



Integrating Special Populations

This presentation includes detailed information about our programs, services and guidelines for use.

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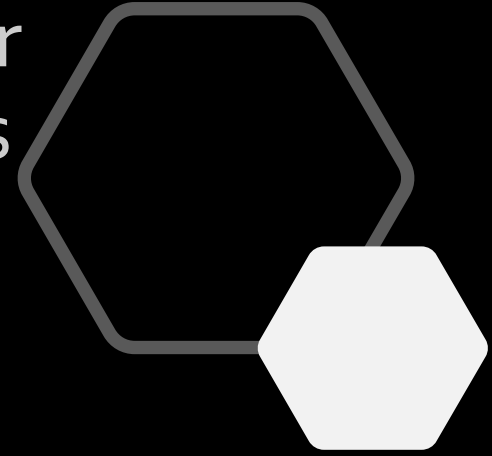
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A black and white portrait of Maya Angelou, an elderly woman with short, curly grey hair, smiling and looking slightly to the right. She is wearing a dark, ribbed top and a multi-strand pearl necklace. The background is dark.

Maya Angelou Center for Health Equity | About Us



MAYA ANGELOU

APRIL 4, 1928 ~ MAY 28, 2014

The [Maya Angelou Center for Health Equity](#) conducts and supports research focused on health equity. We provide education and training opportunities to both internal and external partners and stakeholders.

All activities seek to promote health equity through research, education, training and meaningful engagement.

The Maya Angelou Center for Health Equity houses the **Integrating Special Populations** program in collaboration with the Clinical & Translational Sciences Institute (CTSI) at Wake Forest Baptist Medical Center.

Integrating Special Populations

The Integrating Special Populations (ISP) Program assists Wake Forest Baptist Medical Center (WFBMC) investigators by increasing involvement of special populations in clinical studies. The program especially encourages research opportunities for:

- Older adults (65 years of age and older)
- Children and adolescents (17 years of age and younger)
- Underrepresented racial and ethnic minorities

We offer services to support clinical studies in the inclusion of special populations:

- Voucher Programs
- Translation & Interpreting Services
- Bilingual Research Participant Navigation
- Research Consultations & Trainings
 - Research Ambassador Program
- Coordination with BeInvolved en Español CTSI program



