

RESEARCH 103
Session 5:

Diversity and Inclusion in Research

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Learning Objectives:

At the end of this presentation learners will:

- ▶ Explain the importance of diversity and inclusion in clinical research.
- ▶ Evaluate the effectiveness of practices used in your previous and ongoing research to enhance the inclusion of diverse participants.
- ▶ Examine current project(s) for opportunities to improve the inclusion of diverse study participants using commonly recommended strategies, explaining the rationale for selecting specific strategies.



Definition of Terms

Diversity: What is it?

Diversity is the range of human differences, including but not limited to race, ethnicity, gender, gender identity, sexual orientation, age, social class, physical ability or attributes, religious or ethical values system, national origin, and political beliefs.

<https://www.ferris.edu/administration/president/DiversityOffice/Definitions.htm>

Diversity is more than ways of being, it also includes ways of knowing.

<https://www.qcc.cuny.edu/diversity/definition.html>

Intentional diversity strategies get people to the proverbial table (e.g., into the study), acknowledging that they contribute in a meaningful way to the menu (e.g., data, results, and conclusions).



Inclusion: What is it?

Inclusion is a state of being valued, respected, and supported. It's about focusing on the needs of every individual and ensuring the right conditions are in place for each person to achieve his or her full potential.

https://www.hud.gov/program_offices/administration/admabout/diversity_inclusion/definitions



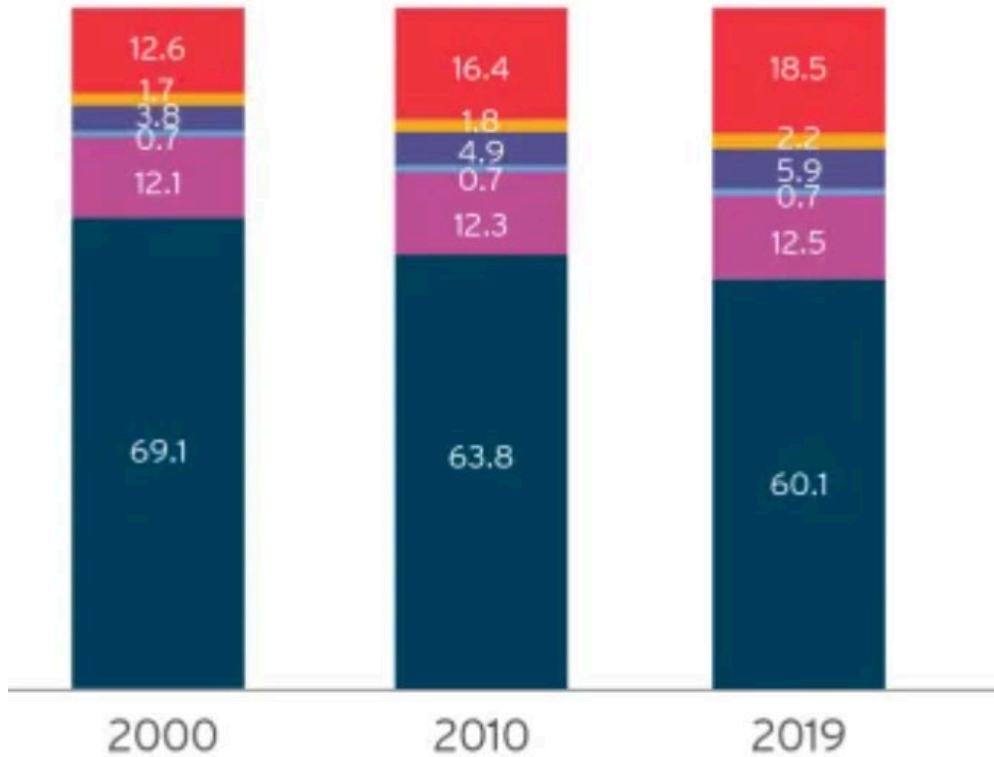
This Photo by Unknown Author is licensed under CC BY

What are the scientific reasons for addressing diversity and inclusion in clinical and biomedical research?

Research is usually performed using a small portion of the overall population with the goal of providing an effective treatment for the entire population. However, without a diverse group of individuals participating in research, researchers will not know whether the results can be applied to all people equally.

