: <a href="http://www.peercorpstrust.org">http://www.peercorpstrust.org</a>
June 1999 - July 1999	<b>Visiting Assistant Professor</b> . Department of Sociology and the Ethnic Studies Program, University of Nebraska-Lincoln, Nebraska.
January 1998 - May 1998	<b>Research Associate</b> . African and African American Studies Program, Louisiana State University, Baton Rouge, Louisiana.
August 1997 - December 1997	<b>Part-time Instructor</b> . Evening School, Louisiana State University, Baton Rouge, Louisiana.
August 1995 - March 1996	<b>Visiting Assistant Professor and Rockefeller Research Fellow</b> . Faculty of Economics and Rural Development, University of Gezira, Wad Medani, Sudan.
2010 - Present	Member, Florida Public Health Association
2007 - Present	Member, National Association of African American Studies
1994 - Present	Member, Mid-South Sociological Association, USA.

### Honors

2007	College of Education and Behavioral Sciences <b>Distinguished Research Scholar Award</b> (for 3 years ending in August 2010). <b>Award terminated at resignation from UTM.</b>
2005	<b>Who's Who Among America's Teachers.</b>
2002	Louisiana State University Sociology Club's <b>Excellence in Teaching</b> award.
2001	Alpha Lambda Delta Freshman Honor Society's <b>Superior Instruction of Freshman Students</b> award.
2001	Louisiana State University Sociology Club's <b>Excellence in Teaching</b> award.
2001	Louisiana Housing Officials Association's <b>Always Hallways</b> award for exceptional support to the mission of residential life.
2000	Alpha Lambda Delta Freshman Honor Society's <b>Superior Instruction of Freshman Students</b> award.
2000	Louisiana State University Sociology Club's <b>Excellence in Teaching</b> award.
Fall 1999.	Alpha Lambda Delta Freshman Honor Society's <b>Superior Instruction of Freshman Students</b> award.

### C. Selected Peer-reviewed Publications

1. Green B. L., Rivers D. A., Kumar N., Baldwin J., Rivers B. M, **Sultan D.**, Jacobsen P., Gordon L. E., Davis J., Roetzheim R. 2013. Establishing the Infrastructure to Comprehensively Address Cancer Disparities: A Model for Transdisciplinary Approaches. *Journal. of Health Care for the Poor and Underserved*. (Manuscript ID: JHCPU-Sep-2012-RF-0612). Accepted. **Forthcoming in November 2013. Vol. 24. No.4.**
2. Mogos, Mulubrhan F., Shams Rahman, Hamisu M. Salihu, Abraham Antonio Salinas-Miranda, Dawood H. **Sultan**. Association between reproductive cancer and fetal outcomes: A systematic review of the literature. *International Journal of Gynecological Cancer*. (Manuscript No. IGC-D-13-00137). **Accepted on June 2, 2013. Forthcoming.**
3. Borysova, Meghan, Dawood H. **Sultan**, Adewale Troutman, Ganna Chornokur, Kyle J. Dalton. Prostate Cancer Disparities throughout the Cancer Control Continuum. Revised and resubmitted September, 2013. (Manuscript ID: socsci-38564). **Forthcoming in October 2013 in Social Sciences.**
4. Mogos, Mulubrhan F., Hamisu M. Salihu, Muktar H. Aliyu, Valerie E. Whiteman, and Dawood H. **Sultan**. 2013. Association Between Reproductive Cancer and Fetal Outcomes: A Population-based Study. *International Journal of Gynecological Cancer*. 2013. 23(2):218-26. doi: 10.1097/IGC.0b013e31827b877b. Available online at <http://www.ncbi.nlm.nih.gov/pubmed/23314281>
5. Wilson, Danyell S., Virna Dapic, Dawood H. **Sultan**, Euna M. August, B. Lee Green, Richard Roetzheim, Brian M. Rivers. Establishing the Infrastructure to Conduct Comparative Effectiveness Research toward the Elimination of Disparities: A Community-Based Participatory Research Framework. *Health Promotion Practice*. **Published online before print February 21, 2013, doi: 10.1177/1524839913475451.** Currently available at <http://hpp.sagepub.com/content/early/2013/02/19/1524839913475451>
6. Norris, Claire M., Dawood H. **Sultan**, Monica Solomon. 2012. "Understanding Mental Health Disparities: Examining Race Variations in the Stress-Support-Distress Process." *Sociological Imagination*. 48(1): 53-67.
7. Mogos, Mulubrhan F., Euna M. August, Abraham A. Salinas-Miranda, Dawood. H. **Sultan**, Hamisu M. Salihu. 2012. A Systematic Review of Quality of Life Measures in Pregnant and Postpartum Mothers. *Applied Research in Quality of Life*. Published online September 9, 2012. Available at <http://www.springerlink.com/openurl.asp?genre=article&id=doi:10.1007/s11482-012-9188-4>
8. Borysova, Meghan E. Ojmarrh Mitchell, Dawood H. **Sultan** and Arthur R. Williams. 2012. Racial and Ethnic Health Disparities in Incarcerated Populations. *Journal of Health Disparities Research and Practice*. 5(2): 92-100. PMID: 23338674 [PubMed]
9. **Sultan**, Dawood H. and Deanna J. Wathington. 2010. "Premonition: Peering Through Time and Into Hurricane Katrina", pp. 153-161 in Deborah G. Plant (ed.), *"The Inside Light": New Critical Essays on Zora Neale Hurston, Santa Barbara, CA: Praeger*.
10. Durant, Thomas J. and Dawood H. **Sultan**. 2008. "The Impact of Hurricane Katrina on the Race and Class Divide in America", pp. 191-201 in Manning Marable and Kristen Clarke (Eds.), *Seeking Higher Ground: The Hurricane Katrina Crisis, Race and Public Policy Reader*. New York, NY: Palgrave Macmillan Ltd.

### Selected Paper Currently Under Peer-review

1. Mogos, Mulubrhan F., Jason L. Salemi, Cara Z. de la Cruz, Maureen E. Groer, Dawood H. **Sultan**, Hamisu M. Salihu. Pregnancy-related toxoplasmosis, its impact on fetal and maternal health and associated health care cost in the United States, 2001-2009. **Submitted to Women's Health Issues September 16, 2013.** (Manuscript Number: WHI-D-13-00233)
2. **Sultan**, Dawood H., Meg M. Comins, Nashrin K. Jahan, Jacqueline Wiltshire. Associations of Age, Income Level, and Comorbidities with Hospitalization Charges for White and Black Stroke Patients. **Submitted to the Journal of Health Care for the Poor and Underserved September 10, 2013.** (Manuscript ID: JHCPU-Sep-2013-OP-0483).
3. Raru, Yonas Yilma, Patricia R. Messmer, Arthur R. Williams, Dawood H. **Sultan**, Ashenafi Berhanu Adale, Yalelet Fentaw Shiferaw, Paul Hart, Hugh Pettigrew. Treatment of Sigmoid Volvulus by Deflation versus Surgery: A Single Site Report. **Submitted to the World Journal of Surgery July 30, 2013. (Manuscript Number WJS-13-07-1108)**
4. **Sultan**, Dawood H, Brian M. Rivers, Ben O. Osongo, Danyell S. Wilson, April Schenck, Rodrigo Carvajal, Desiree Rivers, Richard Roetzheim, B. Lee Green. Affecting African American Men's Prostate Cancer Screening Decision



Making Through a Mobile Tablet-Mediated Intervention. Submitted to the *Journal of Health Care for the Poor and Underserved* June 30, 2013. (Manuscript ID: JHCPU-Jun-2013-OP-0337).

5. Wiltshire, Jacqueline C, Dawood H. **Sultan**, Keith Elder, Roger Brown, Arthur Williams, Sharina D. Person. Variations in Medical Debt by Race/Ethnicity and Age. *Medical Care Research and Review*. Revised and Resubmitted June 14, 2013.
6. **Sultan**, Dawood H., Claire M. Norris and Maryouri Avendano. Baseline for Future Study of Social Support and Mental Health Outcomes in Orleans Parish, Louisiana. Under review by *Health Sociology Review*. Submitted May 8, 2013. (Manuscript ID: 4183).
7. Rivers, Brian M, Rodrigo Carvajal, Dawood **Sultan**, Richard Roetzheim, B. Lee Green. Evaluation of a Concept Map-Based Knowledge Model on Prostate Cancer. Under review by the *Journal of the National Cancer Institute*. Submitted 01/04/2013. (Manuscript No. JNCI-12-1844).

#### **D. Research Support**

##### **Ongoing Research Support**

2013-2014      **Principal Investigator** (Dr. Jamie P. Morano, Dr. Stephanie L. Marhefka, Co-Principal Investigators): "A pilot project to examine the effects of injection drug use status, engagement in unstable mixed and survival sex relationships and attitude towards infectious disease on HIV infection disclosure, attitudes towards HIV testing, post-HIV-infection healthcare seeking behavior and patterns of drug user and nonuser and HIV-infected and non-infected negotiation of sexual relationships in Tanzania". Fully funded at \$19,460 by USF College of Public Health.

