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EnCoRE Session 9

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Research Ethics, IRB, and Good Clinical Practices

Leah Zallman, MD, MPH

Rosy Chang Weir, PhD

Ho'oipo DeCambra M.Ed.

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Enhancing Community Health Center PCORI Engagement (EnCoRE)

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EnCoRE Partners' Geography 2014-2015

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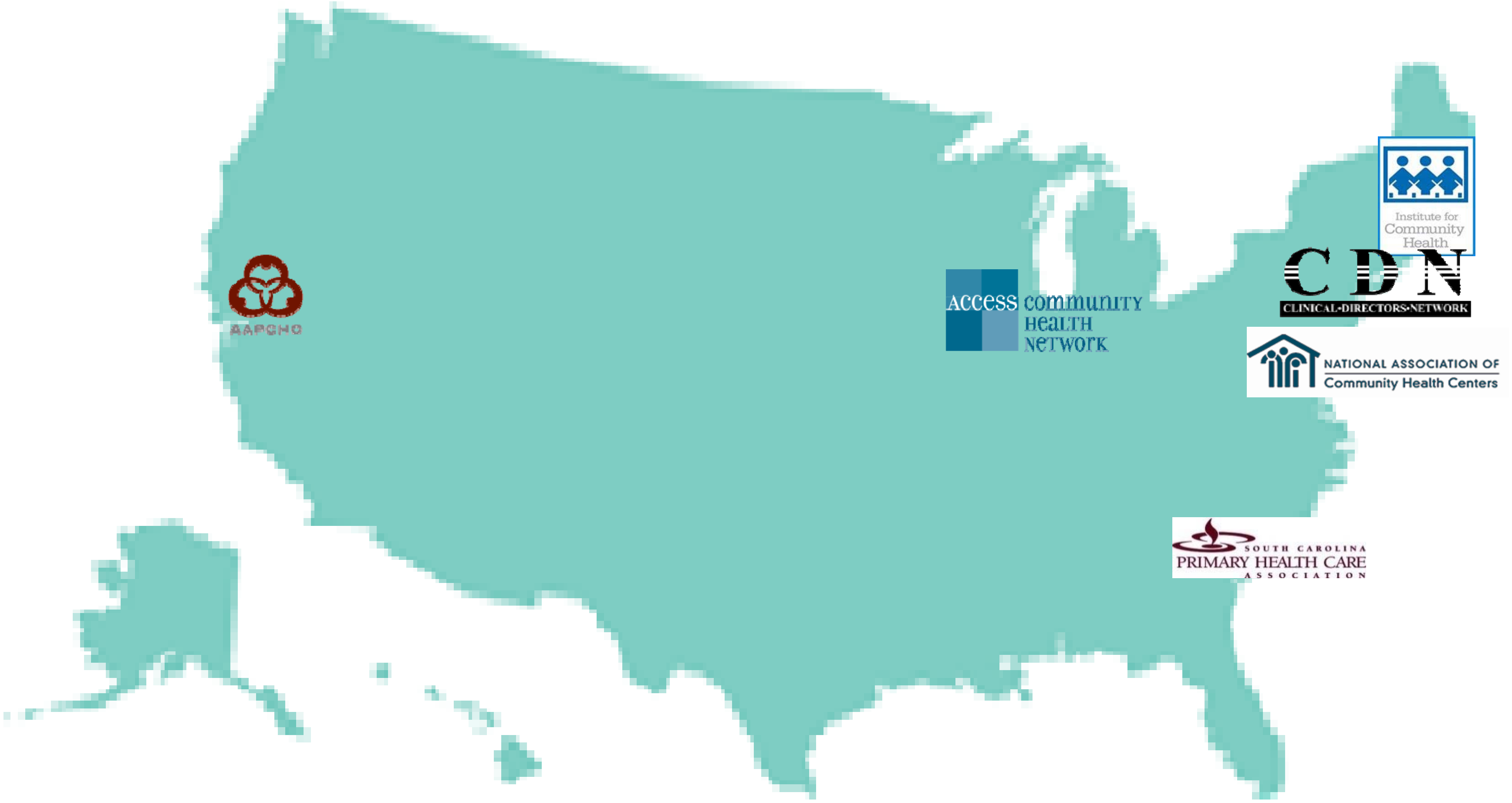

