Overview and Purpose

The National Institutes of Health (NIH) and other public and private sector funders have implemented public policy and dedicated resources to increase the participation of racial and ethnic groups that are underrepresented in clinical research. The disparity between the policy of inclusion and the actual practice of inclusion among research institutions nationally, continues to disproportionately affect racial and ethnic groups across the lifespan including members of African American, Latino/Latinx, American Indian, Pacific Islander, Alaska Native, and Asian American communities. For example, recent studies found that: 1) despite twenty years of a legislative mandate to increase the appropriate inclusion of minorities into NIH-funded research, representation of adults enrolled in cancer clinical trials remains woefully inadequate; 2-7 2) enrollment in clinical trials is still a significant barrier to specific racial, ethnic, and cultural groups, and biases persist among researchers; 8-9 and 3) the estimated Hispanic representation in NIH studies is 7.6% of all research participants, however, a report on industry-sponsored studies found that only 3% of those participants were Hispanic10.

Reaching People in Multiple Language, a website of the National Institute on Minority Health and Health Disparities (NIMHD) is a resources for NIMHD stakeholders who work with populations with limited English proficiency.11 Another NIMHD web portal, Health Information in Multiple Languages, is designed to: (1) provide information on Executive Order 13666 Improving Access to Services for Persons with Limited English Proficiency; (2) feature Grand Round presentations on communicating with diverse populations; and (3) provide resources across NIH for selected priority health areas in languages other than English.12 However, additional tools, resources, and professional development are needed to focus on this often overlooked population in the conduct of clinical research.13-14

The primary purposes of this guide are to provide information to researchers that will enhance their capacity to include individuals and communities with limited English proficiency (LEP) in their studies, and to implement linguistically competent practices. Ultimately, addressing language access will support the policy of increasing the participation of sub-populations in NIH-funded studies by intentionally focusing on differential access caused by language, culture, and associated attitudinal barriers within the research community about people who speak languages other than English and those who have other communication needs.11-14
Why Ensuring Language Access and Linguistic Competence are Essential in the Conduct of Clinical Research

While the broad health research community attends to the variable of race and ethnicity, it often does not address culture as an essential and integral component in studies. While culture defines who we are as human beings, there are sparse references in the acknowledgement, understanding, application, and use of standard guidelines related to the concept of culture in conducting health research in general and clinical health research in particular.\textsuperscript{15-16}

Language and culture are inextricably linked. Culture is encoded in language through forms of expression, communication preferences, and the way words are used. Values, beliefs, attitudes, and a broad array of nuances are enmeshed in words and symbols, forming the base of knowledge and a system for communicating within every culture.\textsuperscript{17} It is impossible to be responsive to language without understanding its connection to culture. Culture informs the language that we use in medicine, health, and research as well as those individuals and communities who speak languages other than English or use American Sign Language (ASL).

Reasons to ensure language access and linguistic competence in clinical research are numerous. The following rationales are not all-encompassing. The intent of this list is to increase awareness and persuade researchers to consider the lack of inclusion of individuals and communities with LEP and those with other communication needs: 1) as contrary to NIH policy, 2) as a contributing factor to the dearth of health interventions for this population of people, 3) leaves a void in the body of knowledge on the health and well-being of LEP populations, and 4) may inadvertently contribute to health disparities experienced by these vulnerable and often underserved populations.

It’s The Law

Title VI, Prohibition Against National Origin Discrimination, 1964 Civil Rights Act, has specific provisions addressing persons with LEP. This Federal law and related guidance mandates developing policies and procedures that address the language assistance needs for effective communication between health and social service providers and persons with LEP participating in programs funded by the federal government.\textsuperscript{18-19} This statute requires that health care professionals and institutions take reasonable steps to provide services and information in appropriate languages other than English to ensure that persons with LEP are informed and can participate in any benefit. Nearly every health care provider and institution are bound by Title VI because federal funding of health care is almost universal and includes researchers and research institutions.

Salient Reasons Why

1. It’s the law
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. Enhance capacity to include individuals with disabilities
6. Address implicit biases
7. Add to the body of knowledge on clinical research for LEP populations and those with other communication needs.

