TRAINING NEW AFRICAN COMMUNITY OUTREACH STAFF
July 30- August 1, 2014 - Johannesburg, South Africa

Genevieve Meyer

They came from Malawi, Mozambique, Zambia, Zimbabwe, South Africa and Tanzania: community educators, recruiters, outreach workers, social scientists and even a clinic coordinator or two. The purpose of the workshop was to understand what the HVTN is, what studies will open in the region, and why it’s important to begin site-level community engagement early. The agenda was developed in collaboration with educators from the HVTN’s long-standing South African sites. As organizers, we wanted to increase the trainees’ understanding of how HIV vaccines work and the unique challenges with outreach and recruitment for phase 1 studies. Yet one of the unstructured, but equally beneficial, aspects of this workshop was the opportunity for staff members to get to know each other, and to learn from each other’s challenges and successes.

Day 1 included an introduction of the HVTN and an overview of the upcoming PS studies in the region. This was followed by an opportunity to hear from each site about the research they have conducted and how their community programs are structured. Next, in a session led by the team from the Aurum Institute in Klerksdorp, came a comprehensive overview of HIV Vaccines 101, myths and misconceptions, and VISP by Kagisho Baebanye, followed by a lively discussion led by Nandisile Luthuli about when to begin Community Engagement activities and special considerations for phase 1 studies. Yet one of the unstructured, but equally beneficial, aspects of this workshop was the opportunity for staff members to get to know each other, and to learn from each other’s challenges and successes.

Participants all received hard copies of the HVTN Training Manual as well as digital versions so that they can use the information at their sites.

...continued on page 11
HVTN 104: Exploring New Pathways to Vaccine Design

Adi Ferrara

When an infection happens, specialized parts of your immune system are mobilized, including antibodies. Antibodies are natural proteins made by the body. They are very specific – an antibody can recognize and fight only one type of foreign invader. This can be a problem with an invader that changes very often, like HIV. An antibody against one strain of HIV may not work against other strains.

Antibodies can also be made in the lab and given to people who have specific illnesses, or who are at risk for getting such illnesses. The use of manufactured antibodies against disease is called “passive immunization.” For example, babies with lung problems can be given monthly injections of palivizumab, an antibody against respiratory syncytial virus (RSV). RSV is a dangerous infection in babies, but in babies with lung problems it can be deadly. Palivizumab protects these babies from RSV.

There is also a special class of antibodies against HIV called broadly neutralizing antibodies (bnAbs). These antibodies, though rare, do work against a wide variety of HIV strains. People who are infected with HIV who also have these antibodies are able to control their infections without medication. Their viral load is extremely low as a result of these bnAbs and the infection-fighting work they do.

HVTN 104

Once the bnAbs were discovered, scientists started making them in the lab. There is no need to use actual HIV-infected cells in order to make them. One such antibody, called VRC01, is now being tested in several clinical trials in HIV-positive and HIV-negative people. In people who are already infected with HIV, it is hoped that bnAbs will help slow down the progression of HIV infection and lower their viral load. It is...continued on page 5
CAPRISA – Centre for the AIDS Programme of Research in South Africa – and its eThekwini Site
Submitted by Dr. Kathy Mngadi

CAPRISA is a designated UNAIDS collaborating centre for HIV prevention research and policy. We were established in 2002 under the NIH-funded Comprehensive International Program of Research on AIDS (CIPRA) by five partner institutions: University of KwaZulu-Natal, University of Cape Town, University of Western Cape, RSA National Institute of Communicable Diseases, and Columbia University in New York.

OUR GOALS:
• To undertake globally relevant and locally responsive research that contributes to understanding HIV pathogenesis, prevention and epidemiology, as well as the links between tuberculosis and AIDS care.
• To build local research infrastructure and capacity in virology, immunology, clinical infectious disease, bioinformatics, epidemiology and biostatics.
• To enhance and strengthen the critical mass of skilled researchers in South Africa, particularly young scientists from historically disadvantaged communities, through well-established training links with Columbia University.