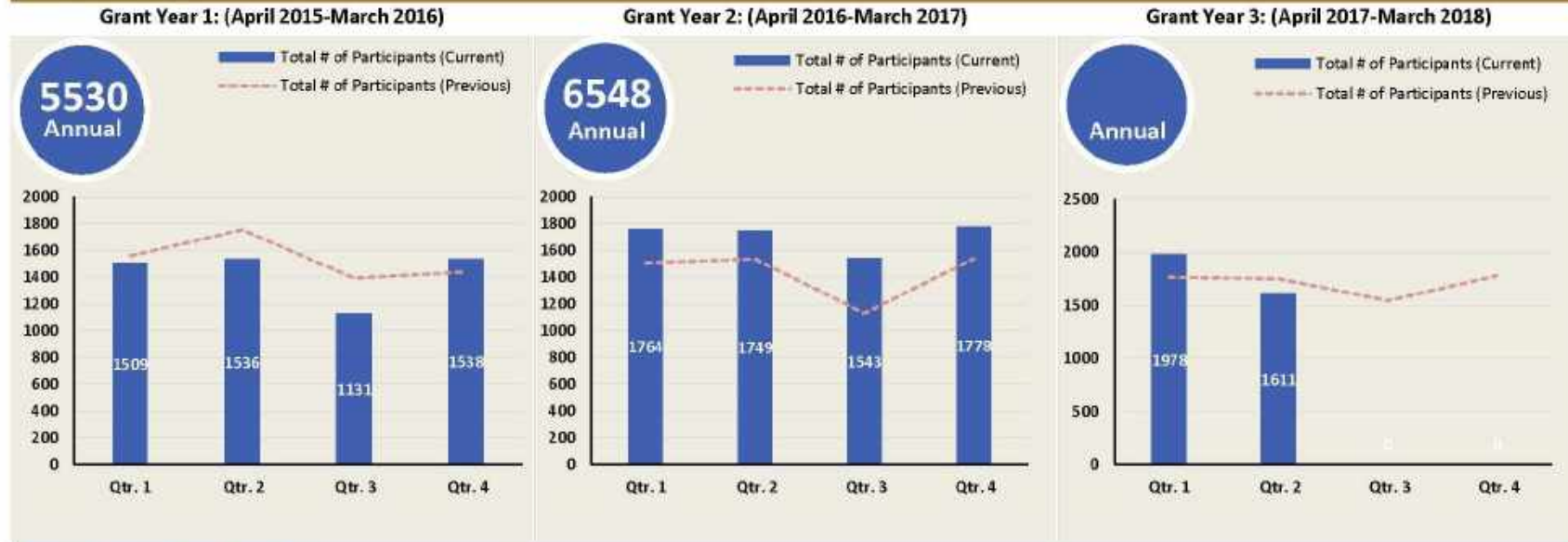


MACHE ISP Impact on Clinical Trial Recruitment

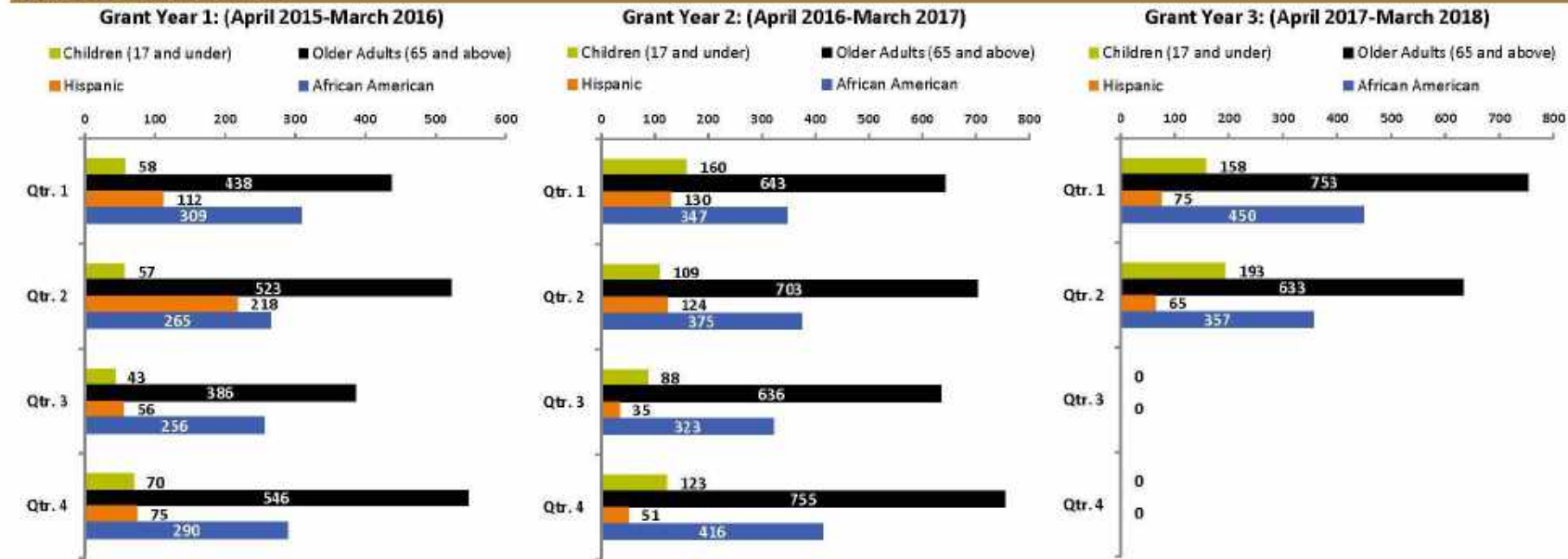
We systematically track the impact of our services on improvements to the integration of special populations into clinical research. We need your help documenting your progress to make this possible!

