Welcome, Empath Health!
The USF IRB is pleased to announce its new partnership with Empath Health. As a non-profit, integrated network of care, Empath Health supports individuals facing chronic or advanced illness by helping patients live as comfortably and meaningfully as possible, and offers assistance to families and caregivers. Empath Health is the newest addition to the USF IRB’s esteemed list of affiliate organizations. Welcome to our research community!

2019 Coordinator / Team Retreat
Join the USF IRB for our annual retreat for USF and affiliate Study Coordinators/Team Members. This retreat is both an opportunity to learn about important regulatory issues affecting study teams engaged in human subjects research, and a chance to hear from guest speakers about cutting edge research being conducted right here in Tampa Bay. This year’s event will be held on two different dates and locations.

Tuesday, March 5, 2019 from 12:00 PM until 2:00 PM
Location: Tampa General Hospital Main Hospital; 1 Tampa General Cir, Tampa, FL 33606
Room: Rehabilitation Center; R200

Friday, March 8, 2019 from 10:00AM to 12:00PM
Location: Moffitt Cancer Center, 12902 USF Magnolia Drive, Tampa, FL 33612
Room: David Murphy

Please register using the following link: http://2019coordinator-teamretreat.eventbrite.com?s=91260878

Attending one of the retreats will fulfill the human subjects research education requirement for USF, and is valid for three years. For any questions, please contact Gina Larsen at glarsen@usf.edu.

Revised IRB Fee Schedule – Clarifications
Last month, the IRB newsletter contained information about a revised fee schedule that will go into effect on July 1, 2019. Many researchers expressed concern and confusion over some elements of the fee schedule. We listened to your feedback! Please find below clarifications regarding the new fee schedule:
1. Research sponsored by non-profit entities will not be charged IRB fees.
2. Consistent with the USF IRB’s previous policy on fees, non-sponsored research conducted by USF faculty and students will not be subject to the fee schedule.
3. Research sponsored by for-profit entities, including clinical trials sponsored by industry, will be subject to the revised fee schedule effective July 1, 2019. All studies sponsored by for-profit entities submitted to the USF IRB for initial review on or after July 1, 2019 will be subject to the revised schedule.

As indicated in the February newsletter, fee reductions or waivers may be requested in exceptional circumstances. If you would like to request a fee reduction or waiver, please contact the USF IRB by e-mail at RSCH-IRB@usf.edu and provide information about the research, including: the name and contact information of the Principal Investigator, name of sponsor and justification for your request.

**Volunteer Appointments in USF Research**

Individuals who do not have a current USF affiliation may be eligible to be added to a USF IRB-approved study if a volunteer appointment is obtained from USF Human Resources. Volunteers who will be engaged in conducting human subjects research are required to undergo a background check. The background check level (I or II) will be determined by the nature of the research and the individual’s proposed role in the research.

To obtain a volunteer appointment for an individual who wants to be engaged in conducting human subjects research, the Principal Investigator (PI) of a study is responsible for the following:

- Completing Human Resource’s [Volunteer Appointment form](#) and submitting it to their college/department HR administrator.
- In regards to roles, the PI must specify on the Volunteer Appointment form whether the volunteer will have access to PII, PHI or Sensitive Identifiable Information. Additionally, the PI must indicate whether, via conducting the research, the volunteer will be interacting with vulnerable populations (e.g. children, individuals with disabilities, etc.).
- Please note, USF Human Resources recently clarified its policy on paying for background checks. HR will no longer cover the cost of background checks. The cost for a Level I background check is $56/applicant. Going forward, departments/colleges are responsible for covering the cost of background checks for volunteers who will be engaged in research.

**Office for Human Research Protections (OHRP) – New Clinical Trial Informed Consent Posting Requirement**

The revised Common Rule requires that for any clinical trial conducted or supported by a Common Rule department or agency, one consent form must be posted on a publicly available federal website.

OHRP has launched a webpage with information on the revised Common Rule’s clinical trial informed consent form posting requirement (45 CFR 46.116(h)). This page will be periodically updated with new information and guidance. You may access this page [HERE](#).
WE-CARE

- Are you a researcher needing to increase enrollment in your studies?
- Want to diversify your participant pool?
- Interested in becoming more engaged in the community?

Submit an abstract to WE-CARE!

WE-CARE is a community-based participatory research program that was started from a NIH P20 grant with the former USF Center for Equal Health. In 2014, the program was reestablished by Dr. Kevin Sneed, Dean of the College of Pharmacy, along with USF public health students.

WE-CARE works to bridge researchers with the community in order to achieve health equity. Through WE-CARE, researchers can engage with the local community to raise awareness about their research and increase enrollment and participation in their studies.

Researchers and clinicians can attend community conversations where panelists of community members provide their perspectives on the fears, challenges and solutions to engaging and participating in research studies. Researchers can also submit an abstract on the WE-CARE website and have a community research review committee give feedback prior to recruiting your study to the WE-CARE community network.

Visit wecare.health.usf.edu and click on ‘For Researchers’ for more information.