OUR RESEARCH PROGRAMMES:
Our research focuses on 5 key areas: Epidemiology and Prevention, Microbicides, HIV/TB Treatment, Vaccines, and Pathogenesis

CAPRISA undertakes globally relevant and locally responsive research that contributes to understanding HIV pathogenesis, prevention and epidemiology. The site’s research agenda includes studies in HIV pathogenesis (Acute infection cohort), microbicides (such as the ASPIRE study using the dapivarine ring), CAP 008 (tenofovir gel post-trial access) and HIV and TB treatment (improving retreatment success). The site participated in the Phambili HIV vaccine study in 2009 and in the HVTN 503-S protocol in 2013. We are preparing for vaccine trials scheduled to begin in 2015.

CAPRISA’s studies of HIV pathogenesis include looking at early viral and immunological events in acute infection, as well as host genetic factors associated with HIV transmission, establishment of HIV infection, and containment of virus replication in humans. This has enabled CAPRISA to study the lifespan of broadly neutralising antibodies. CAPRISA is also involved in HIV vaccine development and clinical trials.

OUR ETHEKWINI SITE
CAPRISA’s eThekwini site is adjacent and attached to the Prince Cyril Zulu Communicable Disease Centre, a primary Health Care Clinic dedicated to treatment of TB and sexually transmitted infections. This facility is conveniently located in central Durban in the transport hub for public commuters by rail, bus or minibus taxis. The Prince Cyril Zulu clinic is one of the largest outpatient TB facilities in South Africa. The HIV prevalence in TB patients is estimated to be between 64.6% and...continued on page 4

“WE ARE ONE OF THE TWO SITES WHERE AN ACUTE INFECTION COHORT HAS BEEN FOLLOWED FOR MORE THAN 8 YEARS, AND IN WHICH THE BROADLY NEUTRALISING ANTIBODY DISCOVERY BY PENNY MOORE WAS MADE.”

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80%. The eThekwini site comprises two sections, a Treatment clinic for HIV-TB co-infected patients, and a Prevention Clinic with a high risk population of STI clients.

The eThekwini Research site was one of the two sites where the game-changing CAPRISA 004 microbicide trial was conducted, that showed that use of 1% Tenofovir vaginal gel before and after sex has 39% efficacy in preventing HIV acquisition. Currently we are conducting the implementation and post-trial access CAP 008 study. We are also one of the two sites where an acute infection cohort has been followed for more than 8 years, and in which the broadly neutralising antibody discovery by Penny Moore was made! The SAPIT trial was also conducted here, which influenced NIH and WHO policy guidelines on when to start ART in HIV patients that are co-infected with TB.

CAPACITY BUILDING:
CAPRISA’s Training Programme has made a significant contribution to training a critical mass of future scientists. The programme is co-funded by the Columbia University-Southern African Fogarty AIDS Training Program.

CAPRISA’s Fellowship programme provides long-term traineeships for international and local pre-doctoral and post-doctoral candidates and medical students from the Nelson R. Mandela School of Medicine. Since 1993, 501 trainees have been admitted to these programmes.

To read other featured profiles on sites within HVTN, visit the TEAM section at hvtn.org/en/team.html and look for the “Featured Profile” link for the latest site profile.
also possible that bnAbs can be used in people who are not infected with HIV as a way to prevent HIV infection.

The HVTN is conducting a trial called HVTN 104 in participants who are not infected with HIV. HVTN 104 tests several different doses of VRC01, given on several different schedules. The antibodies are given in two different ways, either as an injection under the skin or as an infusion directly into the bloodstream.

VRC01 is a monoclonal antibody. That means it is a lab-made copy of one specific antibody from one specific patient. Monoclonal antibodies are already used in some treatments for cancer and autoimmune disease, but there is a difference. In the case of autoimmune diseases and cancer, where your body is fighting back against its own cells and not a foreign invader, the monoclonal antibodies actually interfere with the workings of normal cells which may cause some very serious side effects. In laboratory studies done with VRC01, researchers have found that the antibody only attaches to HIV and prevents it from infecting cells. It does not attach to any other cells, so researchers do not expect it to interfere with how the body normally works. People may still have some side effects from the injection or infusion, but these side effects should be very different than the ones seen in the treatments of cancer and autoimmune disease. One of the goals of HVTN 104 is to test the safety of the VRC01 antibody.