“As no person in the United States shall, on 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.”\textsuperscript{18}

As defined by federal legislation, and delineated in policy guidance, limited English proficiency (LEP) refers to individuals who do not speak English as their primary language and who have a limited ability to read, speak, write, or understand English.\textsuperscript{15}
CLAS – Standards 5-8: Communication and Language Assistance

5. Offer language assistance to individuals who have limited English proficiency and/or other communication needs, at no cost to them, to facilitate timely access to all health care and services.

6. Inform all individuals of the availability of language assistance services clearly and in their preferred language, verbally and in writing.

7. Ensure the competence of individuals providing language assistance, recognizing that the use of untrained individuals and/or minors as interpreters should be avoided.

8. Provide easy-to-understand print and multimedia materials and signage in the languages commonly used by the populations in the service area.20

Demographic Makeup of the District of Columbia and Micro Statistical Area

The District of Columbia and surrounding metropolitan areas have a high degree of linguistic diversity. The District Government lists six languages most frequently spoken in the city including Amharic, Chinese, French, Korean, Spanish and Vietnamese.26 According to most recently available U.S. Census data, the population of the District of Columbia five years of age and over is 657,061.27 A total of 113,022 (17.2%) speaks a language other than English (or American Sign Language – ASL) at home.28 Among these, there are 9,633 limited English speaking households.29 The U.S. Census defines limited English speaking households as those in which no member 14 years old and over: (1) speaks only English or (2) speaks a non-English language and speaks English “very well.”29 Table 1 lists households in the District of Columbia that speak languages other than English and limited English speaking households by language category.

<table>
<thead>
<tr>
<th>All households Speaking a Language other than English N = 113,022 (17.2%)</th>
<th>Estimate</th>
<th>Percentage of Households</th>
<th>Estimate Limited English Speaking (N = 9,633)</th>
<th>Percentage of Households (N = 3.3%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spanish</td>
<td>59,522</td>
<td>9.1%</td>
<td>5,806</td>
<td>23.1%</td>
</tr>
<tr>
<td>Indo-European languages</td>
<td>26,623</td>
<td>4.1%</td>
<td>963</td>
<td>6.1%</td>
</tr>
<tr>
<td>Asian &amp; Pacific Islander languages</td>
<td>13,619</td>
<td>2.1%</td>
<td>1,543</td>
<td>21.9%</td>
</tr>
<tr>
<td>Other</td>
<td>13,258</td>
<td>2.0%</td>
<td>1,321</td>
<td>20.2%</td>
</tr>
</tbody>
</table>

Georgetown University Medical Center, Howard University Medical Center, and other GHUCCTS partners draw patients and potential research participants from the Metro Micro Statistical Area, as defined by the Census Bureau which includes Washington, DC, Maryland, Virginia, and West Virginia metropolitan areas. Linguistic diversity by age group is presented in Tables 2-3.
TABLE 2. Languages Spoken at Home for the Population Five Years and Over
ACS 2020 Year 5 Estimates: DC-MD-VA-WV Micro Statistical Area