Office of Clinical Research Recruitment Dashboard

General Enrollment



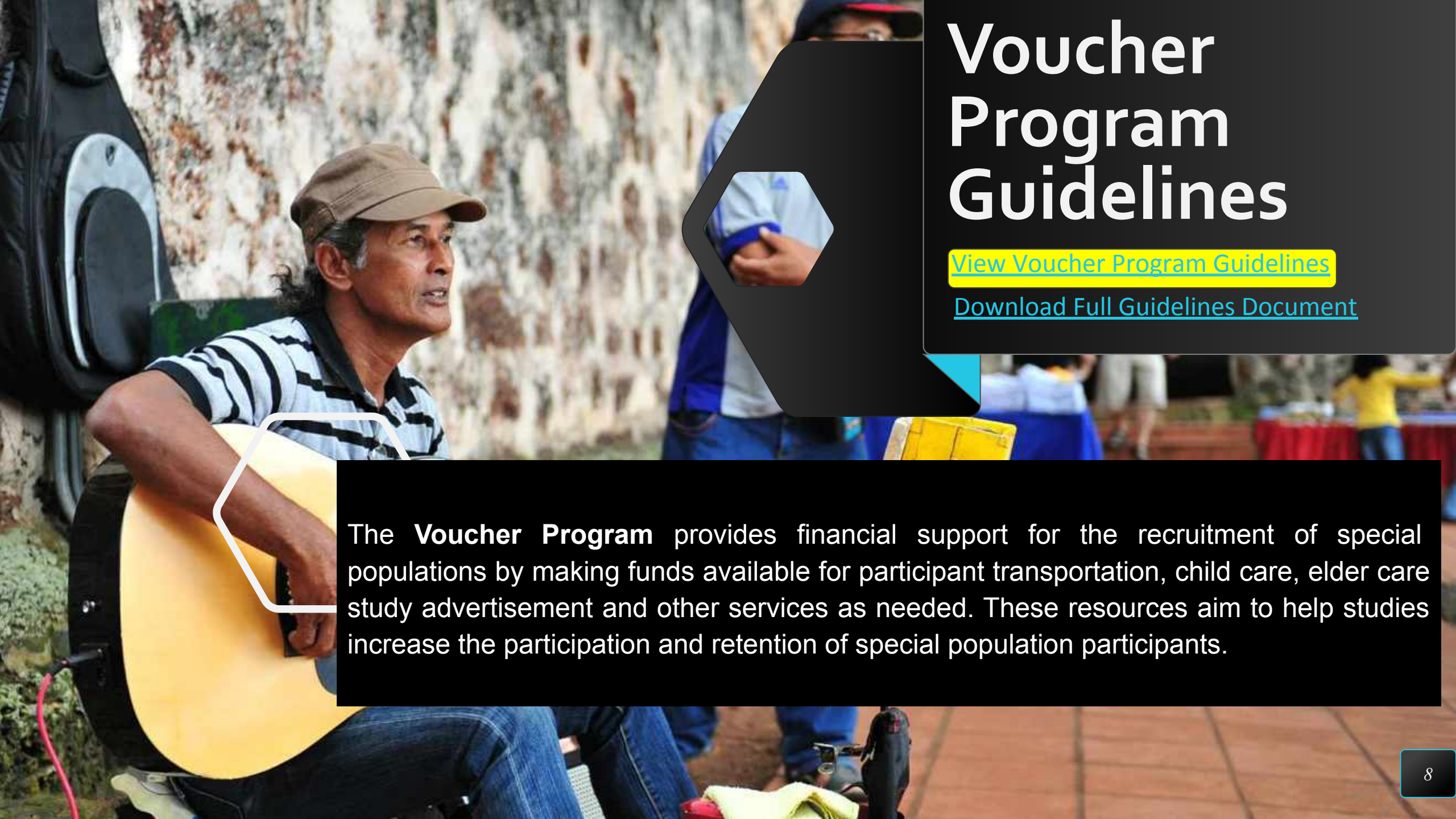
Special Population Enrollment





Voucher Programs

- Transportation
- Caregiving for Elderly and Children
- Study Advertisement
- Other

A man with long hair, wearing a brown cap and a black and white striped shirt, is playing a yellow acoustic guitar. He is sitting outdoors, and a stone wall is visible in the background. Another person in a blue shirt is partially visible behind him.

Voucher Program Guidelines

[View Voucher Program Guidelines](#)

[Download Full Guidelines Document](#)

The **Voucher Program** provides financial support for the recruitment of special populations by making funds available for participant transportation, child care, elder care study advertisement and other services as needed. These resources aim to help studies increase the participation and retention of special population participants.

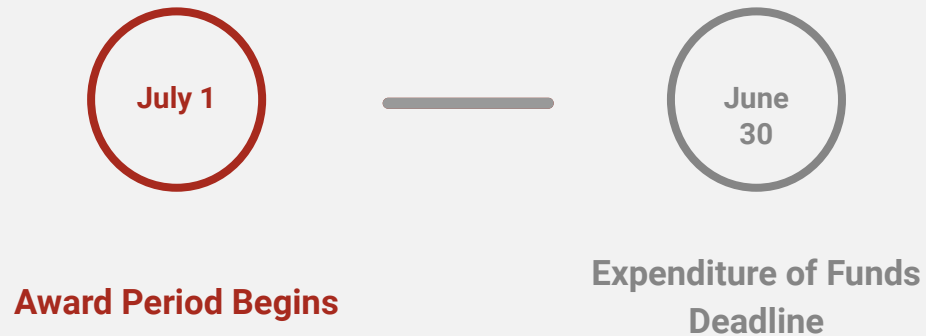
1. Studies that include the participation of special populations.
2. Studies needing financial support to minimize participation barriers and increase study retention.
3. Investigators with immediate needs and those have used the voucher program less than three times will receive priority funding.

Eligibility Criteria

Award Period is July - June. Applications are accepted on a rolling basis.

Studies who do not spend any funding within 6 months forfeit their awards and must reapply.

Funds need to be exhausted by the end of June or within 1 year, whichever comes earlier.



Award Period

1. Type of special population engaging.
2. Type of service requested.
3. Funding specifics for each requested service.
4. Estimated number of participants from special populations to benefit from the voucher program from the time the application is submitted to the end of the Award Period (June 30).
 - a. 4 focus group sessions, 10 participants per focus group, will be conducted within 4 months = 40 participants from special populations
5. Justification for participating in the program.
6. Plan for applying for activities to support recruitment and retention of special populations

A close-up photograph of several red flowers, possibly gerberas, with vibrant red petals and dark centers. The flowers are set against a dark, blurred background, creating a high-contrast, artistic look.

Elements of Application

1. Approval depends upon availability of funds, application significance (potential impact for special populations and potential for future external funding) and study needs.
2. The review team may approve requests below the amount requested.
3. If a request is denied, study teams are encouraged to address recommendations/concerns and reapply.