##### **Completed Research Support**

1. 3P20MD003375-02S1      **Co-Principal Investigator (Richard Roetzheim and B. Lee Green, PIs);**  
07/31/2010-12/31/ 2013  
NIH-funded grant supplement to the University of South Florida and Moffitt Cancer Center Transdisciplinary Center to Address Cancer Health Disparities. The grant supports a comparative effectiveness research project on informed decision making in prostate cancer screening. \$1.4 million
2. 1P20MD003375-01      **Co-Principal Investigator (Richard Roetzheim and B. Lee Green, PIs);**  
04/01/2009-12/31/2013  
This NIH-funded project established a University of South Florida and Moffitt Cancer Center Transdisciplinary Center to Address Cancer Health Disparities. \$6.5 million.
3. 18330-640400      **Principal Investigator**      2011-2013  
Faculty Research Start-up RI Grant, University of South Florida, College of Public Health. Grant amount: \$10,000
4. 640401-10000-PUBSII-0000000      **Consultant (Arthur Williams, PI)**      2011-2013  
"Cross-Cultural Dimensions of Self-Care Engagement by Patients". Fully funded at \$100,000 by USF College of Public Health.
5. 6102100000      **Consultant (Charles Paidas and Deanna Wathington, PIs)**      08/12011-7/31/2012  
"Foundation Enhancing Medical Resident Cultural and Linguistic Competency". Challenge Grant fully funded by the Picker Institute and Goldberg Foundation. Grant amount \$24,999.
6. 2004      **Project Director** (Luther T. Mercer, Co-Director): "Travel Support to Strengthen The Strategic Initiatives of the Office of Multicultural Affairs". Fully funded at \$28,160 by The University of Tennessee at Martin.
7. 1995      **Principal Investigator:** "An Examination of the Mother's Education Advantage Effects on Child Nutrition and Health Outcomes in East Africa." Fully funded (Grant Number: RF 93065,#63; at \$18,350) by The Rockefeller Foundation.

## BIOGRAPHICAL SKETCH

NAME Borysova, Meghan E.	POSITION TITLE Postdoctoral Fellow
eRA COMMONS USER NAME	

EDUCATION/TRAINING			
INSTITUTION AND LOCATION	DEGREE	MM/YY	FIELD OF STUDY
University of Arizona, Tucson, AZ	B.S.	09/99	Molecular and Cellular Biology
H. Lee Moffitt Cancer Center and Research Institute, University of South Florida, Tampa, FL	Ph.D.	03/09	Cancer Biology

### A. Personal Statement

The goal of the proposed program aims to increase vaccine uptake among underserved populations including African American, Caucasian and Hispanic populations in Hillsborough and Polk counties in Florida through an intervention using Lay Health Advisors (LHAs) as Vaccine Health Navigators (VHNs). The program will provide instruction to LHAs/VHNs in minority health profiles and health disparities, with special focus on vaccinations and training in the use of iPad mobile tablets and quick response (QU) barcodes in community settings to affect improvement in vaccination informed decision making (IDM). I, Dr. Borysova, will serve as the primary research scientist for this grant program. My training and experience reflects a distinctive scientific background as both a classically trained molecular biologist/geneticist as well as having extensive postdoctoral training directly in Health Disparities/Health Equity research. My background brings to the research program of this grant a unique perspective on immunity, disease etiologies, vaccinations and vaccine-related scientific discovery. In addition to a proven record of work as a bench scientist, I have spent several years working on NIH-funded comparative effectiveness research activities to eliminate cancer disparities and as well having served as the Principal Investigator on a Department of Defense grant to investigate the health and health care needs of underserved members of society. My experiences bring added insights into health disparities, population-based research, developing community partnerships and scientific discovery. My previous experiences have culminated in the capacity to understand and disseminate information to both lay communities and professional colleagues on the biological aspects of diseases and treatment and prevention strategies, including infectious diseases, vaccines and their efficacies and biological functions. I have gained the valuable training and experience in working with underserved communities for health equity research. Finally, I have the expertise necessary to collect and analyze data and to disseminate through scientific and lay media.

### B. Positions and Honors

#### Positions and Employment

2011-current	<b>Postdoctoral Fellow</b> , Department of Health Policy and Management, College of Public Health, University of South Florida, Tampa, Florida.
2012-2011	<b>Postdoctoral Fellow</b> , Center for Equal Health, Moffitt Cancer Center and Research Institute, Department of Epidemiology, Tampa, Florida.
2004-2009	<b>Graduate Student and Research Assistant</b> , Moffitt Cancer Center and Research Institute, Department of Molecular Oncology, Tampa, Florida.
2003-2003	<b>Research Associate</b> , Moffitt Cancer Center and Research Institute, Department of Molecular Oncology, Tampa, Florida.

1998-2003                    **Research Specialist, Sr.**, University of Arizona, Departments of Molecular and Cellular Biology,     Pediatric Oncology, and Adult Oncology Tucson, Arizona

**Selected Other Experience and Professional Memberships**

2012-current    Member American Association for Cancer Research  
2012-2013      American Public Health Association  
2009-2012      American Medical Writers Association  
2009-2012      Union of Concerned Scientists

**Honors**

2013            Health Equity Leadership Institute Scholar – Competitive Selection  
University of Wisconsin School of Medicine and Public Health, Madison, WI  
2012            Recipient of National Institutes of Health (NIH) Health Disparities Loan Repayment Program  
National Institute on Minority Health and Health Disparities  
2011            Finalist, Robert Wood Johnson Foundation Health & Society Scholar, New York  
2008            Superior Student Poster Presentation Award  
H. Lee Moffitt Cancer Center, Tampa, FL  
2008            Image Selected for Journal Cover  
Journal of Cell Cycle, Vol.7, Issue 18  
2007            Image of Distinction Award  
Nikon International Small World Photomicrography Competition  
2006            Winner of Microscopy Image Contest  
H. Lee Moffitt Cancer Center, Tampa, FL  
2006            Recognition for Service  
Great American Teach-In  
Hillsborough County, FL  
2006            Recognition for Outstanding Contribution  
Chief Organizer of Cancer Biology Tutorial Sessions for Graduate Students  
H. Lee Moffitt Cancer Center, Tampa, FL  
2005            Winner of Microscopy Image Contest  
H. Lee Moffitt Cancer Center, Tampa, FL

**C. Selected Peer-reviewed Publications**

1. **Meghan E. Borysova**, Ojmarrh Mitchell, Ph.D., James Greer, RN MSN, Arthur R. Williams, Ph.D.  
Racial and Ethnic Disparities in an Incarcerated Community  
The Summit on the Science of Eliminating Health Disparities Washington DC 2012
2. **Meghan E. Borysova**, David T. Ensley, Nagi B. Kumar  
Ten Year Retrospective Analysis of Prostate Cancer in the Florida Department of Corrections  
The Science of Health Disparities American Academy for Cancer Research, Miami, FL 2010
3. **Meghan E. Borysova**, Yongping Cui, Thomas M. Guadagno  
B-Raf Regulates Mitosis and Genomic Instability  
H. Lee Moffitt Cancer Center Scientific Retreat. Tampa, FL 2008.
4. Yongping Cui, **Meghan E. Borysova** and Thomas M. Guadagno  
Oncogenic B-RafV600E Drives Mitotic Abnormalities in Melanoma Cells  
International Melanoma Congress. New York, NY. 2007.
5. **Meghan E. Borysova** and Thomas M. Guadagno  
B-Raf Mediates Proper Spindle Formation During Mitosis  
University of South Florida Research Day, Tampa, FL 2006.
6. **Meghan E. Borysova** and Thomas M. Guadagno  
B-Raf Mediates Proper Spindle Formation During Mitosis  
H. Lee Moffitt Cancer Center Scientific Retreat, Tampa, FL 2006.
7. **Meghan E. Borysova** and Thomas M. Guadagno  
B-Raf Mediates Proper Spindle Formation During Mitosis  
Cold Spring Harbor, New York, 2006.

