UNIVERSITY OF LOUISVILLE

HSC Research Forum

What's New at the NIH
Craig McClain, MD
Professor and Associate Vice President for Health Affairs/Research

NIH Review Process
Shirish Barve, PhD
Professor of Medicine and Distinguished University Scholar

Opportunities to Collaborate with the Kent School
Becky F. Antle, MSSW, PhD
Professor and University Scholar, Kent School of Social Work

CTU Resources
Lale Akca, MBA, CCRA
Executive Director, Clinical Trials Unit

K Awards
Irina Kirpich, PhD
Associate Professor of Medicine, Division of Gastroenterology, Hepatology & Nutrition

Jewish Heritage Foundation Enhancement Grants Update
Jon Klein, MD, PhD
Professor and Vice Dean for Research, School of Medicine

UNIVERSITY OF LOUISVILLE

News

- Rob Keynton – Interim EVPRI
- Leslie Sherwood – Director RRF
- Toni Ganzel – Expanded Role as Dean
- Thanks to:
  - Anne Noe
  - Steve Mahanes
- New State Funding for Cancer Center
- HSC Research Strategic Planning to Begin January 2019

NIH National Institutes of Health

NIH Peer Review

Guidelines for the Review of Inclusion on the Basis of Sex/Gender, Race, Ethnicity, and Age in Clinical Research

Requirements and Responsibilities

As required by federal law (42 USC 289a-2) and NIH policy, applications that propose to involve human subjects must address:

1. the inclusion of women, minorities, and children in the proposed research
2. for an NIH-defined Phase III clinical trial, plans for the valid design and analysis of group differences on the basis of sex/gender, race, and/or ethnicity as appropriate for the scientific goals of the study.

Academic Research Enhancement Award (AREA) Program

NIH National Institutes of Health

Office of Extramural Programs

AREA program goals

- Support meritorious research
- Strengthen research environment of schools that have not been major recipients of NIH support
- Expose undergraduate &/or graduate students in such environments to meritorious research
  - -Exposure, not training
  - -Goal = consider research careers
  - -Metric ≠ students eventually get R01

Changes to the R15 Academic Research Enhancement Award (AREA), and Introducing the R15 Research Enhancement Award Program (REAP)

The AREA Parent Announcement, PA-18-504, will expire after the January 7, 2019, AIDS due date and will not be reissued. Instead, the following announcements will be available in December:

- The Academic Research Enhancement Award for Undergraduate-Focused Institutions (R15 – Clinical Trial Not Allowed) PAR-18-714 already requires a signed letter verifying eligibility, and thus will continue on without needing to be reissued.
- An AREA announcement allowing clinical trials
- An announcement for health professional and graduate schools of arts and sciences (Clinical Trial Not Allowed)
- An announcement for health professional and graduate schools of arts and sciences (Clinical Trial Required)

AREA Program Resources

- Twitter @NIHR15
- Facebook NIH AREA Program
- Applicant Resources
  https://grants.nih.gov/grants/funding/area/resources.htm
- Main webpage
  http://grants.nih.gov/grants/funding/area/area.htm
- AREA mailbox R151@mail.nih.gov

NIH Loan Repayment Programs: A Lifeline for Biomedical and Biobehavioral Researchers

The LRPs counteract early-career researchers' financial pressure by repaying up to $35,000 annually ($70,000 over a two-year contract) of a researcher's qualifying educational debt in return for a commitment to engage in research areas important to the mission of NIH.

Nearly 1,400 scientists benefit from the $68 million NIH invests each year through the extramural LRPs. On average, nearly 50% of all new LRP applications are funded.

Register Now for Rare Disease Day at NIH 2019

Rare diseases affect an estimated 30 million Americans. On Feb. 28, 2019, NIH will host an event to raise awareness about these diseases, the people they affect and current research collaborations.

https://ncats.nih.gov/rdd

Alzheimer's-focused administrative supplements for NIH grants that are not focused on Alzheimer's diseaseNotice Number: NOT-AG-18-039

The participating Institutes and Centers (ICs) are inviting applications to expand existing awards in these ICs that are not currently focused on Alzheimer's disease and its related dementias (ADRD) to allow them to develop a focus on ADRD. Active awards with project end dates in FY 2020 or later are eligible. The award may not be in terminal no cost extension or going into no cost extension in FY2019.

It is important to contact staff at the Institute supporting the award when planning the duration of the supplement request.

Submit electronically under PA-18-591 Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional)

In preparing the submission, indicate that it is a response to NOT-AG-18-039 in Field 4.b on the SF 424 form.

