



Culturally and Linguistically Appropriate Services And Clinical Trials

(CLAS-ACT)

Investigator and Institutional Self-Assessment Handbook

Developed by the

Chronic Disease Prevention and Control Research Center

at

Baylor College of Medicine

for the

Eliminating Disparities In Clinical Trials (EDICT) Project



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INTRODUCTION

Background

For many years, the underprivileged were exploited for the ends of medical research. In the 19th and 20th centuries, women, racial and ethnic minorities, the poor, children, those without decisional capacity, orphans and other groups were systematically forced or coerced into risky medical research either without their knowledge or informed consent. While some of these benefitted physically from the experimental interventions, many did not, most were harmed, and all were wronged. Fortunately, codes of conduct, laws, and regulations were passed in the second half of the 20th century to help prevent these wrongs in the future.¹⁻⁵

Unfortunately, when it comes to the inclusion of the underprivileged and vulnerable in beneficial clinical trials, there has been a pendulum swing in the opposite direction. While human subject protections now prevent the abuse of certain populations in medical research, these populations are now, for the most part, *under*-represented in clinical trials. This contributes to health disparities by keeping the newest techniques and drugs out of the reach of disadvantaged groups, and by making approved drugs more dangerous for these populations because they may not have been tested on a sufficiently diverse participant pool to detect population-specific contraindications.

EDICT⁶

Eliminating Disparities in Clinical Trials (EDICT) is a four-year project (2005-2009) of the Chronic Disease Prevention and Control Research Center (CDRC) at Baylor College of Medicine and the Intercultural Cancer Council (ICC).^{7,8} The EDICT Project was designed to develop practical and realizable policy solutions to the problem of clinical trial disparities. The project will eventually attempt to initiate change at the federal, state, and institutional levels as well as in the public, private, and non-profit sectors. The project has two arms – policy research and field research – which provide both a theoretical and practical basis for policy recommendations.

National Standards on Culturally and Linguistically Appropriate Services (CLAS)⁹

The National Standards on Culturally and Linguistically Appropriate Services (CLAS) were developed by the Department of Health and Human Services (DHHS) Office of Minority Health (OMH) to help reduce health disparities as they impact racial and ethnic groups. The CLAS standards are primarily directed at health care organizations. However, individual providers are also encouraged to use the standards to make their practices more culturally and linguistically accessible. The principles and activities of culturally and linguistically appropriate services should be integrated throughout an organization and undertaken in partnership with the community.

National Standards on Culturally and Linguistically Appropriate Services (CLAS)⁹

<http://www.omhrc.gov/templates/browse.aspx?lvl=2&lvlID=15>

The CLAS standards are primarily directed at health care organizations; however, individual providers are also encouraged to use the standards to make their practices more culturally and linguistically accessible. The principles and activities of culturally and linguistically appropriate services should be integrated throughout an organization and undertaken in partnership with the communities being served.

The 14 standards are organized by themes: Culturally Competent Care (Standards 1-3), Language Access Services (Standards 4-7), and Organizational Supports for Cultural Competence (Standards 8-14). Within this framework, there are three types of standards of varying stringency: mandates, guidelines, and recommendations as follows:

CLAS **mandates** are current Federal requirements for all recipients of Federal funds (Standards 4, 5, 6, and 7).

CLAS **guidelines** are activities recommended by OMH for adoption as mandates by Federal, State, and national accrediting agencies (Standards 1, 2, 3, 8, 9, 10, 11, 12, and 13).

CLAS **recommendations** are suggested by OMH for voluntary adoption by health care organizations (Standard 14).

- Standard 1.** Health care organizations should ensure that patients/consumers receive from all staff member's effective, understandable, and respectful care that is provided in a manner compatible with their cultural health beliefs and practices and preferred language.
- Standard 2.** Health care organizations should implement strategies to recruit, retain, and promote at all levels of the organization a diverse staff and leadership that are representative of the demographic characteristics of the service area.
- Standard 3.** Health care organizations should ensure that staff at all levels and across all disciplines receive ongoing education and training in culturally and linguistically appropriate service delivery.
- Standard 4.** Health care organizations must offer and provide language assistance services, including bilingual staff and interpreter services, at no cost to each patient/consumer with limited English proficiency at all points of contact, in a timely manner during all hours of operation.
- Standard 5.** Health care organizations must provide to patients/consumers in their preferred language both verbal offers and written notices informing them of their right to receive language assistance services.
- Standard 6.** Health care organizations must assure the competence of language assistance provided to limited English proficient patients/consumers by interpreters and bilingual staff. Family and friends should not be used to provide interpretation services (except on request by the patient/consumer).