8. **Meghan E. Borysova** and Thomas M. Guadagno  
B-Raf Regulates Spindle Assembly in Human Somatic Cells  
Asilomar Cancer Biology Director's Meeting California, 2006
9. **Meghan E. Borysova** and Thomas M. Guadagno  
B-Raf Regulates Spindle Assembly in Human Somatic Cells  
American Society for Cell Biology, 2006
10. **Meghan E. Borysova** and Thomas M. Guadagno  
B-Raf Mediates Proper Spindle Formation During Mitosis  
Molecular and Genetic Basis of Cell Proliferation Gordon Research Conference, New Hampshire, 2005

#### **D. Research Support**

##### **Ongoing Research Support**

2012-2014    **Principal Investigator:** Department of Defense U.S. Army, Prostate Cancer Health Disparities Award

Office of Congressionally Directed Medical Research programs, Fully Funded

##### **Completed Research Support**

3P20MD003375-02S1

**Postdoctoral Fellow (Richard Roetzheim and B. Lee Green, PIs);**  
07/31/2010-12/31/2013

NIH-funded grant supplement to the University of South Florida and Moffitt Cancer Center Transdisciplinary Center to Address Cancer Health Disparities. The grant supports a comparative effectiveness research project on informed decision making in prostate cancer screening. \$1.4 million

## April C. Schenck

10323 Venitia Real Ave Apt #203 ~ Tampa, FL 33647

Cell: 727.452.9299 ~ [april.schenck@gmail.com](mailto:april.schenck@gmail.com)

### Professional Profile

Ambitious, detail oriented, self-starter with comprehensive written and oral communication skills. Team player with ability to manage multiple tasks, work under pressure and meet strict deadlines. Offer strong technical / analytical skills balanced by equally strong interpersonal and organizational skills. Academic achievements and over 15 years of employment experience has revealed ability to learn multiple systems/applications quickly as well as competency in the following areas:

#### Energy Services

2003-2007

Quantitative Analysis of water and energy performance for government institutions. Provide reports to project management to assist with recommendations for improvements in water and energy conservation measures.

#### Finance / IT

1998-2013

Quantitative and Qualitative Analysis of domestic and international clients / transactions utilizing a wide variety of systems, databases, applications, and reports to identify institutional risk.

#### Health Administration

2010-2013

Qualitative Analysis of Health Disparities in the local community. Improving cultural competence of health service delivery as well as increasing health knowledge and self-efficacy.

### Professional Experience

November 2010- June 2013

Research Coordinator / Research Support Specialist

University of South Florida, College of Public Health

Tampa, FL

- Support Comparative Effectiveness Research for Eliminating Disparities (CERED)
- Abide by strict reporting guidelines to meet IRB and HIPPA requirements
- Provide technical advice and guidance on data collection.
- Execute data collection, data management, and data reporting functions.
- Provide reports to Principle and Co-Principle Investigators on the status or any concerns regarding research.
- Provide assistance with development training and technical assistance on a content area of interest to increase knowledge of program and research staff.
- Organize activities with team members and community partners
- Facilitate educational sessions, focus groups and various conference presentations.
- Participate in ongoing educational sessions
- Community capacity building
- Evaluate organizational and operational problems within a public health setting to develop solutions to the problems.
- Implement evidence based interventions.
- Contribute in the delivery of a domestic public health intervention.
- Establish and maintain effective working relationships with health officials, community representatives and commercial partners at local level.
- Use interpersonal communication skills in advancing public health activities within a multi-disciplinary team.
- Adapt communication style to accommodate coworkers or colleagues from diverse cultures.

- Participate in the development of technical articles for publication in peer-reviewed journals such as “The Journal of Health Care for the Poor and Underserved”.

December 2012 - Present	FIU (Financial Investigation Unit) Compliance and Control Analyst	
August – January 2010	GTS (Global Transactions Services) Analyst	
March – August 2008	AML (Anti Money Laundering) Analyst	
Citi Bank		Tampa, FL

- Reviewing of account documentation for high-risk businesses using judgment and analytical skills in ensuring the accounts meet the required AML standards.
- Managing case investigations through manual and automated processes.
- Interacting with account officers to gather the necessary requirements.
- Performing enhanced due diligence review to determine if the client poses a risk.
- Thoroughly documenting the research and analysis related to these clients.
- Constantly learning and applying knowledge of money laundering processes.
- Escalating negative information to management for review.
- Knowledge of regulations and statutes pertaining to the Bank Secrecy Act (BSA) and Anti Money Laundering (AML)
- Detect money laundering suspicious activity and potential terrorist financing.
- Conduct research that complies with AML standards on business and consumer accounts within a precise deadline by law
- File SAR's with government officials for suspicious activity
- Responsible for review and investigation of unusual transaction activity consistent with the bank's established core anti-money laundering program and applicable laws and regulations
- Conduct research over bank systems, the internet and other databases consistent with the resolution of investigations
- Document and report investigation findings in the case management system and prepare reports to management
- Received stellar evaluations and report audits

May 2005- August 2007

	Energy Performance Analyst	
Housing Authority of the City of Tampa		Tampa, FL

- Prepare monthly reports and tracking schedule for EPC Program utility accounts
- Ensure that costs are allocated according to established procedures
- Gather historical cost data on utility activities, material purchase, labor, repairs, operating expenses, etc.
- Price new services and products by performing audits, developing unit cost and projecting expenses using life cycle cost analysis
- Formulate revisions of the Energy Performance Contract and prepare HUD subsidy request for Utility Expense Level
- Reconcile quarterly reports with energy services company, prepare utility allowances for upcoming budget year, and monitor utility subsidy savings levels
- Analyze, formulate and recommend consistent with guidelines, and follow-up with a report
- Liaise with other project areas to coordinate interdependencies and resolve issues
- Serve as liaison between Energy Services, Accounting and MIS departments to develop and design revisions to financial systems
- Serve as Housing Authority's representative in matters regarding utilities and EPC

- Conducted seminars to educate resident and staff concerning energy conservation through Power Point presentations as well as videos personally developed and directed
- Saved Housing Authority hundreds of thousands of dollars through correcting omissions and suggesting optimal options for savings

February 2003- May 2005

Energy Services Project Accountant

Water & Energy Savings Corporation

St. Petersburg, FL

- Verify, allocate, and post details of business transactions to subsidiary accounts
- Compile reports to show statistical data involving expenditures
- Accounts Payable, Accounts Receivable, Profit and Loss Reports
- Prepare franchise, sales & use tax annual reports for different regions and districts along with weekly financial reports detailing economic interests for Senior Management
- Complete Borrowing Base Certificate for Financial Institutions
- Prepared government contract billing and responded to RFP's

September 2001- January 2003

Financial Advisor / Vault Teller

Central Carolina Bank & Trust

Winston-Salem, NC

- Handle \$1 million each week in cash, portfolios, and via a variety of financial markets
- Accomplished Top Sales and Referrals, stayed abreast of economic variances/factors and potential volatile back-lashes that could affect our customers
- Provide financial assistance via IRA's, stocks, bonds, money market, etc.

August 2000 - September 2001

Investment Services Interim / Teller

Bank of America

Greensboro, NC

- Provide customers with information and resources for IRA's and other investment options
- Assist VP with customer account acquisition, maintenance, and retention
- Serviced customers daily with a variety of account transactions

May 2000- August 2000

Office Manager

SDC Enterprise

Charlotte, NC

- Information Support Analyst
- Control and Maintain Budget/Inventory
- Act as liaison between the company and several Housing Authorities throughout the country
- Managed 10 employees, including their schedules, HR, and reward/discipline

May 1998 - May 2000

IT Interim

RJ Reynolds Tobacco Company (Credit Union)

Winston-Salem, NC

- Maintain database that stored images of customer signatures
- Provided tier 1 help desk/desktop support
- Administrative Support

## Computer Programs/Languages

Citi Smart, Check Vision, AIIRS, On Demand, SARC, Brio, File Maker Pro, Syfact, CRU, Fox Pro, Peachtree, People Soft, Microsoft Office Suite, Visual Basic, HTML, Java, etc.

## Education

2010-2011 Graduate Certificate	University of South Florida, College of Public Health Health Care Management & Leadership	Tampa, FL
2004-2005 MBA, Business Administration	Florida Metropolitan University	Tampa, FL
1995-1999 BS, Management Information Systems (MIS)	Winston-Salem State University	Winston-Salem, NC

## Foreign Languages

	Speaking	Reading	Writing	Listening
French	Low	Medium	Low	Medium
Spanish	Low	Low	Low	Medium

## Foreign Travel

Mexican, Eastern and Southern Caribbean Countries:

Barbados	St. Lucia	Bahamas	St. Maarten
Antigua	Martinique	Dominica	Cozumel



## BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.  
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Jay Wolfson	Distinguished Service Professor Public Health and Medicine		
eRA COMMONS USER NAME (credential, e.g., agency login) JWOLFSON	Associate Vice President Health Law, Policy and Safety		
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	MM/YY	FIELD OF STUDY
Univ. of Illinois, Chicago	AB	1973	History
New York University NYC	MA	1974	European History
Indiana University, Bloomington	MPH	1975	Community Health
University of Texas, Public Health, Houston	DrPH	1981	Hlth Serv Organization
Stetson Univ. College of Law, St. Petersburg	JD	1993	Law
Univ of Southern California, Andrus Center	Certificate	1974	Gerontology

### A. Personal Statement

I serve as a navigator, translator and facilitator for often complex, community health service and policy initiatives that engage public and private sector clinical, social, educational and financial resources to achieve measurably improved health. My goal has been to bring the resources, creativity, energy and demonstrated talents of the University to and into the Community by building relationships among core, affected parties and demonstrating mutual value – including economic value. I've designed, managed and evaluated community-based systems of care, from a public hospital based HMO through the national award winning Hillsborough County Health Plan, and others, reflected in some of the projects referenced in grant-funded research, below. My broad-based education and training across the disciplines of public health, medicine, law and the humanities have been substantially and intimately informed by and tempered in the trenches of large public hospitals, communities of HIV/AIDS patients and families, clinical offices and hospitals implementing electronic health information technology. And I've been on the front line and on the front pages of health care delivery and policy matters ranging from maintaining the financial viability public teaching hospitals to articulating the painful vicissitudes associated with national policy and private individual challenges about end of life decisions through my appointment as Terri Schiavo's special guardian. I've helped to lead the boots on the ground project development and operational relationships with The Villages and its residents that have created the opportunity to deploy the proposed health care innovation and to measure and report its success. My greatest strength has been attracting exceptionally competent, fabulously dedicated and productive people. I thrive on facilitating the design and implementation of complex, time-sensitive, politically, economically and operationally dynamic, public-private, community-based health initiatives. And in the process, I get to wear the very applied hats of scientist, politician, humanist and lawyer.

