Webinar: *Diversify Your Trials:*

Clinicians' Guide to CRC-Powered Hispanic Recruitment

NHHF
National Hispanic Health Foundation

AMGEN

Moderator

ELENA RIOS, MD, MSPH, MACP

President, National Hispanic Health Foundation

Speaker

YVONNE RODRIGUEZ

Founder and CEO
Egality Sciences, Inc

Speaker

CARLA CASULO, MD

Associate Professor of Medicine,
Wilmot Cancer Institute

1.0 CME CREDIT PROVIDED

Feb. 28 | 7-8 p.m. ET

Welcome

Elena Rios, MD, MSPH, MACP
President
National Hispanic Health Foundation

Housekeeping

- All participant microphones will be muted, but please feel free to type your question into the Q & A box for the panelists to address during our Q & A session at the end.
- Please fill out the short post-webinar survey that will be emailed out after the event and also shown as a QR code at the end.
- Recording will be housed on NHHF website (nhmafoundation.org) and sent out one week after the event.

Joint Accreditation Statement

- In support of improving patient care, this activity has been planned and implemented by Amedco LLC and National Hispanic Health Foundation. Amedco LLC is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.

Physicians (ACCME) Credit Designation

- Amedco LLC designates this live activity for a maximum of 1.00 AMA PRA Category 1 Credits™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

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INTERPROFESSIONAL CONTINUING EDUCATION

Objectives

- Emphasize the significance of cultural competence among clinical research coordinators when working with Hispanic populations

- Address the importance of clinical research coordinators in promoting diversity and inclusion within clinical trials, particularly among the Hispanic population, so that physician principal investigators can improve their clinical research outcomes

National Hispanic Health Foundation

NHHF Mission:

The NHHF aims to improve the health of Hispanics in the United States by promoting education and awareness, advancing research, and advocating for policies that address the unique health needs of the Hispanic population. The foundation seeks to reduce health disparities and ensure equitable access to healthcare.

nhmafoundation.org

National Center for Hispanic Health Research

- The mission is to understand and address the unique health needs of Hispanics, with an unwavering commitment to fostering health equity through education and awareness.
- One of the main objectives is to elevate the prominence of Hispanic physicians and researchers in clinical research within Hispanic communities.
- With a steadfast focus on advancing research, education, and advocacy, NCHHR is poised to lead transformative initiatives that promote the health and well-being of Hispanics across the nation.

National Center for Hispanic Health Research

Hispanic Health Research Registry: By establishing a robust registry of healthcare professionals interested in clinical research, NCHHR aims to create a foundational resource for researchers and healthcare practitioners to access data on Hispanic health trends, enabling evidence-based interventions and policy decisions.

Hispanic Health Research Education Program: Through a dynamic blend of conferences and webinar series, NCHHR is dedicated to disseminating knowledge, sharing best practices, and fostering dialogue among stakeholders invested in Hispanic health research, thus nurturing a community of informed advocates and practitioners.

Hispanic Health Research Mentorship Program: Acknowledging the pivotal role of mentorship in shaping the next generation of Hispanic health researchers, NCHHR's mentorship program empowers medical students and residents to pursue careers in clinical research.

Yvonne Rodriguez
Founder and CEO
Egality Sciences, Inc

Objective: Emphasize the significance of cultural competence among clinical research coordinators when working with Hispanic populations.

Who can be a Clinical Research Coordinator?

- A Clinical Research Coordinator (CRC) can be an RN or have a bachelor's degree in a scientific, health-related, or business administration program
  - This is not a rule and there are many physicians in our communities that elevate their most trusted nurse, medical assistant, or LVN to these positions

Why is a Clinical Research Coordinator important?

- A Clinical Research Coordinator (CRC) manages and conducts the day-to-day activities of a clinical trial.

- In general, the CRC ensures the clinical study maintains accordance with the protocol, regulations, Good Clinical Practice (GCP) and Institutional Review Board (IRB) requirements.
  - Beyond administrative duties, responsibilities of a CRC may include acting as a liaison for the clinical site, ensuring staff are properly trained per the protocol, recruiting and/or registering participants, maintaining study guidelines, and collecting, reviewing, and entering the data into a study database.

