Johns Hopkins School of Nursing 2022 Research Retreat

December 2, 2022





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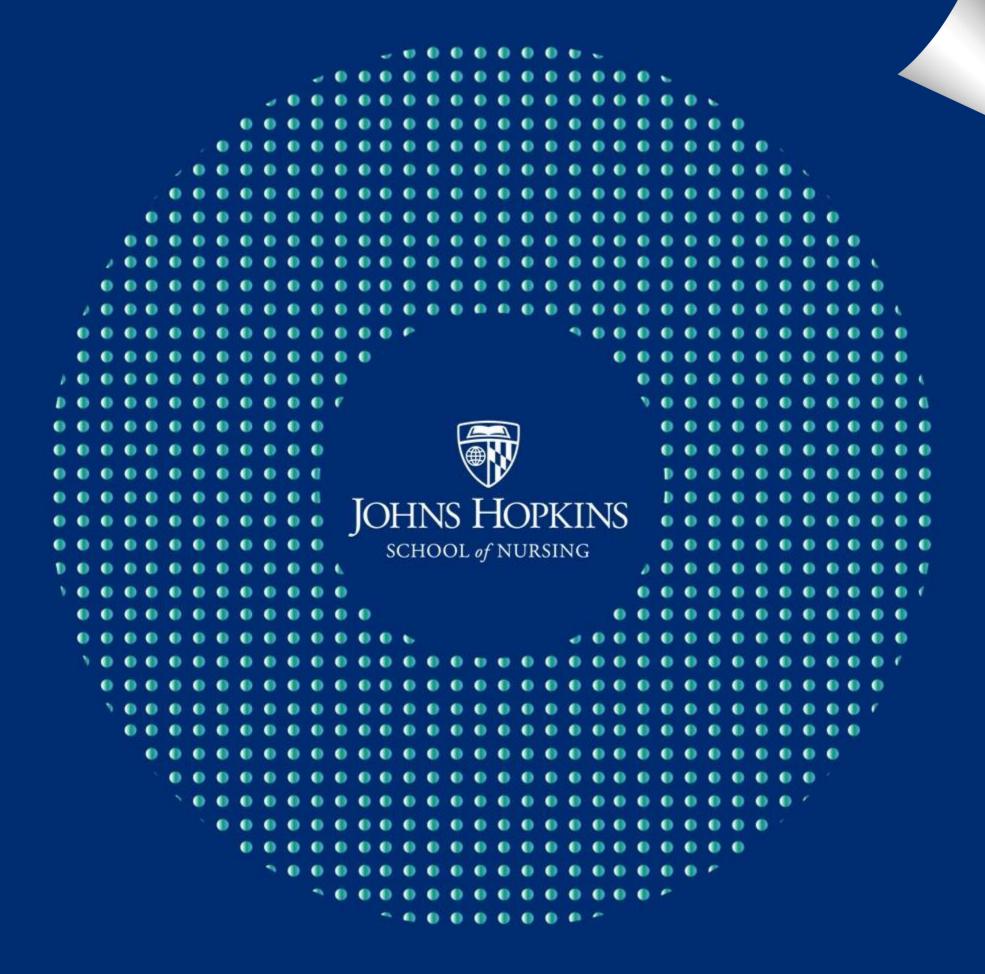
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JHSON Centers

Center for Equity in Aging

nursing.jhu.edu/aging

Center for Equity in Aging



Mission

The Center for Equity in Aging seeks to transform the diverse experiences of aging to enhance equity and well-being across the life course.

We foster collaboration, mentorship and skill development that advances research, education, service, and knowledge translation to scale and sustain initiatives.



The team



Katherine Ornstein

Director



Porscha Reid

Sr. Admin Coordinator



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Strategic Advisor

SON Principal Faculty

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Binu Koirala

Bonnie Swenor

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Kamila Alexander

Kathy McDonald

Katie Marx

Laura Samuel

Lauren Parker

Martha Abshire Saylor

Melissa deCardi Hladek

4.3

Natalie Regier

Nicholas Reed

Quincy Samus

Rebecca Wright

Rita D'Aoust

Valerie Cotter

Research

Develop, implement, and evaluate models of home and community-based care to address pressing public health concerns

Research Training

Mentorship and training opportunities in new approaches to aging research; Post doctoral opportunities

Relationship Building

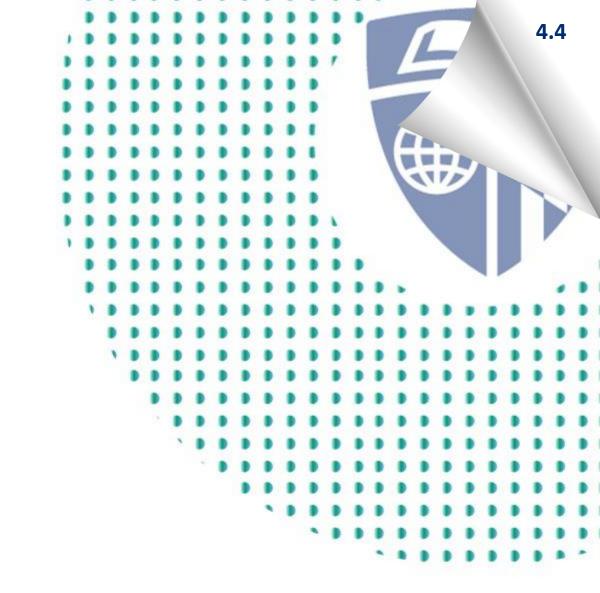
Develop and maintain relationships with aging-related community-based and health organizations to improve interventions

Application of Evidence

Implementation of proven interventions within the community and health care settings

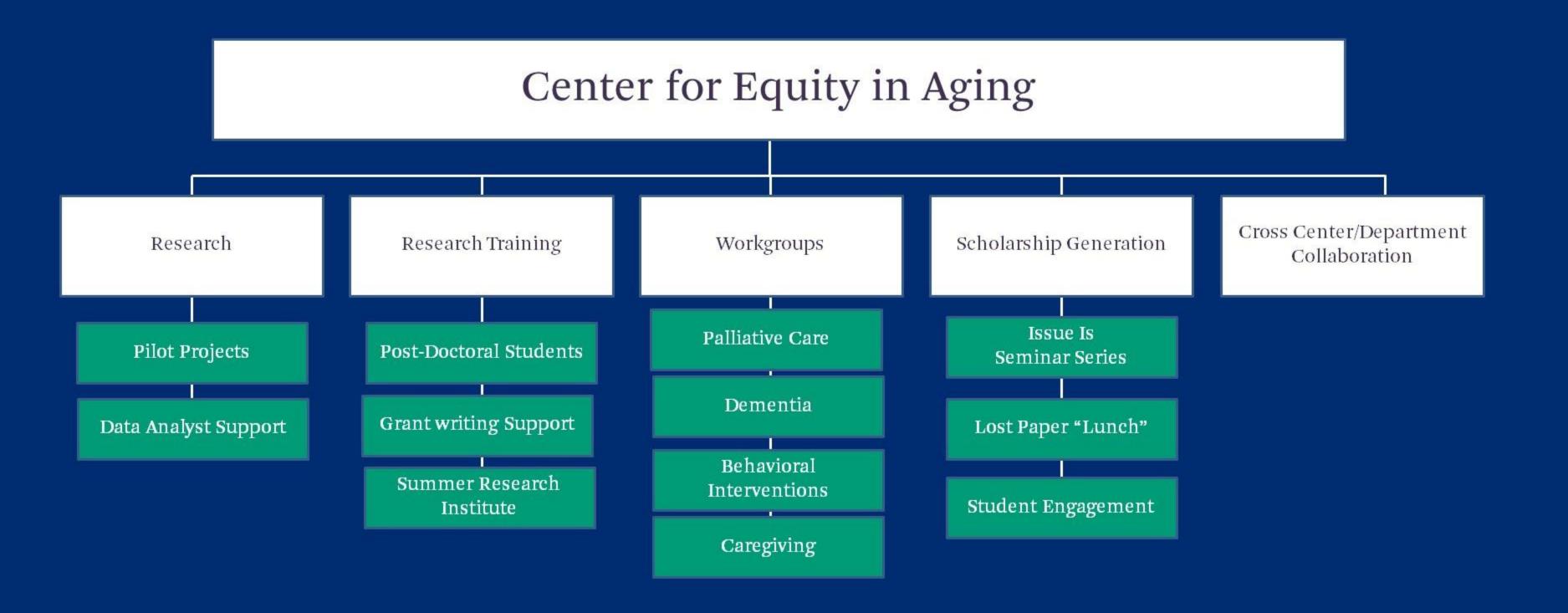
Scholarship Generation

Provide educational and collaborative activities and seminar series focusing on intervention challenges;
Sponsor of lectures from internationally recognized researchers in areas relevant to Center faculty activity



Center Activities

Center Structure



Partner Centers and Departments

Pepper Center

Older Americans
Independence Center
(OAIC)

CoAH

Hopkins Business of Health Initiative

Hopkins' Economics of Alzheimer's Disease & Services Center (HEADS)

Center for Transformative Geriatric Research Johns Hopkins Disability Health Research Center

Lipitz Center for Integrated Health Care Alzheimer's Disease Resource Center For Minority Aging Research Division of Geriatric Medicine and Gerontology, Dept Medicine Health Services and Outcomes Research for Aging Populations Training Program



2021 Pilot Projects

Melissa deCardi Hladek

Using Human-Centered Design to Adapt CAPABLE as a Prehabilitation Intervention for Adults with Frailty Awaiting Kidney Transplant

Safiyyah Okoye

Housing Predictors of Adverse Consequences of Unmet Care Needs Among Low and Moderate Income Older Adults with Disabilities

Junxin Li

The Power of Sound ---40 Hz Smart Music for Older Adults

Kate Perepezko

Evaluating the role of the caregiver in the quality of life of people with Parkinson's disease:
Opportunities for intervention

Mengchi Li

Wearable Activity Device Use and Physical Activity under the COVID 19 Pandemic in Older Adults

Laura Samuel

A natural experiment of the SNAP minimum benefit increase for older adults

Upcoming Activities

Resources

Data Analyst Support **Funding**

Pilot Grants

Activities

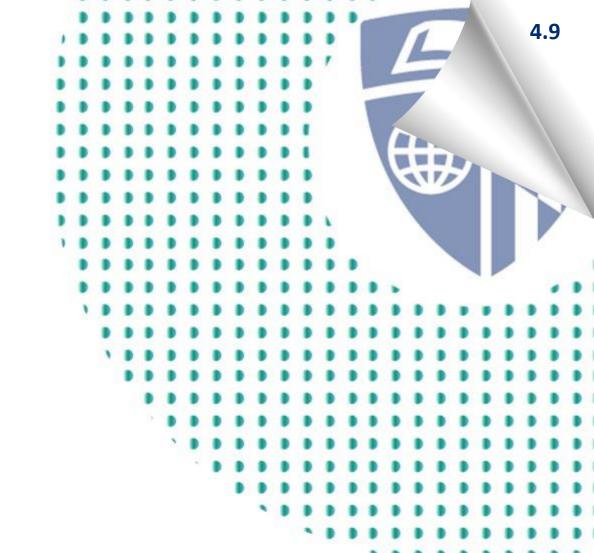
Issue Is first Tuesday of the month

Tell us!

TBD

Lost Article Lunch quarterly

Design Lab monthly





https://nursing.jhu.edu/excellence/aging/center/

AgingCenter@jhu.edu

Connect with us!

Center for Global Initiatives

nursing.jhu.edu/global

Center for Immersive Learning and Digital Innovation

nursing.jhu.edu/cildi

CENTER FOR IMMERSIVE LEARNING AND DIGITAL INNOVATION

Mission

The center for Immersive Learning and Digital Innovation at the Johns Hopkins School of Nursing will foster the development of an internationally recognized immersive learning and digital innovation ecosystem, leveraging technology to enhance the overall mission of the Johns Hopkins University School of Nursing.

Vision

Our vision is to be a global leader in innovative simulation, virtual and augmented reality, and artificial intelligence-enabled solutions to advance nursing and interdisciplinary education and healthcare delivery to promote patient safety.