### B. Positions and Honors

#### Professional Experience

**Associate Vice President, Health Law, Policy and Safety, and Director of Outcomes, Center for Advanced Health Care**, University of South Florida, 2005 -

**Distinguished Service Professor of Public Health and Medicine**, University of South Florida, 2005

**Director**, The Florida Health Information Center, College of Public Health Univ of South Florida, Tampa, 1990

**Director**, Suncoast Center for Patient Safety, (AHRQ funded), University of South Florida, Tampa 2001 - 2008

**Professor, Health Law, Finance and Policy, and Internal Medicine**, Colleges of Public Health and Medicine, University of South Florida, 1995, from Associate Professor, 1984 -

**Professor of Health Law**, Stetson University College of Law, 2000 -

**Governing Board Member**, Florida Joint Medical Malpractice Underwriting Association (representing the Florida Bar), 2008 - 2010

**Board Member** (President 2009-2010), Health News Florida, 2007-

**Assoc Director**, National Patient Safety Ctr of Inquiry, Veterans Health Administration, VISN 8, 1999-2006

**Member**, Medicare Competitive Pricing Review Committee, (HCFA, USDHHS) 1998-2004

**Vice Chair and Board Member**, HealthEase Medicaid HMO, Tampa Florida, 1995-2000

**Trustee, Vice Chair and Chair of Finance**, Hillsborough County Hosp Auth (Tampa General), 1987-1999

**Editorial Advisory Board**, Men's Health magazine, 1998-2001

**Visiting Fulbright Professor**, Univ of Tokyo Med School, and Nat'l Inst of Public Health, Tokyo, Japan 1985.

**Assoc Prof Health Admin**, from Asst Prof, College of Public Health, Univ of Oklahoma, OKC, 1981-1984

**Asst Prof Hth Serv Admin**, College of Public Health, University of South Carolina, Columbia, 1978-1980

### **Special Engagements**

Appointed Special Guardian Ad Litem for Theresa Marie Schiavo, with report to Governor Bush and the Florida Courts (2003-2004)

Special Expert to Florida Attorney General for Dialysis Fraud and Abuse in Florida (2003 – 2009)

### **Honors**

Distinguished Service Professor, University of South Florida, 2005

Faculty Scholar, U.S. Centers for Disease Control and Prevention, 1998-99

Folmer Outstanding Service Award, Healthcare Financial Management Association, 1993

Senior Fulbright Fellow, 1984-1985 (Japan)

W.K. Kellogg Fellow, 1982-1983 (Health Care Finance)

U.S. DHEW Public Health Service Traineeship, 1975-1977

Marcus and Theresa Levi Scholarship for Graduate Studies in Human Services, 1974-1975

New York City Department of Health, Health Research Fellowship, 1974

### **C. Selected Peer-reviewed Publications**

Augustine R. Wilson, Peter J Fabri, Jay Wolfson. "Human Error and Patient Safety", Teaching and Learning in Medicine", 2012, in press

Wolfson, J. and Nir Menachemi. "Just Dating or Soul Mates? Patient Safety Meets Fraud and Abuse", Florida Journal of Health Law, February, 2010.

Wolfson, J. "When Patient Safety Meets Fraud and Abuse" Medical Ethics, October 2009.

Francois, R. M., G. Johnson, I. Hoare, **J. Wolfson**, C. Dziuban, R. Harbison. "Predicting Return to Work in Patients with Coronary Heart Disease" Journal of Medicine, Vol. 39 (1-6) (2008).

Wolfson, J. "Defined by Her Dying, Not Her Death", Journal of Death Studies, March 2006.

Wolfson, J. "The Basis for Decisions to End Life: The Schiavo Dilemma". Clinical Interventions in Aging, January 2006.

Wolfson, J. "Schiavo's Lessons for Health Attorneys: When Good Law is All You Have", Journal of Health Law, Winter 2006.

Wolfson, J. "The Rule in Terri's Case: The Public Death of Theresa Marie Schiavo". Stetson Law Review, Fall 2005

Wolfson, J. "Erring on the Side of Terri Schiavo", Hastings Center Report, July 2005.

Spehar, M., Andrea, R.R. Campbell, C. Cherrie, P. Palacios, D. Scott, J. Baker, B. Jjornstadt, **J. Wolfson**, "Seamless Care: Safe Patient Transitions from Hospital to Home" *Advances in Patient Safety: From Research to Implementation*. Volumes 1-4, AHRQ Publication Nos. 050021 (1-4). February 2005. Agency for Healthcare Research and Quality, Rockville, MD. <http://www.ahrq.gov/qual/advances/>.

Hartman, R., **J. Wolfson**, and S. Yevich. "Military Deployment Health Surveillance Policy and its Application to Special Operations Forces" Journal of Military Medicine, February, 2004.

Wolfson, J. "Patient Safety Center of Inquiry Focuses on Patient Safety Improvement", Veterans Health Systems Journal, Vol 5, No. 5, June 2000

Wolfson, J. "The Dangerous Financial Politics of AIDS Protease Inhibitor "Cocktails" Journal of Health Care Finance, Fall, 1997

Wolfson, J. "Justifying Tax Exempt Status for Not-For Profit Health Care Organizations" Healthcare Financial Management, April, 1996.

Wolfson, J. and S. Hopes. "What Makes Tax-Exempt Hospitals Special? The bases for State and Federal Tax Inquires" Healthcare Financial Management, July 1994, pp 56 - 60.

Ikegami, N., **J. Wolfson**, and I. Ishi. "Comparison of Administrative Costs between U.S. and Japanese Hospitals" The Japanese Journal of Social Insurance, August, 1993, no. 1806, p 18.

Wolfson, J., G. Walker, and P.J. Levin. "Free-Standing v Hospital-Based: Where will Ambulatory Surgery Go?" Healthcare Financial Management, July 1993, pp 27 - 32 (Cover article)

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- Wolfson, J., G. Walker, and P.J. Levin. "Adjudicated Pricing: When Rates are Challenged in Court", *Healthcare Financial Management*, September 1992, pp 47 -51.
- Wolfson, J. and G. Walker "Legislative versus Judicial Regulation of Hospital Charges" *Florida Bar Journal*, April, 1992, pp 64 - 66.
- Coulter, M. and **J. Wolfson**. "The Florida Child Health Study" *Florida Journal of Public Health*, Fall, 1990, Vol II, No. pp 12-14.
- Wolfson, J. and P.J. Levin. "What to Look for in Evaluating Competing Managed Care Products" *Compensation and Benefits*, Fall, 1989, pp 96 - 102.
- Levin, P.J. and **J. Wolfson**. "Health Care in the Balance: Japanese Eurythmy", *Hospital and Health Services Administration*, Sept. 1989, Vol 34, No. 3, pp 311 - 323.
- Levin, P.J., **J. Wolfson**, L. Abberger and R.R. Campbell. "Quality and Financial Regulation of HMOs". *Journal of Insurance Regulation*, March, 1989, Vol 7, No. 3, pp 351 - 363.
- Wolfson, J., P.J. Levin, and R.R. Campbell. "Beyond the Cost of Health Care: The New Era of Quality and Liability in Managed Care" *Journal of the Florida Medical Association*, March, 1988, Vol 75, No. 3, pp 165-169.
- Wolfson, J., P.J. Levin, and W. Brock. "Linking Health Care for the Poor to Health Care for Profit" *Health Affairs*, Vol. 6, pp 129 - 135, Spring 1987
- Levin, P.J., **J. Wolfson**, and H. Akiyama. "The Role of Management in Japanese Hospitals". *Hospital and Health Services Administration*, May, 1987, Vol. 32, No.2, pp 249-261.
- Wolfson, J., and P.J. Levin. "Who's Got the Money? Who's Got the Patients: The Administrator's Response to PPOs and Self-Funding". *Journal of Ambulatory Care Management*, August, 1984
- Levin, P.J., and **J. Wolfson**. "Community Based Ambulatory Health Services Management: The Logic of the 1960s". *Journal of Ambulatory Care Management* August, 1994, Vol 7, No. 3, pp 25-31.
- Levin, P.J., and **J. Wolfson**. "Health and American Business, Again". *New England Journal of Medicine* (letter), Vol. 308, No. 13, p. 782, March 31, 1983
- Glasser, J., and **J. Wolfson**. "Rocky Road: The Flavor of Health Services Research". *Medical Care*, September, 1983, Vol 21, No. 9, pp 939-942.
- Wolfson, J., A. Kapadia, M. Decker, A. Sear, and L Roht. "Effects of Cost Sharing on Users of a State's Health Service Program". *Medical Care*, December, 1982, Vol. 20, No. 12, pp 1178 - 1187.
- Levin, P.J., and **J. Wolfson**. "Health and American Business". *New England Journal of Medicine*, (letter) Vol. 307, No. 5, p. 320, July 29, 1982,

