2023 "HRPP Innovations" Webinar Series

Innovative Practices by
AAHRPP-Accredited Organizations:
Responding to the Concerns of Research
Participants (Standard I-4)

November 14, 2023 1:00 pm – 2:30 pm ET









Attendee Hub

Livestreamed Content
Live Q&A
Chat/Discussions



Webinar Sessions

Three Webinars: April, July, November One Attendee Hub



Community

Continue Discussions after Webinars Conclude

Check Upcoming AAHRPP Events

Resources from Speakers



On-Demand Content

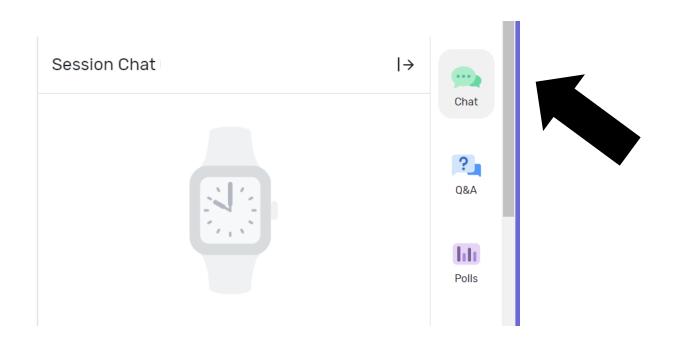
Webinar Recordings on Hub

Available for the Whole Year



Chat Feature

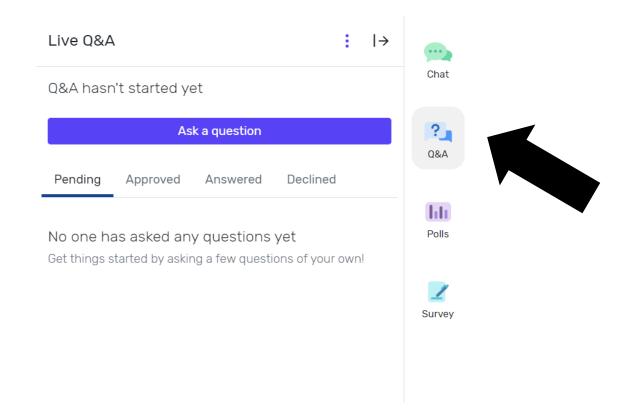
To chat with your colleagues before and after the session, or if you have technical questions, use the "Chat" icon





Questions

To ask questions about the topic for the presenters, please use the "Q&A" icon:







AAHRPP at PRIMR23:

Sunday, December 3, 2023:

Office Hours – 4:30pm – 5:30pm ET

Monday, December 4, 2023:

Office Hours – 12:15pm – 1:00pm ET

Tuesday, December 5, 2023:

- Office Hours 12:00pm 1:00pm ET
- Office Hours 5:00pm 6:00pm ET

Wednesday, December 6, 2023

• "A Dialogue with AAHRPP: - G08 - 11:30am - 12:30pm ET

Visit AAHRPP in Booth #223



Upcoming AAHRPP Webinars:

December 12, 2023, 3:00 pm – 4:00 pm ET:

Ask AAHRPP Webinar: Response to Council Review – Last of the six-part series

Speakers: Robert Hood, AAHRPP; AAHRPP Consultants/Operations Team Members

Moderator: Nichelle Cobb, AAHRPP

2024 Events Schedule Coming Soon!

Webinars (aahrpp.org)



Join Us in San Diego, CA:



CONFERENCE: Science and Standards in San Diego

MARK YOUR CALENDARS FOR ONE OF THE RESEARCH COMMUNITY'S MUST-ATTEND ANNUAL EVENTS. MORE DETAILS TO FOLLOW.

LOCATION:

Sheraton San Diego Hotel & Marina 1380 Harbor Island Dr, San Diego, CA 92101







Nichelle Cobb, PhD
Senior Advisor for Strategic Initiatives
AAHRPP







Sadie Gabler, BS, CCRC
Director, Office of Research Participant Advocacy
University of Utah





Laurene Tumiel Berhalter, PhD
Director of Community Translational Research
University at Buffalo



Session Goals

- Discuss how an organization is awarded an AAHRPP "Area of Distinction"
- Learn about the innovative approaches developed by two AAHRPP-accredited organizations to:
 - promote communication between research participants, the organization (including the IRB), and research teams.
 - advance community engagement in and understanding of research.
 - improve the research process.

Areas of Distinction – What Are They?

