



# Diversity in Clinical Trial Research (DCTR)

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Pragmatic Trial Supplement NIH PA20-272, (HEAL/BiA  
Pragmatic Trial)

# Disclosures

NO RELEVANT DISCLOSURES

# Background

- ▶ Lower engagement of patients of color in research participation has resulted in historical trends of underrepresentation in clinical trials.
- ▶ Among those who do select to engage in research, there is a higher risk of loss-to-follow-up by Black and Hispanic/Latino participants.
- ▶ Solutions offered to address the barriers to participation engagement by Black and Hispanic/Latino patients apply a patient-centered approach that considers cultural, social, and environmental differences include:
  - ▶ Understanding cultural norms and personal interactions
  - ▶ Providing general respect and quality care for participants
  - ▶ Establishing trust to build relationships
  - ▶ Assuring culturally sensitive patient facing material and project terminology
  - ▶ Providing Q&A sessions throughout the research process

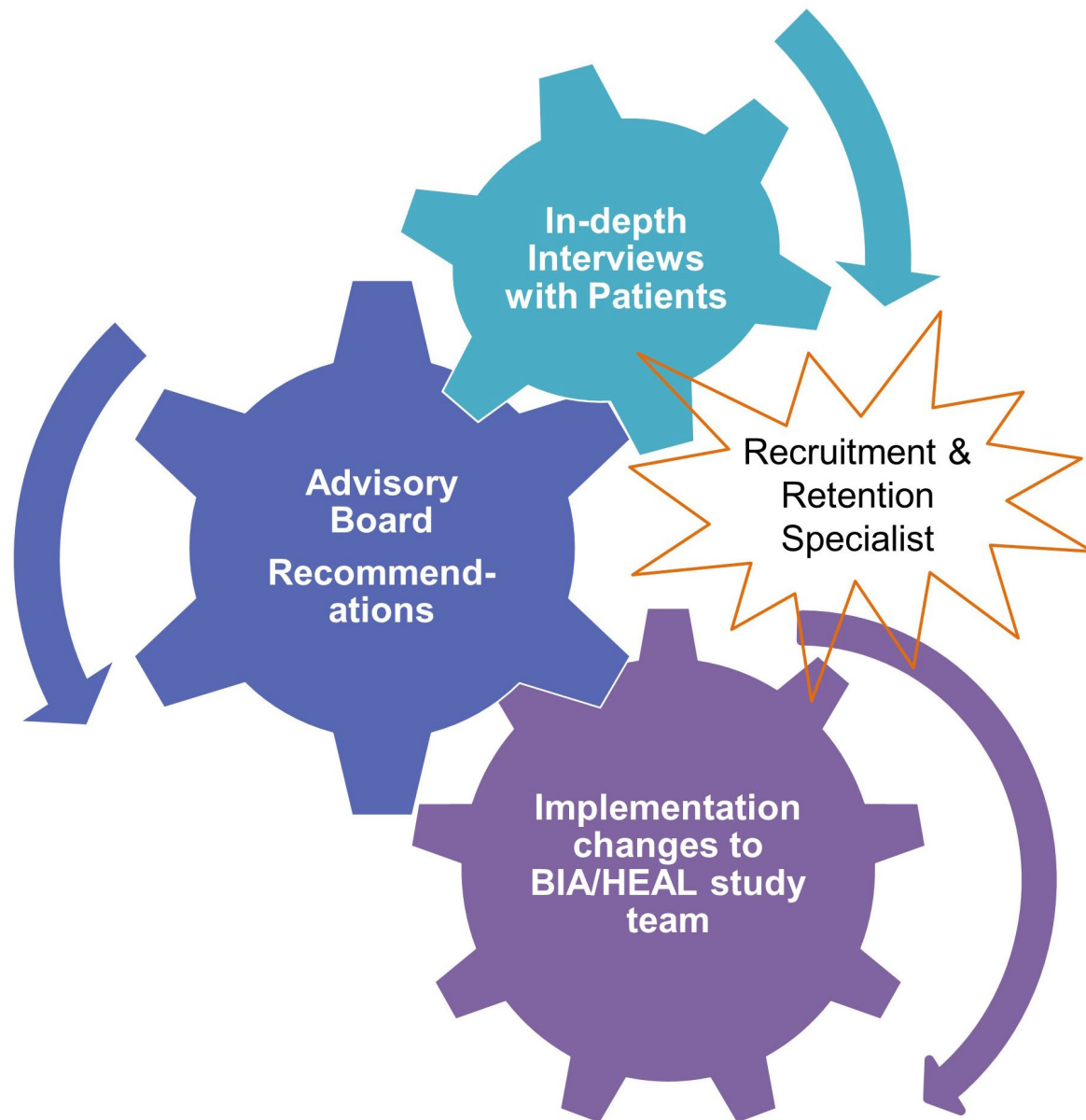


# Diversity Supplement for: BackinAction (BIA) HEAL Study

This is an NIH funded Supplementary diversity and inclusion study running ancillary to the currently funded BIA study; a Pragmatic, three-arm parallel groups multi-site randomized controlled trial: standard acupuncture, extended acupuncture, and usual care

