



Institute for Clinical and
Translational Research
UNIVERSITY OF WISCONSIN-MADISON

Justice, Equity, Diversity, and Inclusion Roadmap

*A Toolkit for Increasing
Community Engagement and
Diversifying Recruitment*

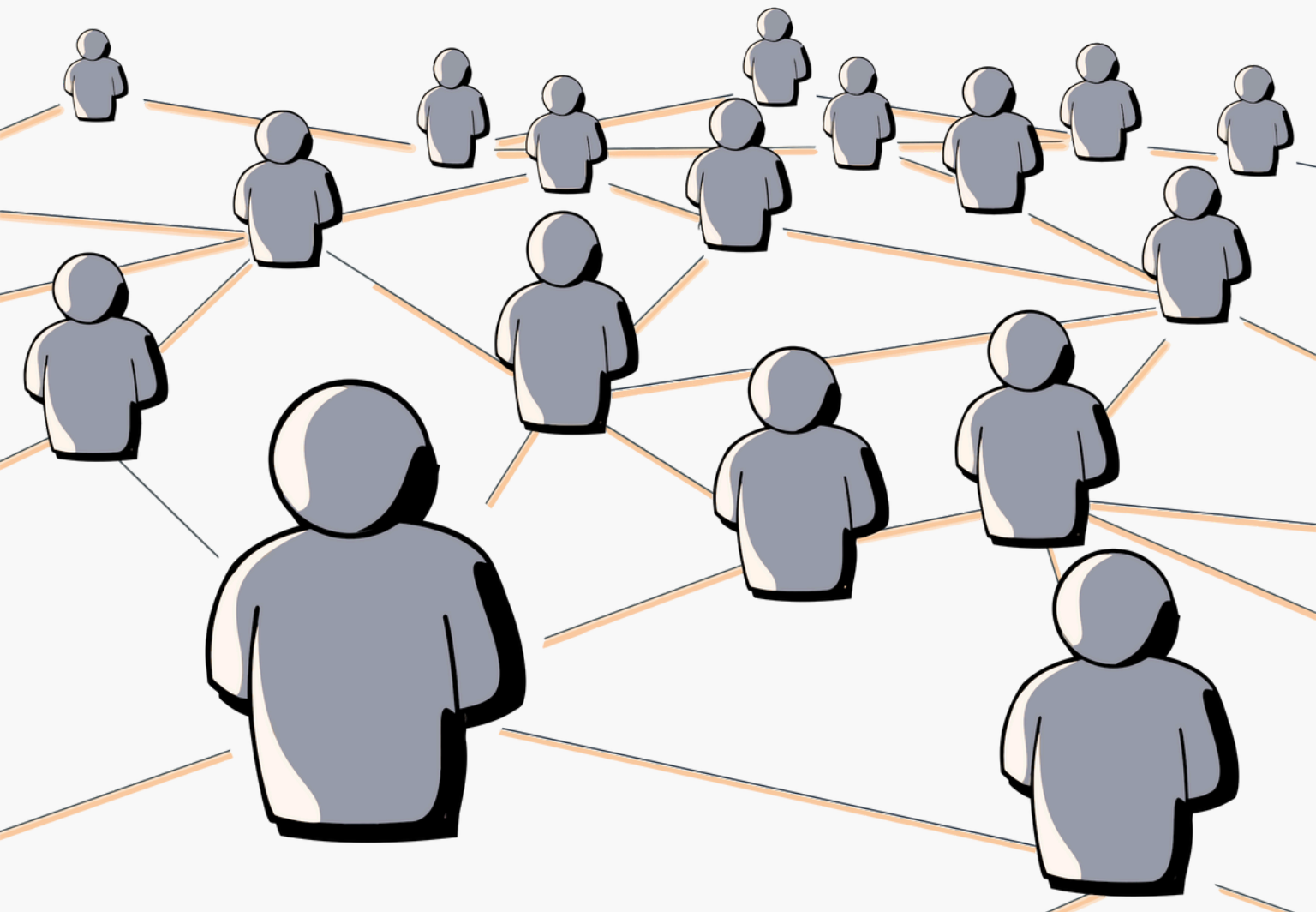


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This resource is curated by the [Protocol Development Program](#) and the [Recruitment and Retention Resource Center](#). It is made possible with the support of the [Wisconsin Partnership Program](#) of the UW School of Medicine & Public Health, and the [NIH National Center for Advancing Translational Sciences](#).

