

CTSA Program Webinar

October 23, 2024

Agenda

TIME	TOPIC	PRESENTERS
2:00 PM ET	Welcome	Lauren Fitzharris, M.P.H., P.M.P. CCOS
2:01 – 2:10 PM	NCATS/CTSA Updates	Michael Kurilla, M.D. NCATS
2:10 – 2:15 PM	CCOS Updates	Kerry James, M.P.H., P.M.P. CCOS
2:15 – 2:30 PM	TL1 Visiting Scientist Working Group	Dexter Lee, Ph.D., Howard University Kathryn Sandberg, Ph.D., Georgetown University
2:30 – 3:00 PM	Housing-Based Socioeconomic Status (HOUSES)	Young Juhn, M.D., M.P.H. Mayo Clinic
3:00 PM	Adjourn	



NCATS/CTSA Program Updates

Michael G. Kurilla, MD, PhD

Director, Division of Clinical Innovation
NCATS

October 23, 2024

Announcements

- ([NOT-OD-25-010](#)) NIH Operates Under a Continuing Resolution (Released Oct 10, 2024) through December 20, 2024 at the FY24 enacted level with no reduction

- [NIH OER Virtual Events](#)

- Subscribe to NIH Grants Events to keep informed at [OER Listservs and RSS Feeds](#)



Virtual

Wednesday, November 13, 2024 / 1:00PM - 4:00PM

NIH Grants Process Primer: Application to Award - Part One

Understanding NIH's overall structure and the foundation of the agency's grants process is vital to successfully applying for NIH funding. To help you on this journey, the NIH invites you to participate in a two-part webinar designed to help inform...



Virtual

Thursday, November 14, 2024 / 1:00PM - 4:00PM

NIH Grants Process Primer: Application to Award - Part Two

Understanding NIH's overall structure and the foundation of the agency's grants process is vital to successfully applying for NIH funding. To help you on this journey, the NIH invites you to participate in a two-part webinar designed to help inform...



Virtual

Thursday, October 17, 2024 / 1:00PM - 2:00PM

NIH Grants Policy Updates: FY2025 Edition

As fall approaches, the federal government enters a new fiscal year. With the change of seasons and move to FY2025, the NIH would like to make sure you have the latest information on NIH policies and processes. Join your peers for an informative,...



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Reminder: Submit Timely Progress Reports

- Failure to submit complete, accurate and timely reports will result in award delays and may result in enforcement action in accordance with the [NIH Grants Policy Statement Section 8.4.1.](#)
- Due Dates for types of grants:
 - Non-SNAP*: Approximately 60 days before the start of next budget period
 - SNAP*: Approximately 45 days before start of the next budget period
 - Multi-Year Funded: on or before award anniversary date
- *SNAP = Streamlined Non-Competing Award Process
- Check your Notice of Grant Award to see what type of Grant your institution has been issued!



Reporting DMS Plan Activities in the RPPR

Recipients must address [NIH Data Management and Sharing Policy](#) in annual RPPRs due on or after October 1, 2024.

For awards for which the NIH DMS Policy applies, recipients will be asked:

- Whether data has been generated to date and what type of data it is;
- Whether data has been shared for use by others;
- If data has been shared, in what repository and under what unique digital identifiers;
- If data has NOT been shared, what is the status of data sharing (e.g., being prepared for submission, submitted to repository, not yet expected to be shared); and
- If data has not been generated and/or shared as outlined in an approved DMS Plan, what corrective actions have or will be taken to comply with the approved Plan.

The updated NIH RPPR Instruction Guide is posted to the [Research Performance Progress Report \(RPPR\)](#) page.



Requesting Revisions to an Approved DMS Plan

Under the final NIH Policy for Data Management and Sharing (DMS Policy), NIH requires a recipient to comply with the DMS Plan as approved by the awarding NIH Institute, Center, or Office (ICO) as a term and condition of the award.

If DMS Plan revisions are necessary (e.g., new scientific direction, a different data repository, or a timeline revision), Plans should be updated by recipients and reviewed and approved by NCATS.

All requests for NCATS prior approval must be submitted by the Authorized Organization Representative (Signing Official (SO) role in eRA Commons) at least 30 days in advance of the requested change, and the currently approved DMS Plan remains in effect for the award until the request is approved by NCATS.

All requests for DMS plan revisions must comply with NIH requirements for prior approval submission. The processing for submitting requests depends on the application/award status. NCATS is required to ensure all DMS prior approval requests are submitted in accordance with the below. **If a DMS prior approval request is submitted outside this process, it will not be reviewed.**



Requesting Revisions to an Approved DMS Plan

Pre-Award: Just-in-Time

- Before the award is made, applicants must use the “Data Management and Sharing Plan (DMSP) Revision” section of the [Just in Time \(JIT\) Screen](#) in eRA Commons, to submit a revised DMS Plan.
- Note: SO/AORs must no longer use the ‘Other File’ section in Just-in-Time to submit the revised DMS plan.

Post-Award: At Time of RPPR

- For changes being requested after the award is made, at the time of the RPPR (i.e., within 30 days of RPPR submission), in the [RPPR Module](#), recipients must use Section C.5.c to select “Upload Revised Data Management and Sharing Plan” and follow the instructions provided to complete the required entry. Refer to the [RPPR Instruction Guide](#).

Post Award: Off-Cycle Requests

- When revisions to the DMS Plans need to be requested off-cycle (other than at the time of the RPPR), recipients must Select “Prior Approval – DMS Request” in the [Prior Approval Module](#) to request the change.
- Note: SO/AORs must no longer use the ‘Other Request’ type in Prior Approval to submit the plan.



HOW YOU CAN HELP WITH NIH CLINICAL TRIALS REPORTING COMPLIANCE



- Investigators, submit your results to [ClinicalTrials.gov](https://clinicaltrials.gov) ASAP
- Institutional leaders, develop internal controls to make it easier for faculty to report results efficiently
- If you receive a letter about a non-compliant trial, be responsive

Reminder about NIH Guidance on Applications Involving Clinical Trials

- For help with the NIH's definition of a clinical trial, please see [NIH's Definition of a Clinical Trial](#) and for help with determining if your human subjects research meet this definition see: [Does Your Human Subjects Research Study Meet The NIH Definition of a Clinical Trial?](#)
- **Delayed Start:** For research projects that can be described at time of application, but research will not immediately begin (will occur later in the funding period) applicants should add a study record for each proposed study involving human subjects if your study has a delayed start. As such, the four questions in the clinical trial questionnaire need to be answered "Yes" if the delayed start study involves NIH-defined clinical trial.
- **Delayed Onset:** For research projects that are anticipated within the period of award, but definite plans are not yet known and cannot be described in the application all applicants should check the Anticipated Clinical Trial box, and complete all related sections. Please see the instructions in [G.500 PHS Human Subjects and Clinical Trials Information](#).
- Consistent with [NOT-OD-15-129](#), delayed onset projects will undergo prior approval (See more information here: <https://ncats.nih.gov/research/research-activities/ctsa/ctsa-program-governance-guidelines/human-subjects-research>).

Please note that **misclassified clinical trial applications may be withdrawn:**

<https://grants.nih.gov/policy/clinical-trials/definition.htm>

Applicants are strongly encouraged to consult with appropriate Program Staff for guidance.



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Federal Award Closeout

Closeout of an award is the process by which NIH determines that all applicable administrative actions and all required work of an award have been completed by the recipient and NIH.

- NIH continues to require and enforce longstanding closeout requirements **due within 120 days** of the project period end date:
 - **Final Research Performance Progress Report (RPPR)**
 - **Final Federal Financial Report (FFR) (SF 425)**
 - **Final Invention Statement and Certification (HHS 568)**
- NIH will initiate unilateral closeout (including potential enforcement actions) if recipients fail to submit final reports on time.
- NIH will report unilateral closeout actions in SAM.gov which has implications for future award actions for the entire recipient organization.
- Please ensure timely submission of all required close-out documents!

Reminder – The new CTSA suite of NOFOs are considered new grants. Close-out documents are required for UL1, KL2 and TL1 grants.

NIH Closeout Policies



Website - <https://grants.nih.gov/grants/closeout/index.htm>



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Public Access Policy Reminders

- Applies to any manuscript that is peer-reviewed, accepted for publication in a journal and arises from any direct federal government grant funding support and/or approved voluntary committed cost share.
- ONLY include publications, along with the PMCID (Pubmed Central ID) found in MyNCBI, that were directly resulting from the award.
- For publications where the UM1/UL1 only contributed shared resources, list and/or summarize these publications in section B2. Publications listed and/or summarized in this section will not count against the section's two-page limit.
- Review publication listings **early** to prevent Public Access Non-Compliance. **NIH cannot issue an award until all publications are compliant.** Repeated submissions of applications with non-compliant publications will result in potential compliance actions.
- For Institutional Training, Career Development, and Related Awards(T32/TL1, R25/RL5, K12/KL2): Trainee, scholar, and participant publications fall under the public access policy if the publication resulted from work conducted while the individual was supported by the award (i.e., receiving a stipend or salary from the award).

**Approximately 18% of CTSA
U RPPR submissions for FY 2024
were non-compliant.**

NIH Public Access Policies



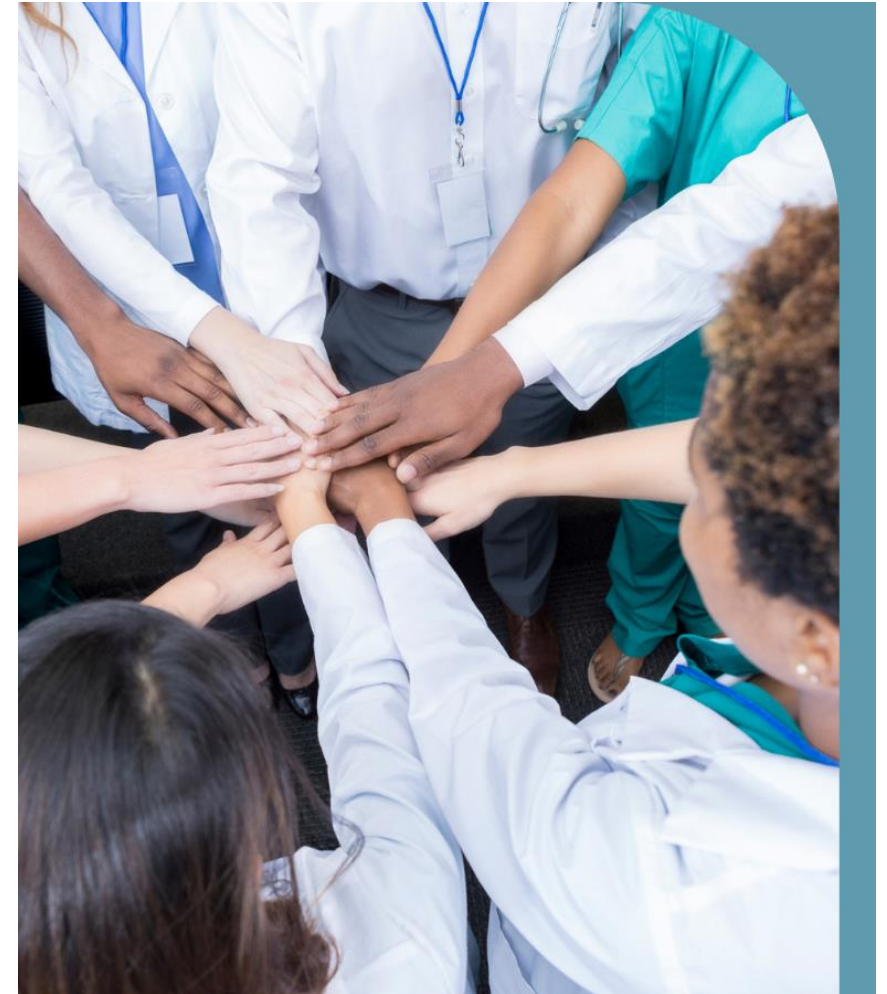
Website - <https://publicaccess.nih.gov/>