## Objectives:

- ▶ To enhance diversity and inclusion in the recruitment of patients
- ▶ To assess and reduce patient opt-out rates
- ▶ To assure retention of a diverse patient sample
- ▶ To understand diversity and inclusion in patient participation in an Integrative Medicine clinical trial



# Approach

# Lessons Learned: Recruitment

## Challenges

- Hispanic patients highly valued input from their clinicians
- Recruitment from the clinician led to some confusion particularly around the EHR integrated “Interested” option.
- Most patients do not understand the meaning of the term “research”

## Solutions

- Adding clinician script in Spanish
- Change the language on the clinical EHR recruitment from “interested” (suggesting interested in being in the study) to “interested in learning more”
- Emphasis on the term “study” rather than “research”



# Lessons Learned: Retention

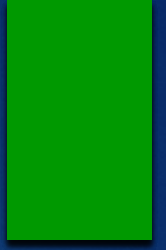
## Challenges

- Patients feeling discomfort or experiencing no benefits from the treatment but are not discussing these with researchers/clinicians
- Patients' family demands take precedence

## Solutions

- Enhanced training to those providing the clinical intervention to initiate discussions about discomfort and response.
- Enhanced training for outreach to include culturally appropriate, patient-centered language to empathize and support patient through these demands.

# Lessons Learned: Dissemination



## Challenges

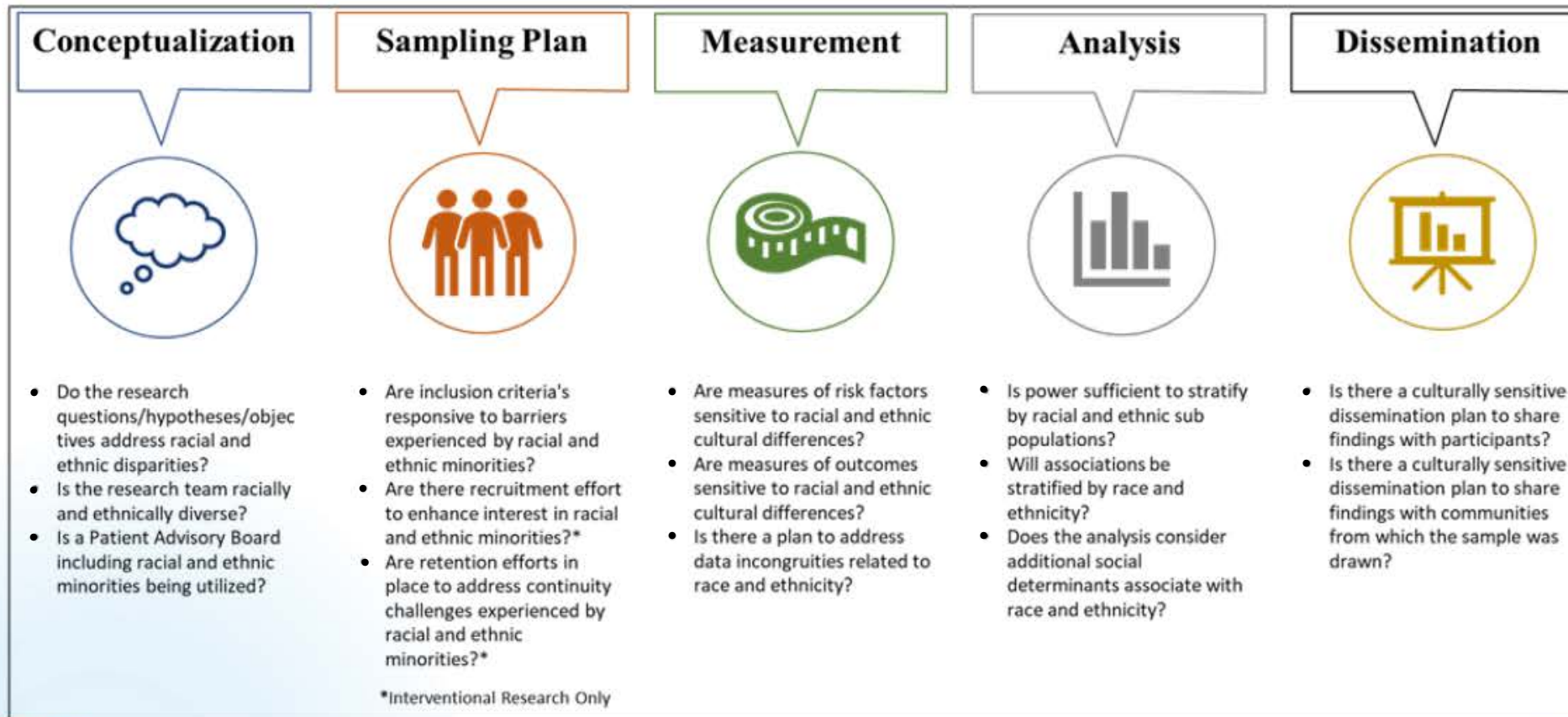
- Participants are interested in knowing the findings.
- Dissemination beyond participants could be a tool to support future recruitment.

## Solutions

- Develop a visually simple but informative dissemination image that participants would be able to share with others.







# Next Steps