The Institute for Clinical and Translational Research is supported by the Clinical and Translational Science Award (CTSA) program, the National Center for Advancing Translational Sciences (NCATS), grant 1UL1TR002373.

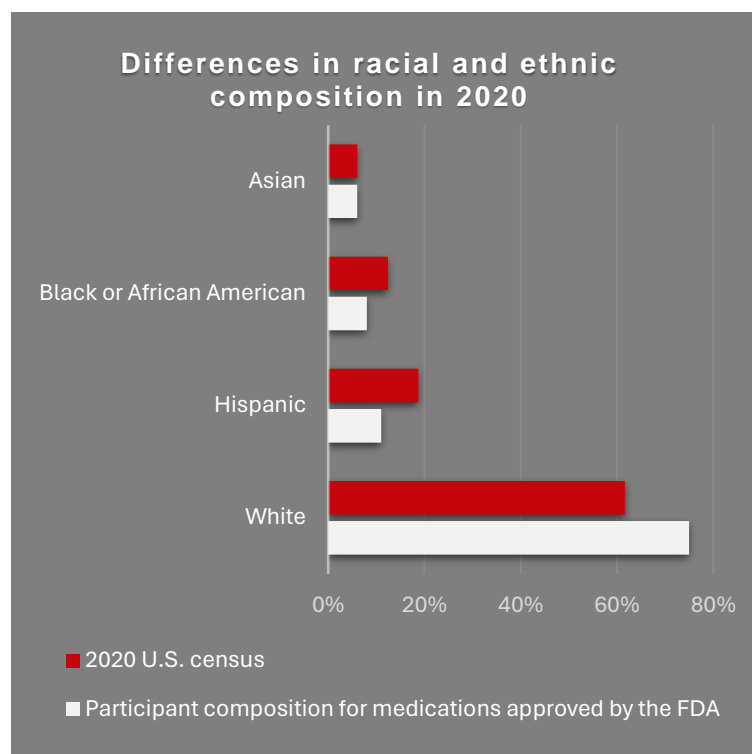
Why is justice, equity, diversity, and inclusion essential in clinical trials?

The U.S. is on track to be a minority-majority country by the 21st century,¹ meaning no single group will represent > 50% of the U.S. population.² Despite this demographic shift, similar trends are not reflected in clinical trials nationwide. The U.S. National Institute of Mental Health published a review of 379 clinical trials that occurred between 1995 and 2004, revealing that all racial or ethnic groups except whites and African Americans¹ were underrepresented* in clinical trials, and only about 48% of studies provided complete racial or ethnic information.³ In 2011, the Food and Drug Administration's (FDA) clinical trials comprised 5% African Americans* and 1% Hispanics*, while the U.S. population comprised 12% and 16%, respectively.⁴ By 2015, only 6% of federally funded clinical trials were comprised of Black* and Latino* participants, while the U.S. population comprised 30% combined.¹

Organizations like the FDA have made efforts to increase their diversity among races and ethnicities. However, diversity is more than just race and ethnic background; it includes age, biological sex, gender identity, disabilities, socioeconomic status, geographic location, education, religion, and language.^{5,6}

The FDA conducted an analysis of global participation in clinical trials in 2020, revealing a significant disparity between enrolled participants and the global population.⁵ Only 30% of the FDA participants were over 65 years of age, and more than half were located within the U.S.,⁵ even though only about 8% of the global population resides within North America.⁷ Older adults are just one example of groups typically underrepresented in

clinical trials. Other groups include younger adults, those within the LGBTQ+ community, birthing people, those who don't speak the primary language of the country, socioeconomically disadvantaged individuals, people experiencing homelessness, those living in rural locations, individuals in larger bodies, people with disabilities (visible and invisible), people who have multiple health conditions, or people who have substance use disorders.⁸



Lack of diversity in clinical trials can have significant consequences for public health as it typically results in inaccurate representations of broader populations,⁹ resulting in drugs and treatments being less effective or even harmful for certain groups.⁹ If a drug is approved to be effective