3 Domains of Innovation



To learn more about the research potentials within CILDI, please go to https://nursing.jhu.edu/excellence/quality-safety/technology/cildi/index.html

To utilize equipment, manpower, and space for your research, please fill out the request forms at https://nursing.jhu.edu/excellence/quality-safety/technology/cildi/cildi-request-forms.html

The pricing model for faculty/student-led research activity is available at https://nursing.jhu.edu/excellence/quality-safety/technology/cildi/documents/JHSON-CILDI-A-LA-CARTE-RATES-FY23.pdf

Do not forget to indicate your request to use CILDI resources in your intent to submit application through NORA.

Center for Infectious Disease and Nursing Innovation

CIDNI.org

Clinical Translational Laboratory

PRECEDE Biomarkers Laboratory

Promoting Resilience through Emerging Clinical and Evolving Determinants of Equity

Director of the Clinical Translational Laboratory: Chelsea Wagner, MS

> chelseawagner@jhu.edu (410) 502-6078

Principal Investigators:

Dr. Jessica Gill

Dr. Jennifer Wenzel

Dr. Cheryl Himmelfarb

Dr. Nada Lukkahatai

Dr. Junxin Li

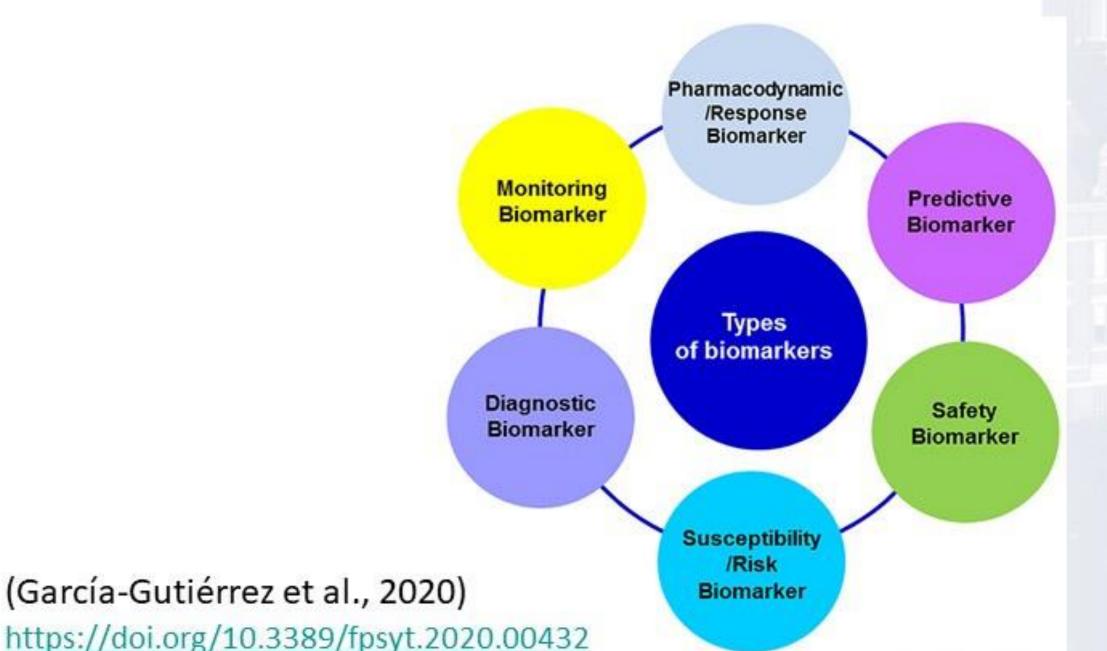
Dr. Melissa deCardi Hladek

Dr. Martha Abshire Saylor
Dr. Jason Farley
Dr. Yeabsira Tufa

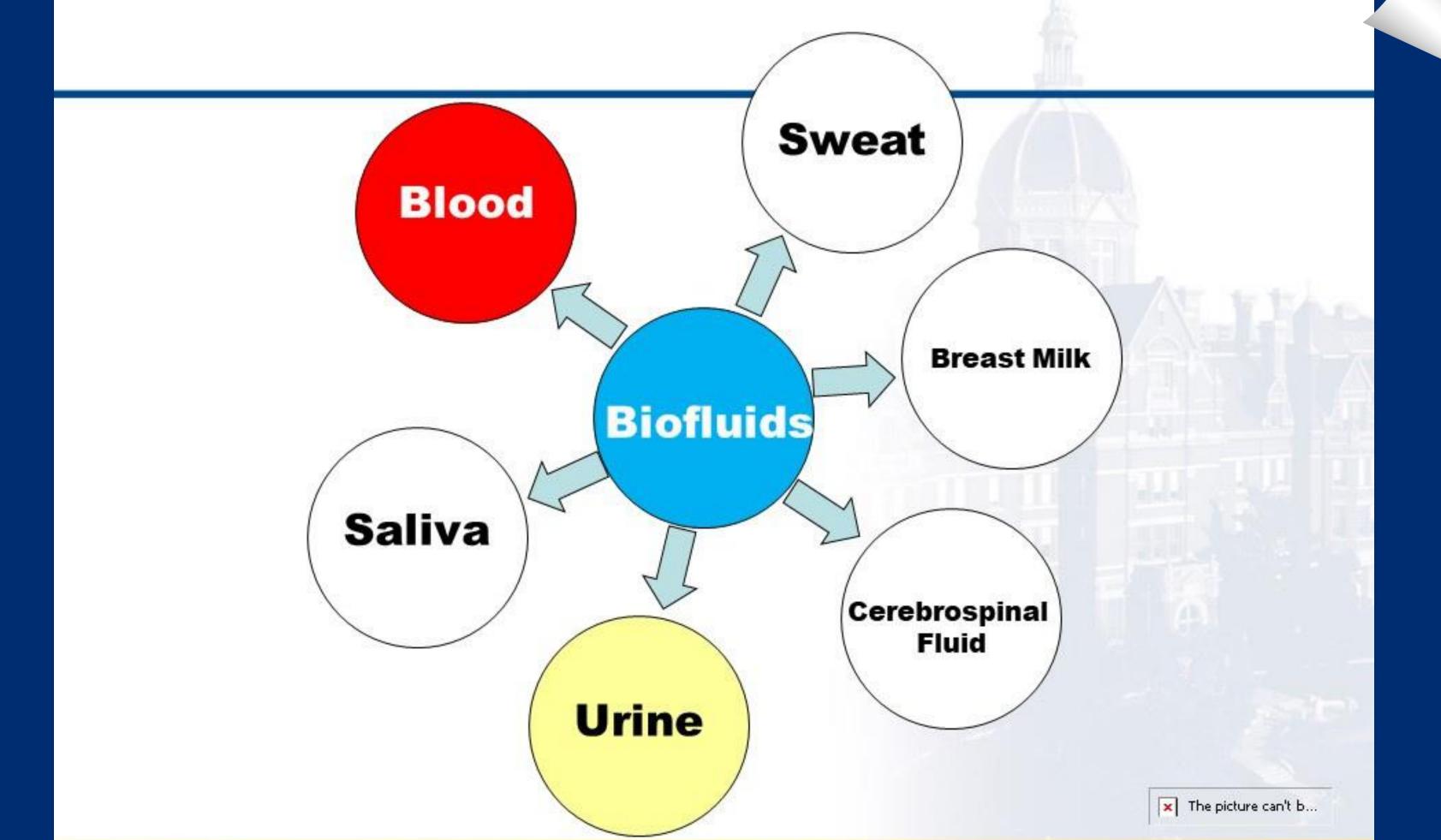
The picture can't b...

What are biomarkers?

 Biomarkers: A defined characteristic that is measured as an indicator of normal biological process, pathogenic process or response to an exposure or intervention (FDA-NIH Biomarker Working Group)



What can we measure?



Protein Quantification Instruments

96 Well Plate

Quanterix HD-X™ Automated Immunoassay Analyzer



Simoa HD-X Benefits

Ultra-sensitivity – Up to 1000x greater sensitivity than traditional immunoassays

Automation – Reproducibility and convenience of sample->answer workflow

Multiplexing - Measure up to 6 biomarkers in single sample at fg/ml concentrations

Flexibility – Supports both highthroughput and rapid result workflows

Efficiency – Precise control of assay conditions allows for use of stored assay calibration values

Menu – Fully compatible with 80+ assays also available on HD-1 as well as customized homebrew assays

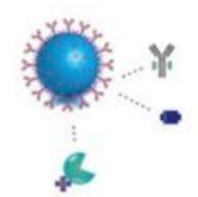
Regulatory Compliance – Enables 21CFR Part 11 compliance with streamlined run reports and user management

×

The picture can't b...

Quanterix HD-X™ Automated Immunoassay Analyzer Process

Paramagnetic particles coupled with antibodies designed to bind to specific targets are added to the sample.



2

Detection antibodies – capable of generating fluorescent product – are added.



3

The objective is to form an immunocomplex consisting of the bead, bound protein, and detection antibody.



At low concentrations, each bead will contain one bound protein, or none.



Quanterix HD-X™ Automated Immunoassay Analyzer Process

5

The sample is loaded into arrays, in the Simoa disc, consisting of more than 200,000 microwells – each large enough to hold one bead.



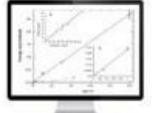
Data analysis – results can be viewed and analyzed on the board or exported to commonly used software packages or LIMS systems.

6

Enzymatic signal amplification with fluorescent substrate, fluorescence imaging and data reduction.







November 28, 2022

6

Protein Quantification Instruments

 Ultra-sensitive assay with up to 10-plex multiplexing scale and flexibility

SP-X Imaging and Analysis System™

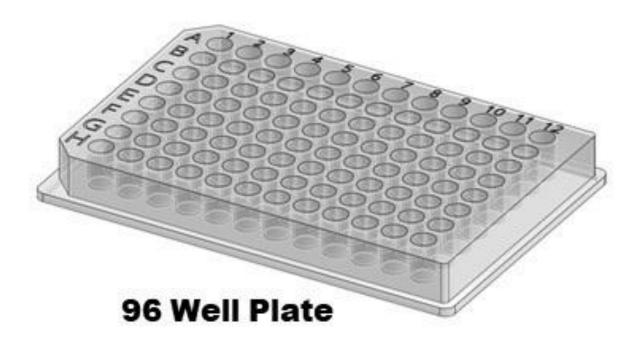
Unleashing the power of next-generation Simoa® Planar Array technology for robust multiplex biomarker detection – even at healthy baseline levels.

1000x

10 in 1

100 +

Up to 1000x greater sensitivity Up to 10 blomarkers in a single assay Compatible with 100+ assays





The picture can't b...

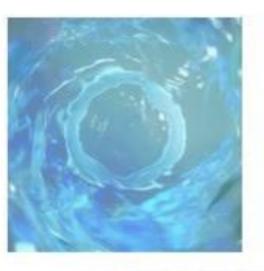
Quanterix SP-X™ Automated Immunoassay Analyzer Process

96-well plates are spotted at the factory with the target analyte(s) of interest



2

Diluted samples and standards added to each well and the plates are to create a unique surface chemistry and "vortex" effect



3

Biotinylated detection antibodies are added to form the other half of the immunocomplex "sandwich"



Quanterix SP-X™ **Automated Immunoassay Analyzer Process**

High sensitivity HRP enzyme-conjugated streptavidin is added in between additional shake cycles.



Finally, a chemiluminescent substrate is added just prior to ultra-sensitive CCD camera imaging, in order to measure the signal intensity produced by each spot.



Protein Quantification Instruments

Utilizes a very sensitive, high-resolution CCD camera and lens system to detect light emitted from MULTI-ARRAY® and MULTI-SPOT® plates.

The custom-designed lens enables highly efficient and uniform collection of electrochemiluminescen ce (ECL) generated light.