Areas of Distinctions are activities, resources, processes, or approaches that are innovative, unique, or a potential best practice that HRPPs at other organizations may benefit from knowing about or adopting.

They are awarded by the AAHRPP Council on Accreditation after a site visit, usually based on recommendations from the site visit team.



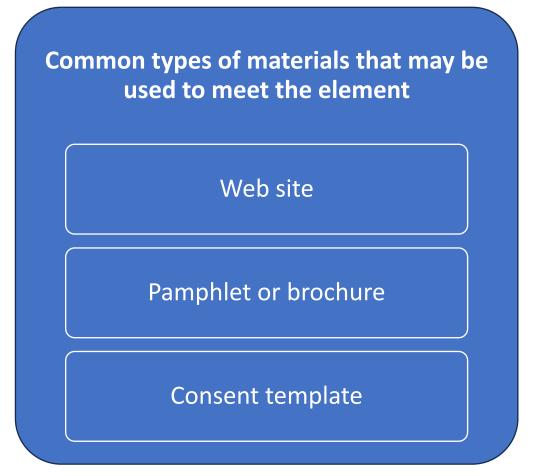
STANDARD I-4: The organization responds to the concerns of research participants.

Standard I-4

- To meet this Standard, organizations must:
 - provide a way for research participants (whether current, prospective, or past) or their representatives to discuss problems, concerns, and questions; obtain information; or offer input with an informed individual who is unaffiliated with the specific research protocol or plan.
 - conduct and evaluate activities designed to enhance understanding of human research by participants, prospective participants, or their communities, when appropriate.
 - promote the involvement of community members, when appropriate, in the design and implementation of research and the dissemination of results.

Element I.4.A

The organization has and follows written policies and procedures that establish a safe, confidential, and reliable channel for current, prospective, or past research participants or their designated representatives that permits them to discuss problems, concerns, and questions; obtain information; or offer input with an informed individual who is unaffiliated with the specific research protocol or plan.



Outcomes

- The organization provides information to current, former, and prospective participants or others about whom to contact in the organization to discuss problems, concerns, and questions; obtain information; and offer input.
- The organization responds to contacts from participants or others.

Area of Distinction: University of Utah

"The Research Participant Advocacy Program seamlessly combined all aspects of the research program for the participants. The program was uniquely structured and acted as the liaison between research participants, researchers, and the IRB. In addition to managing complaints and concerns from participants, the program worked directly with researchers to develop and implement corrective actions, including assistance with amendments, to address any participant concerns. The Program was also represented at each IRB meeting, which resulted in improved communication. A unique feature of this program was the comprehensive translation and interpretation services (providing support for over 27 languages) specific to the particular research project for researchers and their teams, with a particular focus on comprehension by participants. The Program supported numerous community events (i.e., health fairs) with the goal of providing information to the local community about the importance of research, research protections, and research participant expectations. (Element I.4.A.)"



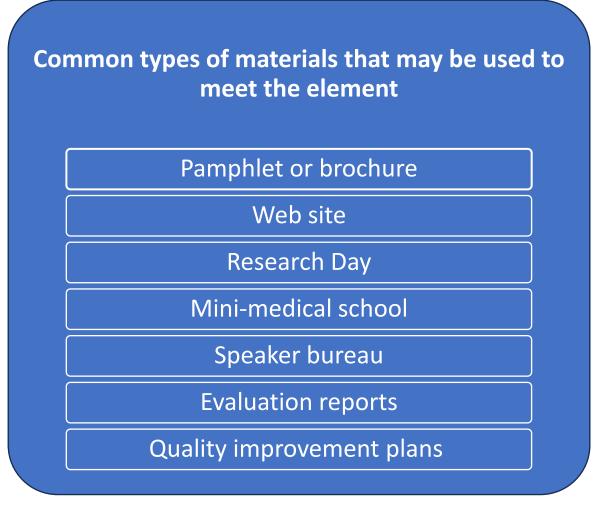
Area of Distinction: University at Buffalo

"Research Participant Advocates regularly provided support to potential participants to ensure a complete understanding of the research process. The advocates acted as an impartial third party with the goal of enhancing the research experience of participants and their families. They receive many calls from research participants and/or their families with questions or concerns. It is clear from the number of calls received that they have effectively communicated the availability of the service they provide to prospective and current research participants and that it is being utilized. (Element I.4.A.)"