AIM

EnCoRE: Enhancing Community Health Center PCORI Engagement

AIM: To build health center capacity to engage in patient-centered outcomes research through an interactive 12-month long training curriculum, walking health centers through the steps and skills needed to develop a patient-centered research proposal www.CDNetwork.org

EnCoRE

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Goal:

To adapt, enhance, and implement an existing year long training curriculum designed to educate and engage Health Center teams including patients, clinical and administrative staff in Patient Centered Outcomes Research (PCOR).

Objectives:

- Build infrastructure to strengthen the patient-centered comparative effectiveness research (CER) capacity of Health Centers as they develop or expand their own research infrastructure
- Develop, implement, and disseminate an innovative online training, which will be targeted to and accessible at no cost to all Health Centers and other primary care practices.
- Content will prepare Health Center patients, staff, and researchers in the conduct of community-led PCOR

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Upcoming Webinars

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Webinar Date	Content	Activities	Presenters
July 21 2:00 – 3:30 pm EST	Grant Writing, Fundraising, and Project Planning	Search for PCORI funding opportunities, develop biosketches and workflows	Danielle Lazar, Leah Zallman
August 18 3:30 – 5:00 pm EST	Preparing Budgets, Work Plans, and Timelines	Developing timeframes and budgets	Shalini Tendulkar, Mickey Eder
September 29 2:00 – 3:30 pm EST	Dissemination and Presentation	Presentation development, communicating research findings	Jonathan Tobin, Michelle Proser

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Available Resources

- EnCoRE Website for Past Webinars and Materials
  - https://cdnencore.wordpress.com/live-session-library/
- Additional resources to build research capacity at health centers
  - www.CDNetwork.org/NACHC

Research Training Catalog

Online Training Resources for Federally Qualified Health Centers

About

Increasingly, Federally-Qualified Health Centers (FQHCs) are engaging in research as a way to achieve higher standards of care, narrow disparities, and improve community health, and many FQHCs are interested in increasing their capacity to conduct community-based research, including Community-Based Participatory Research (CBPR).

CBPR is a collaborative approach to research that engages community stakeholders as equal partners in all phases of the research process. CBPR enables unique partnerships that share interests, resources, and knowledge Given their community setting, governance and local ownership, FQHCs are uniquely positioned to participate in CBPR. To facilitate FQHC involvement in research including CBPR, this website provides training resources to help FQHCs build the skills needed design, implement, analyze, publish and disseminate research with their community stake-holders.

Both individuals and groups of co-workers at FQHCs can use these resources to build a free, on-demand training program for their team. The website is organized into a series of categories that have several resources which cover a range of topics and stages of engagement, ranging from basic introductory modules to more advanced modules. Resources also vary in length and format. For example, journal articles may only take 10 minutes to read, while webinars/webcasts and online courses may take several hours to complete. Many of these resources also count towards Continuing Education (CE) Credits (users need to confirm that CE credits are still available).

Please feel free to email (or call) Michelle Proser, MPP at MProser@nachc.org (202-331-4600), Peter Shin, PhD at PShin@gwu.edu (202-994-4144) or Jonathan N. Tobin, PhD at JNTobin@CDNetwork.org (212-382-0699 x234) with your feedback, questions, technical assistance, or to suggest both additional resources you have identified or ones you would like to see added in the future to this Research Training Website. We anticipate adding new resources, as well as hosting

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Future Funding Opportunities from PCORI