Broad Assay Menu

- · Large menu of commercially available kits
- · Full line of components for user-developed assays
- Access to all product lines for MSD® consumables

Flexibility

- · Single and multiplex assays
- Compatible with all SECTORTM and QuickPlex® products
- · Special pricing for academic customers

Validated

96 Well Plate

- Developed under design control
- · Microsoft Windows 10 compatible
- Simple, fast, and secure data analysis with DISCOVERY WORKBENCH® software





MESO QuickPlex SQ 120MM

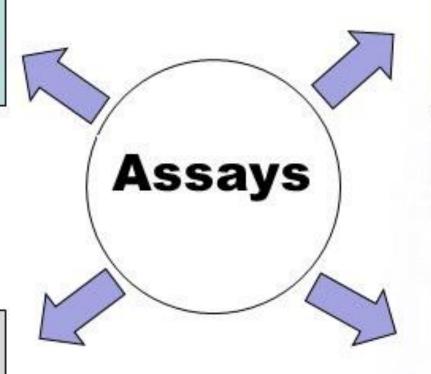
Meso Scale Discovery Technology

The picture can't b...

What can we measure?

Neurology

- Phosphorylated tau (i.e., 181, 231)
- Total Tau
- Neurofilament Light (NfL)
- Amyloid Beta (40, 42)
- Glial Fibrillary Acidic Protein (GFAP)



Immunology/Inflammation

- C-reactive protein (CRP)
- Cytokines Panel (TNF-alpha, IL-6, IL-10, IL-8, IL-1beta)
- VEGF

Oncology

- Programmed cell death protein
 1 (PD-1 or CD279)
- Angiogenesis Factor Panel 1 (ANG-2, FGFB, HB-EGF, HGF, PLGF, VEGF)
- Osteopontin (OPN

Cardiology

- Troponin I
- Troponin T
- Myosin binding protein C
- Heart-type fatty acid binding protein

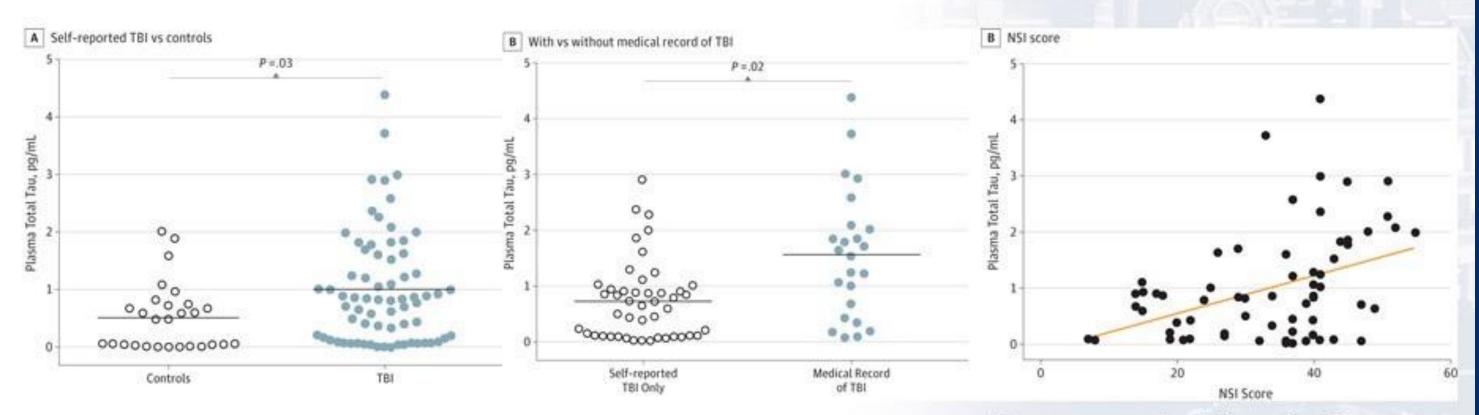
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Scientific Publications

Original Investigation

Peripheral Total Tau in Military Personnel Who Sustain Traumatic Brain Injuries During Deployment

Anlys Olivera, PhD; Natasha Lejbman, BS; Andreas Jeromin, PhD; Louis M. French, PsyD; Hyung-Suk Kim, PhD; Ann Cashion, PhD; Vincent Mysliwiec, MD; Ramon Diaz-Arrastia, MD, PhD; Jessica Gill, RN, PhD



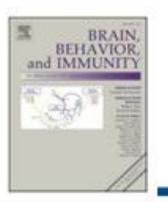
Postconcussive Disorder Symptoms

ELSEVIER

Contents lists available at ScienceDirect

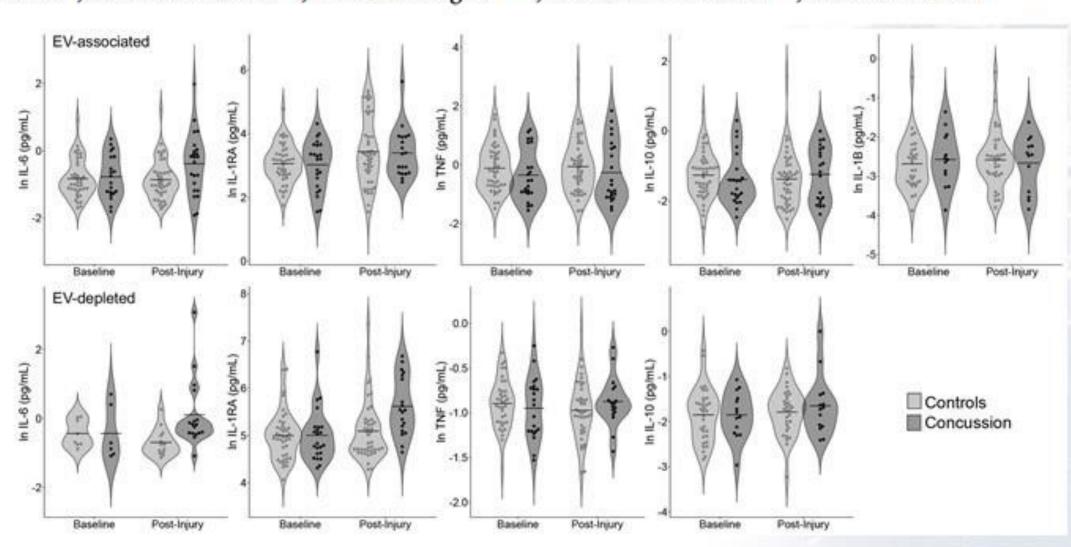
Brain Behavior and Immunity

journal homepage: www.elsevier.com/locate/ybrbi



Extracellular vesicle-associated cytokines in sport-related concussion

Timothy B. Meier a, b, c, 1, Vivian A. Guedes d, 1, Ethan G. Smith d, Dilorom Sass d, Sara Mithani d, Rany Vorn d, Jonathan Savitz e, f, T. Kent Teague s, h, i, Michael A. McCrea a, j, Jessica M. Gill d





Nucleic Acid Quantification Instruments

nCounter Pro Analysis System



nanostring.com

FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES.

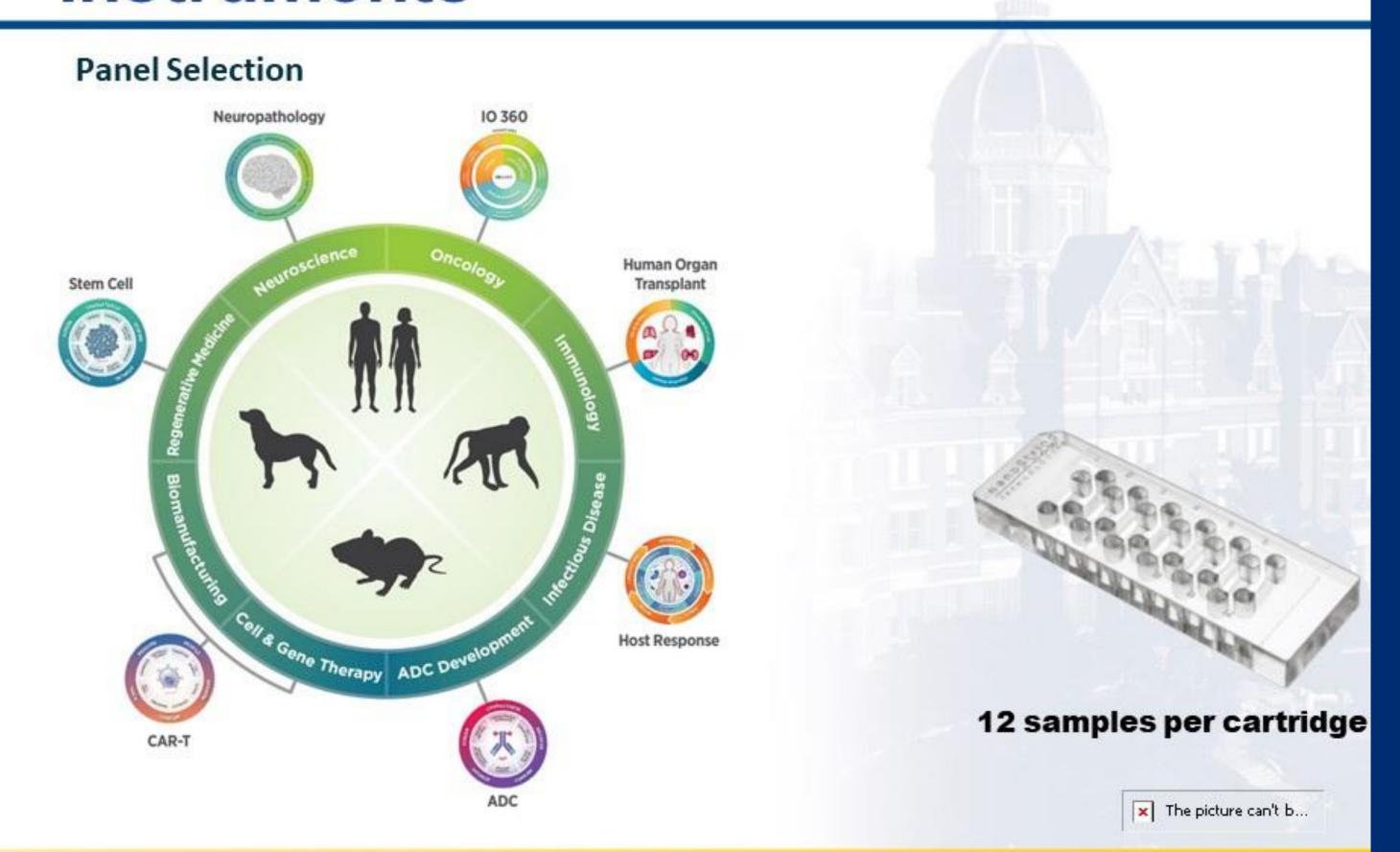
nanoString

800+ targets (messenger RNA and microRNA)

12 samples per cartridge

The picture can't b...

Nucleic Acid Quantification Instruments







Article

Exosomal microRNA Differential Expression in Plasma of Young Adults with Chronic Mild Traumatic Brain Injury and Healthy Control

Rany Vorn ¹, Maiko Suarez ², Jacob C. White ³, Carina A. Martin ¹, Hyung-Suk Kim ¹, Chen Lai ¹, Si-Jung Yun ⁴, Jessica M. Gill ^{5,6} and Hyunhwa Lee ^{7,*}

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- Correspondence: hyunhwa.lee@unlv.edu



ORIGINAL RESEARCH

published: 06 October 2021 doi: 10.3389/fphar.2021.745348



Extracellular Vesicle Proteins and MicroRNAs Are Linked to Chronic Post-Traumatic Stress Disorder Symptoms in Service Members and Veterans With Mild Traumatic Brain Injury

Vivian A. Guedes¹, Chen Lai¹, Christina Devoto^{1,2}, Katie A. Edwards¹, Sara Mithani¹, Dilorom Sass¹, Rany Vorn¹, Bao-Xi Qu^{1,3}, Heather L. Rusch^{1,2,4}, Carina A. Martin¹, William C. Walker⁵, Elisabeth A. Wilde⁶, Ramon Diaz-Arrastia⁷, Jessica M. Gill^{8,9} and Kimbra Kenney^{8,10}*

OPEN ACCESS

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Questions?



