

 Wake Forest® School of Medicine Maya Angelou Center for Health Equity	Maya Angelou Center for Health Equity Voucher Program Guidelines (SOP)	Dept:	CTSI > MACHE
		Effective Date:	06.30.2021
		Revised Date:	07.26.2021
		Contact:	MACHE
		Dr. Capri Foy ISP Associate Director Dorey Ivory ISP Project Maanger	Cfoy@wakehealth.edu divory@wakehealth.edu
Name & Title:			
Signature:			

To view online presentation and summary of Voucher Guidelines and other ISP services, [click here](#).

1) General Procedure/Guideline Statement:

Scientists face multiple challenges as they seek to include underrepresented populations in research and clinical trials. The Maya Angelou Center for Health Equity (MACHE) Voucher Program is part of a cadre of services offered to consult with investigators and study teams to improve recruitment and retention and clinical research engagement with underrepresented populations. The voucher program focuses on defraying costs for pilot/developmental work to include special populations in clinical studies and research projects. These guidelines provides a clear standard operating procedure for the implementation of the MACHE Voucher Program.

- a) **Scope:** All investigators, faculty and staff who have been approved to participate in the MACHE Voucher Program are responsible for complying with this guideline. The MACHE leaders and staff are responsible for the development, revision, approval, implementation, and warehousing of these guidelines.
- b) The Clinical and Translational Science Institute (CTSI) is responsible for ownership, content, supervision and implementation of departmental guidelines.

2) Definitions:

- a) **Guidelines:** Processes or methods for accomplishing a specific task or objective. All guidelines must comply with applicable WFBMC policies and procedures
- b) **Special Populations:** Participants who are (1) 17 years old and under, (2) 65 years old and above, (3) Racial and ethnic minorities, (4) populations with low socioeconomic status (low educational attainment, low-income)

- c) **MACHE:** Maya Angelou Center for Health Equity
- d) **ISP:** Integrating special populations

3) Procedure/Guidelines:

1. Eligibility

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 who have used the voucher program less than three times will receive priority funding.

2. Application Deadline

Applications are received on a rolling basis. When applying close to the end of June, please be aware that funds need to be exhausted by the end of June and new awards will be available in July.

3. Application Process

1. Award Period is July - June, studies should request funding accordingly.
2. Applications are accepted throughout the year.
3. Interested applicants must review the MACHE Voucher Program Guideline before an application can be submitted.
4. Investigators are responsible for completing the application in detail and should include the following information:
 - a. Type of special population engaging.
 - b. Type of service requested.
 - c. Funding specifics for each requested service.
 - d. 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 30th).
 1. E.g. 4 focus group sessions, 10 participants per focus group, will be conducted within 4 months = 40 participants from special populations
 - e. Justification for participating in the program.
 - f. Strategy to support recruitment and retention of special populations

4. Review Process

1. Application approval depends upon:
 1. Availability of funds
 2. Application significance (potential impact for special populations and potential for future external funding)

3. Immediate study needs in terms of recruiting and/or retaining participants from special populations
4. Appropriate and comprehensive plan for recruiting and retaining special populations
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.
4. ISP will periodically evaluate whether study teams are effectively spending the funds and/or need additional funds

5. Award Requirements:

1. Approved studies must read and sign the MACHE Voucher Program Award Agreement.
2. Account balances will be assessed approximately 6 months post-award. Balances may be adjusted based on forecasted needs/expenditure trends. If a study is found not utilizing their awards within 6 months of the award date, they will immediately lose award funding and must re-apply.
3. All approved applications must 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. MACHE ISP encourages award recipients to schedule consultations with voucher program staff to strategize on recruitment efforts and ways to spend the remaining award money. 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.).*
7. If an investigator applies for voucher funding within 2 months of the end of the award period (June 30), they should provide a plan for spending award funds prior to the end of the award period.

6. Post-Award Considerations:

1. Funding must be expended by June 30th.
2. If you have not spent all funds prior to the end of the award period but your study is still in need of funding, you may file a No Cost Extension. The extension 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.
4. Any unspent funds will no longer be available after the end of the MACHE ISP award period (June 30) and investigators must re-apply for voucher funds.

7. Renewal Considerations:

1. Award recipients may only submit one renewal for voucher requests for a total of two years of funding. 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.