CLAS Standards, continued...

- Standard 7.** Health care organizations must make available easily understood patient-related materials and post signage in the languages of the commonly encountered groups and/or groups represented in the service area.
- Standard 8.** Health care organizations should develop, implement, and promote a written strategic plan that outlines clear goals, policies, operational plans, and management accountability/oversight mechanisms to provide culturally and linguistically appropriate services.
- Standard 9.** Health care organizations should conduct initial and ongoing organizational self-assessments of CLAS-related activities and are encouraged to integrate cultural and linguistic competence-related measures into their internal audits, performance improvement programs, patient satisfaction assessments, and outcomes-based evaluations.
- Standard 10.** Health care organizations should ensure that data on the individual patient's/consumer's race, ethnicity, and spoken and written language are collected in health records, integrated into the organization's management information systems, and periodically updated.
- Standard 11.** Health care organizations should maintain a current demographic, cultural, and epidemiological profile of the community as well as a needs assessment to accurately plan for and implement services that respond to the cultural and linguistic characteristics of the service area.
- Standard 12.** Health care organizations should develop participatory, collaborative partnerships with communities and utilize a variety of formal and informal mechanisms to facilitate community and patient/consumer involvement in designing and implementing CLAS-related activities.
- Standard 13.** Health care organizations should ensure that conflict and grievance resolution processes are culturally and linguistically sensitive and capable of identifying, preventing, and resolving cross-cultural conflicts or complaints by patients/consumers.
- Standard 14.** Health care organizations are encouraged to regularly make available to the public information about their progress and successful innovations in implementing the CLAS standards and to provide public notice in their communities about the availability of this information.

CLAS Self-Assessment Handbook For Investigators

The CLAS standards were developed for the clinical care setting rather than research. However, in 2007, the OMH funded the CDRC to collaborate in developing approaches to combining **CLAS And Clinical Trials** – thus, the CLAS-ACT Project.¹⁰

This section will help you to assess how well you address CLAS standards in meeting the needs of participants from various cultural backgrounds in your clinical trials or other research studies.

You can use this Self-Assessment in several ways – you can:

- Discuss the Self-Assessment questions with your research staff and administrators to begin the review process and make them aware of the CLAS issues that need to be addressed.
- Complete the Self-Assessment for a current study in order to establish baseline data against which to compare progress implementing CLAS standards in the future.
- Complete and submit the Self-Assessment online at the CLAS-ACT Website < <http://www.bcm.edu/edict/clas-act> >. CLAS-ACT Project Staff will then send you a personalized report based on the answers that you provide. The Website also has additional resources that can help you reduce disparities in clinical trials.

If you want a hard copy of just the Self-Assessment questions, you can:

- Print pages 6 – 17, below, as a separate document;
- Go to the CLAS-ACT Website < <http://www.bcm.edu/edict/clas-act> >, where the Self-Assessment is available as a .pdf document.

CLAS-ACT Investigator Self-Assessment

Principal Investigator:	
Name of Clinical Trial	
Institution/Organization:	
Address:	
Address 2:	
City/Town:	
State:	
Zip/Postal Code:	
E-mail Address:	
Telephone:	
Fax:	

Standard 1. Health care organizations should ensure that patients/consumers receive from all staff member's effective, understandable, and respectful care that is provided in a manner compatible with their cultural health beliefs and practices and preferred language.

Do you periodically survey your patients/clinical trial participants about whether they experienced your Project staff as being...?	Yes	No
Effective and efficient?		
Easy to understand, whether in English or other languages spoken by the patients/participants?		
Respectful to the patients/participants?		
Sensitive to the cultural and linguistic background of the patients/participants?		
Total (Maximum Score: 4 points)		

Standard 2. Health care organizations should implement strategies to recruit, retain, and promote at all levels of the organization a diverse staff and leadership that are representative of the demographic characteristics of the service area.

Do you...?	Yes	No
Maintain a current demographic, cultural, and epidemiological profile of the community?		
Are your staff and leadership diversity proportionate to the demographic characteristics of your service area?		
Total (Maximum Score: 2 points)		

If you do not have a community profile or maintain staffing diversity similar to the community you serve, resources under Standard 11, below, can help.

Standard 3. Health care organizations should ensure that staff at all levels and across all disciplines receive ongoing education and training in culturally and linguistically appropriate service delivery.