COMPASS Center

nursing.jhu.edu/COMPASS



Center for Community Programs, Innovation, and Scholarship (COMPASS)

Hae-Ra Han, PhD, MSN, RN, FAAN

Professor & Elsie M. Lawler Endowed Chair Associate Dean for Community Programs and Initiatives

D. Layne Humphrey, MSEd. COMPASS Center Manager



Vision:

To promote health and wellness, and reduce health inequities among low-income, uninsured or underinsured populations in Maryland.

Mission:

To create, implement, and evaluate programs that involve faculty and students in nurse-led community care, service-learning, research, scholarship and advocacy in collaboration with the community and other stakeholders including Johns Hopkins Medical Institutions, Johns Hopkins University entities, community-based organizations, business leaders, and health care organizations.

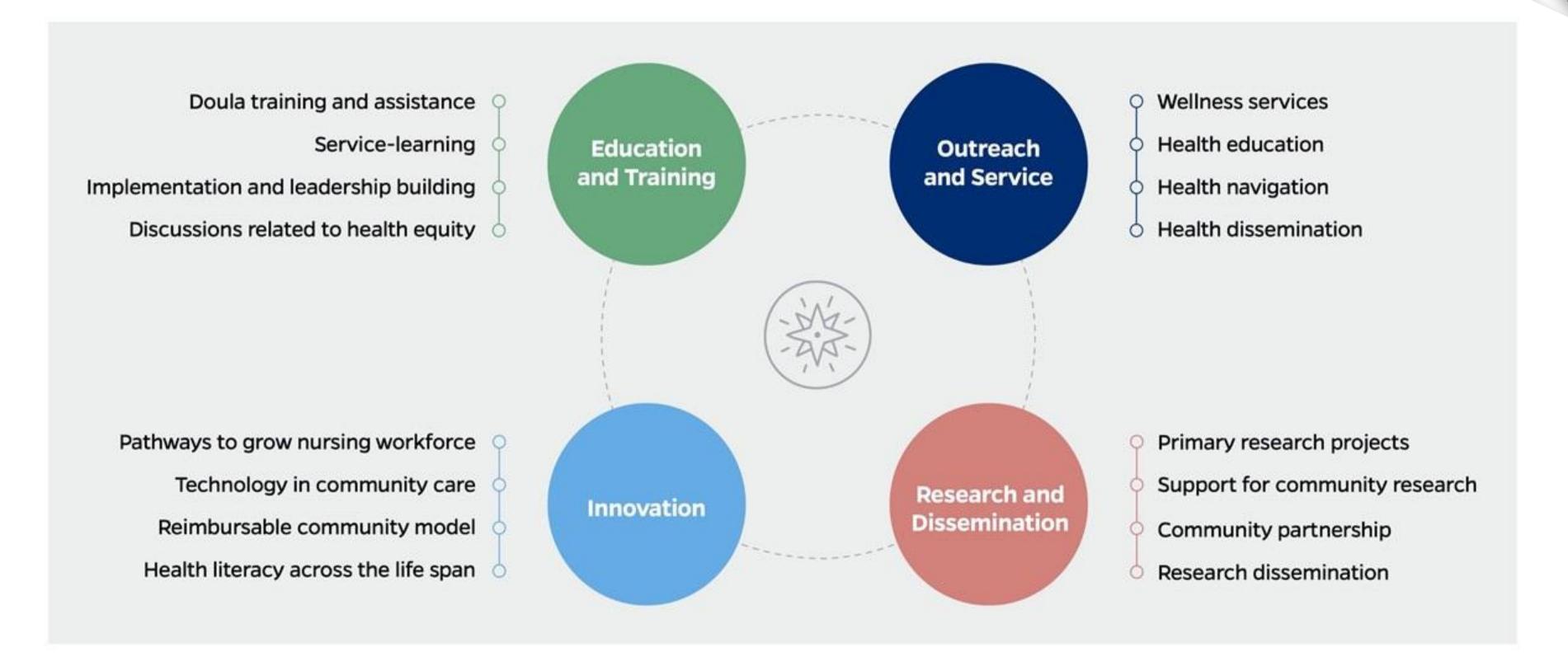
Values:

Diversity, Integrity, Accountability, Respect, Excellence

Health Equity Primary Area of Focus/Target Populations:

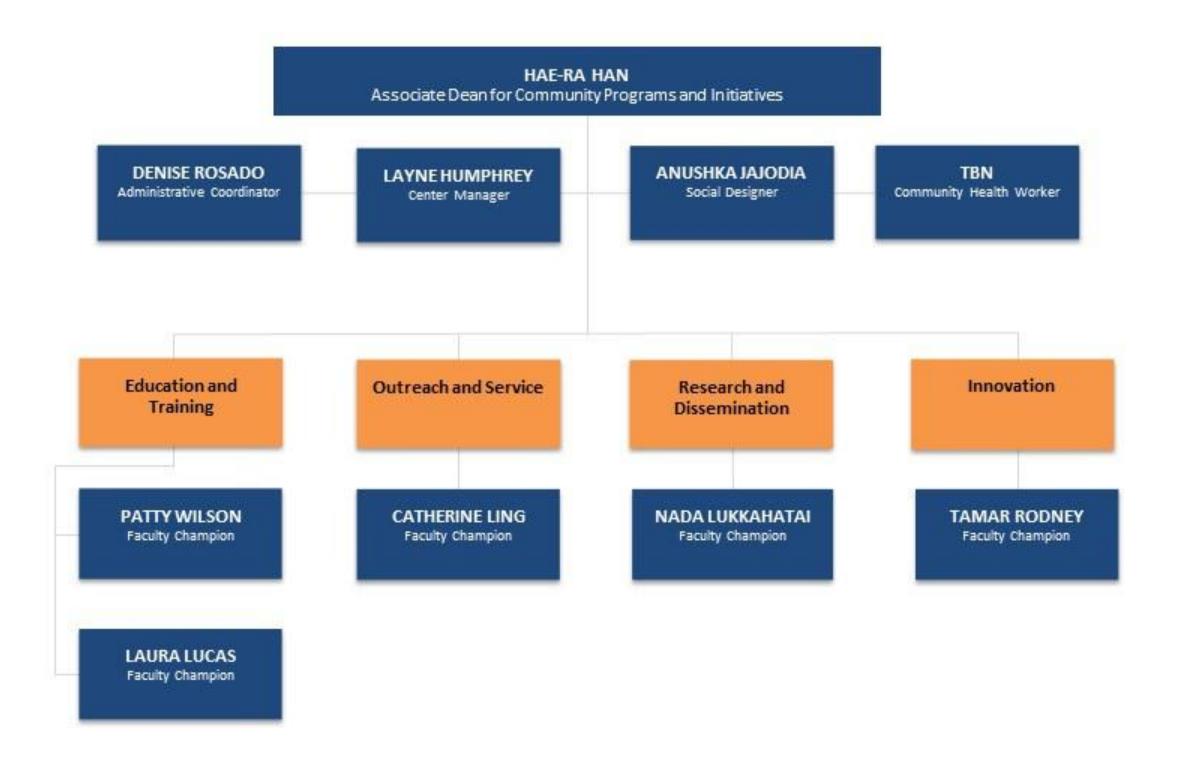
Social determinants of health, mental health, chronic care, wellness, health literacy Residents in Maryland/Underserved populations

For more information visit: https://nursing.jhu.edu/excellence/community/center-community-innovation-scholarship.html





Faculty and Staff Leadership





HAE-RA HAN PHD, MSN, RN FAAN Professor

Associate Dean for Community Programs and Initiatives

Elsie M. Lawler Endowed Chair



PATTY WILSON
PHD, MSN, RN
PMHNP-BC
Assistant Professor



LAURA LUCAS DNP, MS, RN APRN-CNS, RNC-OB, C-EFM Assistant Professor

Associate Director for Clinical Practice, MSN (Entry into Nursing) Program



PHD, FNP-BC CNE, FAANP, FAAN Associate Professor



NADA LUKKAHATAI PHD, MSN, RN FAAN Assistant Professor

Director of the MSN (Entry into Nursing) Research Honors Program



PHD, MSN, RN
PMHNP-BC, CNE
Assistant Professor

DNP Advanced Practice Psych Mental Health Track Coordinator



DENISE ROSADO BS

Administrative Coordinator



MSEd HUMPHREY

Center Manager



ANUSHKA JAJODIA MA

Social Designer



VERONICA LEE BSN, RN

Community Fellow



OPHELIA DAPAAH-GYIMAH FNP-BC, RN

Community Fellow

Examples of Ongoing Projects

- Project 1: Passport2Freedom (PI—Dr. Patty Wilson)
 Target population—Women and children in transitional housing
 Summary—Intervention to deliver and test a model of mindfulness and stress management in the target population
- Project 2: Ask-A-Nurse (PI—Dr. Catherine Ling)
 Target population—Adults 18+ years with limited access to care
 Summary—Development and testing of a wrap-around case management program to address social determinants and chronic care
- Project 3: Nurse-led Reimbursable Care Model (Dr. Tamar Rodney)

Community Engagement Opportunities

Partnering Community Based Organizations:

- SOURCE
- ICTR
- Day at the Market
- House of Ruth Maryland, etc.

Examples of Service-Learning Experiences:

 Community Flu Vaccine Clinics ('20,'21) – Day at the Market @NorthEast Market, Henderson-Hopkins School, Isaiah Baptist Church

Desired Skillsets or Other Requirements:

Prefer students pursuing a degree in health-related fields













Serving East Baltimore since 1994

To learn more, follow us on twitter! @JHUSON_COMPASS

CENTER IMPACT

2016-2020

3692 encounters **79** Henderson-**Hopkins School** D. Wald encounters Community Nursing House of Ruth Center encounters 歸 COMPASS Center 0 四 672 Day at Birth X the Market Companions births attended COP

384
new birth
companions
educated

265 students 5461 no. of hours worked 22 avg no. of community agencies per year



Leading the way in education, research and practice - locally and globally.

RESILIENCE Center

nursing.jhu.edu/resilienceRRTC







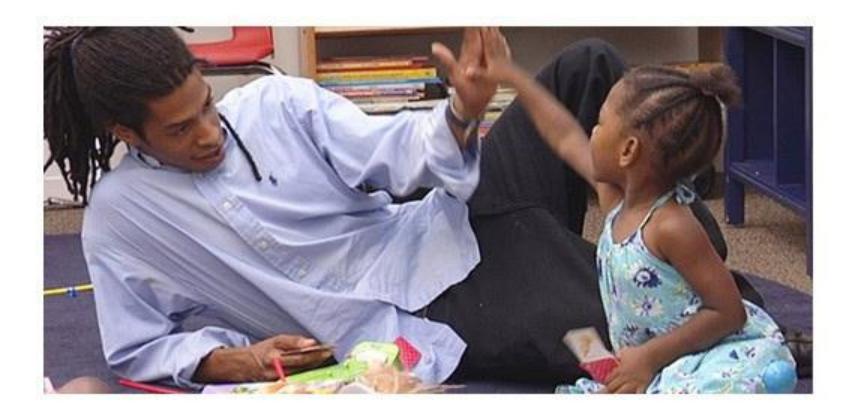
THE RESILIENCE CENTER

Research and Education to Support the Science of Independent Living for Inclusion and Engagement



Our Mission

Improve the health and function of people with disabilities and their caregivers by adapting and scaling two award winning evidence-based programs for children and older adults with disabilities (Chicago Parent Program and CAPABLE)





Design new approaches using key attributes of effective and sustainable programs to ensure program effectiveness, relevance, utility, and scalability.



Our Team



Dr. Sarah SzantonFounding Director



Dr. Janiece TaylorDeputy Director

Dr. Deborah Gross

Director



Alicia Cooke Center Program Coordinator



Brian Fitzek Knowledge Translation Specialist



Kennedy McDaniel Design Strategy Manager



Porscha Reid Senior Admin Coordinator



Our Research: Across the Life Court

Chicago Parent Program

July 2021 – July 2023





Designed With You

July 2022 – July 2024

CAPABLE Family

July 2020 – July 2023



CAPABLE Kids

July 2022 – July 2024

CAPABLE Care Partner
July 2020 – July 2025



Our Research: Our Approa

CENTER APPROACH

In designing ways for people with disabilities and their caregivers to fully participate in the community, this Center utilizes the **Society to Cells Resilience Framework** and **Human-Centered Design** to build on inherent strengths rather than only addressing deficits and stressors.