<table>
<thead>
<tr>
<th>Estimate</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>5,848,577</td>
<td>x</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Total Population</th>
<th>Estimate</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>English only</td>
<td>4,154,170</td>
<td>71.0%</td>
</tr>
<tr>
<td>Speak a language other than English</td>
<td>1,694,397</td>
<td>29.0%</td>
</tr>
<tr>
<td>Speaks Spanish</td>
<td>768,618</td>
<td>13.1%</td>
</tr>
<tr>
<td>• 5-17 years</td>
<td>170,108</td>
<td>2.9%</td>
</tr>
<tr>
<td>• 18-64 years</td>
<td>549,711</td>
<td>9.4%</td>
</tr>
<tr>
<td>• 65 years and over</td>
<td>48,798</td>
<td>0.8%</td>
</tr>
<tr>
<td>Speaks Indo-European languages</td>
<td>372,219</td>
<td>6.4%</td>
</tr>
<tr>
<td>• 5-17 years</td>
<td>50,400</td>
<td>0.9%</td>
</tr>
<tr>
<td>• 18-64 years</td>
<td>269,505</td>
<td>4.6%</td>
</tr>
<tr>
<td>• 65 years and over</td>
<td>52,314</td>
<td>0.9%</td>
</tr>
<tr>
<td>Speaks Asian &amp; Pacific Islander languages</td>
<td>348,903</td>
<td>6.0%</td>
</tr>
<tr>
<td>• 5-17 years</td>
<td>42,171</td>
<td>0.7%</td>
</tr>
<tr>
<td>• 18-64 years</td>
<td>251,354</td>
<td>4.3%</td>
</tr>
<tr>
<td>• 65 years and over</td>
<td>55,378</td>
<td>0.9%</td>
</tr>
<tr>
<td>Other languages</td>
<td>204,648</td>
<td>3.5%</td>
</tr>
<tr>
<td>• 5-17 years</td>
<td>29,529</td>
<td>0.5%</td>
</tr>
<tr>
<td>• 18-64 years</td>
<td>157,183</td>
<td>2.7%</td>
</tr>
<tr>
<td>• 65 years and over</td>
<td>17,936</td>
<td>0.3%</td>
</tr>
</tbody>
</table>

Promote Equity by Increasing Capacity for Participation in Research by Specific Demographic Groups

Ensuring language access and linguistic competence will help mitigate disparities and increase participation by specific ethnic and cultural groups that are underrepresented in clinical research. Compliance with Title VI, intentional focus on engagement within linguistically diverse communities, and partnerships with ethnic- and cultural-specific organizations to conduct, translate, and disseminate research findings promotes equity. Moreover, researchers benefit from increasing their own capacity to conduct studies that include populations with limited LEP by adding to the paucity of published literature on such methods and outcomes.
Increased Capacity to Address Health Literacy in Any Language

Linguistic competence, as defined in this guide, includes the capacity to address health literacy. During the past 20 years, the conceptualization and practice of health literacy as well as the conduct of related research has grown exponentially. A selected review of this literature reveals that: 1) definitions of health literacy continue to evolve; and 2) policy makers, researchers, practitioners, and other stakeholders have yet to reach consensus on a shared understanding and definition of health literacy. Health literacy is essential for all populations—including those who speak languages other than English and ASL—to learn about, understand, provide consent, and benefit from their involvement in all phases of research. This includes but is not limited to formulating the question, design, sampling, instrumentation, data collection and analysis, and dissemination.

Figure A provides two conceptualizations of health literacy that are relevant for clinical researchers. They integrate language, culture, and the responsibility of health care institutions and professionals to address barriers to health information, including access to research, that contribute to health disparities. As previously noted, individuals with LEP and those with other communication needs are woefully underrepresented in clinical research.

**FIGURE A. Defining Health Literacy**

*Health literacy* is defined as “the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions. The term ‘capacity’ refers to both the innate potential of the individual, as well as his or her skills. An individual’s health literacy capacity is mediated by education, and its adequacy is affected by culture, language, and the characteristics of health-related settings.”

Rima Rudd asserts that major responsibility for health literacy should rest in the design and implementation of health care that removes systemic barriers to the communication of health information, and facilitates access to and meaningful engagement of people in such processes. Second, Rudd posits that it is essential to recognize the broader sociocultural contexts in which health literacy is experienced. She postulates that in order to optimize health and well-being, health information must be adapted to the everyday lives of people and the daily occurrences in the communities in which they live. According to Rudd, and commensurate with these insights, health literacy is the capacity of professionals and health institutions to provide access to information and support the active engagement of people.

This definition and other studies stipulate that health literacy skills are necessary for dialogue and discussion, reading health information, interpreting charts, understanding risks, and making decisions about, and the capacity to participate in, research studies.