8. Program Award Agreement

1. Investigators will agree to the following:
 - a. Use Award Chartfield# solely for the purpose of supporting services for Special Populations and stay within the services by which funds were awarded.
 - b. 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.
 - c. 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.
 - d. Provide a copy of 3rd party (not facilitated by MACHE ISP or CTSI) invoice/statements of services to MACHE staff.
 - e. Arrange services with vendors and participants.
 - f. Complete post award progress report a month after the end of the Award Period.

- g. Cite MACHE ISP/Wake Forest CTSI services and submit copies of all cited materials (presentations, publications, abstracts, news articles, etc.).
 - h. Provide a sample of the advertisement to be reviewed by the ISP Team. (Advertisement only)
 - i. Advertise approved advertisement in media outlets and/or sites targeting special populations. (Advertisement only)
 - j. Provide monthly demographics on participants. (Transportation and care-giving services only)
2. The MACHE Voucher Program will agree to the following:
- a. Connect study team with approved vendor if necessary. (Transportation and care-giving only).
 - b. Provide program Chartfield number to study team to pay for services.
 - c. Provide monthly statements to study team with award balance.
 - d. 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.
 - e. Assess account balances in December.
 - f. Adjust balances based on forecasted needs/expenditure trends.
 - g. Drop any study from the program immediately if a study is found not utilizing their awards within 6 months of the award date.
 - h. Provide post award progress report to study team at the end of the MACHE Voucher Program Award Period.

9. Process of Services

- 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.

10. Type of Services

1. The MACHE Voucher Program connects studies to the following services to minimize participation barriers and increase study retention:
 - a. Transportation: 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.

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

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.

- b. Advertisement: 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. 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 (June to July) before estimating cost to ensure that requested amount will be spend by or before the end of June. MACHE may cover the following advertisement costs: printing services, mailing services, radio advertisement, social media promotion, and contracting with direct marking firm services. Advertisement must be reviewed by MACHE to provide content feedback and must be advertised in media outlets and/or sites targeting special populations (pediatrics, seniors and underrepresented minorities).
- c. Care-giving for adults and children. 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. 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 care-giving 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

- d. Other: Provide a detailed explanation of the services (e.g., space rentals, focus group discussion compensation, certifications for study team staff to become medical translator, 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.

11. Reporting on Services

1. The following progress report must be provided at the end of the Award Period for each of the services awarded.
 - a. 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.
 - b. Advertisement—Report on:
 - Total number of participants enrolled in the study.
 - Age, racial and ethnic breakdown of the participants enrolled in the study.
 - Estimated number of enrolled participants recruited through advertisement.

- Estimated age, racial and ethnic breakdown of enrolled participants recruited through advertisement.
 - A summary of any challenges or obstacles that prevented the study from using the advertising voucher efficiently.
 - A summary on how the advertisement voucher has impacted the study.
- c. Care for adults and children— 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 that have requested/benefited from care-giving services for their family members.
 - Total number of people who were cared for through the care-giving voucher.
 - Total number of care-giving hours provided.
 - A summary of any challenges or obstacles that prevented the study from using the care-giving voucher efficiently.
 - A summary on how the care-giving voucher has helped the study maintain or improve retention rates.
- d. Other—to be determined based on specific request.

4) Citing ISP Program services

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).



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).

Examples

CTSI Programs and Services

"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.

"We would like to acknowledge the *** of the Wake Forest Clinical and Translational Science Institute (WF CTSI), which is supported by the National Center for Advancing Translational Sciences (NCATS), National Institutes of Health, through Grant Award Number UL1TR001420."

***Please indicate the type of assistance received. For example, CRU assistance, statistical assistance, editorial assistance, etc.

Pilot Grant Awardees

"The project described was supported by the National Center for Advancing Translational Sciences (NCATS), National Institutes of Health, through Grant Award Number UL1TR001420. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH."

K12 Scholars (KL2)

"The project described was supported by the National Center for Advancing Translational Sciences, National Institutes of Health, through Grant KL2TR001421. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH."

Let Us Know!

Please send us a copy for our files of all publications and presentations in which you acknowledge CTSI programs and services of the WF CTSA. If you have any questions, please contact CTSI@wakehealth.edu.

5) Review/Revision/Implementation:

- a) Review Cycle: This operational guideline shall be reviewed by the ISP Program at least every three (3) years from the effective date.
- b) Office of Record: After authorization, the CTSI shall house this guideline in a guideline database and shall be the office of record for this guideline.

6) Related Governing Policies: N/A

7) References, National Professional Organizations, etc.: N/A

8) Attachments: N/A