SOCIETY TO CELLS RESILIENCE FRAMEWORK

This framework (Szanton & Gill, 2010) posits that society, community, family, and individual factors can promote resilience. Families and communities can develop increased capacity through a particular challenge or life situation (such as caregiving) that they can later generalize and apply in other situations.

HUMAN-CENTERED DESIGN

Human-centered design mindsets and methods are used throughout the research projects lifecycle and to build sustainability into the outputs. Human-centered design is explicitly based on the premise that lived experience is a valuable form of expertise and therefore, people who have direct experience with a disability or health condition and its broader impact on daily life should play a decision-making role in the design of services, products, and approaches to improve their health and wellbeing.



Our Outreach: Built to Scale

seminar series



Built to Scale series explores challenges and successes in scaling evidence-based health interventions for maximum impact.

Sessions brings participants into conversation with leaders in the field, drawing on their experience to gain inspiration and guidance for scaling programs for maximum impact.



Our Outreach: Building for Scale Schol



Program Highlights

Six month program for researchers in the early stages of designing/adapting an innovation or intervention that meet the needs of individuals and families in the disability community.

Scholars participate in intensive learning experiences, including customer discovery and human-centered design.



Stay Connected with



Website:

https://nursing.jhu.edu/excellence/mental-health/resilience-rrtc/



Email:

SON-RESLIENCECenter@jhu.edu

NORA Resources

Human-Centered Design

Schedule your HCD Consultation today!



calendly.com/kennedymcd

Human-Centered Design

Human-Centered Design (HCD) is a creative and collaborative process used to understand and define problems, identify opportunities, generate ideas, and design interventions that support change.

HCD starts with the people you're designing for and ends with new solutions tailored to meet their needs. We center <u>people</u> with lived throughout the design process and view their lived experience as expertise!



Image Source: National Equity Project

WHY USE HCD?

- To build empathy among research team
- To increase equity, inclusion, and opportunities for cocreation in research
- To find deeper insights and innovative solutions

Here's how we can support your research:

- 1-on-1 HCD consultations
- Design strategy and support for research projects
- HCD workshops for research teams
- HCD templates and resources

Let's Connect!

If you're interested in learning more about HCD and how to use it in your research, please contact our Design Strategy Manager, Kennedy McDaniel:



Biostatistics and Methods Core

https://nursing.jhu.edu/faculty_research/research/nora/biostatistics.html



Biostatistics and Methods Core

NORA



Members

- Nancy Perrin, Director
 - Longitudinal data analysis
 - Quasi-experimental design and analyses
 - Psychometrics



- Chakra Budhathoki, Faculty
 - Randomized Controlled Trials
 - Meta-analysis
 - Mixed modeling









- Multilevel regression
- Factor analysis
- Cluster analysis
- Social network analysis
- Eric Slade, Faculty
 - Administrative data analysis
 - Causal inference using observational data
 - Cost-benefit and cost-effectiveness analysis





Wura Olawole, Research Analyst

- Data management
- Descriptive analysis
- Inferential analyses: Regression and classification modeling



- PhD student to assist students enrolled in the SPH Biostatistics courses
- Support Dissertation Data Analysis Clinic





Services

Grant Proposals

- Align aims, methods, and analyses
- Conduct preliminary studies analyses, if needed
- Conduct power analyses
- Write the analysis section of proposals
- Review the budget to ensure support for data management, data cleaning, and analyses
- Expectation is that the Biostatistics Core faculty member will be included as a Co-Investigator



Manuscripts and Presentations (based on unfunded requests)

- Basic consultation on analysis approach
- Work is assigned to a Biostatistics Core member based on interest, expertise, and workload
- Analysis support by research analyst if funds identified for a limited scope of work
- Attend a data analysis workshop



Data Analysis Workshop

- Multi-day workshop for people who are ready to start data analysis
- Each person is assigned to work with a biostatistician to help them conduct the analyses during the workshop



PhD Proposal/NRSA

- Each student is assigned a Biostatistics Core member to work with on the proposal
- The Student, Advisor, and Biostatistician will reach agreed upon aims, research design, and analysis plan
- Help with power analyses, writing of the analysis section
- Please start working with biostatistician at least 45 days prior to the submission date



Dissertation Analysis Support

- Student should participate in the data management training prior to working on their analyses (available online)
- Dissertation Data Analysis Clinic
- Basic consultation with biostatistician or research analyst



Dissertation Data Analysis Clinic

- Drop-in clinic
- Help with programming (STATA, R, SPSS, SAS)
- Help with interpretation of results
- Build community with other students as they work on data analyses

Data management and post award support

- Usually there is a Biostatistics Co-Investigator on the grant that leads the analysis
 - If none then basic consultation
- Also need trained research analyst to join the team
 - Biostatistics Core can help identify people to hire on the grant



Biostatisticians' Goals When Working with You

- Enhance the integrity and validity of your study
- Work with you to ensure the design has strong internal validity, and if possible, external validity
 - Specific aims
 - Measurement quality
 - Sampling plan
 - Randomization procedures
 - Data management
 - Statistical power
 - Appropriate analyses
- This means we have to have a very good understanding of your study



Start Working with Us Early and Always!

- Early in proposal development stage is the best
- Studies have problems, that is okay
 - Definitely consult with a statistician before making changes and hoping for the best
 - If a biostatistician is an active collaborator on the project, they can sometimes see trouble ahead and help to prevent or alleviate it



Research Design and Analysis Seminars

- Monthly seminars
 - Data management
 - Mediators and Moderators
 - Adaptive Trials
 - Pragmatic Trials
 - Cluster Randomized Trials
 - Observational Methods
 - Measurement

- PROMIS measures
- Multilevel modeling
- Handling confounding
- Predictive modeling
- Meta-analysis
- Secondary data analysis
- Network analysis

If there is a topic you are interested in – let us know!



All seminars are recorded and available on demand on the Biostatistics and Methods Core web site

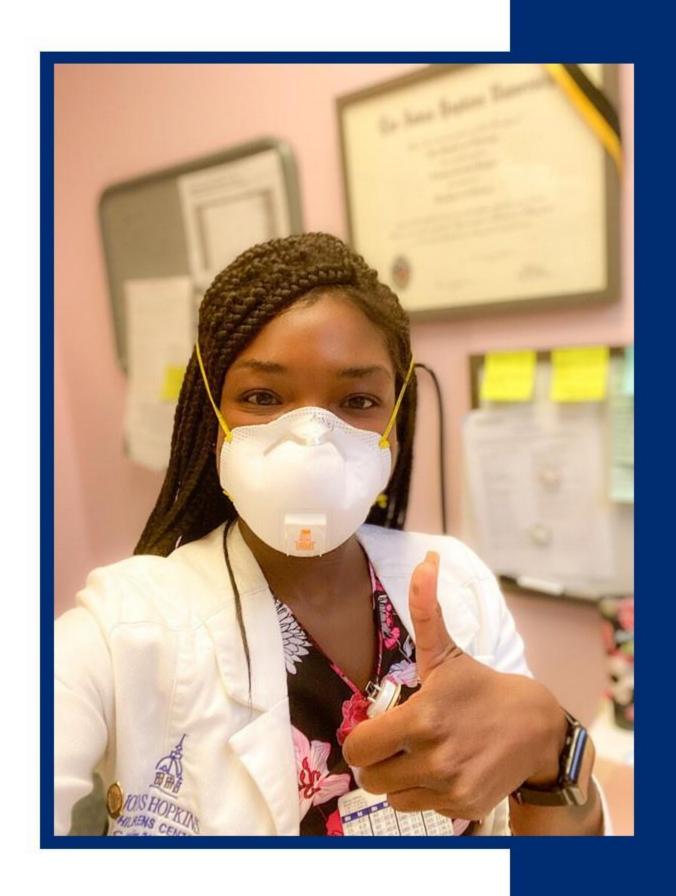
https://nursing.jhu.edu/faculty_research/research/nora/biost atistics.html



Leading the way in education, research and practice - locally and globally.

Nursing Office for Research Administration (NORA)

nursing.jhu.edu/NORA



Nursing Office for Research Administration (NORA)

Cheryl Himmelfarb, PhD, RN
Vice Dean for Research and
Sarah E. Allison Endowed Professor

Javonnia Thomas
Associate Director



Research Key Functions

Research Administration and Monitoring

- SON Research Council
- Metrics (grants, publications, rankings)
- Research / Conflict of Interest / Outside Interest Compliance

Sponsored Projects
Oversight

- Pre-award management
- Post-award management

Scholarship and Research Development

- Methods Core (Qual / Quan), editorial services
- Workshops, internal scientific review, speed aims review, retreats
- Faculty Interest Groups, Assist. / Assoc. Prof Dev Groups
- Internal grants program (DEL, Discovery & Innovation)

Integration of Research Across Programs

- Research Honors Program
- NRSA Bootcamp
- JHSON Research Grand Rounds Series

Internal and External Collaborations

- Key committees, centers and institutes across JHHS / JHU
- External presence / opportunities



Pre-Award Proposal Processing: Intent to Submit \rightarrow Submission

8 Weeks
Prior to Sponsor
Due Date

6 Weeks
Prior to Sponsor
Due Date

4 Weeks Prior to Sponsor Due Date 2 Weeks
Prior to Sponsor
Due Date

5 Full Business Days
Prior to Sponsor
Due Date

- ✓ Complete Intent to Submit (ITS) Form
- ✓ Schedule Internal Scientific Review

- ✓ Meet with assigned Sr. GCA with prepared budget assumptions
- ✓ Confirm consortium arrangements if applicable
- ✓ Complete Internal Scientific Review
- ✓ Submit Biosketches for Review
- ✓ Finalize budget and budget justification with Sr. GCA
- ✓ Final consortium documents due if applicable

- ✓ Submit all final documents to Sr. GCA
- ✓2 Full Business Days for Sr. GCA Review, 3 Full Business Days for JHURA Review
- ✓ PIs must be available for questions



The NORA Team <u>SON-NORA@jhu.edu</u>

Javonnia Thomas	Associate Director
Adrianna Dunnock	Sr. Grants & Contracts Analyst
Nicole Fowlkes	Sr. Grants & Contracts Analyst
Lori Dempsey	Sr. Grants & Contracts Analyst
Carolynn Lodge (Starts Sept. 2022)	Sr. Grants & Contracts Analyst
Gerren Toliver	Sr. Grants & Contracts Analyst (Part-time)
Kimberly Hill	Research Start-Up Specialist
Andrea Mansfield	Administrative Program Coordinator
Nancy Perrin	Director, Methods and Biostats Core
Chakra Budhathoki	Biostatistician Consultant
Ginger Hanson	Biostatistician Consultant
Wura Olawole	Data Analyst
Jennifer Wenzel	Qualitative Methods Consultant
Rebecca Wright	Qualitative Methods Consultant
Janiece Taylor	Qualitative Methods Consultant
Catherine Ling	Qualitative Methods Consultant
Kamila Alexander	Qualitative Methods Consultant
Allison Benner	Associate Dean, Finance and Administration
Cheryl Himmelfarb	Vice Dean, Research



Key Links to Access Resources and Services

Intent to Submit

Editorial Consultation

Biostatistical and Qualitative Methods Consultation

Dorothy Evans Lyne Fund

Discovery and Innovation Fund

Institute for Clinical and Translational Research (ICTR)

ICTR K-to-R Resources

JHM IRB Researchers Tool Kit

Research Start Up Assistance

Funding Opportunities

JHU Data Management Services

Research Compliance Training



How can NORA support you?