Plain Language

The language of health research is complex, technical, and difficult for the average person to understand, and in most instances uses legal terminology for informed consent. The Plain Language Act was passed in 2010 to improve the effectiveness of federal agencies by promoting clear communication with the public. Plain language, also called plain writing by some, is communication that your audience can understand the first time they read or hear it. Written materials are in plain language if the intended audience can: 1) find what they need, 2) understand what they find, and 3) use what they find to meet their needs. Plain language is characterized by writing that is clear, concise, well-organized, and follows other best practices appropriate to the subject or field and intended audience. Plain language has been adapted by many outside of federal government, including those in health care, to communicate more effectively with intended audiences. Plain language is consistent with the definition of linguistic competence in this guide.
Increased Capacity to Include Individuals with Disabilities

The conceptual framework and definition of linguistic competence cited in this guide addresses the capacity of health professionals and institutions, including researchers, to respond to the communication needs of individuals with disabilities. Historical and current research practices often do not integrate people across the broad disability spectrum in studies conducted with the general population—those without disabilities—including studies focused on health disparities and other targeted interventions. Some studies and reports attribute this exclusion to the lack of knowledge about disability competence within the general research community; implicit bias, stereotyping, and unfounded beliefs about the competency of people with developmental disabilities and mental illness.

Guiding Values for Language Access and Linguistic Competence

Research institutions and researchers should identify and reach consensus on guiding values for conducting research for LEP populations and those with other communication needs. The Georgetown University National Center for Cultural Competence offers the following values that are adapted for clinical research for discussion, consideration, and modification.

- Research is conducted in the preferred language of the study participants.
- Written materials are translated, adapted, and/or provided in alternative formats based on the needs and preferences of the study participants.
- Interpretation and translation services comply with all relevant federal, state, and local mandates governing language access and assistance services.
- People with disabilities are provided accommodations to participate in studies.
- Translated documents are tested prior to using with participants with LEP.
- Researchers use processes to assure the quality of language access services.

Probing Questions to Confront Conscious or Explicit Bias in Research

Researchers and research team members, such as study coordinators, are not immune to explicit or implicit biases simply by their membership in the helping professions. Bias is often associated with negative thoughts or behaviors; however, bias is simply a preference for one thing, person, or group over another. Bias is a cognitive tendency among humans to make systematic decisions in certain circumstances based on cognitive factors rather than evidence. We as human beings all have biases. Bias is only a concern when it becomes a prejudice against certain people or groups in ways that are unfair and lead to marginalization or discrimination.

There is a robust body of literature on biases in medicine and health care and its detrimental effects on diverse patient populations. This literature also describes myriad biases including studies of individuals with LEP. It illustrates that these biases are present not only among researchers and other research team members, but also with Institutional Review Boards (IRBs). The following questions were adopted for this resource guide from a course, *Conscious and Unconscious Biases in Health Care* (Georgetown University National Center for Cultural Competence). They are provided to spur self-reflection and probe the extent to which explicit and implicit biases affect the conduct of research.
Explicit Bias

As you contemplate each question, consider how factors such as race, ethnicity, culture, English language proficiency, disability, and literacy affect your research.

- Do my biases:
  - Impact questions and the populations I select for research (e.g., additional level of effort to include some populations, how much accommodations cost to include people with disabilities, the complexities of including populations in study design, implementation, and data analysis)?
  - Influence how I communicate with potential or actual research participants?
  - Interfere with my capacity to interact positively with culturally and linguistically diverse research participants?
  - Hamper my capacity to feel and express empathy toward research participants and the communities in which they live?
- Do you ever perceive that you are less comfortable with research participants who are of a different race, ethnicity, or culture than you?
- Do you believe that recruitment of people with limited English proficiency and/or those with disabilities would be too difficult, burdensome, or costly?
- Do you know whether (or believe that) your colleagues and other staff, with whom you routinely interact, think that your attitudes and behaviors negatively affect your studies? If so, are you open to discussing these issues and the implications for your research with them?
- Have you elicited the views of community partners about perceived biases?
- Have research participants or their families, directly or through satisfaction surveys, raised concern about your attitude or the way you communicate with them?

Answering yes to any of these questions indicates that you could benefit from interventions to mitigate the impact of explicit bias.

