

# Important Considerations for Consenting & Inclusion of People with Limited English Proficiency

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# Your experience with inclusion and consenting of people with limited English Proficiency?



- Which institution do you work for?
- That you are aware of, what are the interpreting and translation services available for study participants at your institution?
- What barriers have you faced or might face in including non-English speakers in research?

# Why Ensuring Language Access and Linguistic Competence are Essential in the Conduct of Clinical Research?

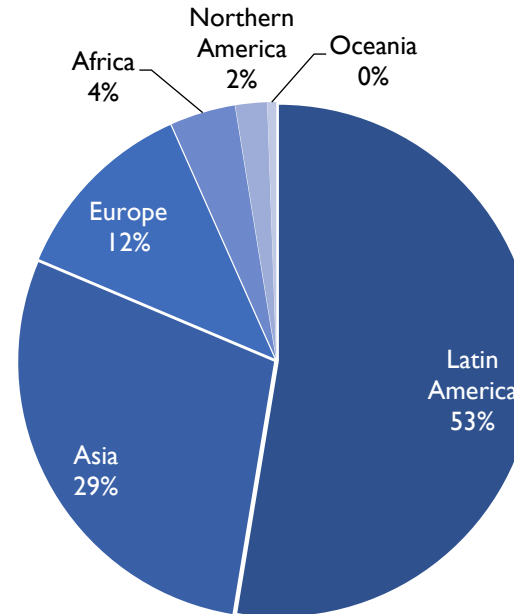
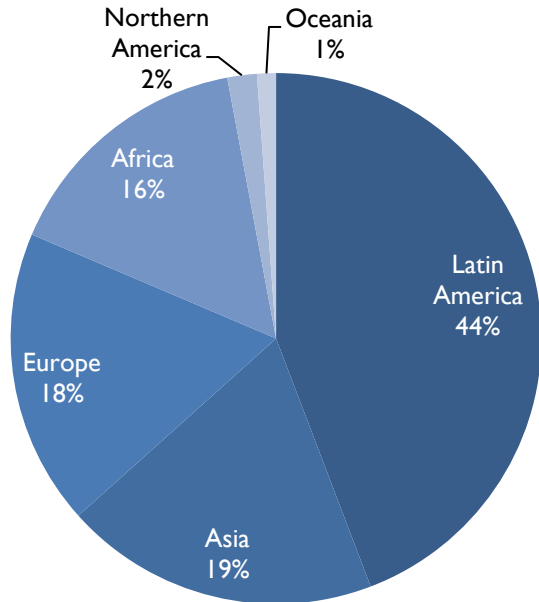
1. It's the law - Title VI: Civil Rights Act of 1964- Nondiscrimination in federally assisted programs: “no person in the US shall in the ground of race, color, or national origin be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving federal financial assistance”.
2. Respond to current and emergent demographic trends in the DMV metropolitan area
3. Promote equity in research participation
4. Enhance capacity to address health literacy
5. Add to the body of knowledge on clinical research for LEP populations and those with other communication needs
6. Address implicit biases