<https://ftdregistry.org/press/minority-voices-ensuring-racial-and-cultural-diversity-research-0>

Total US population



Race - Ethnic Profile for Total U.S. 2000, 2010, 2019

■ White*
 ■ Black*
 ■ American Indian Alaska Native*
 ■ Asian American**
 ■ 2+ and other races*
 ■ Latino or Hispanic

* members of race group who do not identify as Latino or Hispanic
 * non-Latino or Hispanic Asians, Hawaiians and other Pacific Islanders

Source: William H Frey analysis of 2000 US Census and Census population estimates, released June 25, 2020

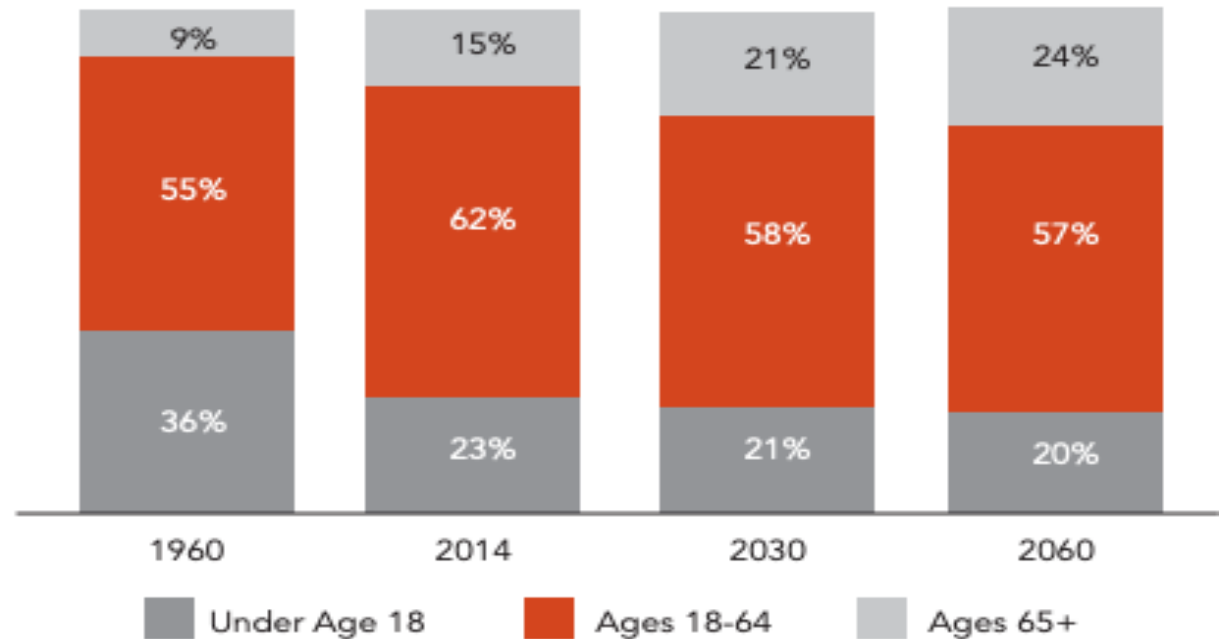
Age: Changing U.S. Population Distribution

► <https://www.prb.org/aging-unitedstates-fact-sheet/>

FIGURE 2

By 2060, Nearly One-Quarter of Americans Will Be Ages 65 and Older.

Percent of U.S. Population in Selected Age Groups, 1960 to 2060



Clinical Research Diversity Profile

U.S. Food and Drug Administration 2018 Drug Trial Snapshots

<u>Subgroup</u>	<u>Population Percent</u>	<u>Clinical Research Percent</u>
Whites	67	83
Blacks, African-Americans	13.4	5
Latino, Hispanic	18.1	< 1

<https://acrpn.net.org/2020/08/10/representation-in-clinical-trials-a-review-on-reaching-underrepresented-populations-in-research/>

Clinical Research Diversity Profile

American Society of Clinical Oncology 2020 Ethnic Minority Enrollment in Clinical Trials (N = 5157)

<u>Subgroup</u>	<u>Clinical Research Percent</u>
<i>Women</i>	38
<i>White, European American</i>	68
<i>African American</i>	4
<i>Asian American</i>	15
<i>Hispanic, Latino</i>	4
<i>Age 65 or older</i>	50%