Defining the CRC Role

- Assisting with the development of protocols, reviewing for standard of care.
  - Academic/Investigator initiated trials
- Recruiting patients
- Collecting Data
  - Creation of source documentation
  - Understanding what data points are critical and must be collected from sponsor companies

Defining the CRC Role

- Maintaining appropriate records – if it's not documented, it did not happen!
  - Training of all staff that takes part in trial
    - Accountability logs for everyone involved in the trial
  - Regulatory filing – Investigator Site File/ Trial Master File
    - Must be kept up to date/accurate
    - Must contain key messages/communications from sponsors
  - Knowledge of proper storage in case of future audit (sponsor/FDA)

Defining the CRC Role

- Ensuring clinical trials are conducted ethically
- Preparing study documents
  - Usually pulling charts and having them ready days prior to patient arrival
    - Knowing what assessments need to take place, knowing what needs to be brought to your attention during the patient's visit (labs, scans, reports)
  - Understanding of the schedule of assessment
    - What's taking place during that specific visit, do things have to be completed in a certain order
    - Ensuring the right staff is present at that date/time for patient

Significance of cultural competence brought by the Clinical Research Coordinator

- Clinical research coordinators need to be well-versed in the cultural nuances of the Hispanic population they are working with. This includes knowledge of language preferences, cultural values, beliefs, and health practices.
- Coordinators ensure that the informed consent process is culturally sensitive. This involves presenting information in a clear and accessible manner, using plain language, and addressing any cultural concerns or misconceptions that patients may have about clinical trials

Significance of cultural competence brought by the Clinical Research Coordinator

- As the primary point of contact –
  - Providing and explaining the consent alongside with PI
    - Engage patients in asking questions to clarify information
  - Scheduling patient visits according to the study protocol
    - Understand who the caregivers are, understand living situation, etc
  - Helping with data collection
    - Medical history & capturing protocol related data points
  - Inquiring about any adverse events/serious adverse events

Significance of cultural competence brought by the Clinical Research Coordinator

- Collectively –
  - All these activities build effective communication strategies and relationships with your enrolled participants/patients fostering respect for the patients brings:

Trust

Increased patient participation and engagement

Improved understanding

And most importantly: Increased Patient Safety

Carla Casulo, MD
Associate Professor of Medicine
Wilmot Cancer Institute

Objective: Address the importance of clinical research coordinators in promoting diversity and inclusion within clinical trials, particularly among the Hispanic population, so that physician principal investigators can improve their clinical research outcomes.

Diversity and Inclusion in Clinical Research – Why Does it Matter?

- Disease may be experienced and manifested differently based on sociocultural backgrounds; drug effectiveness varies based on ancestry
  - Varying responses to the blood pressure-lowering effects of β-blockers and ACE inhibitors in African Americans and Whites
- For all communities to benefit from scientific advances, and generalizability of results, clinical trials must be inclusive of diverse backgrounds
- Lack of diversity in research has created gaps in our understanding of disease biology, prevention, and treatment efficacy across populations

National Institute of Minority Health and Health Disparities
Johnson et al; *Circulation* 2008

Evolution of Diversity and Inclusion Requirements in Clinical Research

- Early historical events (1970's Syphilis Study at Tuskegee) engendered mistrust in clinical research
- Disincentivized racial and ethnic minority communities from research participation
- Led to the Belmont Report addressing ethical principles and guidelines to protect human research participants and ensure safety
- 1990s: NIH Revitalization of Act established guidelines for inclusion of women and persons from racial and ethnic minority populations in clinical research
  - Mandate that clinical trial participants must reflect the diversity of the real-world population to ensure generalizable findings to entire population

Guidance to Help Enforce Diversity and Inclusion in Clinical Research

- In 2020, the FDA published recommendations for sponsors initiating and conducting clinical trials:
  - Broaden the eligibility criteria for clinical trials and avoid unnecessary exclusions
  - Design clinical trials in ways that achieve participant diversity
  - Improve recruitment practices
  - Apply recommendations for broad eligibility criteria to trials of drugs treating rare diseases or conditions
- Responsibility also lies with researchers, and institutions conducting clinical trials to actively address barriers and work towards more inclusive study populations

Importance of Clinical Research Coordinators in Promoting Diversity and Inclusion