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Community Partnerships to Advance Science for Society (ComPASS)

- NIH Common Fund is funding five new research awards to Health Equity Research Hubs that will support community-led research projects
- Provides hands-on research support to 25 [Community-Led, Health Equity Structural Intervention \(CHESI\) projects](#)
- Awardees:
 - Yale University
 - University of Maryland, Baltimore
 - University of Michigan at Ann Arbor
 - New York University
 - University of Mississippi Medical Center
- More info [here](#)



Dental Schools Network Discussion Forum FY 2025 Webinar Series

Every second Friday at 1PM (ET) every two months

<u>Date</u>	<u>Title</u>	<u>Presenters</u>
9/13/2024	Decentralized Clinical Trials	Pablo Cure, NCATS Tom Radman, NCATS
11/8/2024	Successful Collaborations Between Dental Schools and CTSA Hubs. A case study	David Lam, University of the Pacific Ruth O'Hara, Stanford University
1/10/2025	CTSA Program Collaborative Innovation Awards Funding Opportunity	Kris Bough, NCATS
3/14/2025	Diversity Administrative Supplements to the Hub Awards and the training resources	Patrick Brown, NCATS Irina Krasnova, NCATS
5/9/2025	Trial Innovation Network and the Recruitment Innovation Center	Ken Wiley, NCATS
7/11/2025	RC2 presentation and opportunities for the dental school community	Pablo Cure, NCATS

• Link to registration: <https://nih.zoomgov.com/meeting/register/vJlsdu-srz8uHX7mJtOlnGylEwc88gNMzU>

• Questions: [Gallya Gannot, NCATS](#) gannotg@mail.nih.gov or [Raj Prasad, Stanford CTSA](#) rprasad2@Stanford.edu



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Upcoming Dates to Remember

Next CTSA Program Webinar
January 22, 2025; 2-3 PM ET

New Link for 2025 Series: Register [here](#)

Note: November and December 2024 Webinars are Cancelled



NCATS

COLLABORATE. INNOVATE. ACCELERATE.

 ncats.nih.gov

 [@ncats_nih_gov](https://twitter.com/ncats_nih_gov)

 [@ncats.nih.gov](https://facebook.com/ncats.nih.gov)

 [NIH-NCATS](https://linkedin.com/company/NIH-NCATS)



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CCOS Updates

Kerry James
CCOS





Fall 2024 CTSA Program Meeting

Theme: Building CTSA Program
Impact through Innovation,
Collaboration and Equity

Date: November 13-15

Location: Bethesda North Marriott

- [Registration](#) closes on **Nov 1st**
- [Hotel Room block](#) – **full / closed**
- [Poster Submission portal](#) closes at
3pm ET on **Oct 25th (this FRIDAY!)**

See more details on the
[CCOS Website](#)

Questions? Contact
FallMtg@ccos.ctsa.io



Fall 2024 CTSA Program Meeting

- The Fall Program meeting is nearing capacity for in person registration
- CCOS to email Hub Administrators with registrants from their hub to confirm in person registrants
 - Reminder that there is a **5 person per hub limit** for **in person attendance**
 - Speakers and poster presenters are allowed above the 5 person limit
 - Unlimited virtual attendance
- Request to review and approve registrants by Oct 29th

2024 Fall Poster Submissions

Poster Submission portal is **open** on [CCOS website](#)

- **One poster per hub** related to meeting theme
- Poster presenter **not** limited to scholars and trainees
- Hub PIs (U, K and Ts) and Hub Administrator work together to select the poster author to represent hub
- Hub Administrator to submit the poster for their hub

****Poster Submission portal to close on October 25th****

****Poster Gallery to open on November 6th****

Poster Session Jury and Awards

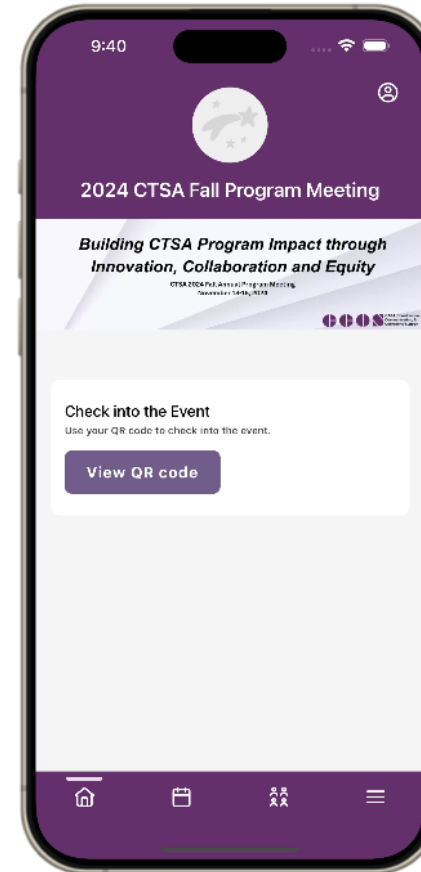
- Poster Sessions will take place on Nov 14th
 - All posters will remain up throughout the day
 - Presentations will be spread across two sessions (one in am and one in pm)
- Poster session will be juried (~26 jury members)
- Posters will be evaluated for:
 - Scientific Value, Presentation Delivery, Poster Design
 - How best they exemplify Innovation, Collaboration and / or Equity
- Awards (8 total)
 - Best overall scores (5 awards)
 - Also awards for top equity, collaboration, innovation posters (3 awards)

Cvent Conference Website & Mobile App

Fall 2024 [Website](#) Live!



Fall 2024 Mobile App



- For Registrants only (both virtual and in person)
- Access to the mobile app will be included in the "Before You Arrive" email the week before the Meeting.
- You may download the CVENT App in the app store.

Cvent Conference Website & Mobile App

- The detailed CTSA Program Agenda is now on [Cvent Fall Meeting website](#)
- You may access the link to the full agenda on the [CCOS Fall Meeting webpage](#)

Meeting Details

Registration

Poster Submission

Poster Gallery

2024 Fall CTSA Program Annual Meeting

November 13, 2024 - November 15, 2024

Building CTSA Program Impact through Innovation, Collaboration, and Equity

The Fall 2024 CTSA Program Annual Meeting brings together personnel from CTSA Program Hubs with active grants for networking, sharing best practices and knowledge sharing. Topics to be addressed include:

- Primary Care Practice-Based Research Networks (PBRNs)
- PCORnet
- The Women's Health Initiative and DEI
- Translational Research to Translational Science
- Generative AI and Large Language Models in Translational Science

Agenda

The agenda for the Fall CTSA Program Meeting can be accessed below.

Agenda

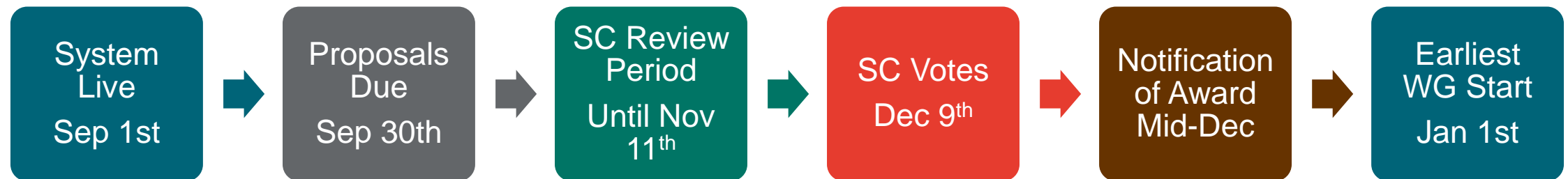


Cycle XIII Working Group Proposals – Under SC Review

Cycle XIII closed on September 30, 2024

Nine proposals received – thank you!

The Steering Committee Review Period is open until November 11th



Decentralized Clinical Trials Collaborative Workshop

Co- Sponsored by:

CTSA Coordination, Communication & Operations (CCOS) Support
University of Southern California Clinical and Translational Science Institute



Wednesday

February 12, 2025

8:00 am – 4:30 pm PT

In-Person Event

The California Endowment
1000 North Alameda Street
Los Angeles, CA 90012

[Event Page](#)

Registration is Open!



TEAM SCIENCE



Why Attend?

Who's Invited

- CTSA Program Representatives
- Researchers
- Clinicians
- Policymakers
- Healthcare innovators
- Opinion leaders
- Other healthcare professionals
- Industry

Panel Sessions

- Demystifying Decentralized Clinical Trials (DCT)
- Building Successful DCT: Key Components
- Navigating the Evolving Landscape

Opportunities

- Form teams around DCT research
- Learn about the ways the CTSA have and can support DCT
- Networking

Stay Updated on Collaborative Workshops!

Visit ccos.ctsa.io/groups/collaborative-workshops

Email collaborative_workshop@ccos.ctsa.io

Thank you!

TEAM SCIENCE



CCOS Website Account

Getting Started

Get step-by-step guidance on getting started including how to create a CCOS account and how to log in can be found here:

[Getting Started Page](#)

Account Access Includes:

- Meeting Materials/Archives
- Collaborative Workspaces /Discussion Forums
- CTSA Hub Directory

Questions? Please email support@ccos.ctsa.io

Want to stay up to date on the CTSA Program?

Follow this link or scan the QR code to join the CCOS All Communications Email List to receive CTSA Program communications and updates:

<http://eepurl.com/iw9nZA>



Remember to add communications@ccos.ctsa.io to your contacts list to prevent important CCOS emails from ending up in your spam folder!

New Program Webinar Registration for 2025 - 2026

Please register using this link and add the new invite to your calendar:

https://zoom.us/webinar/register/WN_NxW6tboxQninVI7UFGfmYQ#/registration

The next webinar is **January 22, 2024; 2-3 PM ET**

The TL1 William Schnaper Visiting Scientist Working Group (WSVS)

Wednesday, October 23, 2024





A pediatric nephrologist H. William “Bill” Schnaper, MD, was an associate chair for Faculty Development in the Department of Pediatrics at Northwestern University.

Through his service on the TL1 Directors Executive Committee, Bill provided critical input on our annual agenda at the Translational Science meetings. He was a key contributor to the design of the national TL1 Survey and he initiated our new TL1 Visiting Scientist Program.