Do you require your staff to...?	Yes	No
Be familiar with Office of Minority Health (OMH) standards for Culturally and Linguistically Appropriate Services (CLAS)?		
Complete training in cultural competence?		
Total (Maximum Score: 2 points)		

If you do not require your staff to be familiar with CLAS standards, then you can provide them with written copies of CLAS standards or refer them to the Office of Minority Health CLAS Standards Website: <http://www.omhrc.gov/templates/browse.aspx?lvl=2&lvlID=15>

If you do not require your staff to complete training to provide culturally and linguistically appropriate services, you can refer them to a number of online resources, for example:

- A Patient-Centered Guide to Implementing Language Access Services in Healthcare Organizations
<https://hclsig.thinkculturalhealth.org/user/home.rails>
This guide is intended to help healthcare organizations implement effective language access services to meet the needs of their limited-English-proficient patients, and increase their access to health care. An interactive Web-based version of the Guide is now available to help you plan, implement, and evaluate language access services.
- Culturally Competent Nursing Care: A Cornerstone of Caring
<http://www.thinkculturalhealth.org/ccnm/>
This is a free online educational program designed specifically for nurses and is accredited by the American Nurses Credentialing Center. The course features video-based case studies and interactive tools that can be completed anytime and anywhere to accommodate busy nurses.
- A Physician's Practical Guide to Culturally Competent Care
<https://cccm.thinkculturalhealth.org/>
This cultural competency curriculum offers information about a variety of cultural, language services and organizational issues using a variety of engaging case studies and real feedback from providers in health care settings. This program equips physicians with awareness, knowledge, and skills to better treat the increasingly diverse U.S. population they serve and earn CME, CNE and CEU credit.
- OMH Introduces Language Services Guide for Healthcare Organizations
<http://www.omhrc.gov/templates/content.aspxID=4375&lvl=2&lvlID=107>
A Patient-Centered Guide to Implementing Language Access Services in Healthcare Organizations is now available from OMH. The guide is intended to help healthcare organizations implement effective language access services to meet the needs of their limited-English-proficient patients, and increase their access to health care.

Standard 4. Health care organizations must offer and provide language assistance services, including bilingual staff and interpreter services, at no cost to each patient/consumer with limited English proficiency at all points of contact, in a timely manner during all hours of operation.

For clinical trial participants with limited English proficiency, do you offer and provide language assistance services, including...:	During Recruitment		After Enrollment	
	Yes	No	Yes	No
Bilingual staff and interpreter services				
Written notices about their right to receive language assistance services?				
In a timely manner during all hours of operation?				
The services above at no cost				
Total (Maximum Score: 8 points)				

Standard 5. Health care organizations must provide to patients/consumers in their preferred language both verbal offers and written notices informing them of their right to receive language assistance services.

Do you provide the following to patients/clinical trials participants in their preferred language?	Yes	No
Verbal information about their right to receive language assistance services?		
Written notices about their right to receive language assistance services?		
Total (Maximum Score: 2 points)		

Standard 6. Health care organizations must assure the competence of language assistance provided to limited English proficient patients/consumers by interpreters and bilingual staff. Family and friends should not be used to provide interpretation services (except on request by the patient/consumer).

When the research staff interact with clinical trial participants, either for recruitment or after enrollment...?	Yes	No
Are professional translators available on call?		
Are volunteer translators available on call?		
Is a telephone translation service available?		
Total (Maximum Score: 3 points)		

Standard 7. Health care organizations must make available easily understood patient-related materials and post signage in the languages of the commonly encountered groups and/or groups represented in the service area.

7.1. List the documents that you give to patients:	
Informed Consent	
Education Materials	
Other	
Other.	
Other.	

7.2. List the types of signs (directions, instructions, etc.) encountered by clinical trials participants after they enter your area:	
Reception	
Waiting	
Interview	
Examination/Clinical	

7.3. List the primary languages spoken by 1st and 2nd generation immigrants in your community:	
Language 1	
Language 2	
Language 3	
Language 4	
Language 5	

7.4. List the languages into which your Informed Consent form is translated.	
Language 1	
Language 2	
Language 3	
Language 4	
Language 5	
Total (Score 1 point for each language used to translate materials.)	

7.5. List the languages into which your Education Materials are translated.	
Language 1	
Language 2	
Language 3	
Language 4	
Language 5	
Total (Score 1 point for each language used to translate materials.)	

7.6. List the languages into which your building and clinic area signage are translated.	
Language 1	
Language 2	
Language 3	
Language 4	
Language 5	
Total (Score 1 point for each language used to translate materials.)	