#### **D. Research and Grant Activity (Selected)**

##### Active

- Co-PI, "USF Health and The Villages: Assessing Health Status for High Risk, High Cost Seniors" The Villages of Lake and Sumter, Inc., \$2,000,000, 2011-2012.
- Principal Investigator, "PaperFree Florida Regional HIT Extension Center" Office of the National Coordinator for Health Information Technology, USDHHS, \$5,884,132, 2010-2014
- Principal Investigator, "Florida Family AIDS Network", U.S. Department of Health and Human Services, Health Resources and Services Administration, \$1,288,000.00, 2011-2012

##### Completed

- Principal Investigator, "Florida Family AIDS Network", U.S. Department of Health and Human Services, Health Resources and Services Administration, \$18,368,000, 1993-2012
- Co-Principal Investigator "The Tampa Bay Regional Health Information Organization Pilot System Development" FI Agency for Health Care Administration, through the Tampa Bay Partnership, \$235,000, 2007-2008.
- Co-Principal Investigator "The Tampa Bay Regional Health Information Organization Pilot System Development" Florida Agency for Health Care Administration, through the Tampa Bay Partnership, \$330,000, 2006-2007.
- Principal Investigator, "Florida Patient Safety Initiative Advancement", Florida Patient Safety Corporation, \$300,000, 2006.
- Co-Principal Investigator, "The Tampa Bay Regional Health Information Organization Implementation Demonstration" FI Agency for Hlth Care Admin, through the Tampa Bay Partnership Foundation, \$467,000, 2006.
- Principal Investigator, "Incentives to Best Practices and Risk Management to Reduce Litigation in Medical Malpractice", Florida Agency for Health Care Administration, \$106,400, 2004.
-

Principal Investigator, "Florida Family AIDS Network" U.S. Department of Health and Human Services, Health Resources and Services Administration, \$1,228,090, 2004-2005.

Principal Investigator, "Retraining Physician's Following Disciplinary Actions for Medical Negligence", Subagreement with University of Florida College of Medicine, FL Agency for Health Care Administration, \$10,000, 2004.

Principal Investigator, "Litigation Alternatives and a No-Fault Demonstration for Medical Malpractice in Florida", Subagreement with University of Miami College of Medicine, Florida Agency for Health Care Administration via University of Miami Consortium Agreement, \$86,000, 2004

Principal Investigator, Suncoast Developmental Center for Patient Safety Evaluation and Research, U.S. Agency for Healthcare Research and Quality, \$504,000, 2001-2004

Co-Principal Investigator "Adolescent Clinical Trials for HIV/AIDS" National Institutes of Health, \$700,000, 2000-2003.

Principal Investigator, "The Florida Dialysis Fraud Study" Florida Agency for Health Care Administration, \$201,593, 2000-2001

Principal Investigator, "Managed Health Care Effects on Safety Net Providers in Florida", Florida Agency for Health Care Administration, \$253,000, 2000-2001

Principal Investigator, "The Impact of Implementing Telemedicine Technology in a Spinal Cord Injury Home Environment" American TeleCare, \$36,000, 2000

Principal Investigator, "Targeted Outreach to Pregnant Woman with AIDS" (TOPWA), Florida State Department of Health, \$100,000, 1999-2000

Associate Project Director and Investigator, "Prevention and Management of Spinal Cord Injuries" U.S. Department of Veteran's Affairs, VISN 8, 180,000, 1999-2001

Co-Principal Investigator, "Evaluation of Florida's Mandatory Managed Care Workers Compensation Initiative" Florida Department of Labor, Division of Workers Compensation, \$150,000, 1996-1997,

Principal Investigator, "The Ability of Health Care Organizations to Prepare and Respond to 'Worst Case Scenario' Natural Disasters – Follow Up to Hurricane Andrew in South Florida" 1993, The Florida Hospital Association and the American Hospital Association. \$10,000

Principal Investigator, "The Florida MediPass Program Evaluation: The Florida Medicaid, Managed Care Demonstration" 1991 through 1993, \$101,000

Investigator "Factors Associated with Viability in the Operation of Adult Congregate Care Facilities" Southmark Foundation on Gerontology, April 1989 through October, 1989, \$75,000

Investigator "Project FAVA: ACLF Financial and Managerial Viability" Florida Department of Health and Rehabilitative Services, May 1989 through October 1989 \$60,000

Principal Investigator "The Future Health of HMOs in Florida" STAR Grant, State of Florida, July 1988 through June 1989, \$37,000

Co-Principal Investigator "Aging Access to Health Care in Florida" Florida State Legislature and Office of the Governor, September 1988 through December 1988, with P.J. Levin, \$50,000

Co-Principal Investigator "Florida Child Health Study" Florida State Legislature, September 1988 through December 1988, with Martie Coulter, \$67,000

Associate Principal Investigator and Associate Project Director "Healthy Beginnings: The Pregnancy Improvement Project for Florida" Florida Medicaid Program Office, DHRS, December 1988 - 1992, \$1,300,000

Principal Investigator "The Japanese and U.S. Health Care Systems" The Associated Japan America Societies of America, November 1987 through April 1988, \$12,000

Principal Investigator, "Updates on Health Insurance and Health Care Financing in Japan" Beverly Enterprises, Dun & Bradstreet Plan Services, U.S. Administrators, Inc., and Mitusi Mutual Life Insurance Company, 1986-1987 \$30,000

Investigator "Long Term Industrial Hygiene Training Grant" The National Institutes of Health, 1984-88, \$300,000.

Principal Investigator "The Financing of Japan's Health Care System" The Japanese Fulbright Commission, 1985, \$60,000

Co-Principal Investigator "The Organization and Financing of Japanese Health Care" The Japan/U.S. Friendship Commission, 1985, with P.J. Levin, \$20,000

Principal Investigator, "Use of Video Games to Stimulate Nursing Home Residents", Mattel Corporation, March 1983 through September 1984, \$10,000

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**BIOGRAPHICAL SKETCH**

NAME Douglas A. Holt, M.D., F.A.C.P.		POSITION TITLE: Professor of Medicine, Division of Infectious Disease & International Medicine Associate Director, Division of Infectious Disease & International Medicine Director, Hillsborough County Health Department	
eRA COMMONS USER NAME			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
Davidson College, Davidson, North Carolina,	B. S.	1980-1984	
University of South Alabama, College of Medicine, Mobile, Alabama,	M.D.	1984	
Internal Medicine, University of South Florida College of Medicine, Tampa, Florida	Residency	1984-1987	Internal Medicine
Division of Infectious Diseases and Tropical Medicine, University of South Florida College of Medicine, Tampa, Florida	Fellowship	1987-1989	Infectious Diseases

**A. Positions and Honors****Positions and Employment**

Assistant Hospital Epidemiologist, Tampa General Hospital Tampa, Florida 1989-1991.

Medical Director, Protective Care Unit, Tampa General Hospital, Tampa, Florida, 1989-1993.

Hospital Epidemiologist, Tampa General Hospital, Tampa, Florida, 1991-1996.

Chief of Medical Staff, Hillsborough County Health Department, Tampa, Florida, 1995-1996.

Director, Hillsborough County Health Department, Tampa, Florida, 1996-Present.

Acting Deputy State Health Officer, Florida Department of Health, September 2001-February 2002.

Associate Director, Division of Infectious Disease and International Medicine, University of South Florida

**Additional Experience and Current Professional Memberships**

Member, American Medical Association, 1988-Present.

Fellow, American College of Physicians, 1993.

Member, Infectious Disease Society of America, 1991-2002

Member, Society for Hospital Epidemiology 1991-2001.

Member, Southern Medical Association, 1992-2002.

Member, American Society for Microbiology 1988-2003.

Member, Hillsborough County Medical Association 1998-Present

Secretary, Florida Association of County Health Officers, 1999.

Vice President, Florida Association of County Health Officers, 2002.

President, Florida Association of County Health Officers, 2004-2006.

President, Florida Public Health Association 2009 – Present

### **Awards and Honors**

Ciba-Geigy Outstanding Resident Award, University of South Florida College of Medicine, Tampa, Florida 1987.

President's Circle of Excellence Award, Tampa General Hospital, Tampa, Florida 1990.

Outstanding Teaching Award, Critical Care Medicine Program, Department of Surgery and Anesthesiology, University of South Florida College of Medicine, Tampa, Florida 1992.