# The DMV – a true melting pot



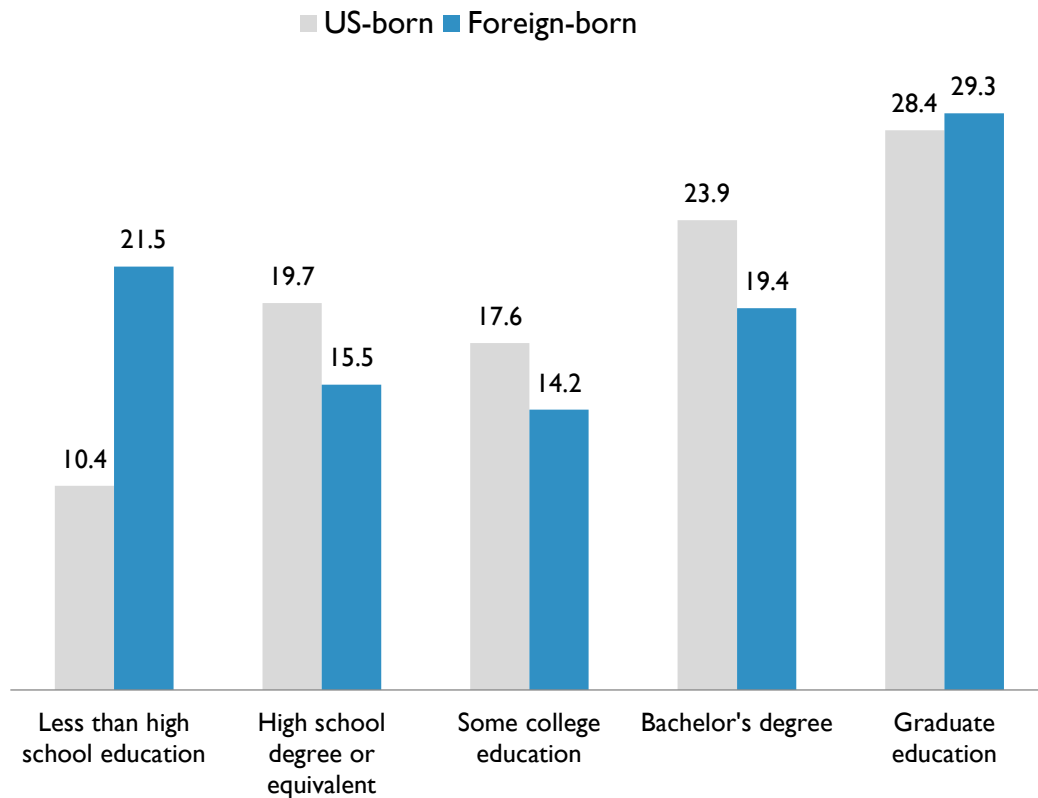
*District of Columbia  
85,300 immigrants*

*United States  
44,450,300 immigrants*



Source: 2012 three-year data from the American Community Survey, accessed through American FactFinder.  
 Note: The top 10 countries of origin among immigrants in the United States are Mexico (28.8%), China (5.5%), India (4.7%), Philippines (4.5%), Vietnam (3.1%), El Salvador (3.1%), Cuba (2.7%), Korea (2.7%), Dominican Republic (2.2%), and Guatemala (2.1%). The top ten countries of origin among immigrants in the District of Columbia are El Salvador (15.8%), Ethiopia (6.2%), Mexico (3.6%), China (3.4%), Guatemala (3.0%), India (2.9%), Nigeria (2.4%), Philippines (2.4%), Jamaica (2.3%), and Trinidad and Tobago (2.3%).