Please reach out to us at SON-NORA@jhu.edu



Qualitative Core



Qualitative Core

Email: SON-QualCoreis@jh.edu

Nursing Office of Research Administration (NORA)

JOHNS HOPKINS SCHOOL of NURSING

Faculty Members Email: SON-QualCoreis@jh.edu

Kamila A. Alexander



Janiece L. Taylor



Anna Beeber



· Jennifer A. Wenzel



Martha Abshire Saylor



· Rebecca J. Wright



Catherine Ling



Purpose of Qualitative Core

Email: SON-QualCoreis@jh.edu

The purpose of the Johns Hopkins School of Nursing Qualitative Core is to lead change and set the example for holistic care and excellence through recognition and support of methodological approaches that highlight, honor, and ensure the inclusion of voices of patients, families, and communities.

Use of Qualitative Methods

Email: SON-QualCoreis@jh.edu

Qualitative methods are used when:

- little is known about a topic
- the research context is poorly understood
- the boundaries of a domain are ill defined
- > the phenomenon under investigation is not quantifiable
- > the nature of the problem is not clear, or the phenomenon needs to be re-examined. (Sandelowski, 2003)

Qualitatively, the researcher "designs studies by conducting them - as opposed to conducting studies by design" (Sandelowski & Barroso, 2003).



Support & Services

Email: SON-QualCoreis@jh.edu

Support for Faculty

- Grant Support
 - Methodologic Advising
 - Analyses
 - Methods
 - IRB Submissions
 - Writing review
- Manuscript Support
 - Development
 - Editing
 - Journal Selection

- Trainings
 - Journal Clubs
 - Invited Speakers
 - Presentations on Qualitative elements (Rigor, Saturation, Mixed Methods, Ethics, Application in practice, etc.)
- Expert Review
 - Grant Submissions
 - Presentations
 - · Project Development

Support for Graduate Students

- PhD NRSA Proposal Support or Other Grant Submissions
 - Student works with one Qualitative
 Core member on the proposal
 - The Student, Advisor, and Qualitative Faculty reach agreed upon aims, research design, and analysis plan
 - Help with determining sampling needs/saturation, coding, analyses
 - Needs to begin working together at least 45 days prior to the submission date

- Dissertation and/or DNP Projects
- If there are qualitative components it is recommended that Qualitative Core Faculty serve on committee
 - · Advise in theory use
 - · Advise data collection
 - Assist in conducting analyses
 - · Review reporting of results



Start Working with Us Early, and Always!

- Early in proposal development stage is the best
- Any question is always better than no question
 - If you are unsure if you need a qualitative consult or if qualitative methods are a good fit, please ask!
- Qualitative Methods
 - Require Rigor and Planning
 - Are Theory Driven
 - Need clear methods
 - Data collection
 - Data Management
 - Data Analyses

Email: SON-QualCoreis@jh.edu



Leading the way in education, research and practice - locally and globally.

JHU Resources

Center for AIDS Research

hopkinscfar.org

What can the CFAR do for you?



Administrative Core

Core Directors: Dick Chaisson and Shruti Mehta

Project Administrator: Anne Efron Program Coordinator: Eileen Martin Contact: <u>CFAR@jhmi.edu</u>

- Provides integration and coordination of the scientific leadership of the CFAR across Cores, affiliated junior, mid-career, and senior faculty, and with other institutional partners.
- · Oversees and coordinates the Scientific Working Groups and other research programs.
- Provides central web and communications platforms for all CFAR cores, working groups and users.

Developmental Core

Core Directors: Andrea Ruff, Jacqueline Campbell, Joel Blankson, Wendy Post, Seun Falade-Nwulia
Contact: Anne Efron (aefron@jhmi.edu)

- Stimulates new areas of HIV/AIDS-related research and supports the HIV/AIDS research community.
- Assists in evaluating programmatic needs and providing seed money.
- Supports recruitment of key investigators for priority research areas and established investigators not currently working in HIV into the field.
- Expands efforts to recruit and develop under-represented minority investigators in HIV/AIDS research.

Clinical Core

Core Director: Richard Moore Co-Directors: David Thomas, Jason Farley, Eileen Scully, Leah Rubin Sr. Manager: Laura Clark (Iclark53@jhmi.edu)

- · Provides assistance in the design and conduct of clinical research.
- Offers support for Institutional Review Board submissions.
- Links investigators to a range of experts in HIV clinical and translational research.
- Provides access to resources that support project implementation.
- Works with investigators to enhance recruitment in clinical trials.

Prevention Core

Core Director: David Celentano Co-Directors: Carl Latkin, Nancy Reynolds, Erica Sibinga

Sr. Manager: Greg Rosen (jrosen72@jhu.edu)

- Supports junior and senior faculty in the processes of grant development and implementation.
 Manages the online CFAR Grant Development and Implementation Toolkit (toolkit.hopkinscfar.org).
- Develops and plans targeted events to collaborate and engage in existing research programs.
- Provides mentoring for junior faculty engaged in prevention science.
- Supports training in existing and emerging methodologies and technologies.

Clinical Laboratory and

Biomarkers Core

Core Director: Mark Marzinke Program Manager: Kristin Bigos (kbigos1@jhu.edu)

- Facilitates access to research labs, clinical labs, and core labs across the Hopkins Enterprise.
- Provides discounted research pricing for the performance of laboratory assays.
- Offers consultation, training and technical support in laboratory practices.
- Provides guidance in meeting regulatory requirements.
- Offers biospecimen storage and potential access to samples banked by other researchers.

Biostatistics and Epidemiology

Methodology Core

Core Director: Bryan Lau Co-Director: B. Aletta Bareng Nonyane Program Manager: Eryka Wentz (ewentz1@jhu.edu)

- Provides leadership to support collaborative, educational, and research initiatives for the HIV/AIDS community to promote and support innovative HIV-related research.
- Links investigators with BEM Core members who contribute HIV/AIDS expertise in the following areas: bioinformatics, biostatistical, epidemiological, and dynamic modeling.
- Provides support for data management through the Johns Hopkins Biostatistics Center (JHBC).
- Trains and mentors staff, students, fellows, and junior investigators in state-of-the-art population and quantitative methods used in HIV research.

IMPLEMENTATION SCIENCE CORE

Co-Directors: Sheree Schwartz, Laura Beres, Stefan Baral Program Manager: Lisa Lucas

Program Manager: Lisa Lucas (<u>llucas@jhmi.edu</u>)

BALTIMORE HIV COLLABORATORY/

GENERATION TOMORROW

Director: Risha Irvin, Kathleen Page Program Coordinator: Jasmine Blue (jblue3@jhmi.edu)

- Resource development including grant review, targeted events, monthly meetings to foster knowledge sharing and on-line repositories and libraries
- Promotion of inter, intra and extra CFAR and JHU networking, collaboration and synergies.
- Implementations Science consultation Hub
- Inter-CFAR IS Fellowship for Early Stage Investigators
- Promotes community linkages between JHU researchers and HIV focused NGOs, the Baltimore City Health Department, and people affected with HIV/AIDS
- Identifies, recruits and trains under-represented minority undergraduates, graduate students and fellows in community-based HIV/AIDS research in Baltimore.
- Training and field experience for students and community-based health workers in Baltimore.
- Summer Health Disparity Scholars Program

Scientific Groups

Adolescent and Young Adult (AYA) SWG

Co-Directors: Allison Agwu, Julie Denison and Renata Sanders. Contact: Eileen Martin (emarti77@jhmi.edu)

Vaccine Response and Immunotherapeutics (VRI) SWG

Co-Directors: Anna Durbin, William Moss, Andrea Cox. Contact: Eileen Martin (emarti77@jhmi.edu)

HIV Aging Mentored-Research Group (HAMR)

Co-Directors: Todd Brown, Greg Kirk. Contact: Eileen Martin (emarti77@jhmi.edu)

Inter-CFAR Sub-Saharan Africa (SSA) SWG

Co-directors: Haneefa Saleem and Dick Chaisson. Contact: Eileen Martin (emarti77@jhmi.edu)

Substance Use and HIV Interest Group

Director: Seun Falade-Nwulia. Contact: Anne Efron (aefron@jhmi.edu)

These groups aim to address scientific gaps; promote multidisciplinary collaboration, education, and synergy; help early-staged investigators find projects/mentors; provide feedback on new ideas and ongoing work; foster career development; pre-review grant applications and other proposals; and create a dynamic forum for scientific discussion.

Programs and Services

CFAR Faculty Development Awards in HIV Research: \$50,000 Pilot grants to junior faculty to enable and support HIV/AIDS research projects. The prime purpose of these awards is to strengthen the individual's ability to secure independent funding.

Mentoring: Both formal and informal mentoring processes are available to young faculty interested or engaged in HIV research at the JH MI through each core as appropriate. You may contact individual cores directly or the Developmental Core for referrals.

Internal Scientific Reviews: JHU Faculty members applying for funding in the area of HIV/AIDS are able to request an internal scientific review of their grant application.

Specific Aims Lightning Rounds: Round table discussions with senior and junior faculty to brainstorm and fine tune aims prior to grant development. Grant Development and Implementation Toolkit: http://toolkit.hopkinscfar.org/

Center for Nursing Inquiry

https://www.hopkinsmedicine.org/nursing/center-nursing-inquiry/





Are you interested in research, EBP or QI? WE'RE HERE TO HELP!



The Johns Hopkins Center for Nursing Inquiry offers a variety of educational resources and expert guidance to help nurses engage in meaningful, high-quality scholarly work.

FOR MORE INFORMATION, VISIT: hopkins.org/CNI











Clinical Research IT Systems and Services



Clinical Research IT Systems and Services

CCDA



REDCap



PACE



OpenSpecimen



ClinicalTrials.gov Program

clinicaltrials.gov



History of our Program

The Johns Hopkins ClinicalTrials.gov Program was developed in June 2016 by Dr. Daniel Ford and Anthony Keyes. This Program was designed to address the needs of our investigators and study team members.

Johns Hopkins is committed to honoring our commitment to research participants by ensuring transparency through the accurate and timely registration, updating and results reporting of clinical research.

Our mission is to increase our institutional compliance to all applicable regulations, such as the FDA Final Rule and the NIH Companion Policy (compliance date April 2017).

The ClinicalTrials.gov Program will assist investigators with:

- Meeting ethical, legal and scientific responsibilities for clinical trials registration and results reporting
- Identifying trials that require registration and results reporting
- Tips, tricks and helpful content
- Up-to-date information on institutional and federal policies
- Direct effort upon request (billable per hour)



Anthony Keyes



Oswald Tetteh



Kimberly Hill



Oswald Tetteh, MD, MPH Kimberly Hill, MS registerclinicaltrials.jhmi.edu

KENNEDY KRIEGER INSTITUTE

Eun Sol Yung JungES@kennedykrieger.org



OHNS HOPKINS

INSTITUTE for CLINICAL &
TRANSLATIONAL RESEARCH

An in-house program assisting investigators and study teams with ClinicalTrials.gov registration and results reporting.



registerclinicaltrials@jhmi.edu https://ictr.johnshopkins.edu/clinicaltrials-gov

ClinicalTrials.gov Program

Things to Remember

School of Medicine & School of Nursing

Anthony Keyes, MBA, Oswald Tetteh, MD, MPH Kimberly Hill, MS

Based at our main office, the team has been working with faculty and research staff at the Schools of Medicine and Nursing since the inaugaration of our program in June 2016. Dr. Oswald Tetteh and Kimberly Hill are available to assist investigators and study team members with any issues that may arise while using the ClinicalTrials.gov Protocol Registration and Results System (PRS) to register and enter results. They ensure that our records are accurate and up-to-date before they are submitted for review and published on ClinicalTrials.gov.

Sidney Kimmel Comprehensive Cancer Center

In April 2018, the Clinical Trials.gov program was introduced to the Sidney Kimmel Comprehensive Cancer Center.

We have been working with the clinical research investigators and study teams to improve compliance and ensure prospective compliance. Each cancer research program is allotted dedicated time to address noncompliant records and share best practices to promote compliance with the study team. In addition, training sessions have been developed in order to teach research staff about current requirements and guidelines as well as how to use the PRS for registration and timely results reporting.