Standard 8. Health care organizations should develop, implement, and promote a written strategic plan that outlines clear goals, policies, operational plans, and management accountability/oversight mechanisms to provide culturally and linguistically appropriate services.

Do you have a written plan for providing culturally and linguistically appropriate services, including the following?	Yes	No
Goals		
Policies		
Operational plans		
Management (persons responsible)		
Oversight mechanism (how standards will be implemented)		
Total (Maximum Score: 5 points)		

Standard 9. Health care organizations should conduct initial and ongoing organizational self-assessments of CLAS-related activities and are encouraged to integrate cultural and linguistic competence-related measures into their internal audits, performance improvement programs, patient satisfaction assessments, and outcomes-based evaluations.

Do you review how well this clinical trial addresses CLAS standards as part of:	Yes	No
Initial and ongoing review of participant recruitment and retention?		
Internal audits?		
Performance improvement programs?		
Patient satisfaction assessments?		
Evaluation of study outcomes?		
Total (Maximum Score: 5 points)		

Standard 10. Health care organizations should ensure that data on the individual patient's/consumer's race, ethnicity, and spoken and written language are collected in health records, integrated into the organization's management information systems, and periodically updated.

Do you collect and record data on clinical trial participants'...?	Yes	No
Race, ethnicity?		
Spoken language?		
Written language, including education and literacy level?		
Total (Maximum Score: 3 points)		

Standard 11. Health care organizations should maintain a current demographic, cultural, and epidemiological profile of the community as well as a needs assessment to accurately plan for and implement services that respond to the cultural and linguistic characteristics of the service area.

Do you have a profile of your community with regard to its...?	Yes	No
Demographics?		
Cultural groups?		
Linguistic characteristics?		
Epidemiology?		
Total (Maximum Score: 4 points)		

If you do not have a community profile, there are several resources that you can use to quickly develop a profile of the community you serve:

Demographics

- US Census Bureau County and City Data Book – 2007
<http://www.census.gov/statab/www/ccdb.html>
The County and City Data Book is the most comprehensive source of information about the individual counties and cities in the United States. It includes data for all U.S. states, counties, and cities with a population of 25,000 or more. It contains additional data for places with a population of 100,000 or more. Also included is a complete set of state maps showing all counties, places of 25,000 or more population, and metropolitan areas. Information in the County and City Data Book includes, among other data, age, deaths, education, health, income, population, poverty, race and Hispanic origin, and social services.

Health Data

- State Health Departments
<http://www.cdc.gov/mmwr/international/relres.html>
- CDC National Center for Health Statistics
<http://www.cdc.gov/nchs/>

Additional Resources

- Statistical Abstract of the United States --The National Data Book
<http://www.census.gov/compendia/statab/>
- USA Counties --Almost 6,000 data items for all counties
<http://censtats.census.gov/usa/usa.shtml>
- State and Metropolitan Area Data Book -- Comprehensive data for states and metropolitan areas
<http://www.census.gov/compendia/smadb/>
- State & County QuickFacts -- Quick, easy access to Census facts about people, business, and geography
<http://quickfacts.census.gov/qfd/index.html>
- MapStats -- Profiles with data from many Federal sources for your state and county
<http://www.fedstats.gov/qf/>

Standard 12. Health care organizations should develop participatory, collaborative partnerships with communities and utilize a variety of formal and informal mechanisms to facilitate community and patient/consumer involvement in designing and implementing CLAS-related activities.

Standard 13. Health care organizations should ensure that conflict and grievance resolution processes are culturally and linguistically sensitive and capable of identifying, preventing, and resolving cross-cultural conflicts or complaints by patients/consumers.

Standard 14. Health care organizations are encouraged to regularly make available to the public information about their progress and successful innovations in implementing the CLAS standards and to provide public notice in their communities about the availability of this information.

Do you...?	Yes	No
Maintain a current demographic, cultural, and epidemiological profile of the community?		
Have an Advisory Group for this project that includes community members from racial/ethnic and socioeconomic background(s) similar to the patient population and community at large?		
Total (Maximum Score: 2 points)		

If you do not maintain a current demographic, cultural, and epidemiological profile of your community, you can develop such a profile using the resources under CLAS Standard 11.

How well do you address CLAS standards in clinical trials?