Attending Physician Award, Protective Care Unit, Tampa General Hospital, Tampa, Florida 1992.  
(Compassionate Care)

Outstanding Teaching Award, Critical Care Medicine Program, Department of Surgery and Anesthesiology, University of South Florida College of Medicine, Tampa, Florida 1993.

Outstanding Community Service Award, University of Tampa, Department of Nursing, Tampa, Florida 2000.

School District of Hillsborough County, Excellence in Education, 2000

Hillsborough County Board of County Commissioners, Certificate of Appreciation, February 28, 2001.

State of Florida, Commendation, Dedicated Service and Outstanding Leadership, December 4, 2001.

Tampa Fire Rescue, Appreciation Award, October 2003

University of South Florida Lifetime Appreciation, 2003

University of South Florida College of Public Health Outstanding Partner Award, Florida Center for Public Health Preparedness, 2004

Bronze Leadership Award for active involvement in the leadership Institute and for demonstrated commitment to excellence in leadership, 2006.

USF College of Medicine, Appreciation Award, Faculty Secretary, 2007-2009

"Elected by his peers for inclusion in Best Doctors in America® from 2007 to 2009."

USF Area Community Civic Association, INC., Edwin Radice Distinguished Service Award, October 2009

### **B. Selected peer-reviewed publications**

Same

## C. Research Support

### (6 new studies)

Casanas B; Somboonwit C; Montero J; Wills T; Holt DA; Efficacy and Safety of VICRIVIROC in HIV Infected Treatment-Naïve Subjects [Protocol No.: P04875 Feb 2009]

Casanas B; Somboonwit C; Montero J; Wills T; Holt DA; 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 [Protocol No.: A4001078]

Casanas B; Somboonwit C; Montero J; Wills T; Holt DA; A Phase 2B Multicenter, Randomized, Comparative Trial of UK-453,061 Versus Etravirine In Combination With Darunavir/Ritonavir And A Nucleotide/Nucleoside Reverse Transcriptase Inhibitor For The Treatment Of Antiretroviral Experienced HIV-1 Infected Subjects With Evidence of NNRTI Resistant HIV-1 [Protocol No.: A5271022]

Casanas B; Somboonwit C; Montero J; Wills T; Holt DA; A Phase 2B/3 Open-Label Rollover Study for Subjects Discontinuing from the UK-453,061 Protocols for the Treatment of HIV-1 Infected Subjects {Protocol No: A5271038]

Casanas B; Somboonwit C; Montero J; Wills T; Holt DA; The SWIFT Study: A Prospective, Randomized, Open-Label Phase IV Study to Evaluate the Rationale of Switching from Fixed Dose Abacavir (ABC)/Lamivudine (3TC) to Fixed-Dose Tenofovir DF (TDF)/Emtricitabine (FTC) in Virologically-Suppressed, HIV-1 Infected Patients Maintained on a Ritonavir-Boosted Protease Inhibitor-Containing Antiretroviral Regimen [Protocol No.: GS-US-164-0216]

Casanas B; Somboonwit C; Montero J; Wills T; Holt DA; A Pilot, Randomized, Controlled Study to Evaluate the Safety and Efficacy of Raltegravir versus NRTIs as a Backbone in HIV-Infected Patients Switched from a Stable Boosted PI Regimen [IISP – 33107]

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## BIOGRAPHICAL SKETCH

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NAME Choe, Ulyee	POSITION TITLE Director, Polk County Health Department Assistant Professor of Medicine, University of South Florida Faculty, Department of Infectious Disease, James A. Haley Veterans Hospital
eRA COMMONS USER NAME	

EDUCATION/TRAINING			
INSTITUTION AND LOCATION	DEGREE	MM/YY	FIELD OF STUDY
University of Florida, Gainesville, Florida	B.S.	05/01	Microbiology
Nova Southeastern University College of Osteopathic Medicine, Ft. Lauderdale, Florida	D.O.	05/05	Medicine
University of South Florida, Tampa, Florida	Residency	06/09	Internal Medicine
University of South Florida, Tampa, Florida	Fellowship	09/11	Infectious Diseases

### A. Personal Statement

Dr. Ulyee Choe is a trained, board certified internal medicine and infectious disease physician with extensive experience in the practical administration of public health as current Director of the Polk County Health Department (PCHD). Dr. Choe oversees county-wide screenings and vaccinations with close coordination with the main Florida Department of Public Health in Tallahassee. He also brings extensive experience in clinical trials, with prior experience with Pfizer pharmaceuticals. He is an active member of the Infectious Disease Society of America and the Florida Infectious Disease Society.

### B. Positions and Employment

2013-present	<b>Director, Polk County Health Department</b>
2011-present	<b>Assistant Professor of Medicine</b> , Assistant Professor of Medicine, University of South Florida College of Medicine, Division of Infectious Disease and International Medicine, Tampa.
2012-present	<b>Chairman Health and Medical Committee of the Eight County Tampa Bay Regional Domestic Security Task Force</b>
2012-2013	<b>Interim Director, Polk County Health Department</b>
2011-2013	<b>Faculty</b> , Section of Infectious Disease, James A. Haley Veterans Hospital, Tampa, Florida.

### Professional Memberships

- Polk County Medical Association, Executive Committee, Public Health Chairman
- Infectious Disease Society of America
- Florida Infectious Disease Society
- American College of Physicians
- DOCARE International
- American Osteopathic Association



### **Selected Other Experience**

2011-present	Member, Institutional Biosafety Committee, University of South Florida
2011	Developer, Laboratory Exposure Identification Protocol, University of South Florida, Tampa
2011-2012	Laboratory Biosafety and Exposures, Division of Infectious Disease, University of South Florida, Tampa
2010	Shigella Outbreak Investigator, Hillsborough County Health Department, Tampa
2010	World's AIDS Day, presenter and organizer, Hillsborough County Health Department, Tampa
2012	Member, Infection Control, Tampa General Hospital, Tampa
2009-2012	STD Clinic Consultation, Hillsborough County Health Department, Tampa
2009-2011	Quality Assurance Specialty Care Clinic, Hillsborough County Health Department, Tampa
2009	World's AIDS Day, developed program to increase public awareness of HIV and STI using social media, Hillsborough County Health, Tampa
2009	Member, Internal Medicine Residency Selection Committee, University of South Florida, Tampa
2008	Member, Internal Medicine Disciplinary Committee, University of South Florida, Tampa

### **Honors**

2012	ECSS Awardee for Educational Excellence, Office of Education, University of South Florida
2011	Gold Star Award for Outstanding Customer Service, James A. Haley Veterans Hospital, Tampa
2011	Traveler's Grant, Poster presentation at Infectious Disease Society of America, Boston, MA
2010-2011	Chief Fellow of Infectious Disease, University of South Florida
2009	Outstanding Third Year Resident, Internal Medicine, University of South Florida, Tampa
2008	Chief Resident of Internal Medicine, University of South Florida, Tampa
2007	Outstanding First Year Resident, Internal Medicine, University of South Florida

### **C. Selected Peer-reviewed Publications**

1. **Choe U**, Oller K, Casanas, B. An Unusual Case of Toxoplasmosis Presenting as a Cecal Mass. Pending publication.
2. Kunadharaju R, **Choe U**, Harris J, et al. Case report: *Cryptococcus gattii* – Emerging fungal pathogen in Florida. *Emerg Infect Dis* 2013; 19(3): 519-21.
3. Carrington M, **Choe U**, Ubilos S, et al. Fatal Case of Brucellosis Misdiagnosed in Early Stages of *Brucella.suis* Infection in a 46-year-old Patient with Marfan Syndrome. *J Clin Microbiol* 2012; 50 (6): 2173-5.
4. Gompf SG, Smith K, **Choe U**. Arenaviruses. eMedicine at WebMD. 2011. Available at: <http://emedicine.medscape.com/article/212356-overview>
5. **Choe U**. HPV Vaccine Recommendations. Florida/Caribbean AIDS Education and Training Center HIV Carelink. 2011; 12 (2).

### **D. Research Support**

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

A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of Elvitegravir/Emtricitabine/Tenofovir Disoproxil Fumarate/GS-9350 Versus Ritonavir-Boosted Atazanavir Plus Emtricitabine/Tenofovir Disoproxil Fumarate in HIV-1 Infected, Antiretroviral Treatment-Naïve Adults

A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of Elvitegravir/Emtricitabine/Tenofovir Disoproxil Fumarate/GS-9350 Versus Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate in HIV-1 Infected, Antiretroviral Treatment-Naïve Adults

A Phase 2, A Phase 2, Open-Label, Multicenter Study of the Safety of Ritonavir-Boosted GS 9137 GS 9137/r) Administered in Combination with Other Antiretroviral Agents for the Treatment of HIV 1 Infected Subjects.