This program is dedicated to him.
(3/16/1950 - 11/19/2020)

Provide trainees networking opportunities and encourage collaborations throughout the CTSA Consortium

Grand Rounds

Senior Predocs and Postdocs

Debate Forum

Trainees



Minisymposia

Students and Fellows

Consortium

Collaborations Among Hubs



TL1 *Debate*

- **Adisa Kalkan**
- Program Administrator
- Washington University in St. Louis



TL1 Debate is the opportunity for trainees to practice their presentation skills and make arguments for or against a concept in clinical and translational science

- 2 Institutions Participating
- Trainees split in 2 groups
 - Group A – "Pro/positive" or "Arguments for" (2-4 trainees)
 - Group B – "Con/negative" or "Arguments against" (2-4 trainees)
- Each group to research the topic and present for 15 minutes
- Moderator - influencer on the topic
- Reading material provided, while trainees are encouraged to find other relevant information that could be used to support topic
- Open floor discussion, closing remarks, and surveys



TL1 *Grand Rounds*

Dexter Lee

TL1 Co-PI

Georgetown-Howard Universities

- **Kathryn Sandberg**
- TL1 PI
- Georgetown-Howard Universities



Previous Grand Rounds :

Date	TL1 Scholar	Home Institute	Host Institute	Title
November 12, 2021	Alexander Brunfeldt, PhD	Georgetown University	The University of North Carolina at Chapel Hill	Technological solutions to therapeutic challenges in stroke rehabilitation
November 29, 2021	Charles Askew, PhD	The University of North Carolina at Chapel Hill	University of California, Davis	Neutralizing Antibody Suppression: Overcoming a natural barrier to viral vectored gene therapies
December 7, 2021	Ben Osipov, PhD	University of California, Davis	The University of North Carolina at Chapel Hill	Sex differences in systemic bone loss after fracture and the effect of estrogen
January 5, 2022	Megan Srinivas, MD, MPH	The University of North Carolina at Chapel Hill	Georgetown University	Health Equity: a Translational Sciences Approach
February 7, 2022	Andreea Waltmann	The University of North Carolina at Chapel Hill	University of California, Davis	Use of the gonorrhea human model of infection for vaccine testing and correlates of protection discovery
February 25, 2022	Vanessa L. Hull, BS, BA, MS	University of California, Davis	Yale Center for Clinical Investigation	Targeting N-acetyl-L-aspartate synthesis and transport to treat Canavan leukodystrophy
March 7, 2022	Tara Bautista, PhD	Yale Center for Clinical Investigation	University of California, Davis	Parenting Mindfully for Health: Examining Stress and Coping Among Parents of Young Children

Benefits:

- Scholars build their network across universities with TL1 peers and faculty members
- Scholars present work in a low-pressure high feedback environment
- Opportunity to present longer presentation to a diverse CTS audience
- Inter-campus collaboration brings our community together for new potential research opportunities
- Supports the greater mission of the CTSA



Outline of Program/Timeline

- Twice a year, requests are sent to Directors (via listserve) to nominate Trainees interested in speaking in the Ground Rounds series
- TL1 trainees will list institutions in which they are interested
- Committee will contact institutions to find a host



Mini Symposium

- Kathryn Sandberg
- Co-PI
- Georgetown-Howard Universities



TL1 Mini Symposium

- Theme: COVID-19: Innovation and evolution of research in the pandemic
- Moderators: Two ITM TL1 postdoctoral fellows reviewed abstracts and led symposium
- 10 pre and postdoctoral presenters each representing a different CTSA
- Presentations organized in two groups: clinical and basic science

Moderators



Maylyn Martinez, MD
Instructor of Medicine
TL1 Fellow 2019-2021
University of Chicago



Laura Magda, MD
Postdoctoral Fellow
TL1 Fellow 2019-2021
University of Chicago

Save the Date

Fall 2024 Mini-Symposium Virtual Event:

Focusing on Unmet Needs in Clinical and Translational Science

Abstract Due: 10/31/24

Acceptance: 11/11/24

Main Event: 12/11/24

[REGISTER HERE](#)

Hosted by the TL1 Translational Biomedical Science Program, GHUCCTS

Please contact TL1 Program administrator for more questions Danika Campbell:
dc1538@georgetown.edu

Outline of Program Timeline

Fall 2024

- Save the date 12/11/24
- Call for abstracts on 10/31/24
- Decision will be announced on 11/11/24
- Event second week in December; 12/11/24

Closing Remarks

To continue WSVS program:

Need other TL1 institutions interest to participate

- Grand Rounds
 - Dexter Lee and Kathryn Sandberg
- Debate
 - Fall 2024 - Adisa Kalkan
 - Spring 2025 - **Needed**
- Mini-Symposium
 - Fall 2024 - Kathryn Sandberg
 - Spring 2025 - **Needed**

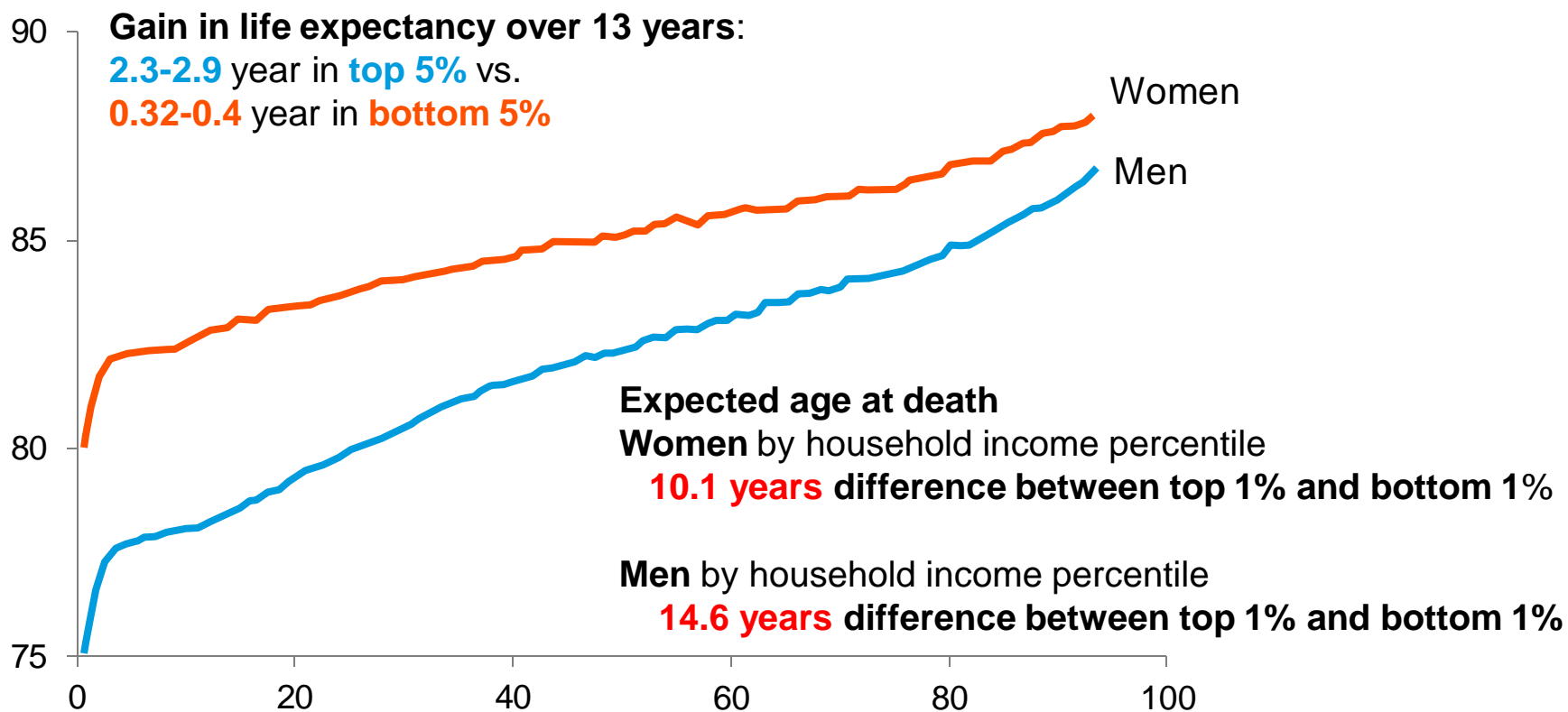
The HOUSES Platform



Novel Social Determinants of Health Metric & A Digital Biomarker in Clinical and Translational Research

Young Juhn, MD, MPH, Professor of Pediatrics
Research Chair, Mayo Clinic Health System
Director, The Artificial Intelligence Program of Department of Pediatrics
Director, Precision Population Science Lab
Director, The HOUSES Program
Department of Pediatric and Adolescent Medicine
Mayo Clinic

HOUSEHOLD INCOME IMPACTS LIFE-EXPECTANCY OF 40-YEAR-OLD PEOPLE DURING 2001-2014



SDOH largely account for disparities in LE in the US

Barriers to and solutions for representative inclusion across the lifespan and in life course research: The need for structural competency highlighted by the COVID-19 pandemic J. Clin Transl Sci. 2023:7(1)

“These (special) populations are adversely impacted by **SDOH** that reduce access and ability to participate in biomedical research.”

NCATS Vision is *More Treatments for All People More Quickly*

CTSA Program Goal, “Improve the efficiency and effectiveness of translational science from discovery to its implementation in clinical care to dissemination to community”

Challenges in Addressing SDOH for Health Equity

Self-reported SDOH data frequently unavailable in EHRs in health care organizations (HCOs) up to 98%

The existing (available) self-reported SDOH data in EHRs is highly biased and unstandardized

HCOs routinely adopt and use inaccurate aggregate-level SDOH measures causing 52% misclassification of individual-level SDOH

“We cannot address
what we cannot measure”