Due dates may vary by awarding IC. See the awarding IC's web site for any applicable Application Due Dates.

HSC Research Forum

Shirish Barve
Professor
Department of Internal Medicine
Division of Gastroenterology, Hepatology & Nutrition

Clinical Trial Requirements for Grants and Contracts

- Grant Review Criteria
- Grant Application Package

Clinical Trial Requirements for Grants and Contracts

- NIH has launched a series of initiatives that have rolled out in 2017-2018 to enhance the accountability and transparency of clinical research.
- These initiatives target key points along the whole clinical trial lifecycle from concept to results reporting.

NIH Definition of a Clinical Trial

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Clinical Trial-specific Funding Opportunities

Beginning from January 25, 2018 due dates, all applications proposing clinical trials must be submitted through a funding opportunity announcement (FOA) designated specifically for clinical trials.

Clinical Trial-Specific Review Criteria

New review criteria will be used to evaluate applications proposing clinical trials or clinical trial research experience.

***A significant new clinical trial-specific review criteria is the review of "study timeline"**

https://grants.nih.gov/policy/clinical-trials/review-criteria.htm

New Human Subjects and Clinical Trial Information Form

A new Human Subjects and Clinical Trial Information form is required for all human subjects and/or clinical trial research beginning from January 25, 2018 due dates.

The most significant change with the new FORMS-E Application Package is the addition of a new PHS Human Subjects and Clinical Trials Information form. This form consolidates human subjects, inclusion enrollment, and clinical trial information previously collected across multiple agency forms.

https://grants.nih.gov/policy/clinical-trials/new-human-subject-clinical-trial-info-form.htm

Single IRB Policy for Multi-site Research

For applications involved in multi-site research, NIH expects that all participating sites which involve non-exempt human subjects research funded by the NIH, will use a single Institutional Review Board (sIRB) to conduct the ethical review required for the protection of human subjects.

https://grants.nih.gov/policy/clinical-trials/single-irb-policy-multi-site-research.htm

Clinical Trials Protocol Template

If the application includes phase 2 or 3 clinical trials that require Investigational New Drug application (IND) or Investigational Device Exemption (IDE) applications, a NIH-FDA template with instructional and sample text is provided to help you write your protocols.

Use of this template is optional.
https://grants.nih.gov/policy/clinical-trials/protocol-template.htm

Clinicaltrials.gov Registration and Reporting

A new regulation and NIH policy has expanded Clinicaltrials.gov registration and reporting to all NIH-funded clinical trials. Learn more about what you need to know about these requirements.

https://grants.nih.gov/policy/clinical-trials/reporting/index.htm

Human Subjects System

Effective June 9, 2018, the Human Subjects System (HSS) has replaced the Inclusion Management System (IMS). HSS consolidates human subjects and clinical trial information in one place. The system is accessed by PIs/signing officials and NIH Staff via eRA Commons.

https://grants.nih.gov/policy/clinical-trials/human-subjects-system.htm

KENT SCHOOL OF SOCIAL WORK: OPPORTUNITIES FOR RESEARCH COLLABORATION

Becky Antle, MSSW, PhD

Professor and University Scholar

Director, Center for Family and Community Well-Being

OVERVIEW

- Collaborative discovery with local, national, and global impact across substantive areas such as
  - Children and families
  - Health and mental health disparities
  - Communities, organizations, and systems
  - Social justice issues

CHILDREN AND FAMILIES

- PROJECT SAFESPACE
  - Crystal Collins-Camargo (PI) & Becky Antle (Co-I) *US DHHS*
  - Intervention research testing universal screening and assessment for trauma needs of children entering out of home care
  - Preliminary results show increase collaboration between systems and capacity to provide trauma informed care, placement stability, and functional improvement in children receiving these services
- CHAMPS 2: CREATING HEALTHY ADOLESCENTS THROUGH MEANINGFUL PREVENTION SERVICES
  - Anita Barbee (PI), Becky Antle (Co-I), & Laura Frey (Co-I)
  - Intervention research testing the effectiveness of a comprehensive relationship education program for the prevention of high risk sexual behavioral and violence among at-risk youth in community-based organizations
  - Prior RCT (CHAMPS 1) conducted an RCT and found that the comprehensive relationship education program was significantly more effective in preventing pregnancy than the traditional contraception based approach and a control curriculum. This project is a dissemination study in which the intervention is being embedded within community-based services such as residential treatment for at-risk youth.