# Educational Attainment of Immigrants versus the Native-Born Population in the District of Columbia

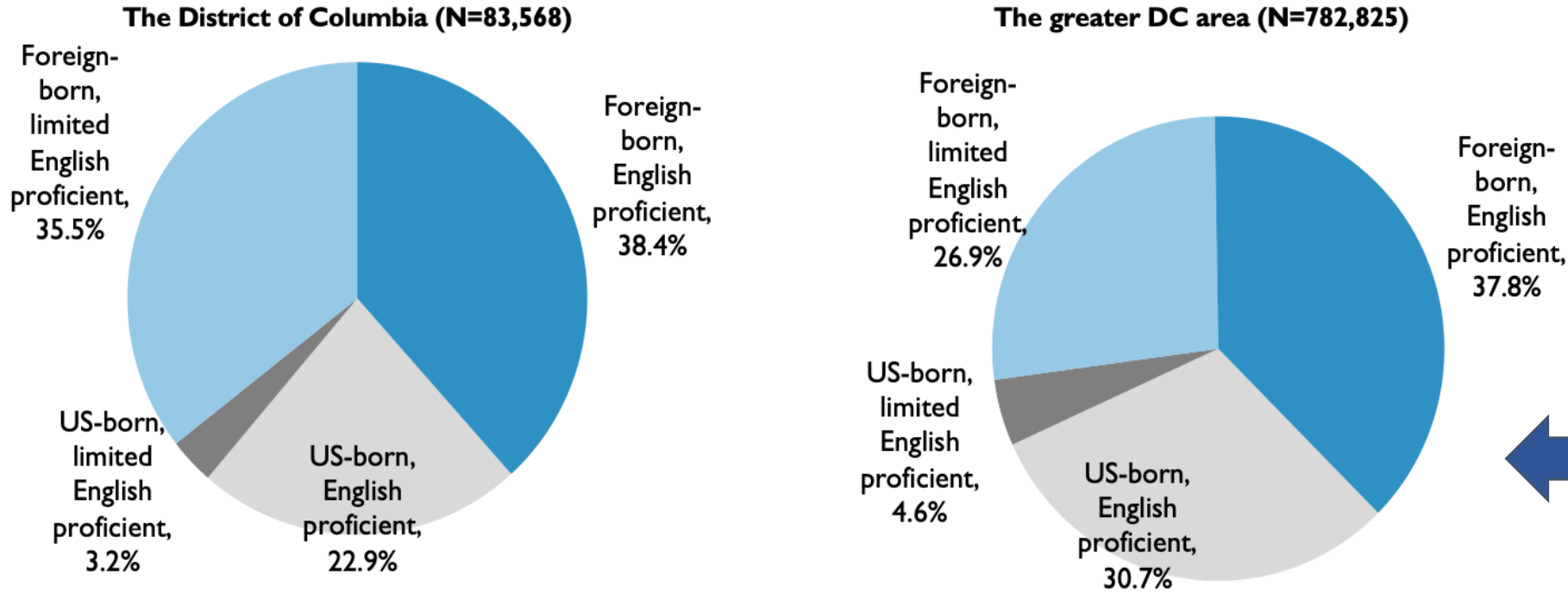


Mix of education levels among immigrants ranging from highly educated to individuals less education and may not be able to read or write.

<https://ohr.dc.gov/sites/default/files/dc/sites/ohr/publication/attachments/Language%20Access%20in%20Washington%20DC%20408%20final.pdf>

Source: 2012 three-year data from the American Community Survey, accessed through American FactFinder.

**Figure 7. Place of Birth and English Proficiency of Those Speaking a Language Other Than English at Home in the District of Columbia and in the Greater DC Area**



Prevalence of Low and No-English Proficiency Residents



Source: 2012 three-year public-use microdata from the American Community Survey, accessed through the Integrated Public Use Microdata Sample (IPUMS) (Ruggles et al. 2010).

DC: 26,400 (5%) of DC residents age are LEP/NEP; f these 85% are foreign-born  
 DMV: 303,500 (11%) are LEP/NEP; of these 92% are foreign-born. o

1. Research is conducted in study participant's preferred language.
2. Ensure provision of quality of language services (interpreting & translation)
3. Written materials are translated, adapted, and/or provided in alternative formats based on study participant needs.
4. Interpretation and translation services comply with all relevant federal, state, and local mandates governing language access and assistance services.
5. Translated documents are reviewed by someone other than person/company translating document prior to participant use.
6. Include diverse advisory board membership (study CAB/PAB)
7. Invest time & effort to make research accessible to any eligible participant.

Goode, Tawara D. (2020) Ensuring Language Access and Linguistic Competence: A Guide for Researchers. Washington, DC: Georgetown Howard Universities Center for Clinical and Translational Science.

# Health Literacy

- Health literacy: evolving concept from individual capacity to organizational capacity and responsibility
  - “Health literacy is the degree to which **individuals have the capacity** to obtain, process, and understand basic health information and services needed to make appropriate health decisions (US Department of Health and Human Services, 2010)
  - Health literacy is the **capacity of professionals and health institutions** to provide access to information and support the active engagement of people (Rudd R. Health Literacy: Time to refocus and expand)

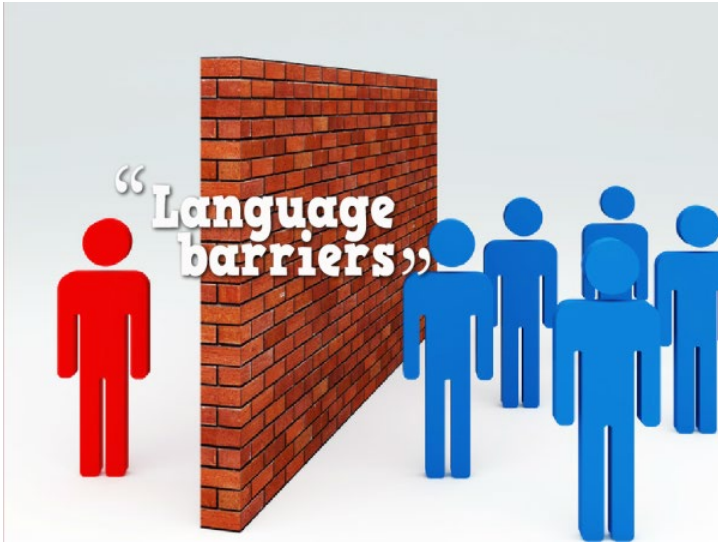


# Barriers for Inclusion of People with LEP

- Limited English proficiency or low health literacy
- Lack of awareness about trials & knowledge of research
- Mistrust in health research
- Lack of transportation
- Low socio-economic status
- Fear (undocumented individual)



