



# **Diversity, Inclusion, and Equity in Human Subjects Research**

Why it matters and where we go  
from here



## Outline

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- Definitions
- History
- Why does it matter?
- What can we do?



# Definitions

## Diversity

- Differences in race, color, place of origin, religion, immigrant and newcomer status, ethnic origin, ability, sex, sexual orientation, gender identity, gender expression and age.

## Inclusion

- The practice of ensuring that all individuals are valued and respected for their contributions and are equally supported.



# Equity

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- The removal of systemic barriers and biases enabling all individuals to have equal opportunity to access and benefit from the program.



# History: Syphilis Study at Tuskegee

- 600 African American men, 399 with syphilis
- Informed Consent was not obtained
- Researchers told participants they were being treated for "bad blood"
- Participants were not offered penicillin when it became the medical standard for treating syphilis and, instead, researchers observed the progression of the untreated disease

# History: Tearoom Trade Study

- Researcher observed men having impersonal sex with other men
- Did not disclose his identity as a researcher
- Recorded identifiable information of participants engaged in acts which were illegal at the time of the study
- Disguised himself and went back to interview the men in their homes a year later under the guise of conducting an anonymous public health survey

# History: Guatemala STD Experiments

- Originally began with prisoners in the U.S. but was moved to Guatemala when researchers were unable to consistently produce gonorrhea infections there.
- Prisoners received \$100, a certificate of merit, and a letter of commendation to the parole board at the end of the study
- 1,500 vulnerable individuals (children, orphans, child and adult prostitutes, Guatemalan Indians, leprosy patients, mental patients, prisoners, and soldiers) were intentionally infected with STDs
- Did not consent or receive treatment after exposed

# Historical Impact



1974: National Research Act signed into law, creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

Late 1970s: Ethics Advisory Board formed to review ethical issues of biomedical research.

1979: **The Belmont Report** summarized three ethical principles that should guide human research: *respect for persons*; *beneficence*; *justice*.

1980-1983: President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research created.

1981: Common Rule – federal ethics guidelines for the conduct of human subjects research





## Why Does Diversity, Inclusion, and Equity Matter in Research?

- Belmont Report principle of justice
- The risks and potential benefits of research should be distributed fairly



“The selection of research subjects needs to be scrutinized in order to determine whether some classes (e.g., welfare patients, particular racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied. Whenever research leads to the development of therapeutic devices and procedures, justice demands both that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.”



## **Why Does Diversity, Inclusion, and Equity Matter in Research?**

- Representation is important in ensuring that research results apply to a broad range of individuals

**Most  
research is  
W.E.I.R.D.**

Western

Educated

Industrialized

Rich

Democratic



Three U.S. ZIP codes are associated with over 40 percent of articles in the top five economics journals and those articles garnered one - half of all citations in these journals from 2000 to 2015.

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## Women and minorities in FDA and NIH clinical trials

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<https://recruit.ucsf.edu/diversity-research-participation-why-its-important>



# Why does it matter?

## COVID-19 Vaccine Studies

- White participants accounted for 78% of all participants
- People 65 and older accounted for 12% of all participants

# What can we do?

- Engage the study population
- Native language and dialects
- Avoid “helicopter research”
- Share results





# What can we do?

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- Be aware of your own biases
- Be willing to learn from others
- [K@TE](#)
- [Project Implicit](#)





## What can we do?

- Accommodations for participants
- Demographic data collection



# Designing Demographic Questions

- Should be methodologically necessary
- Inform participants why collecting demographics
- Keep options in alphabetical order
- Ask participants to select all that apply



# Designing Demographic Questions

## Gender Identity

Please select *all* that apply:

Agender

Female/woman

Gender fluid

Gender non-conforming

Male/man

Non-binary

Transgender

Not listed: \_\_\_\_\_

Prefer not to answer

## Sexual Orientation

Please select *all* that apply:

Asexual

Bisexual

Gay

Heterosexual

Lesbian

Queer

Questioning

Transgender

Not listed: \_\_\_\_\_

I don't know

Prefer not to answer

# Designing Demographic Questions - Race



Please select *all* that apply:

AAPI (Asian American, Pacific Islander)

African American/Black

Arab-American

Born outside of the United States?

Continent: \_\_\_\_\_ Nation/Country: \_\_\_\_\_

Indigenous/First Nations/Native American

Tribal affiliation: \_\_\_\_\_

Latino/x or Hispanic

Multi-racial

Please specify: \_\_\_\_\_

White

Not listed: \_\_\_\_\_

Prefer not to answer



# Continue Learning

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- Diversity and Engagement at UTK: <https://diversity.utk.edu/>
- Office of Community Engagement and Outreach: <https://communityengagement.utk.edu/>







## Additional Resources

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Resource list developed by Miranda N. Rutan and Candace Sapp – doctoral students in CEHHS

[Webinar from UCSF on Recruiting Underrepresented Study Populations](#)

[Best Practices in Equity, Diversity and Inclusion in Research from the Canadian Government](#)





## Additional Resources

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[Guidance from Montclair State University  
Black Lives Matter in Research Working  
Group](#)

[Reading and Reference List from Montclair  
State University](#)

# Questions?



Thanks for joining us!



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