HVTN 104 is not a classic vaccine study. Rather than giving participants a vaccine and waiting to see if their bodies will make antibodies in response, in HVTN 104 participants are being given the antibody directly. These lab-made antibodies do not last for very long in the body, and the body doesn’t make them on its own once they’re gone, so the participants have to be given more antibodies on a regular schedule. One of the questions that will be answered in this study is how long the antibodies last, and what dose and schedule seem to be the best.

Why is the HVTN doing this study?

Though not a classic vaccine study, the results of HVTN 104 will teach us a great deal. Participants in HVTN studies can develop antibodies after they are given an experimental vaccine, but so far these antibodies have not protected against HIV infection. By understanding what types of antibodies are protective, and how much of those antibodies is needed to be protective, scientists can design more effective vaccines and future studies.

Scientists also want to know how the lab-made antibodies move around inside a person. In a regular infection, such as a cold or the flu, your antibodies move around to get to the site of the infection and help fight it. This is called pharmacokinetics, or PK for short. But if you do not have an HIV infection, do the lab-made antibodies move around? In order to learn more about this, participants in HVTN 104 are being asked to give samples of their saliva, rectal fluid, cervical fluid and semen so that researchers can see if the antibodies move to the parts of the body where people might be exposed to HIV.

Passive immunization is also seen as a possible method that could be used to prevent mother to child transmission of HIV. If it is found to be effective, it could be another way to help HIV positive mothers who would like to breastfeed their babies, by giving the antibodies to both the mother and the baby. One of the doses being tested in HVTN 104 is very small, and is given every 2 weeks, which might be the strategy to use with babies.

VRC01 is not the only bnAb being studied in people or animals. Until researchers understand more about how bnAbs work, they will keep testing different ones to find the best antibody that may work for HIV prevention or as a treatment. Many more studies will be needed to help us answer these questions, and the HVTN is already starting to plan for future studies that will build on the results of HVTN 104.
The HIV Research for Prevention (HIVR4P) conference is a new scientific meeting, held for the first time in October, 2014 in Cape Town, South Africa. It brought together all of the biomedical HIV prevention fields, including vaccines, microbicides, pre-exposure prophylaxis (PrEP) and treatment as prevention (TasP). With so many recent research advances and the possibility that future trials may involve combination prevention strategies, this conference was an opportunity to bring together the scientists, social scientists, advocates and community members from all of the biomedical research areas.

Satellite sessions were free and open to the public, allowing many community members to attend. The oral presentations are also webcast and are available online for free listening, and most posters are posted online for viewing.

The HVTN was well represented at HIVR4P with 10 Oral Abstracts, 2 Symposia, 3 Poster Discussions, and 8 Posters. We were also involved with the planning and presentation of 3 Satellite sessions that took place the day before and after the conference. [see related story on page 8 for a list of recommended presentations]

The post-conference satellite was titled “The Road from Cape Town: Laying the Groundwork for a New Era of HIV Prevention R & D” (research and development). It was hosted by the South African Medical Research Council, HVTN, HIV/AIDS Vaccines Ethics Group (HAVEG), University of KwaZulu Natal, AVAC, University of Toronto, Canadian Institutes of Health Research/Canadian HIV Vaccine Initiative, and IAVI. Stacey Hannah of AVAC and Ntando Yola, Community Educator at the Cape Town site, were the moderators during the session.

Dr. Larry Corey, HVTN’s principal investigator, opened the program with a summary of the HVTN’s plans for a series of upcoming studies in Southern Africa in collaboration with the P5 Partnership. The goal of the P5 Partnership is to build on the results from RV144 (the Thai Trial), but adapting the vaccines from that study to be specific to Clade C, the strain of HIV that is most common in sub-Saharan Africa. “You have to respect your pathogen,” he said, noting that in the 5 years since the RV144 results, the vaccine field has come together to better understand the results, the correlates of protection, and what would be needed to prove efficacy in future trials.

He also noted the favorable results coming from HVTN 097, which used the same poxvirus and protein vaccines as the Thai Trial in South Africa. Our study showed that the ALVAC vector and the protein vaccine produce strong immune responses in South Africa as well, suggesting that these are good candidates to move forward into larger Phase 2B studies. Dr. Corey told the audience that hundreds of millions of dollars will be invested in these southern African studies over the next several years, and that there is a tremendous sense of
optimism and excitement among the groups who are working together to bring the science to southern Africa. He concluded by saying, "We could use some luck. If you have a choice between being good and being lucky, choose lucky!"