1. Tally all of your “Yes” answers. There are a total of 44 possible points for “Yes” answers.

CLAS Standard	Number of “Yes” Answers
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	
13	
14	
Total	

2. Divide your Total by 44.

$$\begin{array}{c} \underline{\hspace{2cm}} \\ \text{Your Score} \\ \text{(total number of} \\ \text{“Yes” answers)} \end{array} \div 44 = \begin{array}{c} \underline{\hspace{2cm}} \% \\ \text{implementation of} \\ \text{CLAS Standards} \end{array}$$

3. The resulting percentage score will give you an idea of how well you are implementing CLAS Standards.

Additional Resources

The online resources listed below are selected and are not intended to be comprehensive.

General Information on Cultural Competence

- Cultural Competence Sites

A Family Physician's Guide to Culturally Competent Health by Robert Like.

<http://cccm.thinkculturalhealth.org/>

Ethnomed – developed by University of Washington Harborview Medical Center

<http://ethnomed.org/>

Health Disparities: Toward a Better Understanding of Primary Care Patient-Physician Relationships. Lisa A. Cooper MD, MPH. *Journal of General Internal Medicine*. 19(9):985-986. September 2004

<http://www.blackwell-synergy.com/links/doi/10.1111/j.1525-1497.2004.46002.x/full/?cookieSet=1>

National Standards for Culturally and Linguistically Appropriate Services in Health Care: Final Report.

<http://www.omhrc.gov/assets/pdf/checked/finalreport.pdf>

National Standards for Culturally and Linguistically Appropriate Services in Health Care: Executive Summary.

<http://www.omhrc.gov/assets/pdf/checked/executive.pdf>

Normas nacionales para servicios cultural y lingüísticamente apropiados en la atención sanitaria (Resumen ejecutivo) (National Standards for Culturally and Linguistically Appropriate Services in Health Care: Executive Summary.)

<http://www.omhrc.gov/assets/pdf/checked/spanishexeSum.PDF>

R-E-S-P-E-C-T: Patient Reports of Disrespect in the Health Care Setting and Its Impact on Care

http://www.cmwf.org/publications/publications_show.htm?doc_id=240955

Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care. Smedley, Brian D., Stith, Adrienne Y., Nelson, Alan R. (Eds.). Washington, D. C. : Institute of Medicine/National Academies Press.

<http://www.iom.edu/report.asp?id=4475>

Working With Low Literacy Patients

Culture, Health and Literacy: A Guide to Health Education Materials for Adults with Limited English Literacy Skills. By Julie McKinney and Sabrina Kurtz-Rossi (2000).
<http://www.worlded.org/us/health/docs/culture/>

Working With Interpreters

National Council on Interpreting in Health Care with the Commonwealth Fund.
http://www.ncihc.org/NCIHC_PDF/National_Standards_of_Practice_for_Interpreters_in_Health_Care.pdf

Working With Specific Populations

A Provider's Guide to Quality and Culture – developed by the Management Sciences.
<http://erc.msh.org/mainpage.cfm?file=1.0.htm&module=provider&language=English>

Intercultural Cancer Council
<http://iccnetwork.org>

Las Culturas.com - Cultural Competence
<http://www.lasculturas.com/lib/libCulturalCompetance.htm>

Redes En Acción: The National Hispanic/Latino Cancer Network
<http://redesenaccion.org/>

Salud En Acción: National Health Communication Research
<http://saludenaccion.org>

Centers and Offices

Bureau of Primary Health Care-Quality and Culture
<http://bphc.hrsa.gov/quality/Cultural.htm>

Center for Cross-Cultural Health
<http://www.crosshealth.com>
<http://www.crosshealth.com/links.htm>

Center for Effective Collaboration and Practice - Cultural Competence Page
<http://www.air.org/cecp/cultural/>

Center for Equity and Diversity
American Dental Education Association
<http://www.adea.org/ced/default.htm>

Center to Reduce Cancer Health Disparities
<http://crchd.nci.nih.gov/>

Health Resources Services Administration (HRSA) Office of Minority Health
<http://www.hrsa.gov/OMH/>

National Center for Cultural Competence
Georgetown University Center for Child and Human Development
<http://gucchd.georgetown.edu/nccc/>

University of Maryland School of Medicine
Center for Health Disparities
<http://medschool.umaryland.edu/disparities/>

University of Texas MD Anderson Center for Research on Minority Health
<http://www.mdanderson.org/departments/CRMH/>

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8. Intercultural Cancer Council. Accessible online at: <http://iccnetwork.org/>
9. National Standards on Culturally and Linguistically Appropriate Services (CLAS). US Department of Health and Human Services Office of Minority Health. Available online at: <http://www.omhrc.gov/templates/browse.aspx?lvl=2&lvlID=15>
10. CLAS-ACT Project. Accessible online at: <http://www.bcm.edu/edict/clas-act>