Review Process

1. Read and sign the **MACHE Voucher Program Award Agreement**.
2. Account balances will be assessed in midway through the award period. Balances may be adjusted based on forecasted needs/expenditure trends.
3. Submit a **MACHE Voucher Program Progress Report** midway through the award period and **one month** after the end of the Award Period.
4. Award recipients must **cite MACHE ISP/Wake Forest CTSI services** in any publications and documents that resulted from these resources. For more information on how to site MACHE ISP/CTSI services go to <https://ctsi.wakehealth.edu/cite-ctsa>.
5. Award recipients **must spend all award money** prior to the end of the award period. If all funds are not expended and a no cost extension is not filed, award recipient must **return remaining unspent funds** (or unused gift cards or gas cards) to MACHE ISP.
6. Award recipients are encouraged to **schedule a consultation** with MACHE ISP staff to strategize on recruitment efforts and ways to spend the remaining award money.

Award Requirements

Note: Award money may be spent on additional services to support participants from special populations if the services for the initial voucher request are no longer needed or other participant needs arise (e.g., space rentals, certification of study team staff to become medical translator, etc.).

1. Funding must be expended by June 30th.
2. No Cost Extensions are permitted, but must be filed at least **one month prior** to the end of the award period with a plan on how award recipient will expend funds.
3. Studies may request an adjustment to either increase or decrease award amount at any time.

Post-Award Considerations

1. Awards are limited to three per investigator, unless extenuating circumstances require additional awards. MACHE ISP encourages award recipients to seek external funding and/or integrate voucher related activities into clinical study protocol and budget plans for future research. Note: *MACHE ISP staff will provide consultation on funding mechanisms and best practices for integrating study related activities that support participants from special populations into their clinical study design and budget justification documents.*
2. Renewal applicants should provide evidence that they spent all funds from the previous voucher award or provide justification to explain remaining/returned funds from previous voucher award.

Renewal Considerations

1. Use Award Chartfield# solely for the purpose of supporting services for Special Populations and stay within the services by which funds were awarded.
2. Use awarded funds before or by June 30th. Any unused or left over funds cannot be rolled over to a new MACHE Voucher Program Award Period and may be lost at the end of the Award Period.
3. The study is responsible to pay for expenses exceeding approved funds of services provided to participants who do not qualify under the definition of special populations.
4. Provide a copy of 3rd party (not facilitated by MACHE ISP or CTSI) invoice/statements of services to MACHE staff.
5. Arrange services with vendors and participants.
6. Complete post award progress report a month after the end of the Award Period.
7. Cite MACHE ISP/Wake Forest CTSI services and submit copies of all cited materials (presentations, publications, abstracts, news articles, etc.).
8. Provide a sample of the advertisement to be reviewed by the ISP Team.
(Advertisement only)
9. Advertise approved advertisement in media outlets and/or sites targeting special populations. (Advertisement only)
10. Provide monthly demographics on participants. (Transportation and care-giving services only)

Program Award Agreement: Investigators

1. Connect study team with approved vendor if necessary. (Transportation and care-giving only).
2. Provide program Chartfield number to study team to pay for services.
3. Provide monthly statements to study team with award balance.
4. Invoice study team for any services beyond the approved awarded funds of services provided to participants who do not qualify under the definition of special populations.
5. Assess account balances in December.
6. Adjust balances based on forecasted needs/expenditure trends.
7. **Drop any study from the program immediately if a study is found not utilizing their awards within 6 months of the award date.**
8. Provide post award progress report to study team at the end of the MACHE Voucher Program Award Period.

Program Award Agreement:

MACHE ISP Voucher
Program Staff

1. MACHE will provide Chartfield number to study team to pay for services used. The Chartfield number is provided in the Award Agreement.
2. MACHE staff will connect research staff to appropriate vendors for services requested when necessary.
3. Study staff will be responsible for arranging services with vendors and participants.
4. Vendors will invoice services provided to the study team and study team must provide a copy of invoice to MACHE staff as soon as an invoice is rendered.
5. MACHE staff will confirm demographics and services received by participants with study staff per month. (Transportation only)
6. Investigators/study staff will receive monthly statements with the new balance for awarded services.
7. The study is responsible to pay for expenses exceeding approved funds and/or services provided to participants who do not qualify under the definition of special populations.
8. Any unused or left over funds cannot be rolled over to a new ISP Program Award Period and may be lost at the end of the Program Award Agreement.

Process of Services



Transportation



Advertisement

Voucher Services

Click on each image to view guidelines for each service

[Voucher Program Standard Operating Procedures](#)



Caregiving



Other

Community

The MACHE Program teamed up with the Sticht Center transportation program to offer transportation services for special population participants in studies who are part of the MACHE Voucher Program.

Determining Cost Estimate:

Transportation costs must consider available months between the MACHE Voucher Program Award Period (July to June) before estimating cost to ensure that requested amount will be spent by or before the end of March.

Transportation costs can be estimated using the following formula:

Continue to add groups and use the formula to capture costs of all special population participants to benefit from transportation services.