In the next portion of the program, Stacey and Ntando led the audience in a set of small group discussions that demonstrated the value of the Good Participatory Practice guidelines. Groups debated whether CABs were an effective strategy for community engagement, if “communities” and “stakeholders” were the same or different, and whether the community should define the research priorities. In reporting on their discussions, all of the groups noted that there wasn’t just one correct answer. They also noted that successful community engagement can look different in every community. Stacey Hannah noted that the GPP guidelines are an attempt to articulate a process for having successful community engagement, where the many layers of stakeholders are involved in the research agenda, as well as the many layers of people who are impacted by that agenda.

The group heard from Cape Town Principal Investigator Dr. Linda-Gail Bekker and her staff member Brian Kanyemba, who described their community engagement efforts during the iPrEx trial of PrEP. That study enrolled men who have sex with men (MSM) and transgender women, both new populations that the Cape Town site had not worked with previously. They described the importance of creating safe spaces where community discussions could be held and people felt comfortable to express concerns about human rights and other issues. They also described their efforts to find these “hidden populations” who were somewhat covert in society; they learned that they needed new strategies and new partnerships to help them identify and reach these populations. Dr. Bekker concluded, “If you’ve done your work well, you should be able to say that Africa is better off for doing this trial.”

Representatives from HAVEG and IAVI shared their research on how to improve the informed consent process by doing a better job of assessing the participant’s understanding. Cathy Slack from HAVEG described the work they have done to look at different methods of assessment of understanding (AOU). They have concluded that the most effective approach is to have the participant explain things back to the clinician. Instead of asking a true/false question where the person has a 50% chance of guessing the right answer, when they have to explain it back the clinician can get a better sense of what was truly understood, and can go back over any concepts that were unclear. Another good method is for the clinician to provide a little story, and ask the participant to describe what should be done, which is called using “vignettes.” An AOU process that uses both vignettes and explaining things back can be really effective, and also works well in low literacy settings.

Kundai Chinyenze from IAVI described the work at her site to implement this new AOU procedure. Then she demonstrated how it works by giving a sample consent form to small groups and having them identify the key concepts that participants should be able to explain back. For example, in a microbicide study using a vaginal ring, the consent describes what is known about the safety of the ring from previous studies where the ring was used for birth control. In the microbicide study, it would be important for women to understand and be able to explain that the vaginal ring is being used differently, and does not offer any contraception benefit. If they mistakenly thought it worked for birth control, the women might have unprotected sex, which could increase their risk for HIV.

To bring the satellite session to a close, Mitchell Warren from AVAC led a short Q & A session with representatives working in different roles on clinical trials. The audience heard from study funders, clinical trial physicians, advocates, and CAB members. GCAB member Nombeko Mpongo from Cape Town summarized the CAB’s role beautifully. She said, "We are driven by Ubuntu, the universal bond among all human beings. We are born to love, and we are naturally blessed with the ability to give to others. That’s what makes us feel good and happy about being CAB members, knowing that we are helping others.”

The range of studies that lie ahead are very exciting, and it was great to close the conference with a focus on how communities can be best engaged, participants best educated, and studies conducted most successfully! The HVTN is grateful to all of our partners who came together to present the session.
HIVR4P IS ONLINE!

Gail Broder

All of the sessions from HIVR4P are available on the conference website, and so are most of the posters.

**For Webcasts:** Go to the website [www.hivr4p.org](http://www.hivr4p.org) and click on the icon for webcasts. Look for the name of the session, and then click on “expand session” to the right. This will open a list of the individual speakers during the session. For each speaker, you can choose to watch the video of the presentation including the slides, listen to the speaker giving the lecture without the slides, or download an MP3 file. Note that there are 3 pages of listings.

**For Posters:** Go to the website and click on the icon for ePosters. You can browse through any of the themes listed in the right column. To quickly go to these recommended posters, you can enter the poster number in the search field on the right side of the screen. In the search results, you should see the title of the poster, and you can click on the title to see the poster.

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**SESSIONS RECOMMENDED BY HVTN’S**

**OPENING PLENARY: STATE OF THE ART BIOMEDICAL PREVENTION IN 2014**

- **Jared Baeten** - Advances in Antiretroviral-Based Prevention Research – he talks very fast, but this was a fantastic talk that had everyone at the conference paying attention!
- **Anthony Fauci** - Comprehensive HIV Prevention: Synergy Between Vaccine and Non-Vaccine Modalities – the head of NIAID is one of the great leaders in the field.