CHILDREN AND FAMILIES

- KENTUCKY'S SOBRIETY TREATMENT AND RECOVERY TEAMS
  - Martin Hall (PI) *KY DCBS*
  - Randomized controlled trial on intervention to address co-occurring substance use and child maltreatment
  - Results have shown program reduces risk of subsequent maltreatment and re-entry into foster care; medication-assisted treatment for opioid use improved the odds that families retained custody of their children
- 4 YOUR CHILD
  - Armon Perry (PI), Anita Barbee, Emma Sterrett-Hong & Becky Antle (Co-I)
  - Intervention research on parent education program with solution focused case management services for non-residential fathers to increase father involvement
  - Preliminary results show improvements in parenting knowledge, self-efficacy, and co-parenting conflict management skills
- FIRST STEP NEXT
  - Andy Frey (PI) *Institute for Education Sciences*
  - Efficacy replication study on potency of intervention in preschool settings for improving social/behavioral and academic outcomes to support kindergarten readiness
  - Preliminary results show medium to large effect sizes at pre and post assessments across a variety of social emotional outcomes

HEALTH AND MENTAL HEALTH DISPARITIES

- EXPRESSED EMOTION AND SUICIDE DISCLOSURE
  - Laura Frey (PI) *American Foundation for Suicide Prevention*
  - Studying how adolescent suicide disclosures differ based on suicide severity, family dynamics, parental factors, and treatment adherence
  - Goal is to develop a brief family based intervention to target family factors that impact adolescents' recovery from suicidal thoughts
- COMPUTERIZED COGNITIVE BEHAVIORAL THERAPY FOR DEPRESSION IN PRIMARY CARE
  - Jess Wright (PI), Becky Antle (Co-I), Tracy Eels (Co-I), & Lesley Harris (Co-I)
  - Randomized controlled trial comparing CCBT to treatment as usual for patients diagnosed with depression in a primary care setting
  - Prior research showed relative effectiveness of CCBT for treatment of depression in a traditional mental health setting. This dissemination trial is exploring application in other settings (primary care, urban vs. rural) with a higher-risk population and with phone vs. face to face consultation.
- CENTER FOR PROMOTING RESILIENCY AND RECOVERY
  - Bibhuti Sar (PI), Becky Antle (Co-I), Anita Barbee (Co-I), Jennifer Middleton (Co-I), Adrian Archuleta (Co-I), & Shantel Crosby (Co-I)
  - Intervention research on treatment of trauma using several evidence-based approaches for children who are in the child welfare system, refugee/immigrant families, military families, and victims of trafficking.
  - Previous research (round one of funding) found that TFCBT was effective for the treatment of trauma among children in the child welfare system

HEALTH AND MENTAL HEALTH DISPARITIES

- QUALITY OF LIFE FOR DEMENTIA CAREGIVING DYADS
  - Heehyul Moon (PI) *Robert Wood Johnson*
  - Research examined factors for physical and mental health of holder adults, consequences of stress related to caregiving of people with chronic illness, transition of care within family context, and disparities of life experience and health among immigrant and racial/ethnic minority older adults and family caregivers
  - Results show CGs of older adults rate QOL, decision making, and value of social relationships lower
- FLOURISH PROGRAM
  - Annatjie Faul (PI), Joseph D'Ambrosio (Co-I), & Pam Yankeelov (Co-I) *DHHS*
  - Intervention research on community health navigation, home assessment and care planning in rural counties. Addressed social determinants of health in older adults to improve biological, psychological, environmental, social and health behaviors
  - Results show statistically significant improvement in all indicators
- DEMENTIA AND PHYSICAL DISABLEMENT PROCESSES AMONG AGING LATINOS
  - Sunshine Rote (PI) *National Institute of Aging*
  - Research to analyze 20 years of data from the Hispanic Established Populations for the Epidemiologic Studies of the Elderly to describe the factors that speed up and slow down the disablement processes for older Latinos with dementia
  - Results estimate how many Latinos with dementia need additional support in late life and at which point geriatric public health intervention is most needed

COMMUNITIES, ORGANIZATIONS, AND SYSTEMS

- QUALITY IMPROVEMENT CENTER ON WORKFORCE DEVELOPMENT
  - Anita Barbee (PI), Becky Antle (Co-I), & Martin Hall (Co-I) *DHHS*
  - Research includes efficacy trials to evaluate which workforce interventions are effective to reduce child welfare turnover and enhance child and family outcomes
- YOUTH TRAFFICKING EXPERIENCES STUDY
  - Jennifer Middleton (PI), Maurice Gattis (Co-I), & Laura Frey (Co-I)
  - Survey research measured the scope and prevalence of human trafficking of at-risk homeless youth in Kentuckiana
  - Results showed a prevalence rate of 42% of youth reporting sex trafficking victimization
  - Over ¾ of the sample reported being trafficked at the time of the study
  - Average age of reported entry into sex trafficking was 16 years