¹The language used was taken verbatim from published participant examples and does not reflect the inclusive language suggested by UW Institute of Clinical and Translational Research. Resources: [Inclusive Language](#), ICTR's Recruitment and Retention Resource Center

and is licensed for a disease, it is assumed that it will be effective on everyone equally, and that is inaccurate and can lead to health inequalities in other groups in which it may not be as effective.¹⁰ However, studies have shown that 20% of new drugs demonstrate differences in exposure and/or response across racial and ethnic groups.¹¹

There are currently no guidelines or requirements for clinical trials to be diverse.¹⁰ This lack of diversity results in national healthcare guidelines being developed without fully understanding the effects of the drug on all groups, although all groups are prescribed.¹⁰ However, the FDA has produced recent guidelines on how to enhance the diversity of clinical trial participants, primarily focusing on eligibility criteria (e.g., reducing restrictions), enrollment practices (e.g., enrolling participants who reflect real-world patient populations in regards to age, sex, race, and ethnicity), making trial participation less cumbersome (e.g., requiring fewer site visits, using health technology, working with mobile site professions, and/or offering compensation for costs incurred due to participation), and guidance for industries (e.g., analyzing clinical trial data by race and ethnicity and supplying trial information in multiple languages).¹⁴

When clinical trial populations don't reflect the real world, it creates barriers to finding better treatments and potential cures.¹⁵ This lack of real-world representation can hinder:

1. **Innovation** – unable to explore greater variation in the overall effectiveness of interventions. May not be able to understand how it works in underrepresented groups but also may miss any new biological processes that may lead to new discoveries important to all populations.
2. **Accrual Rate** – May compound low accrual that cause many trials to fail. Between 2008-2017 55% of trials were

Examples of clinical outcomes faced by individuals who are underrepresented in clinical trials.

	Women are more likely to suffer from adverse side effects of medication. ¹²		Medicine dosages have historically been based on clinical trials conducted in men . ¹²
	Cardiovascular medications produce clinical differences between white people of European ancestry and African Americans. ¹³		Clinical trial participants have historically been white people with European ancestry. ¹³
	Albuterol (licensed and widely inhaled) is less effective in people of African descent compared to European descent. ¹¹		Clinical trial participants have historically been white people with European ancestry. ¹¹
	Medication for treating hallucination associated with Parkinson's (Nuplazid) may produce clinical differences between groups. ¹⁰		The clinical trial was composed of 91% white people and 36% women. ¹⁰

Source: Institute of Clinical and Translational Research, University of Wisconsin Madison

terminated, suspended, or discontinued due to low accrual. Improving the participation of underrepresented groups would be one way to increase enrollment.

3. **Access to Interventions** – May lead to lack of access to effective medical interventions. Approval and indications for new therapeutics are often restricted to the demographics of the population included in the clinical study.
4. **Trust** – May undermine trust. Distrust of the clinical research enterprise and medical establishment rooted in historical and contemporary abuse has been documented as a barrier to participation in clinical studies among some populations.
5. **Health Disparities** – Compounds health disparities in the populations currently underrepresented in clinical trials and clinical research.

6. **Cost Implications** – Costs hundreds of billions of dollars. Results from the Future Elderly Model (FEM) suggests that at any point in time, a person’s health and functional status can be translated into a monetary value which is estimated to cost \$150,000 for someone with a disability (this includes a chronic condition like diabetes, hypertension, heart disease, cancer, etc.). This means that by 2050, it is estimated that diabetes will cost society more than \$5 trillion and heart diseases more than \$6 trillion. Much of these costs occurring from Black and Latinx populations and their shorter life expectancies. If health disparities are reduced, which translated into both longer and healthier lives for these populations, societal costs would also decrease.

For more information, see [Why Diverse Representation in Clinical Research Matters and the Current State of Representation within the Clinical Research Ecosystem](#).

Not everyone is going to know how to recruit and retain diverse participants and do so in the best way. It is incumbent on the government, academia, and industry to build best practices alongside their community partners. This is not “one-size-fits-all.” The goal of this roadmap is to help guide you in the right direction, but if you are in need of greater assistance, do not hesitate to reach out to the [Protocol Development Program](#) at UW Institute of Clinical and Translational Research to speak with the clinical trials navigator for individualized assistance. If you are interested in viewing the inclusion statistics across racial groups in NIH funding categories for in your field of interest, [click here](#).