Community Engagement

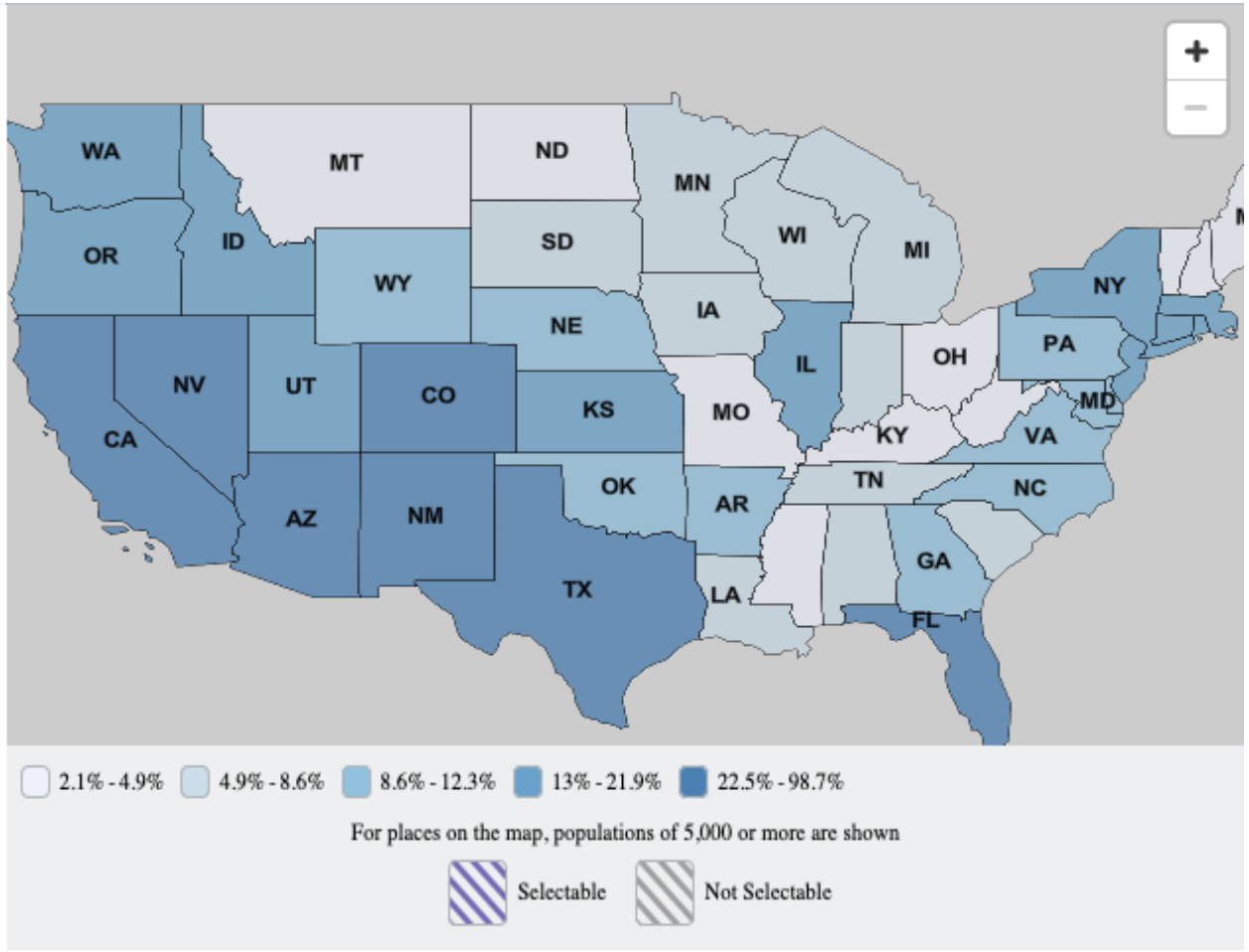
- Coordinators can actively engage with Hispanic communities to raise awareness about clinical trials
- Can collaborate with community leaders, organizations, and healthcare providers to disseminate information, address concerns, and foster a positive perception of research participation

Education and Outreach

- Clinical research coordinators can provide targeted education and outreach programs to inform Hispanic populations on importance of clinical trials, dispel myths, address misconceptions
- Helps potential participants make informed decisions about involvement

Why Clinical Research Requires Diversity and Inclusion

- 2023 US Census:
  - 30-40% of US population comprised of minorities
  - 19 % Latino/Hispanic