Innovative Features of HOUSES Index and Platform



Individual-level
SES measure



Objective and
validated measure



Population-based
standardized measure



Patient contact not
required



Nationwide, HIPAA
compliant & de-identified
cloud technology



Longitudinal trends of
SES Change

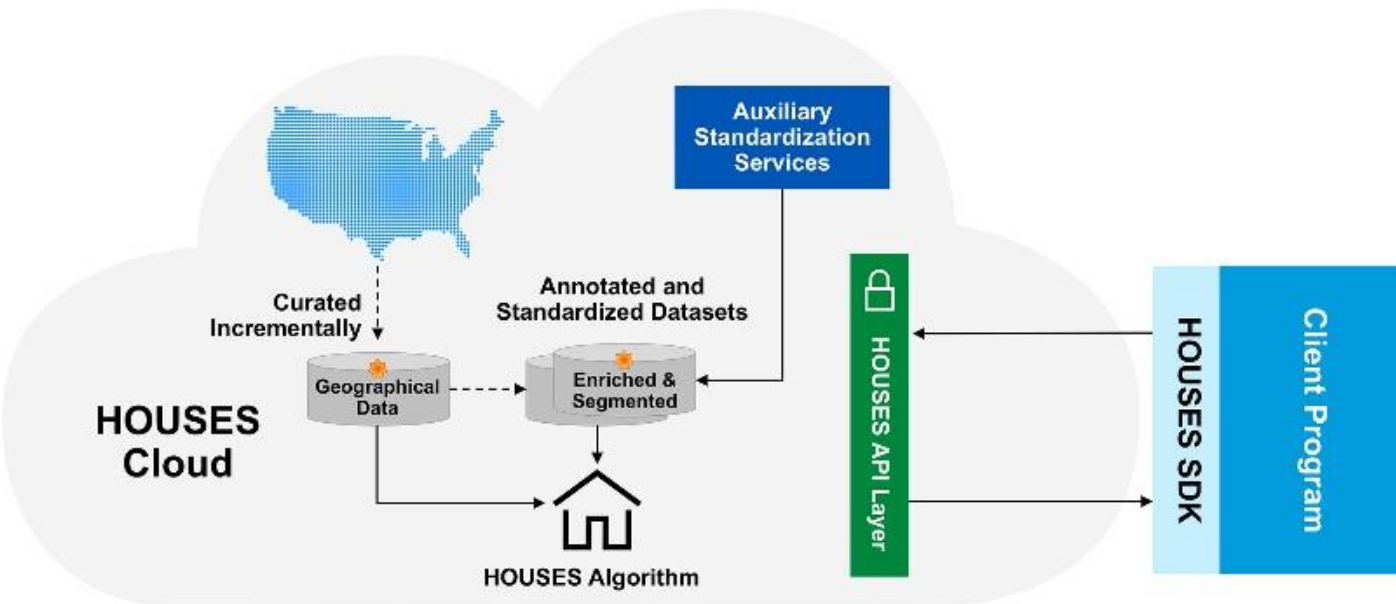


Family mapping for
genetic and environmental
studies



GIS analysis with
geocoded index

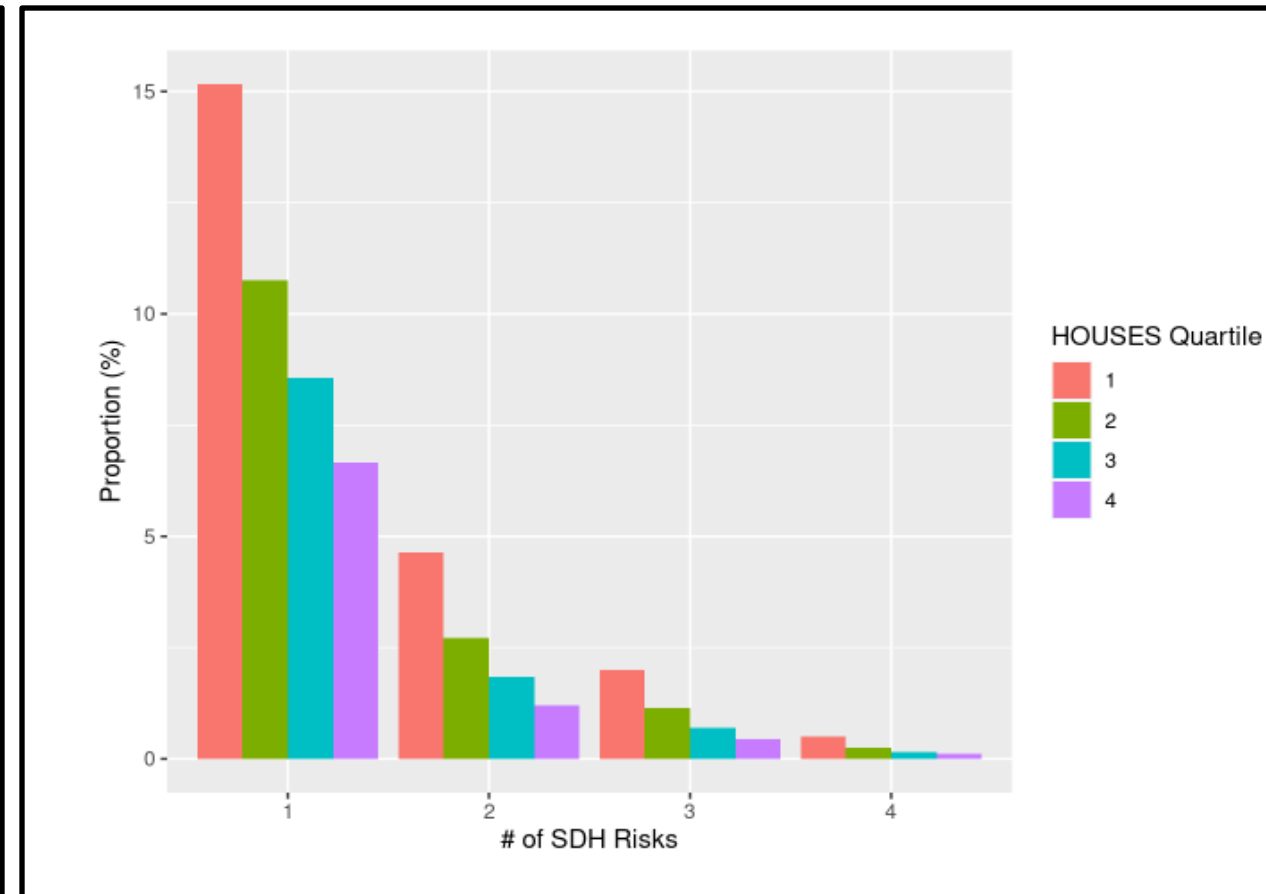
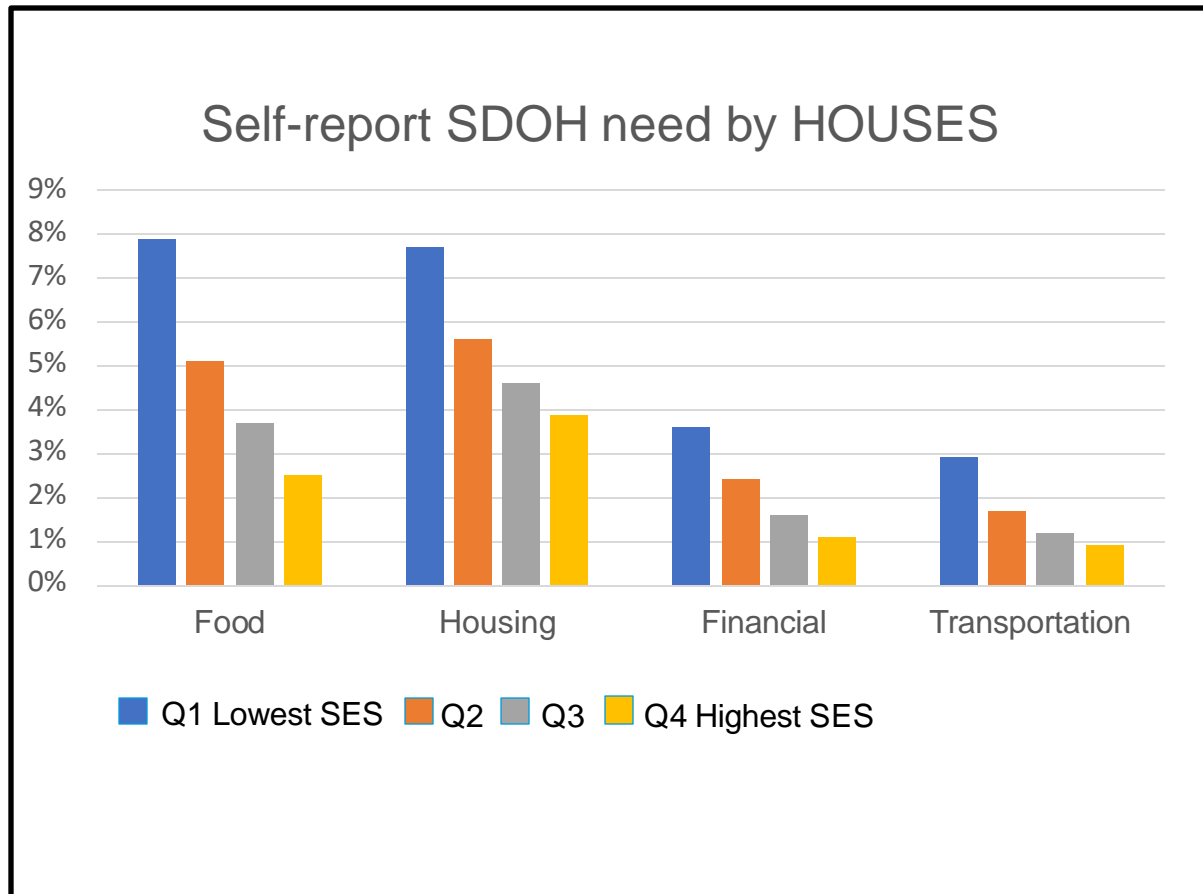
The HOUSES Platform Offers Innovative SDOH Data to the US Health Ecosystem



- Implement HOUSES and other SDOH measures in both clinical care/EHRs and research repositories via API
- The current HOUSES Platform offers;
 - HOUSES index
 - Area Deprivation Index (ADI)
 - Rural classification
 - Distance to a reference point
 - Geospatial report.

Address	Year	HOUSES quartile	HOUSES decile	HOUES percentile	RUCA code	ADI state	ADI national	Distance to Reference Address	Geo-report*
XX, Rochester, MN 55902	2021	2	4	43	1	8	68	12.3km	

HOUSES Predicts SDOH Risk *for Special Populations*



Mayo Midwest panel patients as of Aug 31, 2022, in MN or WI residents / Epic SDH data (self-report) from the prior 3 years

- HOUSES predicts self-reported SDOH (left) and cumulative unmet SDOH needs (right) in a dose-response manner

Track Record

65+

Outcomes in
adults and children

15

Grants funded

1.5M

Patients

97

Projects

45+

Publications



78%

Burden of Diabetes (OR)



35%

Coronary heart disease
risk (OR)



63%

Mood disorder risk (OR)



72%

Elderly falls (HR)



53%

All cause hospitalization
(HR)



140%

Burden of Multiple
chronic conditions (OR)



61%

Cancer mortality (HR)



45%

Delay in recovery
from concussion

HOUSES Predicts Cancer Screening

Colorectal Cancer Screening (n=58,882)		
SDOH	Quartiles	Odds ratio (95% CI)
HOUSES	Q1 (low SES)	0.52 (0.50 – 0.56)
	Q2	0.66 (0.62 – 0.70)
	Q3	0.81 (0.76 – 0.85)
	Q4	Ref
Zip-code level Deprivation Index	Q1	Ref
	Q2	1.03 (0.89 – 1.08)
	Q3	1.01 (0.93 – 1.10)
	Q4 (low SES)	0.98 (0.94 – 1.12)

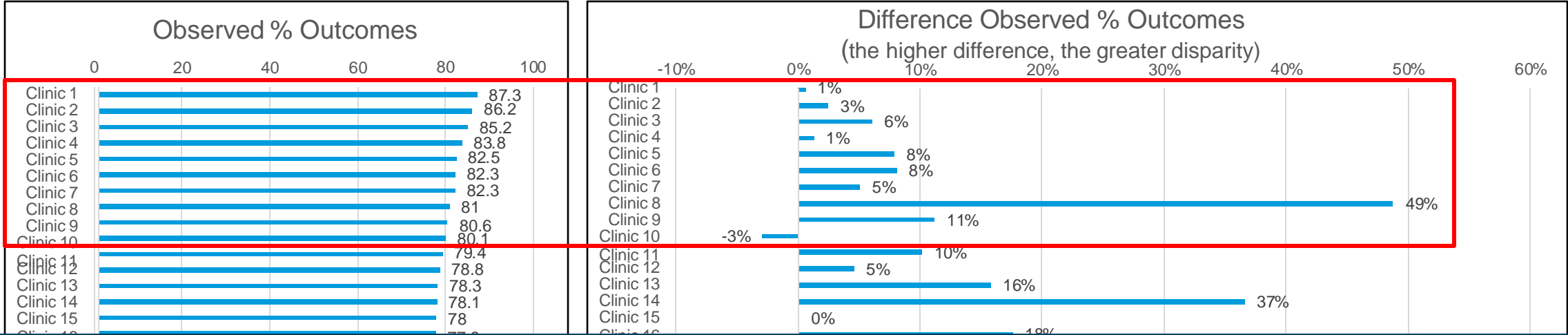
Breast Cancer Screening (n=128,462)		
SDOH	Quartiles	Odds ratio (95% CI)
HOUSES	Q1 (low SES)	0.53 (0.50 – 0.55)
	Q2	0.68 (0.65 – 0.71)
	Q3	0.84 (0.80 – 0.87)
	Q4	Ref
Zip-code level Deprivation Index	Q1	Ref
	Q2	1.06 (1.00 – 1.13)
	Q3	0.97 (0.91 – 1.03)
	Q4 (low SES)	0.73 (0.67 – 0.79)