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11. [Study explores how community engagement can help improve clinical trial diversity. \(n.d.\). The Ohio State University Wexner Medical Center.](#)
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14. [FDA. 2020. Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry](#)
15. [Varma, T., C.P. Jones, C. Oladele, and J.E. Miller. 2022. Diversity in clinical research: public health and social justice imperatives. Journal of Medical Ethics, 49, 200–203.](#)

Destination 1: Building Trust

1. Establish relationships in your community of interest.
 - Learn about the history of “the problem” in the community.
 - “The problem” being your study question of interest, whether it is heart disease, diabetes, or hypertension.
 - What do people think about this problem?
 - Why should they care?
 - What is the difference between what they think verse how scientists think?
 - Attend community events where you can talk about research studies and clinical trials when *you are not* recruiting.
 - Offer to give presentations at local community organizations or libraries.
 - Go to group meetings.
 - Openly discuss potential medical and research mistrust in communities.
 - Engage with your communities regularly.
 - Be a partner in their goals and objectives.
2. Resources:
 - [Building Trust Between Minorities and Researchers](#)
 - [Health Equity Advancement Resources: Learn Methods to Integrate Health Equity into Design of Health-related Interventions](#)
 - Learn about [Patients’ experiences with Clinical Trials](#) at [Health Experiences USA](#)
 - Participate in a Just Research [workshop](#)
 - [Health Equity Guiding Principles for Inclusive Communication](#)
 - [Preferred Terms for Select Populations Groups & Communities](#)

Destination 2: Define Your Subject Population

Before you begin—ask yourself these questions:

- Who am I recruiting?
 - Will I be able to recruit enough diverse participants from this study population?
- What is my definition of diversity?
 - Historically underrepresented or underserved groups?
 - Specific ethnicities, racial groups, age, gender identity, disability, nationality, sexual orientation, language spoken, geography, physical capabilities, etc.?
 - Socioeconomic statuses, rurality, religious beliefs, first-generation professionals, culture, etc.?
 - Will my ideal population be interested in participating in my research?
 - Are they interested in participating in research generally?
 - Do my methods align with this population's religious beliefs and cultural norms?
 - What potential benefits is my study providing to possible participants, the community, and the larger society?

1. Consider the study design.
 - Request a consultation with a Biostatistician knowledgeable in [Health Equity](#) Design.
 - Request a consultation with the informatics team to discuss study feasibility.
 - Determine if additional flexibility can be added for specific situations.
 - Could inclusion criteria be altered to allow for a larger (more diverse) population?
 - Could the data collection experience prioritize the participants experience?
 - Ask prospective participants how they want to be contacted and communicated with.
 - Ask about the participant's opinions or feedback, ask them questions.
 - Consider engaging with the population of interest beforehand to get feedback on design.
 - Consider the comorbidities commonly faced by the population and if that will disproportionately exclude them from your study.
2. Understand potential biases and layout measures to prevent them.
 - Clinicians are sometimes biased against research and think researchers only care about data and not their patients.
 - What steps can I take to help patients feel more comfortable getting involved?
 - What steps and methods can I implement to streamline the workflow of clinical staff participating in my study?
 - What can I do to make asking patients to participate in my research easier for both patients and the Clinicians?
 - Can I provide adequate time and resources for Clinicians to avoid blockages in suggestions CT to patients?
 - Provide Clinicians with an abstract of your work(s) that is at a level they will understand; a poster might also be useful.

3. NIH Resources
 - [Inclusion Across the Lifespan](#)
 - [Inclusion of Women and Minorities as Participants in Research Involving Human Subjects](#)
 - [Available Resources on the Recruitment and Retention of Women, Racial and Ethnic Minorities, and Individuals Across the Lifespan](#)
4. Other Resources
 - [CDC What is Health Equity?](#)
 - [CDC Using a Health Equity Lens](#)
 - [CDC Social Vulnerability Index](#)
 - [Neighborhood Atlas](#)