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Opportunity	Letter of Intent Due	Application Due
Engagement Award: Research Meeting and Conference Support	Not required	July 1, 2015
Engagement Award: Knowledge, Training and Develop, and Dissemination Awards	July 1, 2015	40 days after review and approval of LOI
Patient-Powered Research Networks (PPRN) Research Demonstration Projects	July 31, 2015	September 30, 2015
Improving Methods for Conducting Patient-Centered Outcomes Research	July 29, 2015	November 3, 2015
Communication and Dissemination Research	July 29, 2015	November 3, 2015
Improving Healthcare Systems	July 29, 2015	November 3, 2015
Assessment of Prevention, Diagnosis, and Treatment Options	July 29, 2015	November 3, 2015
Addressing Disparities	July 29, 2015	November 3, 2015

- Visit http://www.pcori.org/funding/opportunities for more information

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Outline

- Ethical challenges in Community and Patient Engaged Research
- Institutional Review Boards
- Cultural Competence in Research

  -Recruiting and retaining minority populations

Assessing the Ethics in Research

- Individual versus community
- Weighing the risks and benefits for community participation in research
- Role of the clinician researcher

Source: Harvard Catalyst Building Primary Care Research Infrastructure at your Primary Care Center
http://catalyst.harvard.edu/pdf/chirp/Module%208-IRB_final.pdf

Limitations of Biomedical Framework

- Focused on protection of individual as research “subject”
- Lacks ethical precepts for:
    - Community collaboration and consideration of culture
    - The ethical conduct of research with community partners
    - Community level concerns and risks

McDonald, M.A. (2009). *Ethics and community-engaged research.* Retrieved from Duke Center for Community Research, Duke University Medical Center. Retrieved August 11, 2011 from https://www.dtmi.duke.edu/for-researchers/training-education/community-engaged-research

Ethical Considerations in Community-Based Research

- How are individuals different from communities or community organizations?
  - Individuals:
    - make decisions for themselves
    - are able to provide informed consent
    - are protected if incapable of giving consent
  - **Communities**
    - often don’t have one decision-maker
    - may include a wide range of diverse opinions

Source: Harvard Catalyst Building Primary Care Research Infrastructure at your Primary Care Center
http://catalyst.harvard.edu/pdf/chirp/Module%208-IRB_final.pdf

Community Values and Ethics

- Some standard protocols may not be acceptable to community organizations
  - Use of control groups
  - Different treatments or interventions
  - Random assignment of participants

Source: Harvard Catalyst Building Primary Care Research Infrastructure at your Primary Care Center
http://catalyst.harvard.edu/pdf/chirp/Module%208-IRB_final.pdf

Ethical Challenges in Patient Engaged Research at CHCs

- Two relationships
  - Patient – Community Health Center
    - Patients engaged (guiding) research
    - Patient as a participant
  - Community Health Center – Academic

Challenges to equitable engagement

- Power dynamic
- Different access to resources (literature, financial resources, time)
- Communication styles
- Linguistic
- Other?

Ethical Issues with Patient Engagement in Research

- IRB processes may not be amenable/accessible to patient involvement
    - Trainings require high literacy level, computer access and computer literacy level
- Solutions/resources:
    - Community member training (Harvard Catalyst CEnR)
        - regulatory@catalyst.harvard.edu
    - Youth training
        - Stendulkar@challiance.org;
        - CES4Health product PSTZDJ5G

Institutional Review Board

A specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research.

Office for Human Research Protections. (1993). *IRB Guidebook*.
Retrieved August 11, 2011 from http://www.hhs.gov/ohrp/archive/irb/irb_guidebook.htm

What is a Human Subject?

- Anybody we gather information from or about while we're doing research

- Information can come from
  - experiments
  - observations
  - medical records review
  - interviews

Who Sits on the IRB?