Cervical Cancer Screening (n=175,712)		
SDOH	Quartiles	Odds ratio (95% CI)
HOUSES	Q1 (low SES)	0.74 (0.72 – 0.77)
	Q2	0.87 (0.84 – 0.90)
	Q3	0.94 (0.91 – 0.97)
	Q4	Ref
Zip-code level Deprivation Index	Q1	Ref
	Q2	1.23 (1.16 – 1.30)
	Q3	1.31 (1.24 – 1.39)
	Q4 (low SES)	1.06 (0.98 – 1.15)

Adjusted for age, sex, race/ethnicity, and comorbidity

- Assessed whether HOUSES predicts cancer screening rate among patients from Mayo Clinic Health System clinics and Mayo Clinic Rochester using 2019 MNMCM and 2023 Mayo Quality Metrics
- HOUSES **predicts** colorectal cancer screening rate
 - Patients with lower SES (HOUSES Q1) have significantly lower cancer screening compared to those with higher SES(Q4).
 - An aggregated SES measure, a ZIP-Code-level Deprivation Index **was consistently not associated** with cancer screening rate

PERFORMANCE OF OVERALL QUALITY OUTCOME VS. PERFORMANCE IN QUALITY DISPARITY IN COLORECTAL CANCER SCREENING



Connecting lab, clinic, and community

Science

Despite great progress in biomedical research, the health of the US population appears to be getting worse. The United States spends substantially more per capita on health care than other wealthy countries, yet US life expectancy ranks low among its peers. Mortality rates have been increasing for segments of the US population, including those in rural areas, certain racial and ethnic

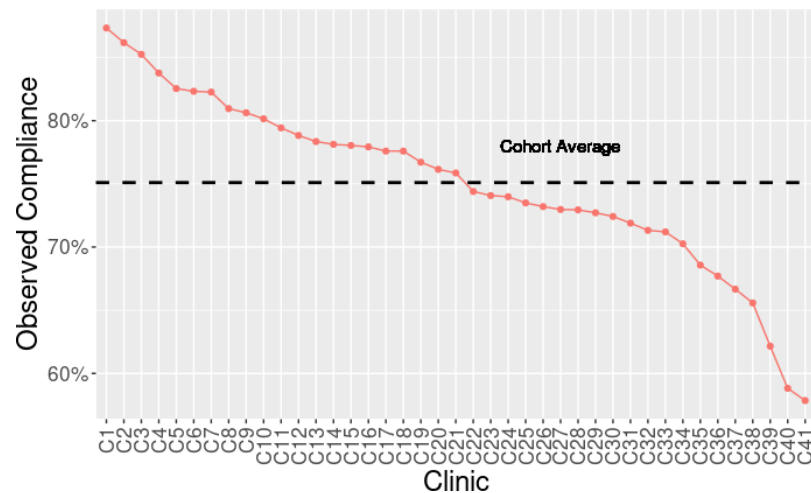
and embed data collection in electronic health records. The CARE for Health network will leverage many existing resources, such as Federally Qualified Health Centers, which offer services for underserved populations, and several existing NIH research initiatives and networks, including the IDeA Clinical & Translational Research Network Award program, which supports biomedical research capacity building in states that have

Monica M. Bertagnolli
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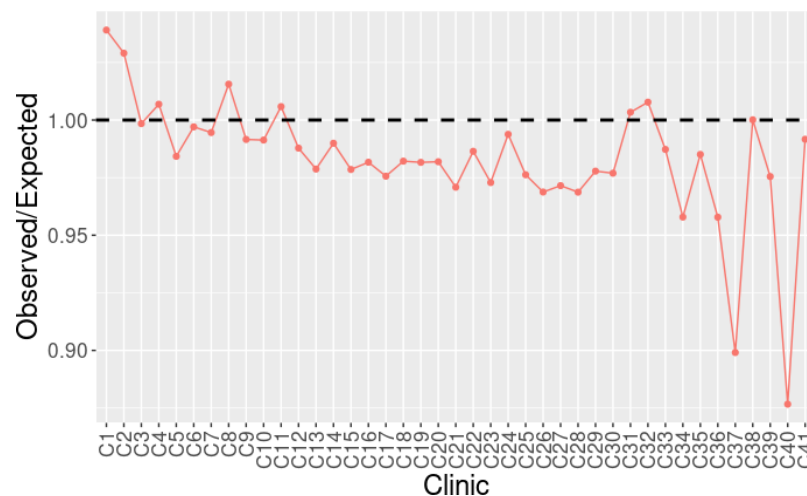


Application of HOUSES to T3 and T4 Translational Science Research

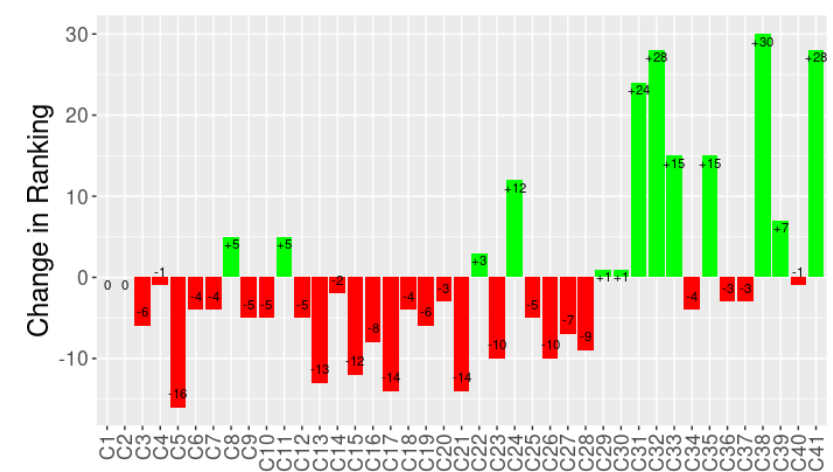
Proportion of patients with colorectal cancer screening across sites (59% to 88%)



Ranking by unadjusted screening rate



Ranking by HOUSES-adjusted screening rate



Ranking change after HOUSES adjustment

Observed/Expected performance metrics

- Expected: Adjusting clinics' colorectal cancer screening rates for **HOUSES**
- >1 for HCOs means exceeding the expectation based on case mix

HOUSES Predicts Post-Kidney Transplant Outcome

Eligibility

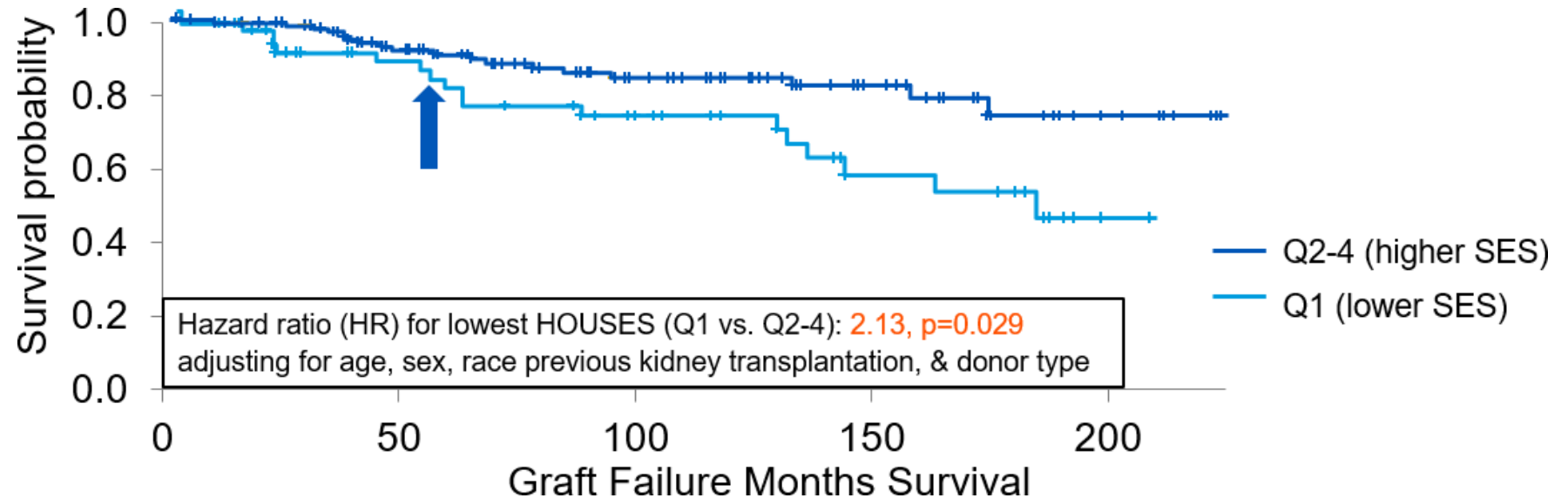
Consent
Estimated GFR ≤ 20 ml/min or dialysis
BMI ≤ 40
Psycho-social clearance (SIPAT)
Financial clearance

Exclusion (2+)

Age ≥ 70
Multi-vessel CAD with ischemia
LVEF ≤ 35
BMI ≥ 35
Severe COPD (FEV1 $< 50\%$ predicted)
Cigarette smoking
Severe peripheral vascular disease
Poor functional capacity





Absolute Contraindications

Can't comply with management
Malignant neoplasm (active)
Infectious Disease (active)
Immune Deficiency (severe)
Inability to perform transplant surgery
Severe comorbid conditions
Life expectancy (with transplant) < 5 years



- Patients with lower SES by HOUSES (Q1) had two times higher graft failure rate, compared to those with higher SES (Q2-4)
- Census **block-group SES measures and individual educational attainment failed to predict** outcome

Assessing socioeconomic bias in machine learning algorithms in health care: a case study of the HOUSES index

Young J. Juhn^{1,2}, Euijung Ryu³, Chung-Il Wi^{1,2}, Katherine S. King ³, Momin Malik ⁴, Santiago Romero-Brufau ⁵, Chunhua Weng⁶, Sunghwan Sohn⁷, Richard R. Sharp⁸, and John D. Halamka ^{4,9}