Destination 3: Find Community Groups

1. Plan meetings with patient groups as you are developing your protocol.
 - Obtain input from:
 - Patient Center Design and Equity Designers: those with experience living with inequities.
 - Design Allies: those with power to address inequities.
 - ([WINRS](#), [CARDs](#), [BOAAs](#)): patients that are diverse in terms of age and diseases.
 - Questions to ask:
 - What participation barriers should I anticipate?
 - How can I address and alleviate these barriers?
 - Is there any advice I can receive to help build trust with this study population?
 - Information to share:
 - Abstract about your work(s) that is [readable by the public](#).
 - Consider a poster to describe your work [containing photographs or cartoon images for accessibility](#).
2. Begin recruitment planning.
 - Recruitment of study participants is one of the most challenging aspects of clinical research. Nearly 80% of clinical studies are delayed due to poor enrollment which increases research expenses and hinders progress.
 - Consider your inclusion and exclusion criteria.
 - These may disproportionately cast aside underrepresented groups (e.g., comorbidities are more prevalent among minorities). Another issue is enrollment bias at recruitment sites, when potential participants are considered “at risk” in terms of loss to follow-up or overall compliance with study procedures due to cultural/community barriers.
 - *Inclusion criteria*:
 - Describes the conditions a patient must meet to be included in a study and should be chosen to demonstrate safety and effectiveness for a large group of patients.
 - Ask yourself these questions for each exclusion criterion:
 - i. Is this criterion common in my population of interest?

- ii. Is this criterion inclusive and going to make it easier for my study population to participate.
 - *Exclusion criteria:*
 - Describes the conditions a patient must not meet to be included in a study that are ethical and scientific. These are only applicable to ideal study conditions because some patients would influence the assessed study outcomes.
 - Ask yourself these questions for each exclusion criterion:
 - i. Is this necessary (i.e., is this criterion going to *actually influence* study outcome)?
 - ii. Is this criterion common in my population of interest?
 - iii. Is this criterion exclusive, therefore making it harder for my study population to participate (e.g., distance to clinic, language spoken, etc.)?
 - Ensure these are clearly defined and distinct as it is helpful for the exact differentiation of efficacy and effectiveness of your study and allows for study replication.
 - Find available federally qualified health centers and carefully examine them using a feasibility analysis to determine if their repository contains adequate amounts of your study population.
 - UW resources available:
 - [Clinical & Health Informatics Institute \(CHI2\)](#) works with investigators to determine data feasibility and help provide electronic records of patients that fit their methodological inclusion criteria.
 - Health Innovation Program, Wisconsin Partnership Program, and ICTR collaborated to create the [HIPxChange](#), a toolkit to identify patients, improve patient engagement, and much more.
3. If you need help finding community partners, check out these experts in equity-based community engagement.
 - [Dissemination & Implementation \(D&I\) Launchpad](#): A consulting service that aims to launch proven health-related innovations from research to clinical and community practice in Wisconsin and beyond.
 - [Wisconsin Public Health Research Network \(WPHRN\)](#): Their mission is to link and support public health practitioners and researchers to answer questions and disseminate discoveries that improve public health practice, promote racial and health equity, and contribute to population health.
 - [Community-Academic Aging Research Network \(CAARN\)](#): A collaboration between academic researchers and community partners to conduct clinical and dissemination research related to healthy aging.
 - [Pharmacy Practice Enhancement and Action Research Link \(Pearl-RX\)](#): Their mission is to lead the country in significant and innovative medication use research through the promotion and conduct of collaborative, patient-centered, practice-based research in partnership with health systems, pharmacy organizations,

- pharmacists, and the communities they serve.
- [Wisconsin Research and Education Network \(WREN\)](#): Their mission is to promote and conduct primary care research and education in partnership with primary care clinicians and the communities they serve.
 - [Wisconsin Network for Health Research \(WINHR\)](#): Was established to promote statewide research and to assist in moving research results from bench to bedside, by allowing investigators to perform clinical, translational, comparative effectiveness and health outcomes research across a variety of platforms.