**PLENARY 02: TARGETING BIOMEDICAL PREVENTION TO DIFFERENT AT-RISK POPULATIONS**

- **Chris Beyrer** - Tailoring Biomedical Preventive Interventions for Key Populations: Towards Safety, Efficacy, Effectiveness – highlighting the epidemiology among sex workers and MSM.
- **Bridget Haire** - Working with Special Populations within HIV Prevention Intervention Programs and Trials – building on Chris’ talk, Bridget looks at these key populations in clinical trials.

**ORAL ABSTRACT SESSION 19: GOOD PARTICIPATORY PRACTICES IN HIV PREVENTION**

We recommend this entire session! All 6 speakers gave interesting presentations with different examples of implementing the GPP guidelines. The session begins with our own **Gail Broder**: Inclusion of Transgender and Gender Non-conforming Communities in Preventive HIV Vaccine Research at the HVTN, and concludes with one of our Durban investigators, **Dr. Kathy Mngadi**: Challenges with Participant Reimbursement: Experiences from CAPRISA 008 - A Post-trial Access Study.

**ROUND TABLE 01: SAFER SEX IN 2014: HAS THE PARADIGM SHIFTED?**

- **James McIntyre** - What Is Safer Sex in 2014? Understanding The Biology of HIV Prevention – this South African investigator speaks the community’s language!
- **Jim Pickett** - Missing the Future is not an Option – this US advocate shares the real experiences and opinions of people in the community.

The roundtable discussion at the end of this session is also worthwhile. It includes the questions asked by the audience, and how the various speakers responded.
SESSIONS RECOMMENDED BY HVTN’S COMMUNITY ENGAGEMENT UNIT:

9

SYMPOSIUM 10: CHALLENGES OF BIOMEDICAL HIV PREVENTION TRIALS

• Jeanne Marrazzo - HIV Prevention Trials: Their Successes and Failures – the chair of the VOICE study shares important lessons learned.

• Ann Strode - Enrolling Adolescents in HIV Vaccine Trials: Will We Be Ready? – this South African investigator gave a terrific talk about preparing for clinical trials with teenagers.

• Jonathan Stadler - Why Context Matters in Understanding the Challenges to Clinical Trials – this lecture speaks to the importance of understanding the influence of local cultures on clinical trials.

CLOSING PLENARY: MIND THE GAP: BRIDGING FROM TRIAL SUCCESS TO ACCESS

• Alex Coutinho - Scaling-up HIV Prevention Science from the Laboratory to the Village – you never knew how many words beginning with “P” were involved in research, but this talk used them all and inspired the audience to consider partnerships, population preferences, people, personalities, priority populations, and so many more!

• Glenda Gray - Antiretrovirals for Prevention – Our very own Dr. Gray helped to bring the conference to a close.

SOME OF OUR FAVORITE POSTERS:

• Morar N. Seven Steps to Strengthen Community Engagement in HIV Prevention Trials in Durban. [P02.03]


• Siskind R, Morar N, Campbell R, Schouten J. Implementing Community Involvement in National Institutes of Health (NIH) HIV/AIDS Clinical Trials Networks. [P07.05]


• Pillay D, Wassenaar DR. Racial Differences in Willingness to Participate in HIV Prevention Clinical Trials amongst University Students in KwaZulu Natal, South Africa. [P42.08]
1. Small group discussions during the CAB Breakout Session
2. Dr. Jerome Kim, US Military HIV Research Program
3. Dr. Glenda Gray of Soweto, South Africa
4. A crowded plenary lecture by John Hural, HVTN Laboratory Program
5. Dr. Giuseppe Pantaleo of Lausanne, Switzerland
6. CAB member Mapule Raborife of Soshanguve, South Africa
7. John Hural also spoke at the Laypersons Lunch session
The group was welcomed on Day 2 by Stacey Hannah of AVAC, who presented an overview of the HIV biomedical research field. She walked through some of AVAC’s many educational and training resources, including guidance documents for implementing Good Participatory Practice (GPP) at sites. Joining the GPP discussion was the Desmond Tutu Foundation’s Ntando Yola (Cape Town) who provided an example of how GPP can be implemented for clinical trials at a national level. Next, Jim Maynard, HVTN Director of Communications and Community Engagement, wowed the group with a presentation and tips for working with the media, and how to be in control during an interview. In the afternoon Ntando led the attendees through an interactive session where they assessed and critiqued different advertising examples and then had the opportunity to work in small groups to design outreach messages and images of their own.