Group A = (# Participants to use transportation) * (# of visits a participant will make)

Group B = (# Participants to use transportation) * (# of visits a participant will make)

Group C = (# Participants to use transportation) * (# of visits a participant will make)

Amount of funds needed for transportation = (Group A + Group B + Group C...) * (average miles a participant travels to and from visit) * .75

Average miles must reflect the miles a participant will travel to and from a visit. For example, a participant may travel an average of 15 to 30 miles per visit. However, this number may be higher depending where the participant lives.

Transportation

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[Transportation Reporting Protocol](#)

Transportation—Report on:

- Total number of participants enrolled in the study.
- Total number of special population participants enrolled in the study.
- Total number of special population participants who used transportation.
- A summary explaining the difference between the estimated numbers of special population participants to benefit from transportation (stated in the application) versus the actual number of participants who used transportation.
- A summary of any challenges or obstacles that prevented the study from using the transportation voucher efficiently.
- A summary on how the transportation voucher has helped the study maintain or improve retention rates.



Transportation Reporting Protocol

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MACHE works with tertiary vendors to provide this service to adults and children under the care of a special population participant. MACHE will take into consideration other vendors the study team would like to work with or have worked with in the past.

Determining Cost Estimate:

Use the following formula to help you identify the cost for providing care to family members to enable special population participants to come to visits. Keep in mind that a minimum of 2 hours of care per participant is required in order to provide this type of service.

To calculate the estimated caregiving cost for special population participants use the following formula:

Group A = (# Special Population Participants to use care-giving) * (# of visits a participant will make) * (average hours needed for care for a Special Population Participant)

Group B = (# Special Population Participants to use care-giving) * (# of visits a participant will make) * (average hours needed for care for a Special Population Participant)

Group C = (# Special Population Participants to use care-giving) * (# of visits a participant will make) * (average hours needed for care for a Special Population Participant)

Total cost for care = (Group A + Group B + Group C...) * 20

Caregiving

for adults and children

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[Caregiving Reporting Protocol](#)

- Total number of participants enrolled in the study.
- Total number of special population participants enrolled in the study.
- Total number of special population participants that have requested/benefited from caregiving services for their family members.
- Total number of people who were cared for through the caregiving voucher.
- Total number of caregiving hours provided.
- A summary of any challenges or obstacles that prevented the study from using the caregiving voucher efficiently.
- A summary on how the caregiving voucher has helped the study maintain or improve retention rates.

Caregiving Reporting Protocol

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Advertisement must be reviewed by MACHE to provide content feedback and must be advertised in media outlets and/or sites targeting special population (pediatrics, seniors and underrepresented minorities).

Provide MACHE with recruitment/advertisement plan to justify the request for funds. The study's recruitment/advertisement plan must consider available months between the MACHE Voucher Program Award Period (April to March) before estimating cost to ensure that requested amount will be spend by or before the end of March.

MACHE may cover the following advertisement costs:

- printing services
- mailing services
- radio
- social media
- contracting with a direct marketing firm



Advertisement

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[Advertisement Reporting Guidelines](#)

In order to apply for advertisement funds, studies must have in place a system for all advertisement services requested in this application to track the population reached. MACHE ISP can provide consultation on the best ways to track these metrics using social media and Google analytics.

You can report the following metrics using social media and Google analytics:

- post likes
- reach
- post shares
- geographic location of users
- age of users
- gender of users

You may also report the venues where you placed study advertisement that targeted special populations (e.g., organizational buildings, meetings, or listservs, community-based events, etc.)

The study's recruitment/advertisement plan must consider available months between the MACHE Voucher Program Award Period (July to June) before estimating cost to ensure that requested amount will be spend by or before the end of June.



Advertisement Reporting Protocol

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Provide a detailed explanation of the services (e.g., space rentals, focus group discussion compensation, language competency assessment test for study team staff, other forms of creative participant compensation and support) the study is requesting and provide the cost of each and the grand total cost. The MACHE Voucher Program may not be able to fund all of the services the study is requesting.

Support

Other

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Reporting to be determined based on specific request.

Community



Standard Operating Procedures

[Transportation
& Parking](#)

[Caregiving](#)

Review the standard operating procedures to learn how to use your award to order services offered by the voucher awards.

CITE CTSI Programs & Services

The number of attributed publications is a key measure of a program's productivity and ability to obtain future funding. All publications, press releases, or other documents that result from the utilization of any Wake Forest CTSI services, including the presentation of data and images acquired through CTSI programs, are required to credit the CTSI and comply with [NIH Public Access Policy](#) (submission to PubMed Central).

EXAMPLE: "The authors gratefully acknowledge use of the services and facilities of the **, funded by the National Center for Advancing Translational Sciences (NCATS), National Institutes of Health, through Grant Award Number UL1TR001420."

**Please indicate the type of resource utilized. For example, Clinical Research Unit, Translational Imaging Shared Resource (TISR), etc.

The Integrating Special Populations Program of the Maya Angelou Center and the Wake Forest Clinical and Translational Science Institute (CTSI) has been made possible by a Clinical and Translational Science Award (CTSA) from the National Institutes of Health (NIH).