Six Interventions to Tackle Unconscious or Implicit Bias

The following six interventions represent the evolving body of knowledge of ways to address implicit bias. These interventions, initially designed for health care practitioners, are adapted for health researchers.50

1. Acknowledge and accept the existence of implicit bias, its manifestations, and its impact on the conduct of research.
2. Assume individual responsibility to address implicit bias in your work.
4. Make good use of neuroscientific methods to combat “hard wiring” in our brains that labels those who are not like us as “the other.”
5. Collect and use data effectively and perform self-monitoring.
6. Incorporate cultural and linguistic competence in your research and practice.
Ensuring Language Access and Linguistic Competence

Action Steps and Strategies for Researchers

Know the Law and the Policies

• Be familiar with the policies and procedures of your institution’s Language Access Implementation Plan. This plan is a requirement for all institutions receiving federal financial assistance. It describes policy, procedures, and processes to ensure effective communication with persons and communities that are non-English speaking and those with LEP.

• Be familiar with and adhere to the policies of NIH and other HHS funding sources specifically related to the participation of persons with LEP in clinical research.

• Be familiar with, and adhere to, federal and state policies governing accessibility of public health related research to people with disabilities and those who are deaf or hard of hearing.

Know Your Population

• Determine the number of individuals or segment of the population requiring assistance or accommodations to participate in a study that:
  − Speaks languages other than English
  − Are neither literate in English nor their language of origin
  − Have low health literacy
  − Have disabilities that require communication assistance
  − Are deaf or hard of hearing

Plan for Language Access & Health Literacy

• Determine, plan for, and incorporate the provision of interpretation services for all phases of research to ensure the participation of LEP populations.

• Attend to cultural differences regarding the use of language among populations that speak the same language.

• Determine translation services that will be needed during all phases of research.

• Test the accuracy and readability of translated documents with a sample of the LEP population that will be included in the study.

• Determine and respond to the health literacy needs of potential and enrolled participants, including written and oral communication.

• Determine and incorporate culturally appropriate images and culturally relevant examples in print documents, web-based, and other media when communicating about the study.

Plan your budget accordingly

• Ensure budgets include the cost of language access and linguistic competence services necessary to conduct the study. This may include but is not limited to:
  − Salaries for bilingual or multilingual staff who have been vetted, received specialized training, or certified by an accredited organization to provide interpreter or translation services.

"NIH is committed to providing meaningful access to its programs and activities to people with limited English proficiency (LEP). In accordance with Executive Order 13166, Improving Access to Services for Persons with Limited English Proficiency, the NIH Language Access Plan, establishes policy and strategy for all 27 Institutes and Centers (ICs). The Plan serves as a blueprint to help NIH ICs develop their own specific implementation strategies, based on their respective needs and capacity."
Sub-contracts with certified professional interpreters; designated budget line items for professional translators;
- Resources for ethnic media and community organizations that serve linguistically diverse populations;
- Focus groups with LEP populations to test translated documents;
- Resources to include people with disabilities who may require accommodations to ensure effective communication;
- Resources for ASL for people who are deaf or hard of hearing.

Plan for dissemination

- Plan and implement dissemination strategies in partnership with the study population to ensure that research findings are:
  - Accessible in languages other than English.
  - Written at the appropriate literacy level.
  - Offered in venues and formats that the populations are likely to access (e.g. ethnic print, television, radio media; faith-based publications and conferences; health fairs; civic organizations; town hall meetings; social media platforms).
  - Accessible to people with disabilities.
  - Specified in the budget and budget narrative including the provision of interpretation, translation, and other communication methods to ensure dissemination to diverse audiences, stakeholders, and constituents.

Summary

The primary purposes of this guide are to provide information to researchers that will enhance their capacity to include individuals and communities with limited English proficiency (LEP) in their studies and to implement linguistically competent practices. The guide is specifically designed for researchers and research teams, and provides rationales, demographic data, legal requirements and guidance, guiding values, action steps and strategies, and key definitions for linguistic competence. It is one resource on the GHUCCTS website devoted to language access and linguistic competence regarding research conduct. The guide is intended to minimize barriers to participation in research caused by language, culture, and associated attitudinal barriers within the research community about people who speak languages other than English and those who have other communication needs.

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Georgetown-Howard Universities Center for Clinical and Translational Science acknowledges members of its Community Advisory Board for their inspiring, knowledgeable, and insightful contributions to the process.
Key Definitions or Glossary of Terms

American Sign Language (ASL) Interpretation

ASL is the most prominent type of interpreting used in the United States. Interpretation occurs between two distinct languages—ASL and English.