<https://acrpn.net.org/2020/08/10/representation-in-clinical-trials-a-review-on-reaching-underrepresented-populations-in-research/>

Diversity Matters

- ▶ Behavioral interventions, drugs, and medical devices should be studied in samples reflecting targeted treatment populations
- ▶ Some groups respond differently to medicines (e.g., women, older adults), experiencing different side effect profiles
- ▶ May lead to more robust and complete data that increases understanding differences in treatment responses across diverse groups and avoidance of adverse events that may be linked to specific patient populations

(Clark et al., 2019; Miseta, 2020)

Diversity Matters: An Example

- ▶ Example: Pacific Islanders and antiplatelet drug (e.g., clopidogrel)

(Bruchard, 2015)



Table 1. Insights from studies conducted in diverse race/ethnic groups.

Trait	Findings
Breast cancer	Differences in Native American ancestry at the estrogen receptor locus led to discovery of a genetic variant that was protective against breast cancer in Latinas [11].
Heart failure	A post-hoc analysis of clinical trials of fixed-dose combination of hydralazine and isosorbide dinitrate suggested that black, but not white patients had a significant reduction in mortality compared to placebo [12].
Increased preterm birth rate	Exposures to endocrine disrupting chemicals such as bisphenol-A (BPA) are more common among minorities who live in low socioeconomic strata. BPA causes epigenetic alterations of the germ line resulting in increased preterm birth rate; these alterations can pass down to future generations [13].
Stevens-Johnson syndrome	The risk of carbamazepime-induced Stevens-Johnson syndrome due to HLA-B*1502 is highest in populations of Southeast Asian and East Asian ancestry [14].
Kidney disease	Genetic variants of <i>APOL1</i> have been associated with kidney disease in individuals of African ancestry whose ancestors lived in regions of Africa endemic with trypanosomiasis; these renal risk variants are largely absent in individuals of European or Asian ancestry [15].
Response to efavirenz	Blood levels and treatment response to this antiretroviral drug are influenced by individual ancestral make up, which can be accounted for by polymorphisms of cytochrome 2B6 and genetically defined ancestry [16,17].

doi:10.1371/journal.pmed.1001918.t001

Oh SS, Galanter J, Thakur N, Pino-Yanes M, Barcelo NE, et al. (2015) Diversity in Clinical and Biomedical Research: A Promise Yet to Be Fulfilled. PLOS Medicine 12(12): e1001918. <https://doi.org/10.1371/journal.pmed.1001918>

<https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001918>

Diversity Matters

Lack of diversity in clinical trials is a moral, scientific, and medical issue. When trial participants are homogenous (e.g., primarily one gender, race/ethnicity, or age group), findings may be skewed and result in a body of clinical knowledge that is not generalizable.

(Clarke et al, 2019)

Why do we exclude populations?

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Exclusion of ethnic minority groups is multi-faceted and complex

- ▶ Influenced by potential subject, provider, funder, and investigator factors.
- ▶ Exclusion may be planned, unintentional, reflect non-participation, and a combination of factors.





Fear of Exploitation

Unethical Human Research: Historical Trauma in Marginalized Groups

- ▶ Tuskegee Study of Untreated Syphilis in the Negro Male (1932-1972)
- ▶ Havasupai Tribe Type 2 Diabetes Project (1990)
- ▶ Willowbrook Study of Children with Cognitive Disabilities Exposed to Viral Hepatitis (1950s - 1972)
- ▶ Jewish Chronic Disease Hospital of Older Adults Injected with Live Cancer Cells (1962)
- ▶ San Antonio Contraception Study on poor Mexican American women (1971)

https://www.gc.cuny.edu/CUNY_GC/media/CUNY-GraduateCenter/PDF/GC%20HRPP%20Documents/Agreements%20and%20other%20Info%20Docs/Unethical-Human-Subjects-Research-Final-MA.pdf?ext=.pdf

What are the barriers to ethnic minority enrollment and participation?

Lack of minority investigators

Absence of study sites where diverse participants live and work

Providers unaware of clinical trial availability

Many patients are never asked to participate

Lack of trust associated with unethical practices

Language and cultural barriers

What are the barriers to ethnic minority enrollment and participation?