Service Requests

- Translation & Interpretation
- Bilingual Research Participant Navigation
- Consultations
- Trainings on Health Literacy, Cultural Sensitivity, Communication, and Implicit Bias

Provide the following information with your request on REDCap:

- a. Send documents in Word document
- b. Obtain IRB approval before submitting a request
- c. Provide timeline of when the study needs the documents
- d. Indicate if the study is already enrolling participants
- e. If more than one document, indicate if the study needs all the documents at the same time

Translation & Interpretation Services

[Guidelines for requesting bilingual navigation](#)

Language Services supports studies through document translation, on-site interpretation and the use of the Video Remote Interpreting system, which connects participants (and their family members) with live, on-demand translation for 20 spoken languages, including American Sign Language.


Research Participant Navigation

[Guidelines for requesting bilingual navigation](#)

Research Participant Navigation services support non-English speaking participants in studies. The research participant navigator plays a key role as a liaison between the research team and the subject, guides study teams in the correct process of consenting non-English speakers, and provides extra sets of hands to support the study team with screening, recruitment and consenting of participants, patient management and other types of assistance involving special populations. The research participant navigator also helps guide non-English speaking participants throughout the research process by offering moral support and continuous interpreting, establishing trust, providing emotional support, and connecting participants to additional hospital and community resources.

Guidelines for study teams when requesting bilingual navigation:

- ISP navigator becomes part of the study team. S/he should be added to the IRB and be informed of all the activities involving Spanish speaking patients such as activities, confirmation of dates, location and changes.
- If ISP navigator is involved in recruitment over the phone, the study team needs to send a list of potential participants at least two weeks in advance and the list should only include Spanish speaking participants. Recruitment, retention and **follow up communication with English speaking participants will be conducted by other study team members**, not by ISP navigator.
- If participant **transportation** is requested, the study team will communicate directly with James Lovett and coordinate pick up for English speaking participants. ISP navigator will help Jim with communication with non-English speakers

The background image shows a beach scene. In the foreground, there is a wooden signpost with several horizontal signs. The top sign is red and has the text 'On Chih Littered Foundation'. Below it is a blue sign with the text 'NUESTRO PROBLEMA ES EL PARAÍSO'. At the bottom is a white sign with the text 'ESTACIONAMIENTO PARA TABLAS DE SURF'. To the left of the signpost, there is a large poster. The poster has a diamond-shaped logo at the top with a silhouette of a person surfing. Below the logo, the text reads 'OLEAJE FUERTE DANGEROUS SHOREBREAK'. There are also smaller logos and text on the poster, including 'AQUATICA', 'FREEDOM', 'CROWD CONTROL', 'ZOL', and 'bed'.

Bilingual Navigation Guidelines

Cultural sensitivity

- Cultural differences can be a **barrier to participation**. ISP suggests practicing cultural sensitivity at all times, when working with special populations. If a conflict arises or when in doubt about how to proceed, the ISP navigator can also serve as a cultural broker.

The ISP program provides consultations on:

- **Health literacy**
- **Culturally appropriate material and communication**
- **Cultural sensitivity and implicit bias**

Bilingual Navigation Guidelines

Cultural Sensitivity

Interpreting and Translations

- Please share with ISP navigator the translated material (if already approved by IRB) or submit a request for translation of IRB approved written material in advance. For other languages you may request outsourcing translation services to ISP by submitting a service request.
- **We do not recommend and we are not responsible for the use of Google translate or other automated translation services used to communicate with participants.** [Inaccurate translations can be fatal.](#)
- If the ISP navigator is not able to go to a specific site visit with a patient, you may request ISP to help you find an in-house WFBH interpreter or use the video remote system. The ISP navigator is a certified healthcare interpreter and is trained in consecutive and simultaneous interpreting.
- You may request simultaneous interpreting for groups and studies with more than 2 people. The ISP program has a specialized translation equipment and earphones for up to 10 participants

Simultaneous Interpreting



Consecutive Interpreting



[What's the difference
between simultaneous
and consecutive
interpreting?](#)

Bilingual Navigation Guidelines

Interpreting and Translations



Best practices for communicating through an interpreter (simultaneous or consecutive):