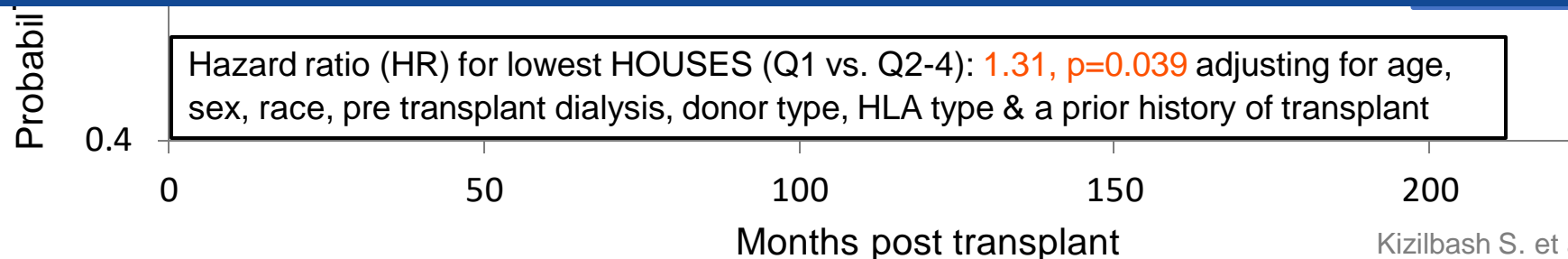
Assessment of Bias for GBM and NB Estimating 1-year Asthma Exacerbation Risk Using BER Between Groups of Children with Different SES by HOUSES

Groups	Balanced error rate (BER=[FPR+FNR]/2)	
	Gradient Boosting Machine (GBM) model	Naïve Bayesian (NB) model
SES (HOUSE) Q1 (lowest SES) Q2-Q4 Ratio (Q1/Q2-Q4) (1=no diff)	0.54 0.43 1.25	0.53 0.39 1.35
Area Deprivation Index (ADI) 76-100 (higher deprivation) 0-75 Ratio (76-100/0-75) (1=no diff)	Not computable (NC) 0.37 NC	NC 0.39 NC

- There was significant AI model bias by SDOH measured by HOUSES
- FDA acknowledges about the lack of regulation for post-deployment AI model bias by SDOH

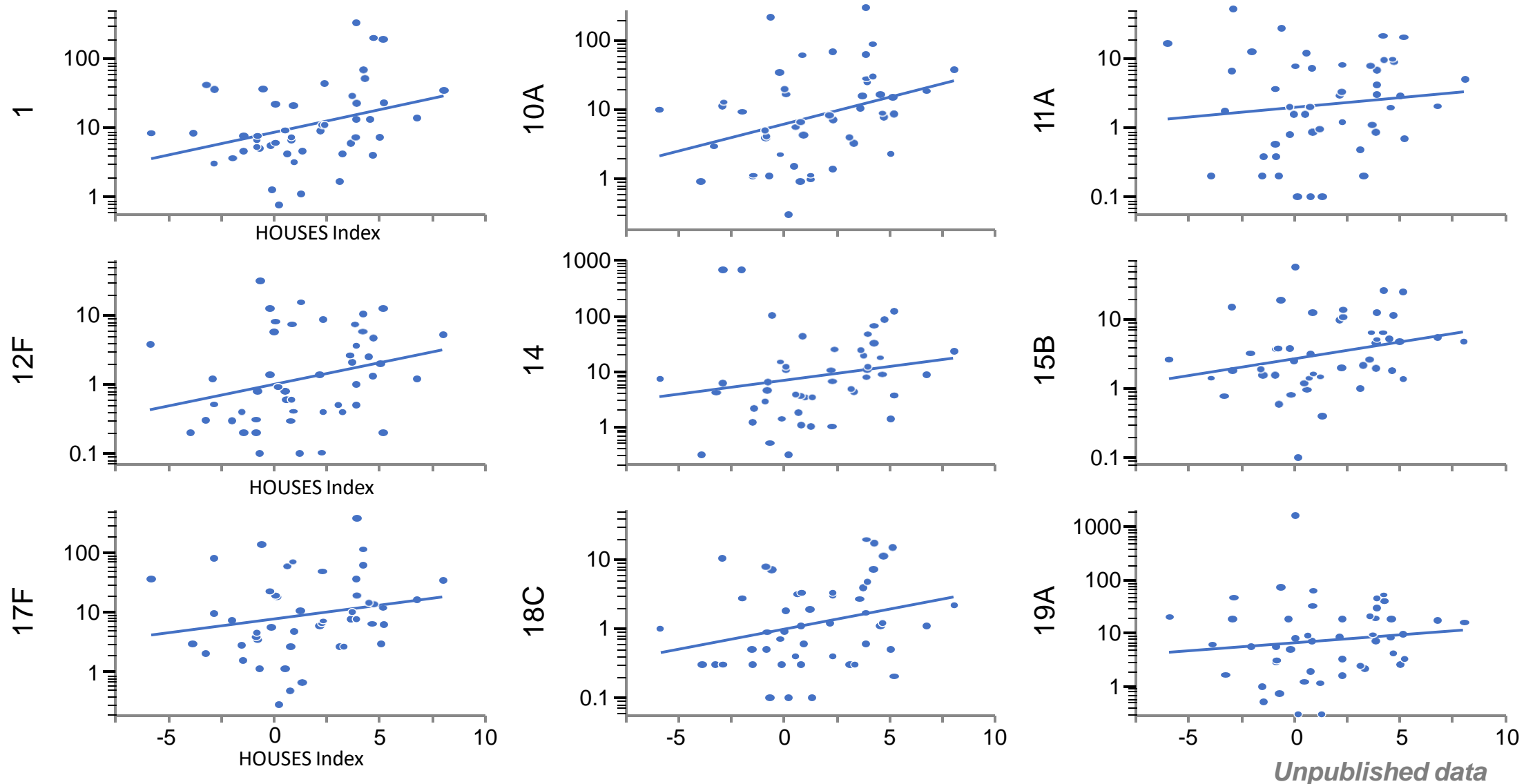
Replication: HOUSES Predicts Post-Kidney Transplant Outcome

- Replication at University of Minnesota in **both adults and children**
 - N=2,194 (median age [range]: 51 [0.77-81.8])
- HOUSES index predicted graft failure: patients with lower SES by HOUSES (Q1) had higher graft failure rate, compared to those with higher SES (Q2-4)
- Despite reassuring SDOH screening, HOUSES still predicts outcomes at the time of transplantation
- These observations make HOUSES Index a potential 'digital biomarker' for a high-risk subgroup



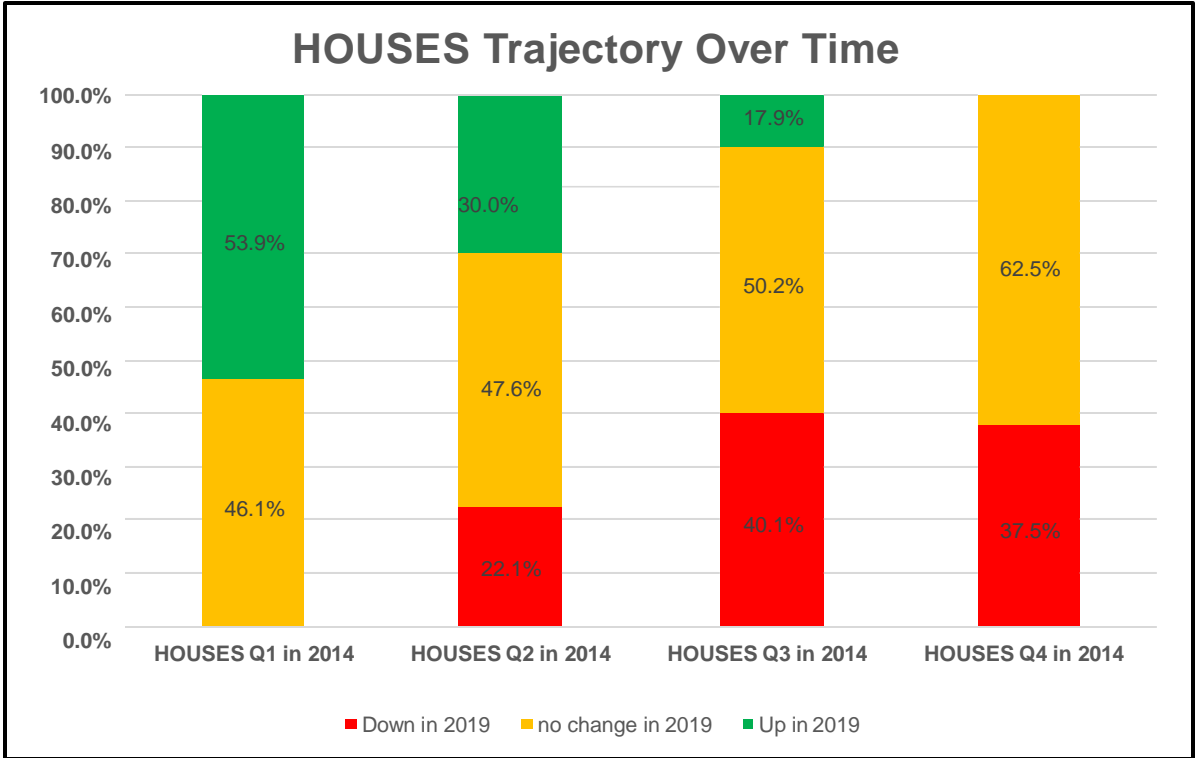
HOUSES as a Digital Biomarker May Predict Biological Responses

(Anti-pneumococcal antibody titers against 23 serotypes)



HOUSES and Longitudinal SES Change and Residential Histories (Exposome)

(NO ₂ : ppb)		Winter			
		Indoor NO ₂		Outdoor NO ₂	
		Median (IQR)	p-value	Median (IQR)	p-value
Overall		4.7 (1.2,18.6)	-	4.0 (0.8,7.8)	-
Living area					
	Rural	6.7 (2.4,16.2)	0.022	2.7 (1.6,4.9)	0.014
	Urban	3.2 (1.2,18.6)		4.0 (0.8,7.8)	
HOUSES			0.54		0.026
	Q1	3.1 (1.3,8.2)		5.2 (2.8,5.6)	
	Q2	4.0 (2.2,12.8)		4.4 (3.5,7.3)	
	Q3	3.8 (1.5,18.6)		4.3 (2.3,7.8)	
	Q4	3.0 (1.2,16.2)		3.2 (1.6,5.3)	
Gas stove			<0.001	NA	
	No	2.9 (1.2,11.4)			
	Yes	7.2 (3.1,18.6)			



Post-Operative Outcomes by HOUSES

- **Study Cohort:** 20,532 Mayo Rochester patients who underwent total joint arthroplasty (2004 to 2019).
- **Characteristics:** 54.7% female, 95.4% white (90.5% were non-Hispanic); 66.3 (IQR:16.6) years old.
- **Residence:** 80.7% of them reside in MN, WI or IA.
- **Surgeries:** 48.6% hip; 51.4% knee
- **Outcomes:**
 - 1.4% (n=290) surgeries resulted in post-op infection in 1 year
 - 16.6% (n=3,418) resulted in death over 15 years.