Trial design

Lack of financial resources

Job and other commitments

Not invited to participate

Unaware of clinical trials and what participation entails



Myth: Ethnic Minorities Won't Participate in Research

...minority ethnic groups are willing to participate in research if the study has direct relevance to them and their community and if they are approached with sensitivity and given clear explanations of what is involved.

(Redwood & Gill, 2013)

The background features abstract, overlapping geometric shapes in various shades of green, ranging from light lime to dark forest green. These shapes are primarily located on the right side of the slide, creating a modern, layered effect. The text is positioned on the left side of the slide, set against a plain white background.

How do I achieve sample diversity
and inclusion?

A 3D rendering of a puzzle with one red piece standing out among several white pieces. The red piece is in the center-left, and the white pieces are scattered around it. The puzzle is set against a white background with a green gradient on the right side.

Community Engagement

Perhaps one of the most effective ways to address the puzzle of achieving diversity and inclusion in research is to *engage with communities* to determine research questions and design studies.

Potential Strategies

Pilot

Pilot test recruitment approaches in exploratory and feasibility studies to support diversity recruitment and enrollment plans for large scale trials (e.g., CORNET Award).

Interview

Interview study participants after every study to gain insights that inform future studies with the population - disseminate findings.

Identify

Identify critical community organizations whose members are members of target populations that can help develop successful diversity recruitment and enrollment plans and inform solutions to enrollment barriers.

Create

Create opportunities for enhancing cultural humility in all study team members

Potential Strategies

Invite

- Invite diverse community residents and other stakeholders to townhalls, sharing study opportunities and study results. Have former participants join these events as champions.

Enlist

- Enlist diverse former study participants to serve as part-time paid and trained study champions to recruit for new studies.

Consider

- Consider technology and telehealth approaches to engage participants when possible

Make

- Make diversity a mandate for all trials.

Potential Strategies

Engage

Engage with ethnic minority provider groups informing them of your trial and potential benefits to their patients, sending study newsletters as updates