Day 3 began with a presentation by Mluleki Nompondwana on behalf of the Desmond Tutu HIV Foundation (Cape Town) on experiences with low risk recruitment, using lessons learned from HVTN 097 to help strategize for HVTN 100. He led an activity where small groups worked to explore the various challenges and opportunities of reaching “low-risk” participants. Next, Maaza Seyoum of IAVI led an interactive session based on her organization’s training curriculum “Integrating Gender Issues into AIDS Vaccine Research.” She had the group on their toes and in heated discussions about terminology such as “gender” versus “sex,” and role reversal brainstorming sessions in which the men had to think about challenges for female participants enrolled in HIV clinical trials, and vice versa. The last part of the day was dedicated to HVTN internal operations such as navigating the HVTN’s public and Members websites, and understanding how and why to complete the Quarterly Reports and Annual Work Plans. Sites had the opportunity to pair off and provide peer review of each other’s draft Annual Work Plans.

Before concluding, each site was given copies of the HVTN Training Manual for Community Outreach Staff. This training manual, the result of more than a year of consultation with South African community educators and CAB members, includes 14 stand-alone lessons on things like Research ethics, How to read a protocol, VISP, and Developing your community engagement plan. Each site, via its attendees at the workshop, now has 2 copies of the Manual on a flash drive and 1 hard copy. These materials are intended to help provide the knowledge and capacity that new community engagement staff at sites need to do their job optimally. Many of the lessons can also be used for CAB training or during community education activities.

While the 3-day agenda was packed with structured learning, sharing, and collaborative opportunities, one of the most valuable experiences may have been the development of closer working relationships between staff members across sites. The HVTN can provide tools and resources to support the work of sites and to increase knowledge about the vaccine field, but it is the opportunity to share first-hand experiences of working in the community that are integral to these training sessions. This is why it is invaluable to bring staff together, not only for learning but also to be each other’s support.

Community Educator Emilder Chihota from the Seke South site (in Chitungwiza, Zimbabwe) reports back on her small group’s discussion about strategies for reaching low risk participants.

“THIS TRAINING WAS AN EYE OPENER FOR ME. I HAVE LEARNED SO MANY THINGS AND HAVE LISTENED TO HOW OTHER CEs ARE RECRUITING IN THEIR AREAS. WE SHARED IDEAS AND STRATEGIES.”

—WORKSHOP ATTENDEE
Welcome, Nandi!

The HVTN’s Community Engagement Unit (CEU) is excited to welcome its newest member, Nandisile Luthuli, “Nandi.” Starting in January, 2015, Nandi will be working closely with Genevieve Meyer as a Community Education Training Manager based in Johannesburg, South Africa. She will be the primary point person for a portfolio of sites in Southern Africa, helping to support their community engagement programs. She will also be serving on protocol teams and working groups within the HVTN to help ensure community views and CAB perspectives are communicated within the Network. In addition, Nandi will be coordinating the new VISP Testing Service for Southern Africa.

Nandi graduated from the University of Kwa-Zulu Natal where she studied media, communications and political science. She later completed a Postgraduate Diploma in Industrial Relations. For the past 3 years, Nandi has worked as the Community Engagement Officer for the Aurum Institute in Klerksdorp, where she managed their community outreach staff, their recruitment and retention planning, and their Community Advisory Board, as well as overseeing the HIV counseling and testing program at their clinic and through their mobile testing unit. Adding to her expertise, she is also trilingual in English, IsiZulu and IsiXhosa. Beyond her incredible skills, Nandi also brings her passion for finding an HIV vaccine that will one day stop the untimely passing of our brothers and sisters. She looks forward to joining the HVTN Core family and working to make a difference in the lives of those most impacted by HIV. When she does find time to relax, Nandi enjoys socializing and spending time with her friends and family.

Please join the CEU in welcoming her to our team!!