- Board chair
- Staff
- Experts in the field
- Community residents/representatives
- Balance by gender, ethnicity

Source: Harvard Catalyst Building Primary Care Research Infrastructure at your Primary Care Center
http://catalyst.harvard.edu/pdf/chirp/Module%208-IRB_final.pdf

The Belmont Report

Principle	Applications
Respect for Persons	•Informed consent •Privacy (Confidentiality and Anonymity)
Benefits/Harms	•Protecting participants from harm •Assessment of risks and benefits
Justice	•Choosing participants fairly

What Does the IRB Review?

- **Research** that involves:
  - Review of medical and administrative record data
  - Research that uses leftover tissues
  - Health services research
  - Survey research
  - Behavioral research
  - Biomedical and other clinical research

Source: Harvard Catalyst Building Primary Care Research Infrastructure at your Primary Care Center
http://catalyst.harvard.edu/pdf/chirp/Module%208-IRB_final.pdf

Types of Review

Full Full IRB committee review	Clinical trials Vulnerable populations (children, prisoners)
Expedited Reviewed by a selection of staff/experts in the field	No more than "minimal risk" Interviews, focus groups Surveys Specimens, non-invasive
Exempt Not reviewed by IRB, IRB chair makes decision	Non invasive Educational settings, educational tests Document review

Source: Harvard Catalyst Building Primary Care Research Infrastructure at your Primary Care Center
http://catalyst.harvard.edu/pdf/chirp/Module%208-IRB_final.pdf

Criteria for IRB Approval

- Risks
  - Minimized, reasonable in relation to anticipated benefits
- Selection of participants is equitable
- Informed consent
  - Sought from each participant
  - Informed consent is appropriately documented

Source: Harvard Catalyst Building Primary Care Research Infrastructure at your Primary Care Center
http://catalyst.harvard.edu/pdf/chirp/Module%208-IRB_final.pdf

Criteria for IRB Approval

- Data collection monitored for participant safety
- Privacy and confidentiality of participant is protected
- Additional safeguards are included for vulnerable populations
  - Children
  - HIV
  - Prisoners
  - Pregnant women

Source: Harvard Catalyst Building Primary Care Research Infrastructure at your Primary Care Center
http://catalyst.harvard.edu/pdf/chirp/Module%208-IRB_final.pdf

Informed Consent

- Explain the study
- Explain participant's role
- Explain what is going to happen
- Describe possible risks and benefits
- Explain how the participant is protected
- Voluntary
- Signatures and dates

Types of consent

- Written consent – gold standard
  - Written consent waived – very low risk (e.g., online or mailed survey, telephone interview)
- Telephone consent – rare (e.g., pts very ill, debilitated and very minimal risk)
- Assent (not a form of consent but appropriate in addition to consent if participant can make a judgement – some adolescents, mentally ill patients)

https://catalyst.harvard.edu/programs/regulatory/participantsrsa.html

Clinical Trials:
Good Clinical Practice

1. Ensures ethical standards
2. Scientific quality
3. Rights, safety and wellbeing of trial subjects

Clinical Directors Network has Good Clinical Trials Bootcamp webcasts available in webcast library.

http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm155713.htm

IRB, what IRB?

- Internal IRBs- Committees at academic institutions and medical facilities to monitor research studies involving human participants
- External IRBs - Independent or commercial IRBs with identical responsibilities to academic or medical institution IRBs.
- Creating your own IRB

Case Study – WCCHC IRB

- Creating own IRB – WHY?

Twenty-five years ago, in one year, the WCCHC had almost 30 requests for research projects from outsiders. Although there was a Research Committee that reviewed such requests, it lacked a community health center IRB. At that time researchers were not reporting their findings to the communities .

The WCCHC IRB was formed in order to:

- Support the community becoming participants rather than subjects of research
- Increase community control, knowledge and understanding of research findings in order to change health disparities.
- Build capacity to conduct research ourselves as a community, including developing the infrastructure necessary to support substantial NIH grants coming directly to the community health center

Case Study – WCCHC IRB

What does it take in terms of resources and effort to develop your CHC's own IRB?