Federal requirements per FEMAA 881 and Mill Composion Policy Any non-compliance will be subject to fines up to \$11,306/study/day as well as petential loss of grant funding by the NIH. TA the Nic (2 Cit Pet 11)

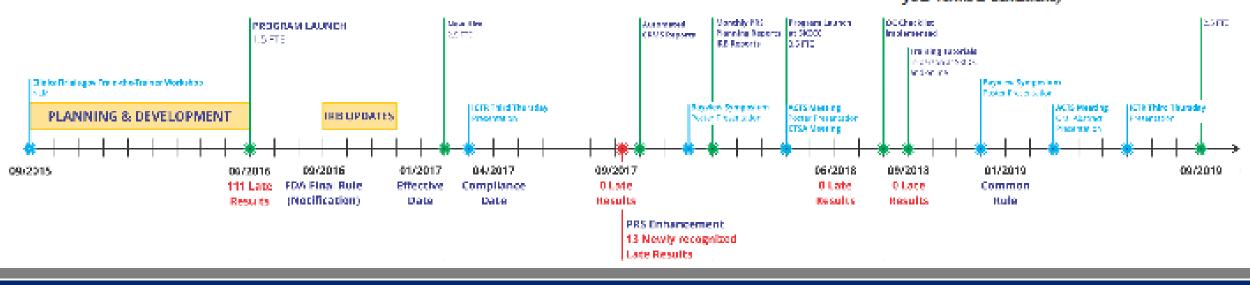
Important Deadlines

- Register before enrollment*
- Verify your record once-a-year
- Update your record within 30 days of any change
- Enter Results** for the primary outcome measure within 12 months of the Primary Completion Date
- Enter Results for all remaining outcome measures within 12 months of the Study Completion Date
- Reply to PRS Comments
 within 15 calendar days for
 registration/updated records
 within 25 calendar days for resultsrelated issues

*Federal regulations require all Applicable Clinical Trials to be registered within 21 days of starting enrollment, but ICMJE requires registration BEFORE enrollment to be eligible for publication. We therefore, recommend all studies to register BEFORE starting enrollment!

**Results reporting is required for all Applicable Clinical Trials, NIH-funded trials, and some other grantors (check your Terms & Conditions)

Program Timeline



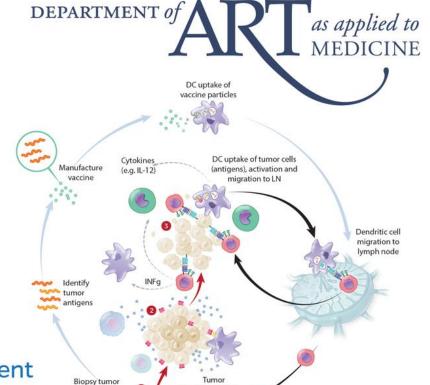
Community Research Advisory Council (C-RAC)

https://ictr.johnshopkins.edu/community-engagement/c-rac/

Department of Art as Applied to Medicine

medicalart.johnshopkins.edu/services





Faculty and Staff in the Department of Art as Applied to Medicine

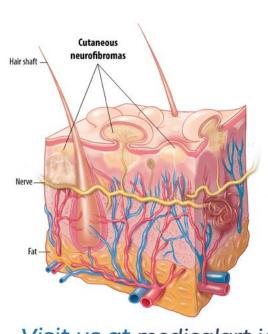
collaborate with Johns Hopkins colleagues to support research, education and clinical care.

Services include

- · Medical & Scientific Illustration
- Animation
- 3D Printing & Visualization
- Facial Prosthetics
- · Graphic Design
- Scientific Presentations
- Websites and Mobile Apps

Contact us to schedule a free consultation:

medart-info@jhmi.edu (410) 955-3213





Education and Training Opportunities at the Johns Hopkins Center for Health Equity

healthequityhub.com



Education and Training Opportunities at the Johns Hopkins Center for Health Equity

Deidra C. Crews, MD, ScM

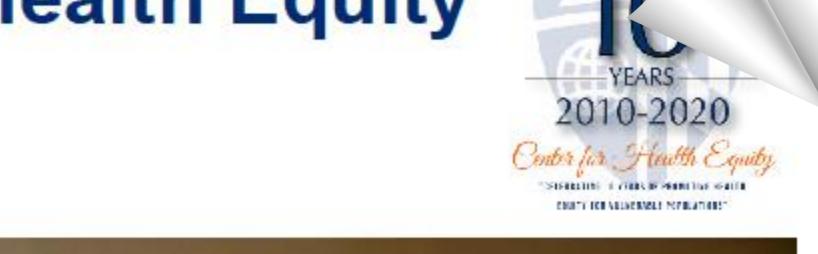
Professor of Medicine, Johns Hopkins University School of Medicine Deputy Director, Johns Hopkins Center For Health Equity

Johns Hopkins Center for Health Equity

MISSION

Promote equity in health for populations experiencing health disparities through:

- Advancing scientific knowledge
- Educating and training leaders
- Partnering with communities
 - Raising public awareness of health inequities
 - Promoting sustainable changes in practice and policy





Training Program

- Created a training program for health professionals and researchers in 2010
- Trained ~200 individuals ranging from high school and undergraduate students to Master's and pre-doctoral students, postdoctoral fellows, and junior faculty
- Trainee accomplishments include:
 - National awards, grants, and faculty positions
 - Health equity publications
 - Leadership roles
 - High school and undergraduate students who matriculated into medical, nursing, public health or other graduate programs in science

















Education & Training Programs



Johns Hopkins Center for Health Equity Education and Training Program Activities

Health Equity
Jam Sessions

Monthly seminars featuring senior and trainee health equity researchers

Special symposia to advance the national agenda on priority areas

Networking and collaboration opportunities with experts in the field

Research Study Opportunities

Participation in Center research meetings and study activities

Opportunities to engage in faculty research activities

> Health Equity Researcher Resource e-newsletter

Faculty Mentorship

Novel trainee intake process for individualized faculty mentoring

Annual speed mentoring events

Faculty showcase to highlight available training opportunities Didactic Coursework

Applications of Innovative Methods in Health Equity Research

Local and Global Best Practices in Health Equity Research

Foundations of Health Equity Research Community Engagement

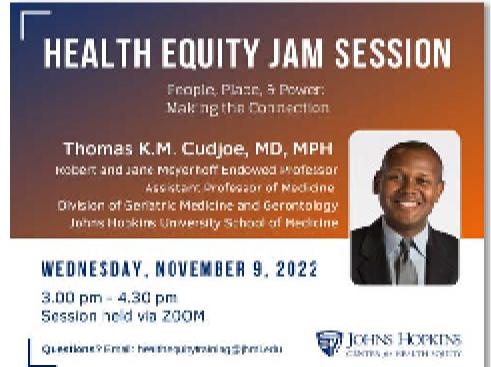
Opportunities to attend community advisory board meetings

Community partner practicum opportunities

Longitudinal relationship building with partners

Purnell TS, Golden SH, Foti K, Oakley K, Leifheit KM, Vargas GB, Oduwole M, Onuoha C, Opara C, Cooper LA, 2022, under review.

JAM Sessions and Special Events





Addressing Food Insecurity in Baltimore to Promote Health Equity. An Expert Panel Discussion

- Provides a forum for faculty and trainees working on health equity research to discuss research-inprogress, new research ideas and proposals, responses to peer review, collaborations and funding, and career development – as well as to be inspired and energized by each other in an informal setting
- We also hold special events and cosponsor seminars with other research programs

Mentored Research Opportunities

- Individualized mentoring by Center faculty
- Participation in research team meetings
- Opportunities to
 - Participate in community engagement activities
 - Contribute to study materials and protocols
 - Interview patients, clinicians, other healthcare staff, and community members
 - Collect anthropometric measures and other medical tests
 - Analyze qualitative and quantitative data
 - Contribute to scientific presentations and manuscripts







Health Equity Courses for Academic Credit

Bloomberg School of Public Health

- Applications of Innovative Methods in Local and Global Health Equity Research (3rd Term – Cooper)
- Health Equity Research Methods to Address Social Determinants of Health (4th Term – Purnell)
- Promoting Anti-Racist Policies and Practices Across Healthcare Settings (Cooper & Marsteller)

School of Medicine

- Health Equity TIME Course for medical students
- JH Equitable Healthcare A Virtual Clinical Elective for medical students
- Racism, Medicine and Our Community Conference series for Internal Medicine and Pediatrics residents
- General Internal Medicine Fellowship



Massive Open Online Courses (MOOCs)

- We have also developed two MOOCs on the Coursera platform and trained over 7,000 people around the world since the beginning of 2020
- In early 2023, we will release a new MOOC focused on local global bidirectional learning to advance health equity

https://www.healthequityhub.com/online-learning-mooc-courses-home





Community Engagement Activities













Investigator Development Core



- Established as a pilot project program in 2022 to support innovative research related to cardiometabolic health equity
- The program consisting of Early-Stage Investigators includes a built-in community network, faculty mentoring, and structured didactic training to support awardees

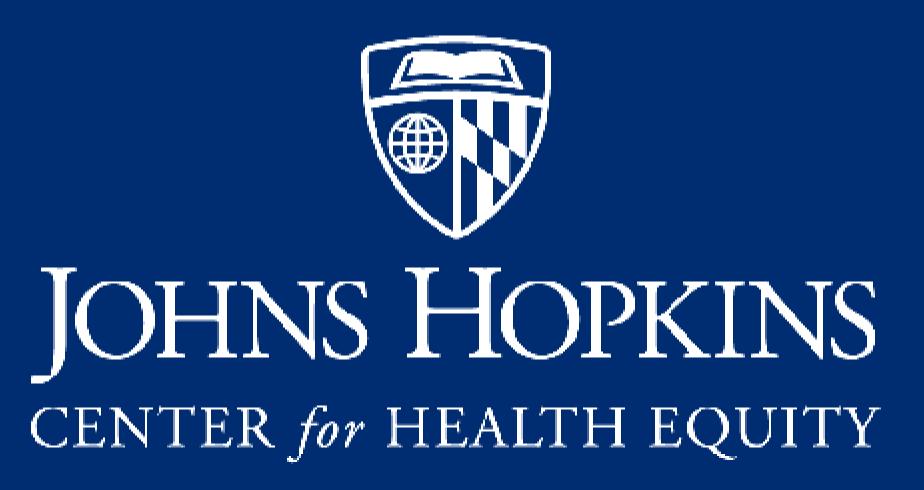
https://www.jhumacche.org/investigator-development-core

How Do I Become a CHE Trainee?

- Send an email to healthequitytraining@jhmi.edu
 - We will ask you to complete a confidential online survey to tell us your primary content and methodological areas of interest
 - Share specific training opportunities provided by Center faculty
 - Try to match you with an appropriate faculty mentor, research study group and/or community-based experience



Visit our website for more information www.healthequityhub.com





healthequitytraining@jhmi.edu



www.healthequityhub.com



@JHhealthequity



@JHhealthequity

I-Corps Program

https://ventures.jhu.edu/programs-services/fastforward/resourcesprograms/icorps-program/

Johns Hopkins Sheridan Libraries

https://www.library.jhu.edu/staff/peter-lawson/

REDCap

redcap.jhu.edu



BEYOND REDCAP: EXPORTING YOUR DATA

REDCap makes it easy to export your data, and allows you to do so in multiple formats

- Export data formatted for Excel (CSV)
 or for your statistical tool of choice (via
 SPSS, SAS, R, or STATA), or download
 it as a CDISC ODM file
- Easily strip identifiers from your data before exporting—and manage other users on your project can export them at all
- Shift dates by a different amount for each record—you can still calculate date differences, but others can't trace them to a specific appointment



ABOUT

REDCap is a HIPAA compliant database program that you can use to manage clinical research and JHU QI data. It's available (in some instances, at no cost) to researchers performing IRB-reviewed research and employees at JHU (SPH, SOM, SON, KKI, APL).