COMMUNITIES, ORGANIZATIONS, AND SYSTEMS

- CREATING A TRAUMA RESILIENT COMMUNITY IN LOUISVILLE
  - Jennifer Middleton (PI), Shantel Crosby (Co-I), & Heather Storer (Co-I) with Mayor's Office for Safe and Healthy Neighborhoods
  - City-wide initiative to promote resiliency and equity for Louisville's youth and families disproportionately affected by trauma, systemic inequities, violence, and civil unrest.
  - This project will provide trauma informed system of care capacity building; trauma responsive community, first responder, and referral source education; trauma focused youth and family centered evidence-based interventions; and consumer feedback and evaluation
- OLDER ADULTS IN KENTUCKY PRISONS STUDY
  - Stephanie Prost (PI), Seana Golder (Co-I), & Adrian Archuleta (Co-I) with Kentucky Department of Corrections
  - Longitudinal study to describe the health, quality of life, and justice issues of older incarcerated adults in Kentucky
  - Purpose is to develop programs to increase quality of care, decrease costs, and reduce recidivism among older adults

SOCIAL JUSTICE ISSUES

- *Projects funded by the Collaborative Consortium for Transdisciplinary Social Justice Research*
- TRANSFORMING LEARNING COMMUNITIES
  - Shantel Crosby (PI)
  - A multi-year project supporting teachers of adolescents
- AFRICAN AMERICAN OLDER ADULTS LIVING WITH HIV
  - Lesley Harris (PI)
  - Exploring stress, stigma, and engagement in HIV care
- LGBTQ ADOLESCENT HEALTH IN LOUISVILLE
  - Maurice Gattis (PI)
  - A community based, mixed methods approach to identifying and addressing local priorities
- PROJECT STAAR: SURVIVORS OF TRAFFICKING CREATING ART, AGENCY, AND RESILIENCE
  - Jennifer Middleton (PI), Maurice Gattis (Co-I), & Lesley Harris (Co-I)
- ELUCIDATING THE STORIES OF WELL-BEING AMONG THE WEST LOUISVILLE COMMUNITY
  - Emma Sterrett-Hong (PI)
  - A phenomenological study

QUESTIONS?
CONTACT
BECKY.ANTLE@LOUISVILLE.EDU

Clinical Trials Unit (CTU) Resources

Focus on ResearchMatch

Administrative services

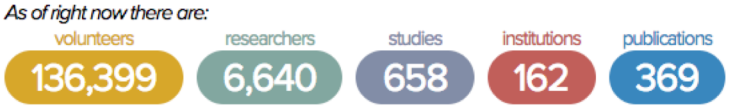
- Feasibility and planning
- Budget development
- Coverage analysis
- Budget negotiation
- Contract submission
- Post-award account management
- Reporting
- Institutional Review Board submission
- Development of Essential documents
- Maintain regulatory file
- Data monitoring and management
- Standard Operating Procedure writing
- FDA submissions
- CAPA and SOP development

Clinical Services

- Sponsor visit coordination
- Source documentation obtention and creation
- Pre-screening, screening, recruitment, and scheduling study subjects
- Subject participation and payment reporting
- Study visit conduct and procedure coordination
- Paper or electronic case report form (CRF) completion
- Drug/device accountability and administration
- Specimen Processing, packing, and shipping
- Clinic/hospital logistics, as needed
- Data query resolution
- AE and SAE reporting

What is ResearchMatch?

- ResearchMatch is a national platform which connects researchers with people interested in research
- The researcher sends IRB approved messages via email to potential participants!
- People that are interested in hearing more about a study release their contact information --- via ResearchMatch --- to the researcher



ResearchMatch.org

National online recruitment platform

info@researchmatch.org

1. Register yourself
2. Register your IRB approved study
3. Create a cohort using the filters
4. Send your IRB approved message via the RM system
5. Reply to everyone that shared their contact information with you!

6. Watch the videos online and take the free webinar training!

Step 1: Potential volunteers register themselves to indicate a willingness to be contacted for research studies. They report demographic, health conditions, and medication information.