Interact

Interact with health care personnel at potential sites during their slow periods

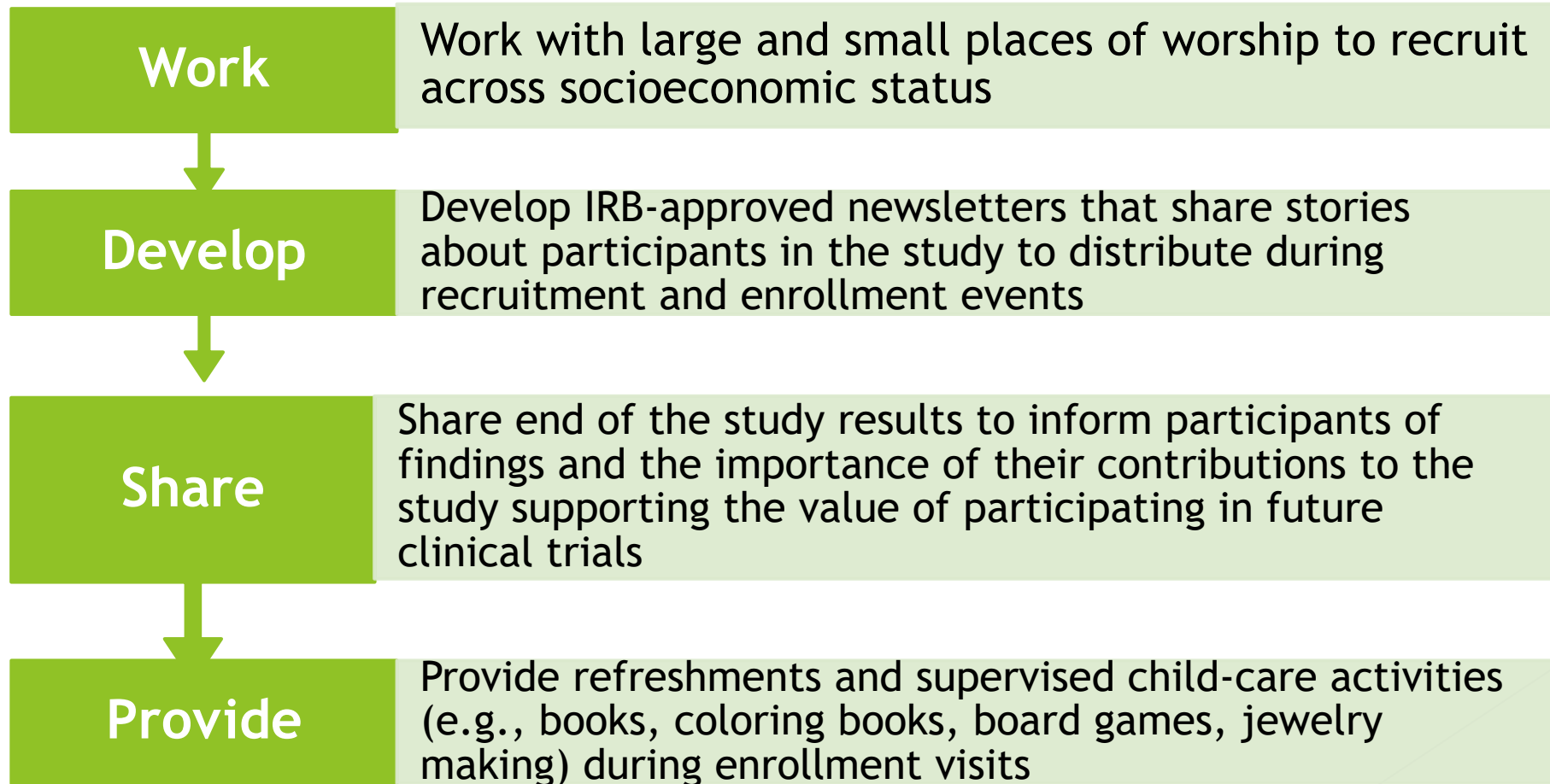
Work

Work with community-wide initiatives that align with your research focus (e.g., Diabetes Awareness month, health fairs, street fairs)

Create

Create an advisory board of patients and family caregivers to inform the study questions, design, and interventions

Potential Strategies



Potential Strategies



Routinely monitor and evaluate recruitment strategy success as a team, adding new IRB-approved approaches to achieve enrollment goals.



Invite advisory board members to contribute as co-presenters and co-authors to maintain their interest and commitment to the study's diversity goals designed to make research responsive to participating communities.



Recruit diverse team members as patients often feel comfortable when they see study team members who they identify with



Have open, informed dialogues about recruitment challenges, consulting with colleagues who have been successful

Number of adolescent participants with uncontrolled asthma referred or enrolled through each recruitment source

Sources	Total Referred n (%)	Total Enrolled n (%)
Word-of-mouth*	104 (20%)	76 (20%)
Clinician referrals*	94 (18%)	72 (19%)
School referrals*	72 (14%)	51 (14%)
School events*	59 (12%)	41 (11%)
ED/clinic direct recruitment*	36 (7%)	34 (9%)
Study flyer*	40 (8%)	32 (8.5%)
Community/group events*	44 (9%)	32 (8.5%)
Clinical practice patient registries	34 (7%)	18 (5%)
Previous study contact database	20 (4%)	14 (4%)
Self-referral through the study website*	3 (.06%)	2 (.05%)
Newspaper ad	1 (.02%)	1 (.03%)
Radio	1 (.02%)	0 (0%)
Total	508	373

(Grape, Rhee, Wicks, Tumiel-Berhalter, & Sloand, 2018)

How do I decide which approaches to use?

No single approach will work for every population as there is significant diversity within and across populations

Do the work to know your population; results require intentionality and an investment in time

Pay-off is increasing success, defined as reaching targets and conducting research that can be generalized

Conducting post-trial interviews is a useful for gaining understanding regarding what worked and why



Beyond Diversity and Inclusion: Representativeness

“Representativeness” means a sufficient number and types of people are included to ensure those enrolled represent the target population for whom the treatment is intended. It refers to “who” and “how many” individuals to include to, as closely as possible, represent the broader target patient population.

(Perfetto & Ragante, 2020)



Parting thought: Does your study team respond to the healthcare needs of all U.S. taxpayers who fund clinical and biomedical research?

(Oh et al, 2015)