- Sign Language Interpreter Tip Sheet: https://www.nationaldeafcenter.org/resource/sign-language-interpreters-introduction
- U. S. Department of Justice, Civil Rights Division, Disability Rights Section: ADA Business Brief: Communicating With People Who Are Deaf or Hard of Hearing in Hospital Settings: https://www.ada.gov/hospcombr.htm

Interpreting

The process of understanding and analyzing a spoken or signed message and re-expressing that message faithfully, accurately, and objectively in another language, taking the cultural and social context into account.


Interpretation

The oral restating in one language of what has been said in another language; should accurately convey the tone and meaning of the information given in the original language.


The process of understanding and analyzing a spoken or signed message and re-expressing that message faithfully, accurately, and objectively in another language, taking the cultural and social context into account. Interpretation and translation are often incorrectly used interchangeably. The term translation is used for the process of converting written messages from one language to another.


Examples of Three Types of Interpretation

Simultaneous Interpretation—the interpreter converts the sentence from the source language into the target language while simultaneously listening. The goal is not to paraphrase, but convey the exact language.

Consecutive Interpretation—the speaker stops every 1–5 minutes (usually at the end of every paragraph or complete thought), and the interpreter then steps in to render what was said into the target language.

Telephonic Interpretation—can be simultaneous or consecutive. This form of interpreting is performed during an established appointment (or on demand) where none of the parties see each other as interpretation is via telephone.


Interpreter

A person who renders a message spoken or signed in one language into a second language. Interpreters strive to render the message accurately, conveying the content and spirit of the original message, taking into
consideration the cultural context. Professional interpreters bide by a code of ethics. The terms interpreter and translator are often mistakenly used interchangeably.


Language Assistance Services

Language assistance services are mechanisms used to facilitate communication with individuals who do not speak English, those who have limited English proficiency, and those who are deaf or hard of hearing. These services can include in-person interpreters, bilingual staff, or remote interpreting systems such as telephone or video interpreting. Language services also refer to processes in place to provide translation of written materials or signage, sign language, or Braille materials.


Limited English Proficiency

As defined by federal legislation, and delineated in policy guidance, limited English proficiency (LEP) refers to individuals who do not speak English as their primary language and who have a limited ability to read, speak, write, or understand English.


Linguistic Competence

There are several definitions of linguistic competence in the health literature. This guide features the conceptual framework and definition of linguistic competence developed by the Georgetown University National Center for Cultural Competence. Linguistic competence is the capacity of an organization and its personnel to communicate effectively, and convey information in a manner that is easily understood by diverse groups including persons of limited English proficiency, those who have low literacy skills or are not literate, individuals with disabilities, and those who are deaf or hard of hearing. Linguistic competence requires organizational and provider capacity to respond effectively to the health and mental health literacy needs of populations served. The organization must have policy, structures, practices, procedures, and dedicated resources to support this capacity.


Plain Language

Plain language, also called plain writing or plain English, is communication your audience can understand the first time they read or hear it. Written materials are in plain language if the intended audience can: 1) find what they need, 2) understand what they find, and 3) use what they find to meet their needs. Plain language is characterized by writing that is clear, concise, well-organized, and follows other best practices appropriate to the subject or field and intended audience.

- What is plain language? Retrieved on 5/22/20 from https://www.plainlanguage.gov/about/definitions
**Sign Language Interpreter**

An interpreter is a specially trained professional whose job is to convey the messages of people who do not share the same language, culture, or mode of communication. The purpose of providing an interpreter is to allow hearing, deaf, and hard of hearing people equal access to information and interactions.

- Laurent Clerc National Deaf Education Center, Gallaudet University. Retrieved on 5/22/20 from https://clerccenter.gallaudet.edu/

**Translation**

The written conversion of written materials from one language to another; a process in which text is transferred from the source language to another language.


**Translator**

A translator is a professional that converts written materials from one language into another language, while maintaining the meaning and cultural nuances of the original written document.


**References**