# Research Team Barriers for Inclusion of People with LEP



- Limited number of bilingual staff
- Lack of interpreting & translation funds
- Limited availability of hospital interpreters
- Time and effort needed to meet IRB requirements
- Time and effort required to plan for provision of quality language access (both interpreting and translation services)

*GHUCCTS Inclusion of Diverse Population Core, Environmental Scan - HU, GU, Medstar, DCVAMC (Jan 2018)*

# Strategies for Inclusion of PwLEP



- Ensure **quality language access** (translation & interpreter)
- Budget for interpreting & translation from very beginning (If industry trial, negotiate)
- Check with the IRB and study sponsor for interpreter/translation requirements

## Translation

- Have all patient facing study documents translated (i.e. consent, surveys, recruitment material)
- Northwest Translation
- Request a translator from same or similar region as study participants
- Sixth grade level or less
- Have someone within your institution (bilingual) review translated material



# Strategies for Inclusion of PwLEP

## Language Interpreter

- Use certified interpreter when possible or ensure person interpreting has experience doing so in medical settings.
- Avoid using family or friends
- Preferably in-person (i.e. picks up non-verbal communication)
- Where possible, allow interpreter to become familiar with documents shared with participants prior to study visits.



# Types of Interpreter Services

Interpreter Type	Pros	Cons
<b>Bilingual staff (preferred)</b>	<ul style="list-style-type: none"> <li>- Trained &amp; familiar with study protocol, consent, procedures</li> </ul>	No study budget allocated or limited availability of bilingual candidates
<b>In house hospital interpreter</b>	<ul style="list-style-type: none"> <li>- Possibly no cost</li> <li>- Good for simple studies</li> <li>- Could be training on study documents prior to interpreting session</li> </ul>	Lack of availability (especially for multiple & long study visits)
<b>Interpreter company*</b>	<ul style="list-style-type: none"> <li>- Access to multiple language</li> <li>- Negotiate \$</li> <li>- In person, video</li> <li>- Certified interpreters</li> </ul>	<p>High hourly rates, particularly on rare languages</p> <p>Not likely to be trained on study documents</p>
<b>Freelance interpreter</b>	<ul style="list-style-type: none"> <li>- Lower hourly rate (typically)</li> <li>- Can be trained on study</li> <li>- Ensure certified and liability insurance</li> </ul>	<ul style="list-style-type: none"> <li>- Limited to one language</li> <li>- Look for these individuals and set up as vendor</li> </ul>

\*May be vendor available at the medical center or research institution.

# Important Considerations When Including PwLEP



Ensure participants are not asked to provide immigration status, SS#, or any financial information

Be prepared to educate participants on basics of health research & why it is important

Providing quality language access takes time, effort, and resources. Be prepared to make this investment.

# Considerations for consenting PwLEP



- It is important to confirm participant understanding of information presented during consent process.
- Avoid asking “Did you understand?”
- Use Teach-Back Method - A way of checking understanding by asking patients to state in their own words information provided to them (written or spoken)?
  - “I will go over some information from the consent form, and I want to make sure I explained things clearly. I will stop a few times and ask you to share what you understood.”
- Plan for additional time

## **Question**

**Why would including people with LEP be important to the research you are part of?**



# GHUCCTS Support for Inclusion of Diverse Groups



- ✓ Consultation services for strategic planning & budgeting
- ✓ Networking opportunities with community organizations representing diverse communities
- ✓ Access to community events for study promotion – on-site and virtually
- ✓ Translation & Interpreting referrals
- ✓ Resources for:
  - Capturing expanded demographic data
  - Inclusion of people with limited English proficiency
  - Community Engaged Research (CEnR) best practices



**For questions or to schedule a  
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