Element I.4.B

The organization conducts activities designed to enhance understanding of human research by participants, prospective participants, or their communities, when appropriate. These activities are evaluated on a regular basis for improvement.



Outcomes

- The organization provides information designed to enhance the understanding of research involving participants and their community.
- IRB or EC members and researchers can describe the characteristics and culture of the communities in which they oversee or conduct research, respectively.
- The organization makes improvements to its outreach activities as needed, based upon a periodic assessment.

Element I.4.C

The organization promotes the involvement of community members, when appropriate, in the design and implementation of research and the dissemination of results.

Common types of materials that may be used to meet the element

Research studies using a communitybased participatory research design

Use of community advisory boards

Use of participant advocates

Partnerships with community-based organizations

Outcomes

- When appropriate, the organization supports mechanisms that allow researchers to involve community members in the research process, including the design and implementation of research and the dissemination of results.
- When appropriate, researchers involve community members in the design, conduct, and analysis of data.
- When appropriate, researchers inform community members about the results of the research study and utilize community members to help disseminate results.

Area of Distinction: University at Buffalo

"The University's CTSI has an extensive and successful community engagement program that has worked with various communities in western New York. The engagement program developed and implemented the Buffalo Research Registry for individuals 18 years and older who have an interest in participating in research. Strong community partnerships with the Patient Voices Network, the African American Health Equity Task Force, the Jericho Road Community Health, and others have been cultivated and valued. Members of the program regularly attended community health fairs, visited under-served communities, and produced research newsletters to educate the community about University at Buffalo, The State University of New York's research program. These outreach activities have not only served to engage with the community but have created bidirectional communication between the University at Buffalo, The State University of New York and the community. This was evidenced by the recent request received by the university for researchers to meet with community leaders about research ideas they wish to pursue. (Elements I.4.B. and I.4.C.)"

University of Utah

Sadie Gabler, BS, CCRC Director, Office of Research Participant Advocacy (ORPA) University of Utah



ORPA Team



Sadie Gabler



Amanda Barrios



Diana Cufino

Our Collective WHY:

To serve our community by providing services that support equitable access and opportunity to research by removing barriers and serving as a liaison between research participants, researchers and regulatory bodies (IRB, COI, OQC) to increase trust, respect, and satisfaction.



Taanisha Rhone



Ana Corona

Highlights

- Office created: October 2008
- 2009-10: Established mission for office with overarching aim to serve as a voice for participants.
- 2011-16: Demands grew; Increased FTEs, community awareness activities began, developed public facing CTs site, software purchased to support human translations.
- 2017-19: Stand alone office with independent budget.
- 2020 COVID!
- 2021-22: Vaccine Rollout!
- 2023: IRB Policy include Spanish speakers for IRB approval!

ORPA EVOLUTION

Fall 2008

Creation of Research Participant Advocate (RPA) - funded by CTSA

The position replaced the role of the research ombudsman which had previously been held by

2009-10

Office Development

- RPA contact info added to all ICFs.
- RPA is included in all IRB panel mtgs. 1 FTE Spanish translator/interpreter hired. Funded by the AVP for Research Integrity

2011-16

Office Growth

- 2 FTE Spanish Translators/Interpreters. FTE Proofreader/Interpreter. 1 FTE support
- · Translation software was purchased to support efforts and ensure the consistency of terminology across studies.
- Community outreach.
- Develop public-facing CTs website.
- Developed working relationship with a vetted 3rd party vendor for additional inguages outside of Spanish.

2020

COVID-19

- · ORPA office saw a 3-fold increase in demand. Staff worked round the clock to serve our community.
- Assisted the HR and PRs office in disseminating info on testing, vaccine research, research updates, remote consent witnessing, etc.

2017-19

Cont. growth in institutional

- · Increased departmental training and
- · ORPA became a standalone unit FY 2019 with a budget of its own.
- Intial operating budget \$285,771.
 Current budget \$396,586.

2021-2

/accine Rollout/ CTs Website

- Vaccine rollout info support Langage access and health literacy needs, outreach Office STEM ambassador training 2/2021
- · 2021 The website began to be redesigned to be institutionally inclusive of all human subject research, not just CTs.
- . 2022 The Spanish version of the site rolled out.
- · Added training series to REd.