A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial of a Novel CCR5 Antagonist, UK-427,857, in Combination with Optimized Background Therapy versus Optimized Background Therapy along for the Treatment of Antiretroviral-Experienced HIV-1 Infected Subjects. [Pfizer A4001027]

A randomized, controlled, partially blinded Phase IIb dose-finding trial of TMC125, in HIV-1 infected subjects with documented genotypic evidence of resistance to currently available NNRTIs and with at least three primary PI mutations. [TMC125-C223]

A Phase II, Randomized, Blinded, 12-Week Comparison of Elvucitabine in Combination with Efavirenz and Tenofovir Versus Lamivudine in Combination with Efavirenz and 4 Tenofovir in HIV-1 Infected, Treatment-Naïve Subjects, with a 12-Week Extension Treatment Period. [ACH443-015]

A Large, Simple Trial Comparing Two Strategies for Management of Anti-Retroviral Therapy. [SMART CPCRA 065]

A randomized, controlled, open-label trial to compare the efficacy, safety and tolerability of TMC114/ritonavir versus lopinavir/ritonavir in treatment-naïve HIV-1 infected subjects. This trial will be referred to as ARTEMIS. [TMC114-211]

A Phase IIb, Randomized, Partially Blinded, Dose-Finding Trial of TMC278 in Antiretroviral Naïve HIV-1 Infected Subjects. [TMC278-204]

An Open-Label Trial with TMC125 in HIV-1 Infected Subjects, Who Were Randomized to a TMC125 Treatment Arm in a Sponsor-Selected TMC125 Trial and were Treated for at least 48 Weeks. [TMC125-C229]

A 96-Week, Phase IV, Randomized, Double-Blind, Multicenter Study of the Safety and Efficacy of Epzicom Versus Truvada Administered in Combination with Kaletra in Antiretroviral-Naïve HIV-1 Infected Subjects. [EPZ104057] –HEAT

A Randomized, Prospective Study of the Efficacy, Safety and Tolerability of Two Doses of GW433908/Ritonavir Given with Abacavir/Lamivudine Fixed Dose Combination. [COL100758]

A Probe Study to Evaluate the Safety, Tolerability, and Immunogenicity of the MRK Adenovirus Serotype 5 Vector (MRKAd5) Human Immunodeficiency Virus Type I (HIV-1) gag Vaccine in HIV-1 Infected Individuals. [Merck V520 – 014]

A Randomized, Controlled, Open-Trial to Compare the Efficacy, Safety and Tolerability of TMC114/RTV versus LPV/RTV in Treatment-Experienced HIV-1 Infected Subjects. [TMC114-C214]

## BIOGRAPHICAL SKETCH

NAME Somboonwit, Charurut		POSITION TITLE Associate Professor of Medicine	
eRA COMMONS USER NAME			
EDUCATION/TRAINING			
INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
Srinakharinwirot University, Bangkok, Thailand	MD	1995	Medicine
Choa Praya Yomaraj Hospital,Suphan Buri, Thailand	Internship	1995-1996	Internal Medicine
State University of New York at Brooklyn: affiliated program, St. John's Episcopal Hospital, Far Rockaway, New York	Residency	June 1998- June 2001	Internal Medicine
University of South Florida College of Medicine, Tampa, Florida	Fellow	July 2001 - June 2003	Infectious Diseases

**A. PERSONAL STATEMENT :** My expertise is in disease prevention, HIV clinical care and clinical trials with the areas of interest of HIV therapeutics; HIV-comorbidities and access to care. As the Director of Clinical Research and Communicable Diseases at Hillsborough County Health Department, Tampa, FL; I provide medical oversight to communicable diseases programs including immunization and Epidemiology and STD. Moreover, I developed curriculum and training for infectious disease fellows and epidemiologists, teach and mentor clinical practice and public health aspects of infectious diseases. Recently, I served as a lead clinician for the ETAC HIV/HCV treatment demonstration projects which I oversee over 10 sites across the country. I have served as a member of Institutional Review Boards for both University of South Florida and Florida Health Department. I serve in several committees and organizations involving community services, research integrity and teaching including faculty of the Florida-Caribbean AIDS Training Center (FL-AETC). Internationally, I participated in clinical STD and HIV training in India in conjunction with USF College of Medicine and College of Public Health CHART-India program.

### **A. Positions and Honors**

#### **Positions and Employment**

2011-present Associate Professor, University of South Florida, Morsani College of Medicine, Department of Internal Medicine, Division of Infectious Diseases

2006-2011 Assistant Professor, University of South Florida College of Medicine, Department of Internal Medicine, Division of Infectious Diseases

2006-present Director of Clinical Research, Hillsborough County Health Department, University of South Florida, College of Medicine

2005-present Director of Communicable Diseases, Hillsborough County Health Department

2002-present Faculty, Center of HIV Academic and Research Training – India (CHART-INDIA)

#### **Other Experience and Professional Memberships**

2007 -present Co-Director, Scholarly Concentration in Research for Medical Students: University of South Florida College of Medicine

2002-present Member, Florida Infectious Diseases Society

2001-present Member, Infectious Diseases Society of America

1998-present Member, American College of Physicians

1998-present Member, American Medical Association

## **Awards and Honors**

- 2009 Elected Member, Alpha Omega Alpha Gamma Chapter  
2009 Citation, Best Doctors in America  
2008 Elected Fellow, American College of Physicians  
2008 Elected Member, Gold Humanism Society, University of South Florida, College of Medicine, Tampa  
1994 *Professor Wasant Jongjetana Award*  
Merit award for the best clinical performance based on proficiency and doctor-patient relationship.

## **B. Selected peer-reviewed publications (in chronological order).**

1. Giunta B, **Somboonwit C**, Tellinghuisen T, Scott WK, Duncan R, McCoy C, Page JB, Tan J, Fernandez F, Shapshak P. Psychiatric Aspects of Hepatitis-C Infection. *Crit Rev Neurobiol* 2007; 19(2-3): 79-118.
2. Shapshak P, Tellinghuisen T, Scott WK, Duncan R, McCoy C, Page JB, **Somboonwit C**, Giunta B, Fernandez F. Molecular Mechanisms in HCV and Drug Abuse. *Bioinformation* 2008; 3(1):53-57.
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4. Giunta B, **Somboonwit C**, Nikolic WV, Rapo E, Tan J, Shapshak P, Fernandez F. Psychiatric implications of hepatitis-C infection. *Crit Rev Neurobiol* 2009; 19(2-3): 79-118.
5. **Somboonwit C**, Kurtyka D, Velez AP. Abacavir and lamivudine combination. *Expert Opin Drug Metab Toxicol* Dec 2009; 5(12):1599-606.
6. Shapshak P, **Somboonwit C**, Drumright LN, Frost S DW, et al. Molecular and Contextual Markers of HCV and Drug Abuse. *Mol Diag and Ther* 2009; 13(3):153-179.
7. Pham T, Alrabaa S, **Somboonwit C**, Le Hung, Montero J. The HIV Virologic Outcomes of Different Interventions Among Treatment-Experienced Patients With 2 Consecutive Detectable Low-Level Viremia. *J Int Assoc Physicians AIDS Care (Chic)*. 2011 Jan-Feb;10(1):54-6
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9. Shapshak P, Duncan R, Duran EM, Farinetti F, Minagar A, Commings D, Rodriguez H, Chiappelli F, Kanguane P, Levine AJ, Singer E, **Somboonwit C**, Sinnott JT. Gene Expression for HIV-Associated Dementia and HIV Encephalitis in Microdissected Neurons: Preliminary Analysis. *Neurobehavioral HIV Medicine* 2011; 3:53-78
10. Shapshak P, Pandjassaram K, Fujimura RK, Commings D, Chiappelli F, Singer E, Levine A, Minagar A, Novembre F, **Somboonwit C**, Nath A, Sinnott JT. NeuroAIDS Review. Editorial. *AIDS* 2011; 25:123-141.
11. Shapshak P, Duncan R, Kanguane P, **Somboonwit C**, Sinnott JT, Commings D, Singer E, Levine A. HIV Associated Dementia and HIV Encephalitis II: Genes on Chromosome 22 Expressed in Individually Microdissected Globus Pallidus Neurons (Preliminary analysis). *Bioinformation* 2011; 6(5): 183-186
12. Zetterberg E, Neuhaus J, Baker JV, **Somboonwit C**, Llibre JM, Palfreeman A, Chini M, Lundgren JD; INSIGHT SMART Study Group. Platelet count kinetics following interruption of antiretroviral treatment. *AIDS*. 2013 Jan 2;27(1):59-68.

## **B. Research Support**

### **Ongoing Research Support**

START	Role: <b>PI</b>	2009-Present
Strategically Timing of Antiretroviral Therapy. CPCRA START		
John Hopkins University	Role: <b>PI</b>	2006-Present
Pilot Study for a Multisite HIV/AIDS Clinical and Resource Use Data		

### **Selected Completed Research Support**

SMART	Role: <b>PI</b>	2006-2007
A Large, Simple Trial Comparing Two Strategies for Management of Anti-Retroviral Therapy. SMART CPCRA 065		

**APPENDIX D**  
**Letters of Commitment**



October 11, 2013

Dear Grant Committee:

This letter confirms The University of South Florida's support of the proposal entitled "The VaccineLink Project"/ "La Salud Conexion" to Pfizer prepared by Dr. Jamie Morano with the Department of Internal Medicine, College of Medicine and Dr. Dawood Sultan with the Department of Health Policy & Management, College of Public Health.