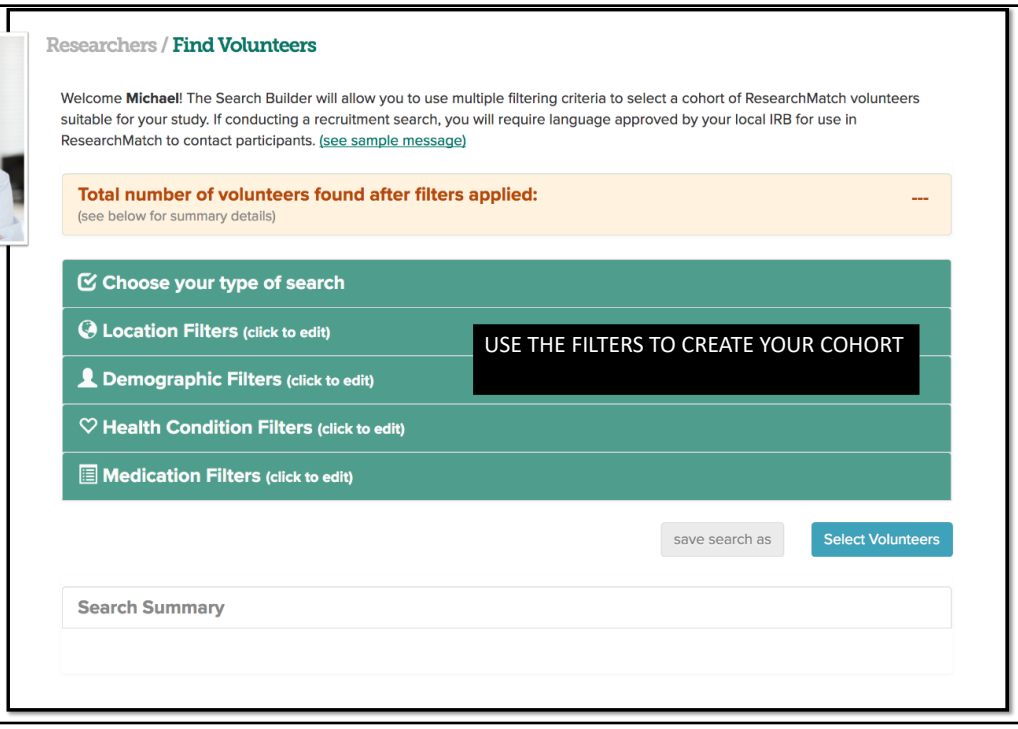
Step 2: Registered researchers search for individuals based on study inclusion criteria and geographical location

Two Types of Access:

Feasibility Access –aggregate information - no IRB required.

Recruitment Access – requires IRB-approved protocol and message.

- IRB of record approved your study
- IRB of record gave you approval to use ResearchMatch
- IRB of record approved the contact message
- IRB of record approved the REDCap survey
- Follow your institutions instructions
- Follow the RM Researcher Agreement



Volunteer has the control over release of information

research match.org

Difficult diseases have met their match.

A research team with University at Buffalo in Buffalo, NY, believes you might be a good match for the following study:

This is a psychological study of behavior in relationships. You will complete some questionnaires assessing your thoughts and feelings about yourself and your relationship. You will also complete a computer game. The study takes approximately 30 minutes and will take place entirely online. In order to qualify for the experiment, you must correctly answer several eligibility questions.

Please complete the study in a quiet, private location. The study must be completed on a computer with a keyboard and mouse (NOT on a smartphone or tablet). To ensure your privacy, please close all browser windows after submitting your responses.

If you are interested in this study and having the research team contact you directly, please select the "Yes, I'm interested" link below. By clicking the "Yes, I'm interested" link, your contact information will be released to the research team. If you select the "No, thanks." link or do not respond to this study message, your contact information will not be released to the research team.

Yes, I'm interested! No, thanks.

Thank you for your interest in ResearchMatch.

ResearchMatch Disclaimer
You are receiving this email message since you have registered in the ResearchMatch registry. Should you wish to edit your profile please click here to login and update your profile.

ResearchMatch is a free and secure tool that helps match willing volunteers with eligible researchers and their studies at institutions across the country. ResearchMatch is only providing a tool that allows you to be contacted by researchers about their studies. ResearchMatch therefore does not endorse any research, research institution, or study. Any recruitment message that you may receive about a study does not mean that ResearchMatch has reviewed the study or recommends that you consider participating in this study.

If you no longer wish to be part of ResearchMatch, please remove your account by clicking here.