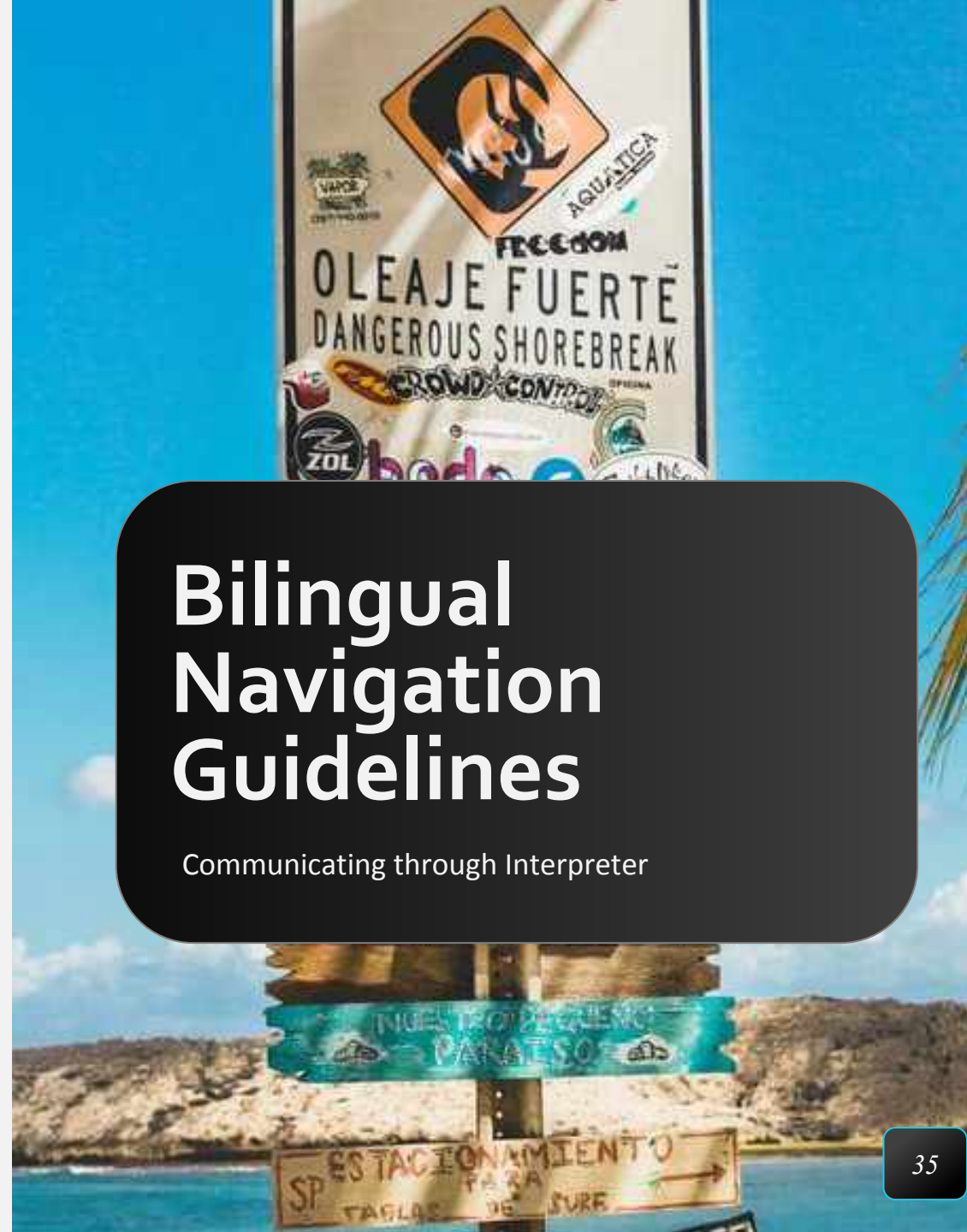
1. Acknowledge the interpreter as a professional in communication, please respect his or her role.
2. Speak directly to the participant and use the first person (avoid using phrases such as: “tell her, or ask the patient”)
3. Speak in short phrases but finish the sentence, grammatical structure in other languages is different and the interpreter often needs to hear the complete sentence before restructuring. Give the interpreter time to process information in his/her mind and present it in a culturally and linguistically appropriate manner. **Speaking English does not mean thinking in English.**
4. Speak clearly and do not speak louder than usual unless the interpreter is not close to you or the participant cannot hear you well.
5. Allow time for the interpreter to finish the sentence when interpreting consecutively and speak slower when interpreting simultaneously
6. Avoid complicated sentence structure or idioms and colloquialisms. Remember that humor can be different, difficult to interpret and the interpreter may have to think of the equivalent of a joke
7. Assume that everything that you say will be interpreted
8. **Avoid patronizing or infantilizing the patient.** A lack of English language skills is not a reflection of low cognitive function or a lack of education.
9. Make sure only one person speaks at a time

Adapted from:

<https://refugeehealthta.org/access-to-care/language-access/best-practices-communicating-through-an-interpreter/>

Bilingual Navigation Guidelines

Communicating through Interpreter



A photograph of a smiling woman and three children (two girls and one boy) in a grassy field. One girl is holding a string attached to a white balloon with gold polka dots. The background is slightly blurred, showing trees and a fence. A white hexagonal outline is in the top right corner, and a black hexagonal shape with a white inset image is on the left side of the text box.

Be Involved

Be Involved is a clinical research recruitment site focused on easing the process of searching for and enrolling into clinical research conducted at Wake Forest Baptist Medical Center. The site is maintained by the WF Clinical and Translational Science Institute (CTSI).

Be Involved en Español advertises in Spanish for studies that are specifically trying to recruit Spanish-speaking participants. Studies that are part of Be Involved can apply for all MACHE ISP services and have access to bilingual research staff to seamlessly include Spanish-speaking participants.

Visit [Be Involved](#) to learn more.