Strategies Promoting Diversity and Inclusion

- **Tailoring Recruitment Strategies Geographically**
  - Clinical trial sites should be located in areas with higher concentrations of underrepresented racial/ethnic minorities
- **Health care Providers in Clinical Trials**
  - Ideally patients may prefer healthcare providers of their own race/ ethnicity; instilling sense of belonging and value
  - FDA recommends that sponsors consider selecting diverse healthcare providers *and* study coordinators to assist with clinical trial recruitment and implementation

Recruitment Strategies to Increase Diversity

- **Tailoring Recruitment Strategies**
  - Coordinators tailor recruitment strategies to effectively reach the Hispanic population. This may involve utilizing culturally appropriate communication channels, community events, and partnering with local healthcare providers to identify potential participants
- **Hispanic Representation in Clinical Trials**
  - Coordinators can collaborate with researchers and sponsors to advocate for diverse participant recruitment strategies

Importance of Clinical Research Coordinators in Promoting Diversity and Inclusion

- **Health Literacy Considerations:**
  - Coordinators can assist in developing consent forms and other study materials to improve health literacy of the Hispanic communities, ensure information is clear and understandable for all education levels.

- **Advocacy for Inclusive Research Practices**
  - Coordinators can advocate for inclusive research practices within their institutions, promoting policies that prioritize diversity in recruitment and ensure equitable access to research opportunities

Coordinators Have an Important Role

- Through cultural competence, community engagement, education, and advocacy, coordinators contribute to the overall success and impact of clinical research while ensuring that diverse perspectives, including Hispanic communities, are represented in clinical research
- Clinical trial coordinators can have a fulfilling career trajectory (https://acrpnet.org/)

Q&A

NHHF Programs Updates

Upcoming Events:

- NHMA and NHHF 30th Anniversary Celebration & Leadership Summit
  - Clinical Trials Diversity, Plenary Breakfast
  - Saturday, April 13, 2024; 7:30 am; Hyatt Regency Washington on Capitol Hill

- Robert A. Winn Diversity in Clinical Trials Award Program
  - Career Development Award application open through May 13, 2024

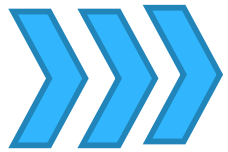
- Clinical Research Webinar – May 14, 2024
  - More details to come!

Post-webinar Survey

- Please support and submit
  - The QR code is on the next page

NHHF Programs Updates

Complete our post-webinar survey!



If you have any questions about our programs or events, please email us at nhhf@nhmafoundation.org.