CTU Contact Information

- Rachel – 502.852.1006
- Chris – 502.852.2906
- http://louisville.edu/research/ctu

Phone/Fax

- Financial matters: 502-852-3808
- Grants and editing: 502-852-2906
- Investigator questions: 502-852-1006
- Billing questions: 502-852-2604
- Sponsor inquiries: 502-852-1006
- Facsimile: 502-852-2610

Service E-mail Accounts

- Clinical Trials Unit: ctu@louisville.edu
- Financials: ctufin@louisville.edu
- Regulatory: ctureg@louisville.edu
- Clinical Coordinator Pool: ctuclin@louisville.edu
- HIDRA Support: ctuit@louisville.edu

Mentored Career Development (K) Awards

- **K01** Research Scientist Career Development Award

  Transition Ph.D., or equivalently trained, junior faculty to Independence

- **K08** Clinical Scientist Research Career Development Award

  Translational Research

  - Clinical doctoral degree: MD, DO, DDS, DMD, OD, DC, PharmD, DVM
  - PhD or other doctoral degree in clinical disciplines such as clinical psychology, nursing, clinical genetics, speech-language pathology, audiology or rehabilitation

- **K23** Early-career Patient-Oriented Career Development Award

- **K24** Mid-career Investigator Award in Patient-Oriented Research

K-Awards

- 3-5 years of support

- Parent K01-K08-K23 - Independent Clinical Trial Required
- Parent K01-K08-K23- Independent Clinical Trial Not Allowed
  (not all NIH institutes have Parent grants)

- Eligibility: Generally limited to individuals with no more than 6-10 years of postdoctoral/research experience at the time of application

  (It varies between NIH Institutes and programs)

Contact NIH program staff prior to preparing an application to verify eligibility

K25 Mentored Quantitative Research Career Development Award

for investigators with an engineering background outside of biology or medicine who focus their research on basic or clinical biomedical research

Eligibility

- **Candidates with advanced degree in a quantitative area of science or engineering (M.S.E.E., Ph.D., D.Sc., etc.)**
- **Candidates must identify a mentor with extensive behavioral, biomedical, bioengineering, or bio-imaging research experience**

Career Transition Award

K99/R00 Pathway to Independence Award

K99 phase – mentored research (1-2 years)
R00 phase – independent research (R01) support (~ 3 years)

Eligibility: limited to postdoctoral scientists with no more than 4 years of postdoctoral experience

- **Clinical or research doctorate (including PhD, MD, DO, DC, ND, DDS, DMD, DVM, ScD, DNS, PharmD or equivalent doctoral degrees)**
- **Clinicians (including those with MD, DDS, DVM and other licensed health professionals)**

Additional Information on K Award Eligibility

There is NO citizenship requirement for K99 applicants

By the time of K award, the individual must be:

K01
K08
K23
K24
K25

- a citizen the United States or
- a non-citizen national of the United States or
- have been lawfully admitted for permanent residence (*i.e.*, possess a currently valid Permanent Resident Card USCIS Form I-551, or other legal verification of such status)

Scored Review Criteria

1. **Candidate**

   Appropriate prior training and research experience; academic, clinical, and research record; potential for independent research career

2. **Career Development Plan/Career Goals and Objectives**

   Short and long term career goals; formal didactic training; scientific research training; career development activities, milestones and monitoring

2. **Research Plan**

   Significant scientific and technical merit; strong scientific premise, robust and unbiased approach, *etc.*

4. **Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s)**

5. **Environment & Institutional Commitment to the Candidate**

Update on Intramural Grants and the HSCRO

December 2018

HSCRO Grant Navigator Program

- **Funding provided for an additional FTE (our 3rd) by the EVPRI, Dental School and SPHIS**
- **New Grant Navigator hired, starts January 8th**
- **Grant Navigator services will be extended to Dental School and SPHIS**

Jewish Heritage Fund for Excellence

- **JHFE has completed a strategic planning process**
- **Conducted by the Grants Committee of the JHFE**
- **Approved by the Board of JHFE in April 2018**

New Structure to JHFE Funding

- **Investigator initiated grants are eliminated**
- **Funding is increased to $1.2M per year**
- **Funding will be allocated to 2 areas**
  - **Competitive enhancement grants (CEG) and pilot projects**
  - **Recruitment packages for new investigators**
    - **Recruitment funding will be $200,000 allotments.**
    - **Departmental chairs will submit two page proposals**
    - **Final decision will be by Dr. Ganzel**