In the event that the project is funded, we agree to carry out the contract and grant administration policies and responsibilities as are assigned or delegated to the award.

We look forward to providing the support necessary to ensure an effective initiative.

Sincerely,

A handwritten signature in purple ink that reads "Rebecca Puig".

Rebecca Puig, M.S.  
Assistant Vice President  
USF Research & Innovation  
University of South Florida  
3702 Spectrum Blvd., Suite 165  
Tampa, Florida 33612  
Phone: (813)974-5465  
Email: [rpuig@usf.edu](mailto:rpuig@usf.edu)



**Mission:**

To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

**Rick Scott**

Governor

**John H. Armstrong, MD, FACS**

State Surgeon General &amp; Secretary

**Vision:** To be the Healthiest State in the Nation

October 7, 2013

Dear Grant Committee:

As Director of the Florida Department of Health-Hillsborough, I am writing a letter of support for the project entitled VaccineLink / La Salud Conexión and the work of principle investigators Dr. Jamie Morano and Dr. Dawood Sultan. This exciting academic-community-government sector partnership is a true opportunity to improve current gaps in vaccine delivery in our community and to create a sustainable linkage to record current vaccinations administered.

The DOH-Hillsborough is the local public health organization for Tampa and its surrounding population of over one million residents. Our mission is to promote, protect, and improve the health of all people in Florida. We work in coordination with local medical providers and the patients we serve are largely minorities and people of color. Our annual budget for FY 13/14 is \$38,769, 902.00, and, over the past year, we have been responsible for administering 5291 vaccines to the people of our community. This included 972 influenza shots and 625 Tdap vaccines.

Specifically in support of this proposal, we will be able to offer our clinic venues for patient surveys and as also able to offer the administration of influenza, pneumonia, and Tdap vaccines directly in our clinics. Further, we are linked to key pharmacies in the community and can provide the platform to disseminate county-wide informational material on the availability of vaccinations.

We are able to interface with the state-wide Florida Shots data system, which is conveniently housed in our own facilities, allowing more convenient data retrieval and analysis for the investigators.

I am also a Professor and Director of Infectious Diseases at the University of South Florida Morsani School of Medicine and this partnership between both agencies will allow ongoing support for the project aims and goals. In conclusion, I strongly support the project entitled VaccineLink / La Salud Conexión and look forward to successfully implementing the strategies to improve vaccination rates in adults who live and work in my community.

Sincerely,

A handwritten signature in blue ink, appearing to read "Douglas Holt", with a long horizontal line extending to the right.

Douglas Holt, MD, FACP

Director, Florida Department of Health-Hillsborough County

**Florida Department of Health – Hillsborough County**

Office of the Director

P.O. Box 5135

Tampa, FL 33675-5135

PHONE: (813) 307-8000 • FAX: (813) 272-6984

**www.FloridasHealth.com****www.hillscountyhealth.org**

TWITTER: HealthyFLA

FACEBOOK: FLDepartmentofHealth

YOUTUBE: fldoh

**Mission:**

To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.



**Rick Scott**  
Governor

**John H. Armstrong, MD, FACS**  
State Surgeon General & Secretary

**Vision:** To be the Healthiest State in the Nation

October 8, 2013

Dear Grant Committee:

As Director of the Florida Department of Health in Pinellas County, I am writing a letter of support for the project entitled VaccineLink / La Salud Conexión and the work of principle investigators Dr. Jamie Morano and Dr. Dawood Sultan. This exciting academic-community-government sector partnership is a true opportunity to improve current gaps in vaccine delivery in our community and to create a sustainable linkage to record current vaccinations administered.

The Florida Department of Health in Pinellas County currently sees over 64,177 patients a year and has been responsible for administering 33,278 vaccines over the past year to the people of our community. This included 3,916 influenza shots and 4,268 Tdap vaccines.

Specifically, we will be able to offer our clinic venues for patient surveys and also be able to offer the administration of influenza, pneumonia, and Tdap vaccines directly in our clinics. Further, we are linked to key pharmacies in the community and can provide the platform to disseminate county-wide informational material on the availability of vaccinations.

We are able to interface with the state-wide Florida Shots data system. This will make data retrieval and analysis more convenient for the investigators.

We support and endorse this project and look forward to partnering with the investigators.

Sincerely,

Claude M. Dharamraj, MD, MPH, FAAP  
County Health Department Director

**Florida Department of Health**

Pinellas County  
205 Dr. Martin Luther King Jr. St. N. • St. Petersburg, FL 33701-3109  
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[www.pinellashealth.com](http://www.pinellashealth.com)

**[www.FloridasHealth.com](http://www.FloridasHealth.com)**

TWITTER: HealthyFLA  
FACEBOOK: FLDepartmentofHealth  
YOUTUBE: fldoh



**Mission:**

To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

**Rick Scott**

Governor

**John H. Armstrong, MD, FACS**

State Surgeon General &amp; Secretary

**Vision:** To be the Healthiest State in the Nation

October 7, 2013

Dear Grant Committee:

As Director of the Florida Department of Health in Polk County, I am writing a letter of support for the project entitled **VaccineLink / La Salud Conexión** and the work of principle investigators Dr. Jamie Morano and Dr. Dawood Sultan. This exciting academic-community-government sector partnership is a true opportunity to improve current gaps in vaccine delivery in our community and to create a sustainable linkage to record current vaccinations administered.

The Florida Department of Health in Polk County currently sees over 29,000 patients a year and has been responsible for administering 37,111 vaccines over the past year to the people of our community. This included 2761 influenza shots and 2930 Tdap vaccines.

Specifically, we will be able to offer our clinic venues for patient surveys and as also able to offer the administration of influenza, pneumonia, and Tdap vaccines directly in our clinics. Further, we are linked to key pharmacies in the community and can provide the platform to disseminate county-wide informational material on the availability of vaccinations.

We are able to interface with the state-wide Florida Shots data system. This will make data retrieval and analysis more convenient for the investigators.

We support and endorse this project and look forward to partnering with the investigators.

Sincerely,

A handwritten signature in dark ink, appearing to read "Ulyee Choe", with a stylized flourish at the end.

Ulyee Choe, DO

Director

Florida Department of Health in Polk County

**Florida Department of Health in Polk County**

OFFICE OF THE DIRECTOR

1290 Golfview Avenue, 4<sup>th</sup> floor • Bartow, FL 33830-6740PHONE: (863) 519-7900 • FAX: (863) 534-0293 • [www.MyPolkHealth.org](http://www.MyPolkHealth.org)**[www.FloridasHealth.com](http://www.FloridasHealth.com)**

TWITTER: HealthyFLA

FACEBOOK: FLDepartmentofHealth

YOUTUBE: fldoh

## APPENDIX E

### References:

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2. Florida Department of Public Health, Division of Public Health Statistics & Performance Management. County Health Profile. Available at: [http://www.floridacharts.com/charts/mapp\\_report.aspx](http://www.floridacharts.com/charts/mapp_report.aspx). Accessed July 10, 2013.
3. U.S. Census Bureau. Hillsborough County, Florida, State & County QuickFacts. Available at: <http://quickfacts.census.gov/qfd/states/12/12057.html>. Accessed July 10, 2013.
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**Pfizer Independent Grant for Learning & Change Letter of Intent  
“The VaccineLink Project” / “La Salud Conexión”**

**Organizational Detail**

The University of South Florida Health network (USF Health), is one of the premier clinical research institutions in Central Florida and encompasses an extensively integrated academic network of health care delivery experts, physicians, scientists, and experienced public health advocates with extensive NIH-supported track records of partnering with local communities for sustainable community-based change innovations. The USF Morsani School of Medicine successfully garnered \$81.8 million in awarded grant projects in FY 2012-13.

For over 75 years, the Hillsborough County Health Department has provided quality public health services and disease control intervention and prevention to the local community. As an agency of the Florida Department of Health (DOH), one of the largest agencies in state government, the mission of public health as defined by Florida Statute is: to promote, protect, maintain and improve the health of all residents and visitors in the State of Florida. The Hillsborough County Health Department strives to achieve this mission locally through major commitments to environmental health, communicable disease control, and health education in a large metropolitan area with an estimated population exceeding 1 million, and an additional 400 new residents arriving each week. This public health mission is currently carried out by a staff of 400 health care professionals and support personnel with fiscal expenditures exceeding \$40,000,000.00.

The University of South Florida and the Morsani School School of Medicine is fortunate to have extensive experience with working in partnership with community health care and vaccine providers in the context of community based medical outreach. The Moffitt Cancer Center Comparative Effectiveness Research for Eliminating Disparities (CERED) group already has established relationships with key minority opinion leaders and has ready networks available upon which to build a vaccine delivery infrastructure.

The Florida Medical Association, Hillsborough County Medical Association, and Florida Pharmacy Association are all ready partners in this endeavor, local pharmacies, grocery store vaccine providers, and local broadcast and print media.