Consultations

Consultation Services provide feedback on research design for including special populations.

We have expertise in:

- Recruitment and retention strategies
- Ongoing research engagement
- Protocol review
- Marketing of advertisement materials
- Cultural sensitivity
- Health Literacy
- Developing culturally appropriate material and communication
- Cultural sensitivity and implicit bias
- Crowdsourcing as research engagement
- Social marketing
- Implementation science
- Qualitative methods



Trainings

We provide trainings on various topics to build research team capacity to promote integration of special populations into ongoing studies.

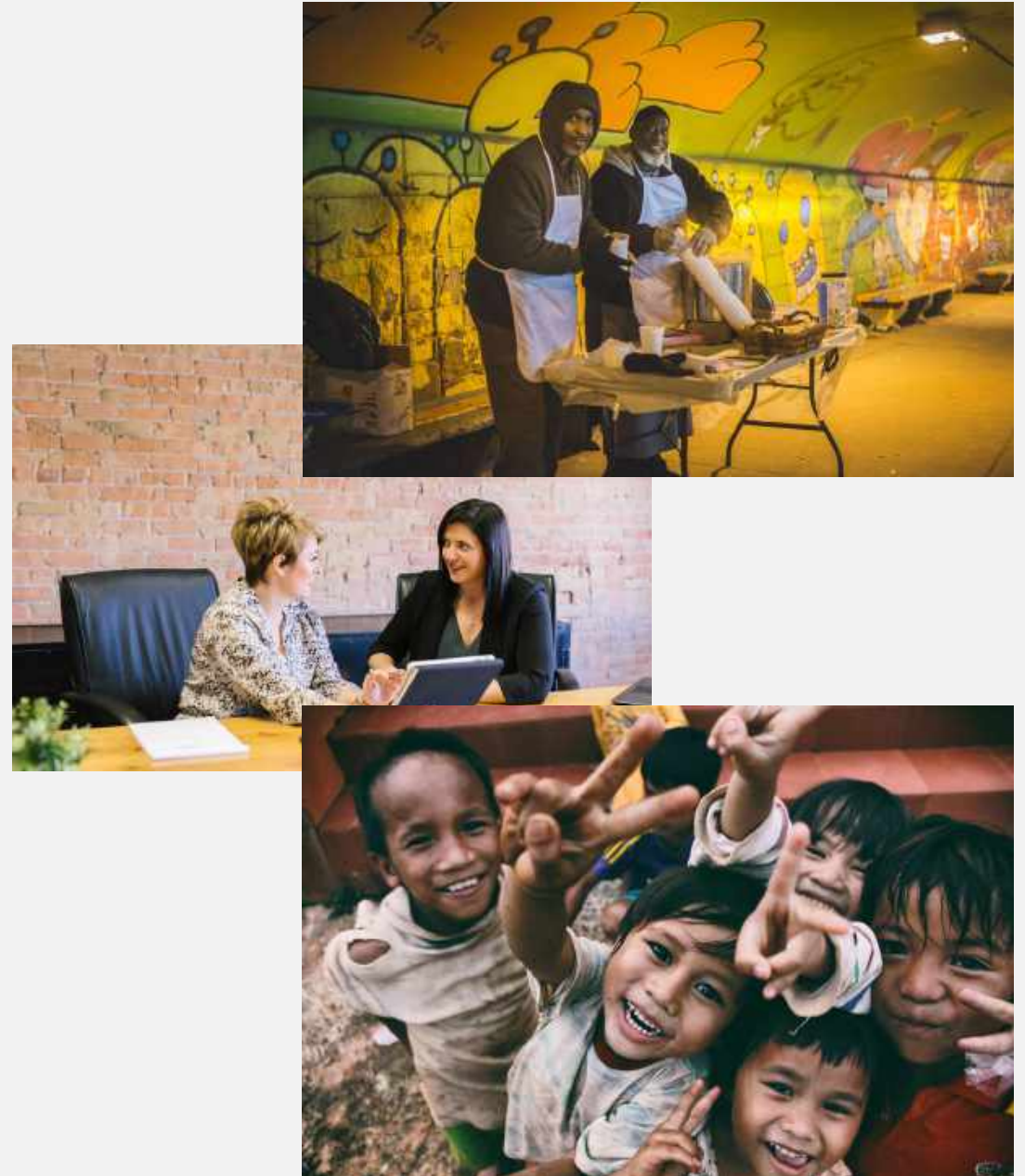
- How use remote interpreter system
- Cultural sensitivity
- Health literacy
- Implicit bias

Research Ambassador Program

The Research Ambassador Program (RAP) empowers study coordinators to serve as ambassadors for the integration of special population research throughout the WFBH. RAP is meant to provide an avenue for ambassadors to build and exchange knowledge regarding the barriers faced by underrepresented populations as they participate in research, and to reinforce the value of developing and maintaining asset-based community partnerships.

RAP meets quarterly to address emergent topics and provide in-person trainings.

Contact Mariana Pardy mpardy@wakehealth.edu to be added to the email list for meeting announcements.





Thank You

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