Destination 4: Contact Community Groups

1. Set recruitment methods.
 - Consider creating these types of recruitment materials.
 - Flyers, pamphlets, brochures, and social media:
 - Consider the reading level of your participants. Keep the language simple without making them feel dumb and inadequate.
 - Consider differences in how the English language is used by different racial and ethnic groups.
 - Use terms like “we” and “us”.
 - Recruitment video:
 - Include diverse groups of people in recorded materials.
 - Ask community members and those within the research group to help with recruitment.
 - Leaders in the community may better help tailor strategies to their populations.
 - Can help consider community incentives (i.e., adding information to the library or needed contributions to the group or community).
- Ask yourself: Will my study need multiple recruitment materials that are edited differently to best suit my study population(s)?
- Considering the timing and implementation
 - Are you going to recruit outside of typical working hours?
 - Are you going to include alternative communication methods such as social media?
2. Offer incentives for community groups to participate in studies.
 - Volunteer efforts by study team.
 - Fundraising efforts by study team.
3. If you need recruitment help, check out these experts in recruitment and retention.
 - [Recruitment & Retention Resource Center](#): A service that aims to aid investigators and study teams in fulfilling enrollment goals and timelines through multifaceted strategies and collaborative consultations. Their consultations incorporates recruitment, retention, and engagement guidance from members of the [Collaborative Center for Health Equity](#), [Multisite Research](#)

[Networks](#), and [Dissemination & Implementation Launchpad](#).

4. Resources to help:
 - [CARDS](#) – Community Advisors on Research Design and Strategies; they provide a unique and exciting way to get valuable, actionable, candid feedback on how to make materials clearer, more engaging, more inclusive, and easier to read.
 - [Just Research](#) – A program to learn skills to promote research equity and diversity in study participation.

Destination 5: Make Participation Accessible

1. Data collection
 - Consider data collection locations.
 - Could my location be more convenient for participants?
 - Could I collect my data at my participants' local clinic, rather than having them travel to see me?
 - Consider more specific details, such as: a) How far will the participants have to walk? b) Will it be wheelchair accessible? c) Will there be wheelchairs or other mobility devices available? and d) Will the front desk staff be able/capable of arranging for a wheelchair or golf cart to transport participants if needed?
 - Plan what to do with uninsured participants.
 - Is there a way to reduce or cover study costs for my participants?
 - Collect more demographic data to help document diversity and define populations.
 - Local demographic data (zip code + 9, etc.)
 - Education
 - Insurance Coverage
 - Residence Type
 - Socioeconomic Status
2. Documentation
 - Informed consent
 - Consider e-consent options.
 - Consider alternative methods for those with memory issues.
 - Consider multilingual forms.
 - It helps to have multilingual staff or coordinators. If that is not possible, have access to interpreters.
 - Improve readability.
 - Consider making it around a 3rd grade reading level as 25% of native English speakers have lower than a 6th grade reading level. If you are unsure how to write at this level, try using an AI readability analyzer, like [Hemingway Editor](#), to check the readability of your document.
 - This includes creating [accessible and inclusive tables and images](#) to explain processes and activities.
 - Train staff to talk through the informed consent with participants.
 - Ensure forms are culturally appropriate for your study populations.
 - Ask the community leaders or community group volunteers to help construct,

- or review, documents so ensure they are appropriate.
- Resources:
 - UW Madison's policy on [Digital Accessibility](#)
 - [Plain Language](#) makes it easier for the public to read and understand.
 - [Plain Language Training](#)
 - CDC Inclusive Images
- 3. Offer flexibility
 - Consider offering participation times after average working hours, at night, and on weekends.
 - Consider collecting data in clinics more convenient to your study population.
 - Provide travel options:
 - Give participants a list of services available in their communities (bus schedules, taxi services, Ubers, Lifts, etc.).
 - Offer to pay for their travels at the beginning of the study.
 - Offer child or elder care.
 - Offer reimbursement that is available immediately after participation.
 - Have your study pay for appropriate medical treatments for the participant, rather than the participant having to pay out of pocket or the co-pay and later reimbursed by insurance.

Destination 6: Implement in Protocol

1. If you need assistance thinking about interventions that incorporate justice, equity, diversity, and inclusion, use the '[Who, What, When, Where, and How Framework](#)' for a systematic approach.
 - WHO has the disparity?
 - Health disparity is a particular type of health difference that is closely linked with social, economic, and/or environmental disadvantages (Healthy People 2030).
 - Be specific when describing WHO. Who is selected as the reference population and the reasoning for selection requires critical thought.
 - To disentangle and clarify WHO has the disparity, it is important to determine the contribution of race/ethnicity, socioeconomic status, or other factors to guide intervention.
 - WHAT kind of disparity?
 - Health disparities refers to differences in burden of illness, disability or mortality experienced by one population compared to another.
 - Health care disparities refers to differences in health care coverage, access, and quality of care.
 - It is important to distinguish between these two as the population sources and solutions are distinct!
 - WHEN did the exposure underlying the disparity occur?
 - Key concept underlying life course population health is the critical and sensitive periods of