2023

IRB Policy July 1, 2023

- · Effective July 1, 2023, U of U investigators seeking approval for new studies with participant interaction in Utah must include Spanish speakers to receive IRB approval.
- · Studies approved before this date must follow the policy by April 1, 2024.
- · Outreach activities Employee Appreciation Day, Career Fair at external University

VP for Research and CTSA Support

VP for Research and CTSI - current commitment to the ORPA:

- CTSI 85% Director salary 25% Admin. salary
- VP for Research supports 3 FTEs and remaining salaries of CTSI funded staff.
- Support includes professional development of staff.
- Current annual budget \$396,586
- Initial operating budget in FY 2019 \$285,771





Current Translation Fee Structure:

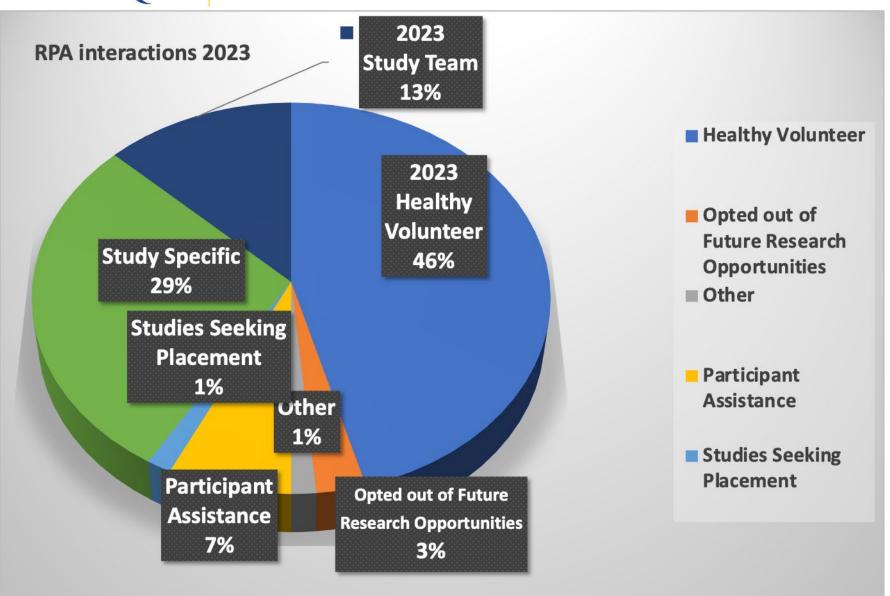
Office of Research Partic	ipant Advocacy (ORPA) New Cost Structure for Spanish
Translations Only as of July 1, 2023	

Translations Only as of July 1, 2023			
New Document Translations			
Federal/Non-Profit	<u>Industry</u>		
\$250.00 *Bundle/site	\$0.15/word		
Or			
\$0.08/word for any other document with a minimum of \$75.00.			
Amendments to Materials Previously Translated By ORPA			
Federal/Non-Profit	<u>Industry</u>		
\$75.00 *Bundle/site	\$0.08/word. **		
Or			
\$25.00 minimum for other documents.			
*Bundle = 1 to 3 documents (ICF, PPF and Assent)			
**Entire document word count will be used to	**Entire document word count will be used to assess fees		

^{**}Entire document word count will be used to assess fees.

Prices DO NOT include F&A fee.









Where we are today:

- Translation/Interpretation utilization up 68% since 2019 with no addt'l FTEs
- Short form available in 59 languages.
- Audio/video recordings available in 14 languages, includes ASL.
- ORPA offers 5 Biannual trainings through the Office of Research Education (REd), independent departmental trainings.
- Community outreach and education, including presentations to juveniles in the criminal justice system about careers in research, i.e. interpreters, translators, researchers, etc.





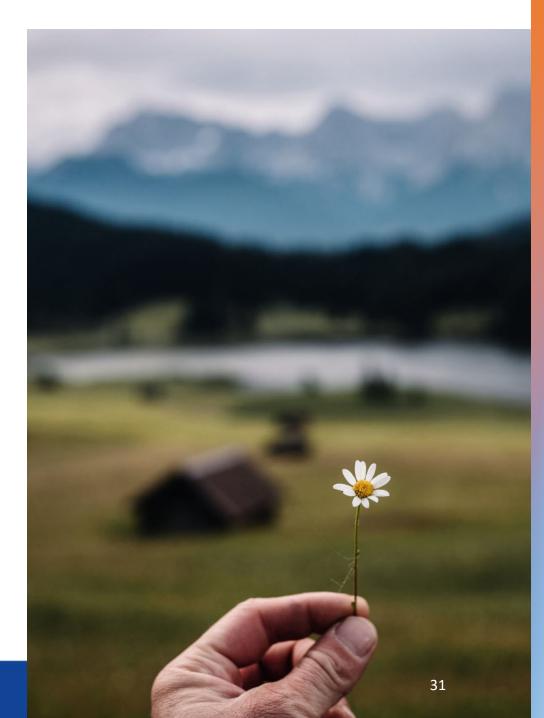
2024 and Ahead:

Externally – Increase outreach scope!