CONTACT US

Email: redcap@ihu.edu

REDCap Website: redcap.jhu.edu





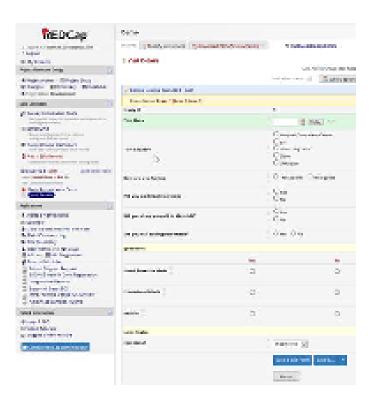






REDCap at Johns Hopkins University

Research Electronic Data CAPture



REDCap IS A HIPAA COMPLIANT, JH APPROVED TOOL FOR MANY TYPES OF PROJECTS:

- Research and QI Projects
- Projects containing sensitive information (PHI, PII);
- Single and Multi-site projects;
- Projects that include surveys;
- Longitudinal projects (structured and unstructured.)
- EPIC Integration
- Multi-Language Management

REDCap IS SECURE:

- Approved by JH Data Trust Council;
- JHED Enabled;
- User rights tailored to specific requirements for each user's role;
- PHI/PII field tagging.

HOW DO I GET STARTED?

Not sure where to start? No worries! Visit

www.redcap.jhu.edu and click on the "Getting

Started with REDCap" link. This document will walk

you through, one step at a time.

HOW MUCH DOES IT COST?

There are three REDCap support tiers: Bronze, Silver, and Gold. Please review the "Getting Started with REDCap" document (mentioned above) for more detailed information.

REDCap <u>Alerts</u> automatically notify your team of key conditions (e.g. a survey response requiring immediate attention)!

SURVEYS

REDCap handles surveys very well. You can send out survey links manually or you can setup automated survey invitations (and reminders) to be sent at appropriate intervals or based on some other condition within the data.

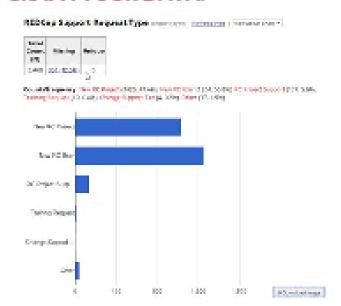
ALERTS

Receive automated notifications based on data received in a survey ("I wish to speak to someone about my treatment").

LONGITUDINAL PROJECTS

REDCap allows for easy setup of longitudinal projects, including making it easy to schedule participants based on your study's timeline.

GRAPH YOUR DATA!



BEYOND DATABASES

REDCap is designed to support the collection of high quality research/ QI data, via:

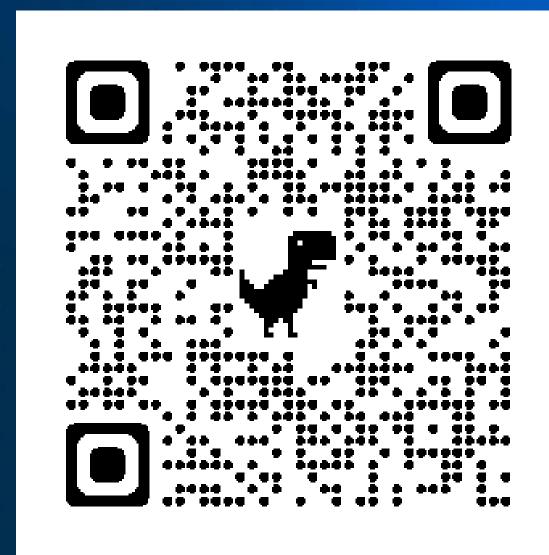
- Structured data types (text, number, date/time, yes/no, email, ...) ensure entered data conform to data standard;
- Tag fields as identifiers (name, dob...);
- Branching logic (hide fields, when appropriate);
- Min/Max ranges (numbers, dates...);
- Flag "required" fields;
- Calculate values on the fly;
- Create your own data quality rules;
- Auditing: ALL project activity is logged, from page views to field edits.
- Restrict user rights to only those needed for their responsibilities.;
- Use Data Access Groups (DAG's) for multi-site studies, allowing site members to see only their site's data;
- And much more...

REDCap also has additional data quality tools to support the highest quality data possible.



redcap.jhu.edu

Scott Carey
Sr. Software Engineer
Sr. REDCap Administrator
Institute for Clinical and Translation Research
School of Medicine
Johns Hopkins University





Research Coordinator Support Services (RCSS)

https://ictr.johnshopkins.edu/service/study-conduct/rcss/



The ICTR Research Coordinator Support Service (RCSS) supports more than 25 investigators working on over 30 studies.

Investigators turn to RCSS:

- To take on projects they would normally have to turn down
- To support research teams that have lost staff members
- To supplement their own staffing/knowledge gaps
- To grow research portfolios

Requesting Support

We work with Investigatators all across Johns Hopkins

SCHOOL OF MEDICINE SCHOOL OF PUBLIC HEALTH SCHOOL OF NURSING SIDNEY KIMMEL COMPREHENSIVE CANCER CENTER

https://ictr.johnshopkins.edu/service/ study-conduct/rcss/

- 1.) Go to our website.
- 2.) Click on the blue "Make a Request" field in the upper-right corner

Make a Request

3.) A member of our team will contact you within 1 business day.



Research Coordinator Support Service (RCSS)

The ICTR Research Coordinator
Support Service (RCSS) is a pool of
research coordinators that are
available for hire on a part-time
basis by Johns Hopkins
researchers.



https://ictr.johnshopkins.edu/service/ study-conduct/rcss/

Research Coordinator Support Service (RCSS)

Scheduling

About Us

Formerly known as SCAMP, the ICTR
Research Coordinator Support Service
(RCSS) is a pool of trained coordinators able
to handle a wide range of customizable
responsibilities to best fit the needs of your
research team. The pool consists of
apprentices (who are a part of the Coordinator
Apprenticeship Program (CAP)), research
program coordinators (many of whom have
completed the Apprenticeship Program),
senior coordinators, and a program manager.

Training

All staff receive training prior to beginning work assignments and continual mentoring to ensure the study is running efficiently and per federal and University guidelines and regulations. Staff will have completed the following minimal training: Human subject research protections, Good Clinical Practices (GCP), eIRB, CRMS (Clinical Research Management System), Epic, DOT/IATA, clinical skills (i.e., vital signs, ECG, and phlebotomy) and CPR.

Program Timeline

This Program started in 2012 and has hired and trained over 100 Coordinators, most still in clinical research and many still here at Johns Hopkins.

Scheduling is based on the number of hours needed per week. Hours may also be built into grants and/or as a salary support model based on the full-time equivalent (FTE) support needed.

If an investigator/department makes a coordinator hire, or no longer needs support, the RCSS Coordinator will assist with the transition process and will continue providing support until the transition is complete.

Coordinator Responsibilities

RCSS Coordinators are available to work with study teams at all stages of research. They are experienced with drug and device studies, pharmaceutical-sponsored, federally-funded and investigator-initiated studies across several disease states and disciplines. They can assist with (but not limited to) the following:

- eForm and informed consent creation and modification
- eIRB applications (i.e., initial, changes in research and continuing reviews)
- participant screening and recruitment consenting
- performing study visits
- data entry, and resolving queries
- creating and completing source documents and case report forms
- sample collection, processing and shipping

Payments & Fees

Things to Remember

RCSS coordinators are available as a fee-forservice program, making the process of finding a part-time coordinator easier. This service is ideal for junior faculty to seasoned investigators. Any investigator may find themselves in need of a coordinator due to sudden absences, resignation, or retirement and we work quickly to provide services.

RCSS coordinators are not added to your payroll. Study teams are provided a detailed monthly invoice billed directly to their internal order number. The process is straightforward even for investigators with multiples studies or departments using multiple internal order numbers.

Effective July 1, 2022: (rates inclusive of all fringe)

- Research Coordinator support is \$60/hour
- Research Regulatory Specialist support is \$65/ hour
- Senior Research Program Coordinator support may also be available for more complex studies and situations at \$65/hour

Prior to beginning a work assignment, a study start-up meeting will be scheduled with the study team. At this meeting, a concise work agreement will be established with the study team that will outline the responsibilities and tasks that the RCSS coordinators will perform, and the hours required by the study team. The work agreement may be modified as situations change.

School of Medicine Biomedical Informatics and Data Science Courses





Biomedical Informatics and Data Science Courses

Introduction to Public Health and Biomedical Informatics

Core principles applied to the range of health, from prevention through illness, to population and public health

Applied Clinical Informatics

Focused on leveraging clinical information systems and technology to improve patient and family-centered care

Leading Change Through Health Informatics

Prepares learners to lead organizations implementing new IT systems

Informatics and the Clinical Research Lifecycle: Tools, Techniques, and Processes

Addresses the entire life cycle of a clinical-research program from idea generation through results dissemination

Health Information Systems: Design to Deployment

Project-based course covering the research stages to deployment of software design and development

Clinical Decision Analysis

Theory and practice of decision analysis as applied to the clinical context, focused on clinical decision support

Data Science Track

Introduction to Precision Medicine Data Analytics

Evolving field of precision medicine and the role of big data analytics in improving patient care

Database Querying in Health

Relational databases using SQL along with special issues related to health information systems

Clinical Data Analysis with Python

Discussion and interactive Python exercises provides practical experience working with EHR data

Observational Research with Observational Medical Outcomes Partnership (OMOP)

Practical exercises with the OMOP common data model (CDM) from the OHDSI community

Implementing Fast Healthcare Interoperability Resources (FHIR)

Hands-on experience working on integrating digital health and clinical interoperability

Natural Language Processing in the Health Sciences

Orientation to the various applications of NLP in biomedicine, healthcare, and public health

SON Research Retreat 2022 ICTR Informatics Presentation

CCDA

Core for Clinical Research Data Acquisition (CCDA) assists researchers with accessing clinical data for research



Services we Provide

- Data Feasibility for Grant Applications
- Sample-Size Estimates
- Data navigator for PMAP
- MyChart Recruitment
- Research Data Extracts
- Data De-identification services
- Honest Broker services
- SlicerDicer & TriNetX tools assistance

Data Sources we can Access

- Epic Clarity
- EDW
- PMAP
- OMOP
- CaseMix Datamart
- CRMS

CCDA for PMAP

Core for Clinical Research Data Acquisition (CCDA) provides full data navigator services for PMAP users



Navigator Services for PMAP

- Data wayfinding from study development to study close
- IRB protocol assistance for registries and secondary protocols
- Data specification documents
- Database projections
- Training on data analytics tools
- Epic workflow expertise

REDCap



- REDCap (Research Electronic Data Capture) is a secure, HIPAA compliant, webbased application that supports data capture and management for research studies. REDCap at Johns Hopkins is co-sponsored by the Johns Hopkins School of Public Health and the Johns Hopkins School of Medicine.
 - ✓ Secure / HIPAA Compliant
 - ✓ Easy to use
 - ✓ Robust
 - ✓ Integrates with EPIC

PACE

PACE (Program to Accelerate Clinical Research using Epic) helps clinicians collect data by building customized tools and content in Epic

Research Recruitment

MyChart

Reporting Workbench

In Basket Alerts Patient-Reported
Outcomes via
Questionnaires

Automatic Assignment

> Response Alert

Synopsis & SmartPhrase

Discrete Data Collection

Flowsheet

SmartForm

Reports

Make a Request





OMOP Common Data Model



- Observational Medical Outcomes Partnership
- OHDSI Community: International, collaborative, open-source
- Patient data mapped to standard concepts
- Results and analyses shared among institutions
- CCDA is now able to provision data in the OMOP format
- Fully de-identified OMOP accessible to all Hopkins entities coming soon!

OpenSpecimen



We Offer

- · Annotation of research and clinical data
- Specimen information interfaced with PMAP
- Query capability
- Specimen and derivative tracking
- Specimen event tracking
- Epic patient lookup-enabled
- Considered a "Tier A" best practice for storing biospecimen metadata, including PHI

Clinical Research IT Systems and Services











Welch Center

https://www.hopkinsmedicine.org/gim/news/2010_News_Items/10-7-10.html



NURSING OFFICE OF RESEARCH ADMINISTRATION