Post-Operative Periprosthetic joint infections

Term*	HR (95% CI)	Pvalue
HOUSES Q4	Ref	
HOUSES Q3	1.34 (1.00, 1.81)	0.054
HOUSES Q2	1.58 (1.16, 2.16)	0.004
HOUSES Q1	1.45 (1.01, 2.08)	0.043

Post-Operative Mortality

Term*	HR (95% CI)	Pvalue
HOUSES Q4	Ref	
HOUSES Q3	1.15 (1.05, 1.26)	0.003
HOUSES Q2	1.32 (1.20,1.46)	<0.001
HOUSES Q1	1.39 (1.26, 1.54)	<0.001

*Adjusted for age, sex, and comorbidity

HOUSES CAPTURES LONGITUDINAL RESIDENTIAL HISTORIES (EXPOSOME)

WHERE YOU LIVE MATTERS: *INTEGRATION OF INDIVIDUAL RESIDENTIAL HISTORIES INTO CANCER RESEARCH*

Department of Health and Human Services	
Part 1. Overview Information	
Participating Organization(s)	National Institutes of Health (NIH)
Components of Participating Organizations	National Cancer Institute (NCI)
Funding Opportunity Title	Integration of Individual Residential Histories into Cancer Research (R01)
Activity Code	R01 Research Project Grant
Announcement Type	New
Related Notices	<ul style="list-style-type: none">• March 10, 2020 - Reminder: FORMS-F Grant Application Forms & Instructions Must be Used for Due Dates On or After May 25, 2020. New Grant Application Instructions Now Available. See Notice NOT-OD-20-077.• August 23, 2019 - Clarifying Competing Application Instructions and Notice of Publication of Frequently Asked Questions (FAQs) Regarding Proposed Human Fetal Tissue Research. See Notice NOT-OD-19-127.• July 26, 2019 - Changes to NIH Requirements Regarding Proposed Human Fetal Tissue Research. See Notice NOT-OD-19-128.• November 26, 2018 - NIH & AHRQ Announce Upcoming Updates to Application Instructions and Review Criteria for Research Grant Applications. See Notice NOT-OD-18-228.• NOT-OD-18-009 - Reminder: FORMS-E Grant Application Forms and Instructions Must be Used for Due Dates On or After January 25, 2018.
Funding Opportunity Announcement (FOA) Number	PA-17-298

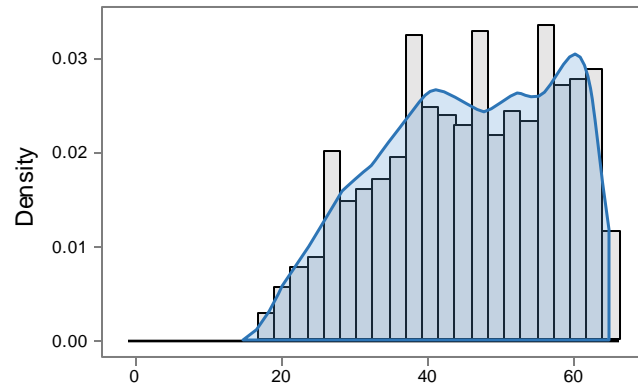
Notice of Special Interest (NOSI): Integration of Individual Residential Histories in Cancer Research	
Notice Number: NOT-CA-21-092	
Key Dates	
Release Date:	July 9, 2021
First Available Due Date:	October 05, 2021
Expiration Date:	March 08, 2024
Related Announcements	
PAR-19-309 - Modular R01s in Cancer Control and Population Sciences (R01 Clinical Trial Optional)	
PAR-21-190 - Stimulating Innovations in Behavioral Intervention Research for Cancer Prevention and Control (R21 Clinical Trial Optional)	
PA-20-185 - NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed)	
Issued by	
National Cancer Institute (NCI)	

- Systematic review and meta-analysis of residential radon and lung cancer in never-smokers
- Examining socio-spatial mobility patterns among colon cancer patients after diagnosis
- Cumulative vs. critical (life stage) effect of social and physical environment on disease risk and outcome

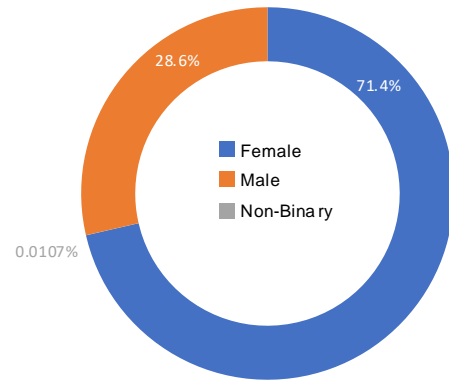
[Cheng et al, Eur Respir Rev 2021](#); [Namin et al, SSM Popul Health 2021](#); [Wiese et al 2022, SSM Popul Health](#)

HOUSES-Integrated Technology-enabled Subject Recruitment System Enhances Equitable Subject Recruitment

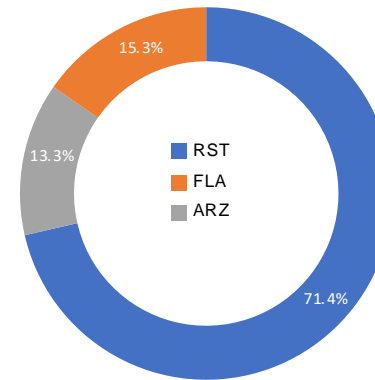
Age at Consent



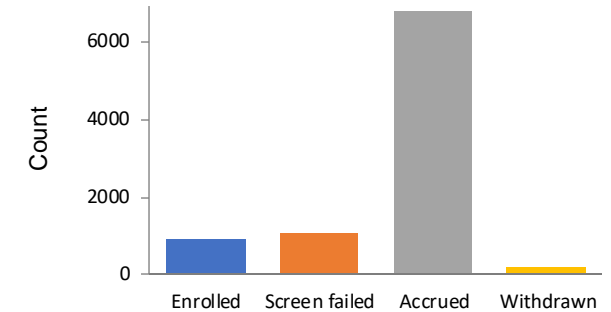
Gender



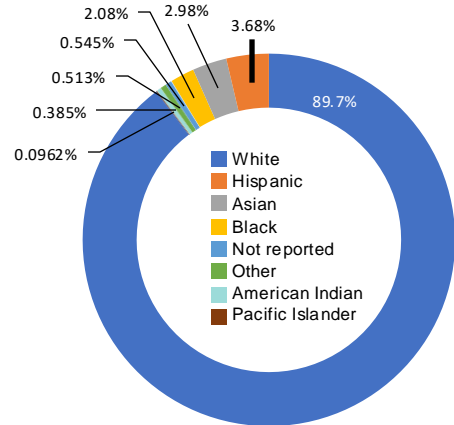
Site



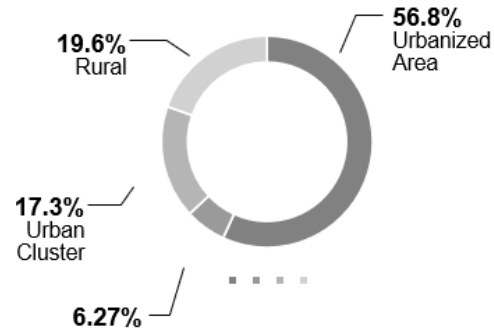
PTRax Status



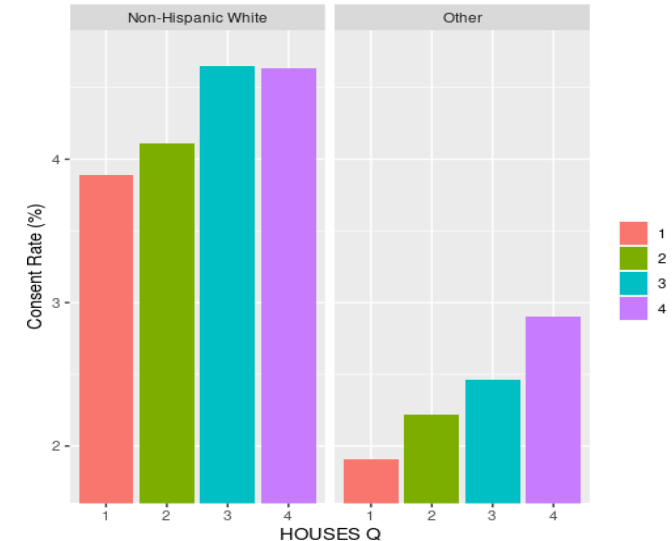
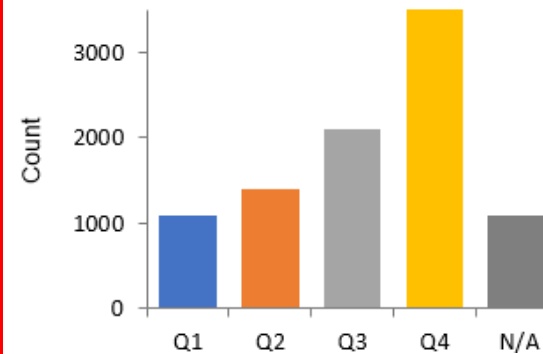
Race/Ethnicity



Urban/Rurality



HOUSES Index by Quartile (Q)
(Q1 represents under-resourced population)

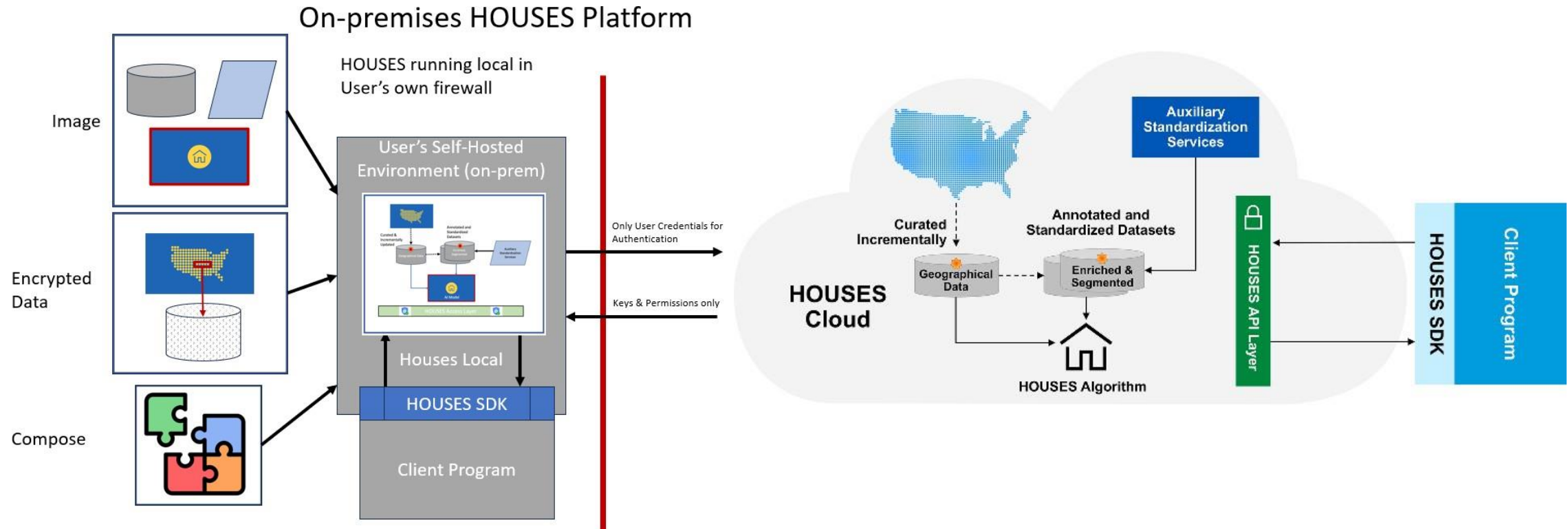


The potential interaction between SES and asthma susceptibility gene in the risk of asthma