- Peer Institutions.
- PCP/Clinics outside of U.
- Untapped community organizations.
- Reengage with in-person events.

Internally – Build more bridges!

- Increase awareness of services.
- Continue building language library.
- Refine tracking to better measure impact of services.



Contact Information

Sadie Gabler, BS, CCRC

Director, Office of Research Participant Advocacy

Office: 801.581.3803

Sadie.gabler@hsc.utah.edu

participant.advocate@hsc.utah.edu

https://rpa.utah.edu/

https://studiesforyou.utah.edu

For Research Language Access Services

801.585.6745

research.translation@hsc.utah.edu



University at Buffalo

Laurene Tumiel Berhalter, PhD
Associate Professor, Department of Family Medicine
Community Engagement Core Director,
UB's Clinical and Translational Science Institute



About WNY

WNY

- 8 counties
- Buffalo and City of Niagara Falls largest urban areas

Erie County

- Population 950,312 (2020 census)
- 19.8% under 18, 19.5% over 65
- 77.9% white, 14.1% Black, 6.1% Hispanic
- 13.7% population in poverty

Buffalo

- Population 278,301 (2020 census)
- 22.5% under 18, 12.9% over 65
- 47.8% white, 33.3% Black, 12.2% Hispanic
- A top ten city resettlement of New Americans since 2002
- 27.6% population in poverty

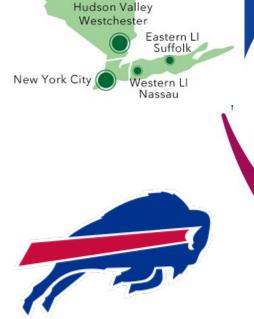


Rochester

Buffalo

Central

Syracuse



Capital Region

Albany





It Takes a Village..











AAHRPP Association for the Accreditation of Human Research Protection Programs, Inc.® Community and Stakeholder **Engagement Research Module**

Community & Special **Populations**

Build Awareness and Knowledge of Research

Support and document successful linkages and recruitment

> Community Based Healthcare **Providers**

Build Awareness and Knowledge of Community and Research

Researcher/ Research Institution

Build Awareness and Knowledge of Community







Our CSERM Team



T. Quattrin, PhD Core Director



L. Tumiel-Berhalter, PhD Core Director



R. Cadzow, PhD Special Populations Task Leader



A. Stromeier, MEd Clinical Recruitment Coordinator



A. Regling, MA Clinical Recruitment Coordinator



G. McKenzie, M.Ed Community Engagement Specialist



A. Regling, MA Clinical Recruitment Coordinator



E. O'Byrne, MA Senior Administrator



R. Benedict, MD
Core Faculty



K. Szigeti, MD, PhD Core Faculty



K. Tornatore-Morse, PharmD Core Faculty



Y. Chang, PhD, RN, FGSA, FAAN, FIAAN Core Faculty



E. Gage- Bouchard, PhD Core Faculty



Consultations

Researcher Consultations

- ✓ Community Based Recruitment
- ✓ Community Based Research Program Development
- ✓ Community Integration
- Community Consults: 8 in 2022 and 7 (and counting) in 2023
 - ✓ Linking Community Organizations to Researchers
 - ✓ Helping communities establish events, programs, and other projects
 - ✓ Sharing networks and opportunities to promote health equity

Participate in Research Portal

- 44 protocols listed
- **158 requests** submitted by volunteers



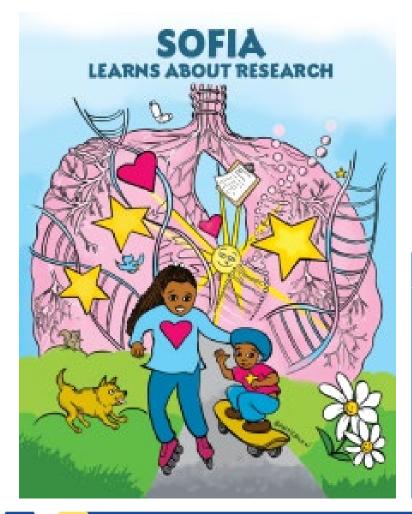
Buffalo Research Registry

- A database of people from Buffalo and Western New York who have shown interest in becoming research study volunteers.
- 7,173 enrollees with specific health profiles
 - 3,865 enrollees recruited through Emergency Departments
 - 50% identify as racial minority
 - 50% from under resourced Zip Codes





Science Literacy





Science Cafes



CTSI OPEN RESEARCH OFFICE

presents:

PLAIN LANGUAGE FOR RESEARCHERS

Andy Strohmeier M.Ed.