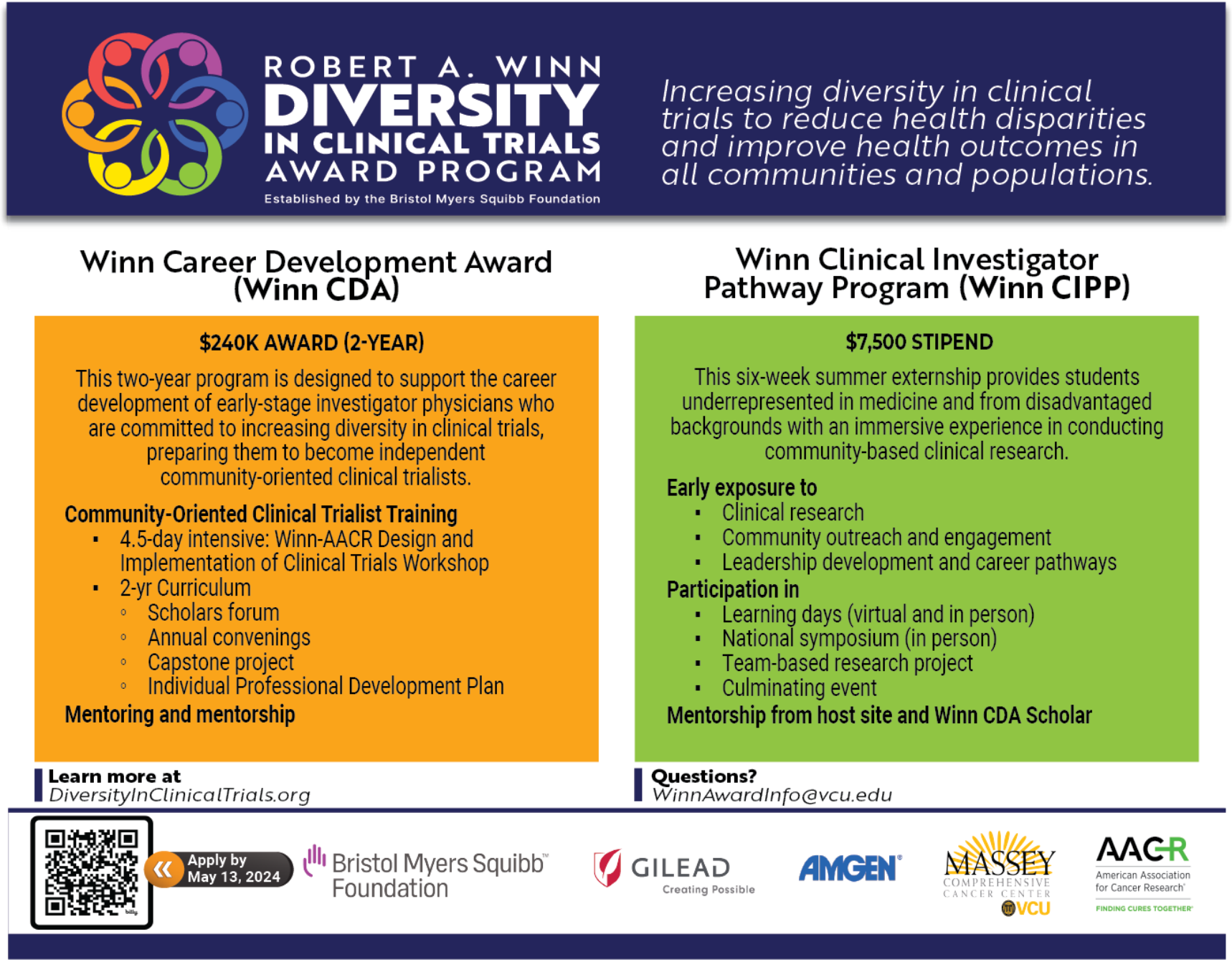
Honoring Our Past, Embracing the Now and Shaping Our Future

30TH ANNIVERSARY CELEBRATION & LEADERSHIP SUMMIT

April 12-13, 2024
Hyatt Regency,
Capitol Hill
Washington, D.C.

NHMA
National Hispanic Medical Association

NHHF
National Hispanic Health Foundation


ROBERT A. WINN
DIVERSITY
IN CLINICAL TRIALS
AWARD PROGRAM
Established by the Bristol Myers Squibb Foundation
Increasing diversity in clinical trials to reduce health disparities and improve health outcomes in all communities and populations.
Winn Career Development Award (Winn CDA)
$240K AWARD (2-YEAR)
This two-year program is designed to support the career development of early-stage investigator physicians who are committed to increasing diversity in clinical trials, preparing them to become independent community-oriented clinical trialists.
Community-Oriented Clinical Trialist Training
4.5-day intensive: Winn-AACR Design and Implementation of Clinical Trials Workshop
2-yr Curriculum
Scholars forum
Annual convenings
Capstone project
Individual Professional Development Plan
Mentoring and mentorship
Winn Clinical Investigator Pathway Program (Winn CIPP)
$7,500 STIPEND
This six-week summer externship provides students underrepresented in medicine and from disadvantaged backgrounds with an immersive experience in conducting community-based clinical research.
Early exposure to
Clinical research
Community outreach and engagement
Leadership development and career pathways
Participation in
Learning days (virtual and in person)
National symposium (in person)
Team-based research project
Culminating event
Mentorship from host site and Winn CDA Scholar
Learn more at
DiversityInClinicalTrials.org
Questions?
WinnAwardInfo@vcu.edu
Apply by May 13, 2024
Bristol Myers Squibb Foundation
GILEAD
Creating Possible
AMGEN
MASSEY
COMPREHENSIVE CANCER CENTER
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American Association for Cancer Research
FINDING CURES TOGETHER

NHHF
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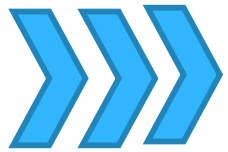
Please visit our website for:

- Sponsorship opportunities
- Mentorship
- Programs
- Donations to NHHF



Visit our website at ***nhmafoundation.org***

National Hispanic Health Foundation

Thank you!