17q21 Variants Disturb Mucosal Host Defense in Childhood Asthma

- Study cohort
 - A subset of Mayo Genome Consortium data in adults (N=396)
- Study design
 - Outcome: Asthma status defined by ICD code (17%)
 - Genetic variant of interest: The GSDMB rs2305480 SNP (located in chr 17q21), a gene associated with asthma in children (early onset asthma not late-onset asthma) Bouzigon E. NEJM, 2008
 - SES: HOUSES index
- Results
 - Overall, having minor allele was associated with lower risk of asthma (OR=0.85)
 - **Potential interaction** between HOUSES and rs2305480
 - In subjects with lower SES (less than median HOUSES),
 - No association between the SNP and asthma status (OR=1.02)
 - In subjects with higher SES (greater than median HOUSES),
 - **Observed (protective effect)** association between the SNP and asthma status (OR=0.68)

THE **ON-PREMISES** HOUSES PLATFORM



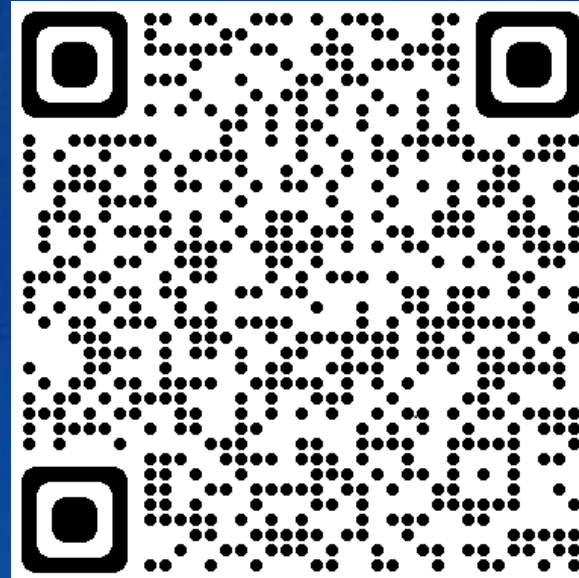
PROPOSED CTSA COLLABORATIVE AND INNOVATIVE ACCELERATION AWARD: ENHANCING AND DISSEMINATING THE HOUSES PLATFORM

Overall study design and key milestones for UG3 and UH3 phases				
Year 1	Year 2	Year 3	Year 4	Year 5
Alm1: Development, Expansion and Implementation (UG3)			Aim 2: Dissemination and Evaluation (UH3)	
1. Develop a new On-Premises HOUSES Platform 2. Expand new SDOH features 3. Develop new education modules 4.Implement HOUSES platform into REDCap via Application Programming Interface (API) (at Mayo first, then two CTSA sites) 5.Soliciting and selecting demonstration projects across the translational research spectrum (T1-T4) leveraging the HOUSES Platform at each site			Evaluation of the impact of disseminating HOUSES Platform on outcome metrics for demonstration projects	

Thank You



Video: HOUSES Summary



Video: How to use
HOUSES

Juhn.young@mayo.edu

Implications on T1-T4 Translational Science Research



Clinical Trials and Translational Science

- Identifies and addresses unmet SDOH needs of participants for inclusion of special populations
- Enables race-agnostic disparities research



Basic Research

- Enables efficient gene*env interaction scanning
- Inclusion of under-resourced population in translational research (T1-T4)



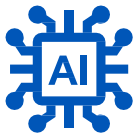
Rare Diseases

- Identifies patients with unmet SDOH needs
- Equitable access to new diagnostics and therapeutics (NIH Clinical Center implements HOUSES)
- Improve health equity in outcomes of RD



Enhance the NIH and Other Agencies

- **NIH**- Helps other NIH institutes meet the NIH mission (“turning discovery to health”)
- **CMS**- Improves more accurate and fairer pay-for-performance policy at budget neutral position
- **FDA**- Enables post-deployment surveillance on AI model bias by SDOH



Tools and Technologies

- Improves performance of AI models
- Assesses and mitigates AI model bias by SDOH
- Assess cumulative vs. critical effect of environment
- Enhances the utility of big data (N3C)



CTSA Consortium

- Enhances clinical and translational science capabilities
- Better address CHNA results and community needs
- Accelerate national effort for improving health equity

Scientific Value and Rigor of the HOUSES Index and Platform

Development of HOUSES Index

SUMMARY STATEMENT (Privileged Communication)		Release Date: 07/06/2005
V. Jeffrey Evans (301) 496-1174 evansvj@mail.nih.gov		
Application Number: 1 R21 HD051902-01		JUHN, YOUNG J MD MAYO CLINIC ROCHESTER DEPT OF PED & ADOLESCENT MED 200 FIRST STREET SW ROCHESTER, MN 55905
Review Group: ZRG1 HOP-B (90) Center for Scientific Review Special Emphasis Panel		
Meeting Date: 06/17/2005 Council: OCT 2005 Requested Start: 07/01/2005	RFA/PA: PA03-107 PCC: DBS -JE Dual PCC: I1 Dual IC(s): AI	
Project Title: Individual Housing Data and Socioeconomic Status		
SRG Action: Priority Score: 125 Percentile: 1.2		

Deployment of the HOUSES platform

SUMMARY STATEMENT (Privileged Communication)		Release Date: 10/15/2020 Revised Date:
PROGRAM CONTACT: PARTHA BHATTACHARYYA (301) 496-3131 bhattacharyyap@nia.nih.gov		
Application Number: 1 R21 AG065639-01A1 Formerly: 1R21AG065639-01		Principal Investigator JUHN, YOUNG J
Applicant Organization: MAYO CLINIC ROCHESTER		
Review Group: HSOD Health Services Organization and Delivery Study Section		
Meeting Date: 09/29/2020 Council: JAN 2021 Requested Start: 04/01/2021	RFA/PA: PA20-195 PCC: 2CHSRPB	
Project Title: Improving the Risk Adjustment Method for Quality Care Measures through Application of an Innovative Individual-Level Socioeconomic Measure		
SRG Action: Impact Score:21 Percentile:2		



School Based Health Centers - An approach to address health disparities among rural youth.

Project Number 1R01MD018385-01A1	Former Number 1R01MD018385-01	Contact PI/Project Leader TENNYSON, SHARON Other PIs	Awardee Organization CORNELL UNIVERSITY
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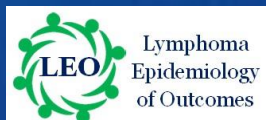
Description

Abstract Text

Project summary abstract Low-income rural youth face negative social determinants of health and challenges in accessing health care. School-Based Health Centers (SBHCs) are an innovative response to increase access, but their impact in rural communities is not well documented. This project proposes a multilevel mixed-methods evaluation of an SBHC network operating in 4 low-income rural counties in New York state. Run by the Bassett Healthcare Network, these SBHCs are permanent, on-site, year-round and attend to the full range of healthcare needs (physical, dental, mental, chronic and acute) at no out-of-pocket cost to patients. The setting permits a quasi-

- Cornell- affiliated Bassett Healthcare System implemented HOUSES which helped them secure their first R01 funding
- NIH Clinical Center and other programs are implementing HOUSES for clinical research and care

MN EHR Consortium



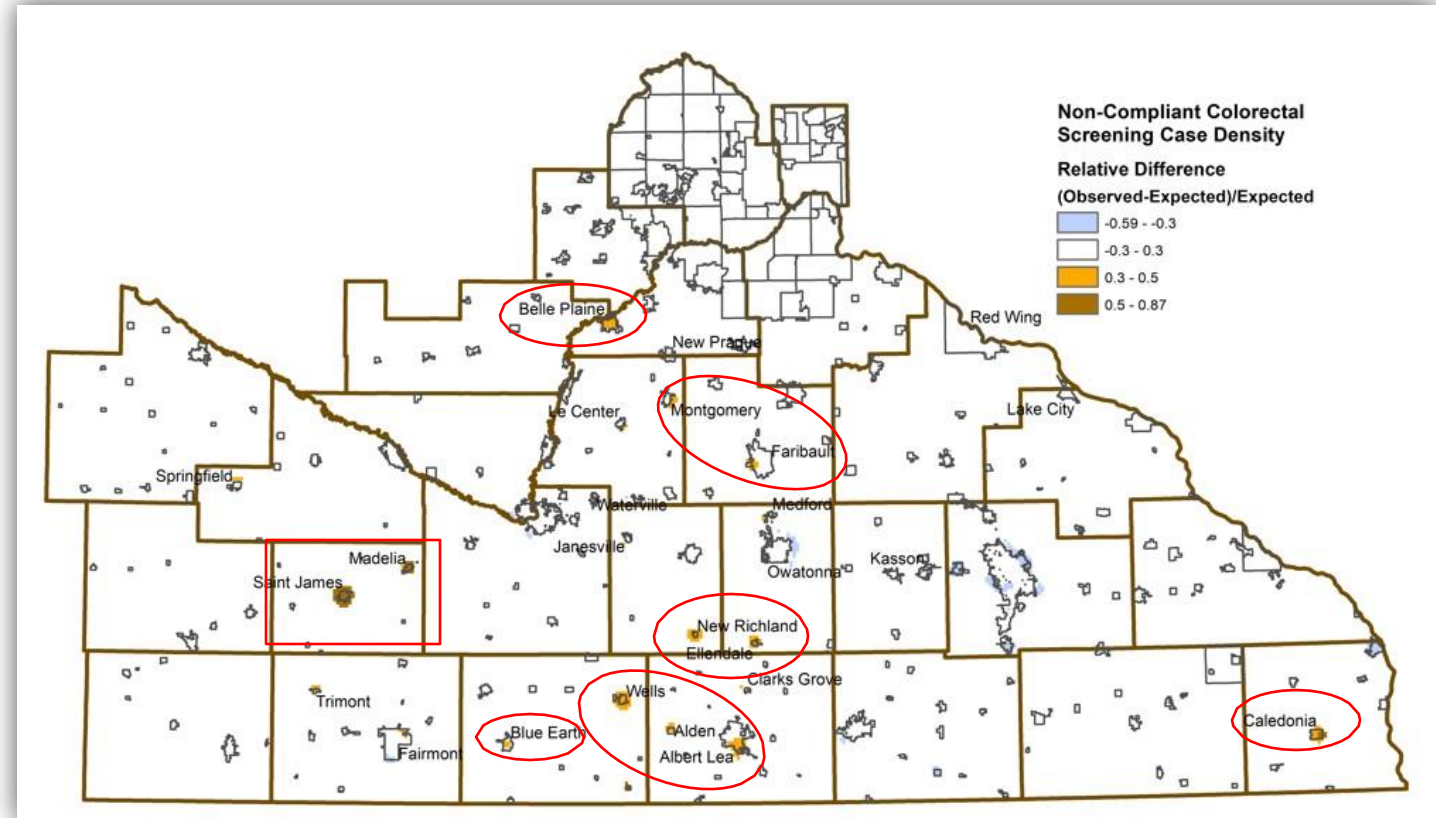
HOUSES-Enabled Geospatial Analysis for Population Clusters without Colorectal Cancer Screening



Sherburn, MN
Mobile Health Clinic
Appointments: 507-238-8500



Kenyon, MN
Mobile Health Clinic
Appointments: 507-451-1120



Hotspots for non-compliant colorectal cancer screening and potential intervention via community outreach

Reminder: January 2025 CTSA Webinar

The next webinar is **January 22, 2025; 2-3 PM ET**

Please register with the new link and add the new invite to your calendar:

https://zoom.us/webinar/register/WN_NxW6tboxQninVI7UFGfmYQ