Community Engagement Studios

- Developed by Meharry Vanderbilt CTSA
- A one-time consultation by potential study participants
- Inform the development, implementation and/or dissemination of a research study
- Bi-directional conversation





Community Partnerships Seed Grants

- \$5,000
- Awarded to academic-community teams for:
 - **Developing** community-engaged research partnerships that align with the mission, vision, and culture of the partnering community-based organization
 - Aligning priorities and exploring possibilities for collaboration (for example program evaluation, intervention development, and resource development)
 - Developing innovative community-engaged research proposals to be submitted for additional funding

Community Outreach

- Types of events: wellness fairs, symposiums, festivals, etc.
- Location of events: Buffalo, Niagara Falls, rural WNY
- Sign up for Buffalo Research News
- Sign up for the Buffalo Research Registry
- Interactive









Buffalo Research News



- 4 issues of email newsletter (2,212 recipients)
- Most Clicked Stories (Top 3):
- ✓ Research Roundup: UB Looks at How to Make Online Grocery Shopping Easier and Healthier
- ✓ Research Roundup: Studying Eating, Activity, and Health in Kids and Teens
- ✓ Dealing With Emotional Trauma: Community Insights From UB Experts



Educational Programs

- Students at the CTRC Day
 - Buffalo Charter School (14 students)
 - Panel on Research Professions
 - "Investigate the investigator" activity
 - Tour of CTRC
- Community Engagement Workshop (Aug, 2023)
 - Interactive ½ day session
 - Attended by diverse faculty and staff (genomics, geography, etc.)
 - Intro to Community Engagement and Plain Language
- Human Subjects Research Workshop
 - Buffalo City School (44 students)
 - Overview of the IRB
 - Talks by people doing diverse human subject's research
 - Round Robin conversations with researchers



Strategic Collaborations



Supermarkets and Pharmacies



Community Based Organizations



Health care practices



Science Museum



United Way



Coalitions



Patient Voices Network

- Since 2010
- "A community of educated and involved patients working hand in hand with physicians in making decisions about their own health care"
- Low-income, predominately Black, complex health issues
- Steering committee meets twice a month
- Serve as consultants on research materials



Patient Voices



Community Health Equity Research Institute

About Us

Why Health Disparities Matter

Working With the Institute

Community Partners

Contact Us

SEARCH Q



The Community Health Equity Research Institute is excited to announce the launch of its

Igniting Hope 2023: 'Building a Healthy, Just Community for All'



Health Equity Pilot Studies Program!



IRB Collaborations

- CIRTIfication
 - Community friendly human subjects research training
 - Certified adopter
- Recruit non-affiliated IRB board members
- Offer co-education for faculty
- Bi-directional consults
- Essential to be on the same page





Research Advocacy



- Offered though our Clinical Research Office (K. Brunton and P. Anderson)
- Receive routine phone calls and emails
 - either participated in trials
 - are interested in learning more about the trials we have ongoing or upcoming
- Address any participant complaints
 - Very few research complaints that required notification to the IRB
 - Usually revolve around reimbursement/compensation for participation or scheduling of visits.
 - Miscommunication or misunderstanding that is easily rectified by connecting them with the right study team member
- Connect participants with investigators
- Follow up to ensure questions/concerns were properly addressed
 - Genuinely thanked for calling them back or listening/addressing to their concerns
 - Surprise that they received call backs or communication addressing their concern
 - Provide the opportunity to answer questions they may have about research in general



University Commitment

- University and School Priorities
 - Strategic planning efforts
 - Associate Dean of Undergraduate Education and STEM Outreach
- Institutional Funding
 - Health Equity Pilot Studies (Institute)
 - Civic Engagement Research Fund (University)
- Community Engaged Researchers
 - Span the entire University

This program is supported by the National Center for Advancing Translational Sciences of the National Institutes of Health under award number UL1TR001412 to the University at Buffalo.





Thank You!





Questions?