- exposure and their effects on future generations.
 - Risk factors associated with disparities will vary depending on timing or developmental age and magnitude of exposure.
 - WHERE did the exposure underlying the disparity occur?
 - HOW (why) did the disparity occur?
 - Research must go beyond just describing the disparities and understanding the WHY and HOW. Creating a conceptual map or model incorporating the WHY and HOW is vital to describe underlying assumptions regarding how various factors may contribute to a specified disparity. This openly invites challenge and evaluation of new theories and mechanisms which are critical to guide appropriate interventions.
 - It is important to understand and account for the context in which the disparity occurred.
 - Where can provide vital information on the cultural, social, and other specific local circumstances that need to be evaluated to address the disparity.
2. Consider your study team composition.
- Does your study team reflect diversity, have diverse backgrounds, and/or represent the study population of interest?
 - Consider your own biases when hiring team members.

Destination 7: Dissemination

1. Develop a plan to maintain community relationships throughout your project and after your project is complete.
 - Send information to assisting clinicians about progress and preliminary results.
 - Send thank you notes to community partners and/or groups, to participants, to experts who helped, etc.
 - Meet with community groups once enough data has been collected, or after study has been completed, to discuss outcomes and findings.
 - Get creative to increase engagement. Have a panel discussion. Give a presentation.
 - Send out information about what was learned after the study is complete.
 - Tell the participants how their information was useful, how it can benefit their community or society in general.

Additional Resources

Papers to read.

- 2023. [Why Nature is Updating its Advice to Authors on Reporting Race or Ethnicity.](#)
- A. Castro et al. 2021. [Building Sustainable Organizational and Community Capacity for Research Partnerships: A Decade of Experience.](#)
- T.L. Cheng et al. 2023. [Clarity on Disparity.](#)
- M. Coakley et al. 2012. [Dialogues On Diversifying Clinical Trials: Successful Strategies for Engaging Women and Minorities in Clinical Trials.](#)
- D.M. Gray et al. 2021. [Diversity in Clinical Trials: An Opportunity and Imperative for Community Engagement.](#)
- C. Heller et al. 2014. [Strategies Addressing Barriers to Clinical Trial Enrollment of Underrepresented Populations: A Systematic Review.](#)
- A. Flanagan et al. 2021. [Updated Guidance on the Reporting of Race and Ethnicity in Medical and Science Journals.](#)
- S.R. Passmore et al. 2016. [Building a “Deep Fund of Good Will”: Reframing Research Engagement.](#)
- S.R. Passmore et al. 2022. [“There’s not much we can do…” Researcher-Level Barriers to the Inclusion of Underrepresented Participants in Translational Research.](#)
- N. Stedman 2023. [Increasing the Diversity of Clinical Research Participants.](#)
- S.J. UyBico et al. 2007. [Recruiting Vulnerable Populations into Research: A Systematic Review of Recruitment Interventions.](#)
- V. Washington et al. 2022. [Diversity, Equity, and Inclusion in Clinical Research: A Path Toward Precision Health for Everyone.](#)
- V.A. Welch et al. 2017. [CONSORT-Equity 2017 Extension and Elaboration for Better Reporting of Health Equity in Randomized Trials.](#)

Recorded seminars available to watch.

- [“Building Stronger Communities and Research Programs with Equity and Inclusion”.](#)
Gina Green-Harris (2022)
- [“Recruitment: Building Trust Between Minorities and Researchers”.](#)
Susan Passmore (2019)
- [“Oneida Nation of Wisconsin and the Alzheimer’s Disease Research Center: a Model of Engagement That Worked”.](#)
Hector Salazar (2020)
- [“Engaging with LGBTQ+ Populations in Research”.](#)
Stephanie Budget (2021), *need to Login to using wisc account and then use password Prep2021 to access recording.
- [“Disability, Inclusion and Accessibility for Researchers”.](#)
Ruben Mota (2022)
- [“Measuring and addressing health disparities through a statewide quality improvement collaborative”.](#)
Matt Gigot and Jennifer Weiss (2022)