- Desire to control research conducted in their community
- Commitment of adequate staff and resources from CHC administration
- CHC staff who are knowledgeable/willing to learn about federal human subject protections, and community protection issues, and have time to serve on IRB, conduct reviews

Case Study – WCCHC IRB

What have been the CHC benefits from having its own IRB?

- Ability to control the type of research conducted in the community
- Increased understanding of research requirements, processes
- Credibility with research funding resources
- Training for community IRB members (CHC staff and community members)

Resources

- NIH online training in research with human subjects
  - http://phrp.nihtraining.com/users/login.php
- HHS Office of Human Research Protections IRB Guidebook
  - http://www.hhs.gov/ohrp/archive/irb/irb_guidebook.htm
- Building Primary Care Research Infrastructure at Your Community Health Center: Harvard Catalyst Toolkit
  - http://catalyst.harvard.edu/pdf/chirp/Module%208-IRB_final.pdf
- Informed consent form
  - click on 'Informed Consent (Adults)' under New Protocol Applications
  - http://www.challiance.org/Academics/FormsandTemplates.aspx

- Cultural Competence in Research

  -Recruiting and retaining minority populations

What are Culturally and Linguistically Appropriate Services (CLAS)?

Services that are respectful of and responsive to individual cultural health beliefs and practices, preferred languages, health literacy levels, and communication needs and employed by all members of an organization (regardless of size) at every point of contact.

-HHS Office of Minority Health

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National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care

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What is the purpose of the *National CLAS Standards*?

- Advance health equity
- Improve quality of services
- Help eliminate disparities

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The Case for Culturally and Linguistically Appropriate Services

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Quality of Care

Education on cultural and linguistic competency and the introduction of interpreter services improves the quality of care delivered (Pearlman, 2012).

Patient Adherence

Effective provider-patient communication impacts patient outcomes, including measures such as increased patient satisfaction, increased trust, and greater patient adherence (Education in Palliative End-of-Life Care for Oncology, 2013).

Preventive Services

The quality of care received by racial and ethnic minorities continues to be suboptimal in preventive care. Health education and healthy behavior promotion can help postpone or prevent illness and disease; detecting health problems at an early stage increases the chances of effectively treating those problems, often reducing suffering and costs (HHS AHRQ, 2014).

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The *National CLAS Standards*

Principal Standard

- Standard 1

Governance, Leadership, and Workforce

- Standards 2-4

Communication and Language Assistance

- Standards 5-8

Engagement, Continuous Improvement, and Accountability

- Standards 9-15

Principal Standard

1. Provide effective, equitable, understandable, and respectful quality care and services that are responsive to diverse cultural health beliefs and practices, preferred languages, health literacy, and other communication needs.

Standards on Governance, Leadership, and Workforce

2. Advance and sustain organizational governance and leadership that promotes CLAS and health equity through policy, practices, and allocated resources.

3. Recruit, promote, and support a culturally and linguistically diverse governance, leadership, and workforce that are responsive to the population in the service area.

4. Educate and train governance, leadership, and workforce in culturally and linguistically appropriate policies and practices on an ongoing basis.

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Standards on Communication and Language Assistance

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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.

Standards on Engagement, Continuous Improvement, and Accountability

9. Establish culturally and linguistically appropriate goals, policies, and management accountability, and infuse them throughout the organization's planning and operations.

10. Conduct ongoing assessments of the organization's CLAS-related activities and integrate CLAS-related measures into measurement and continuous quality improvement activities.

11. Collect and maintain accurate and reliable demographic data to monitor and evaluate the impact of CLAS on health equity and outcomes and to inform service delivery.

Standards on Engagement, Continuous Improvement, and Accountability

12. Conduct regular assessments of community health assets and needs and use the results to plan and implement services that respond to the cultural and linguistic diversity of populations in the service area.

13. Partner with the community to design, implement, and evaluate policies, practices, and services to ensure cultural and linguistic appropriateness.

14. Create conflict and grievance resolution processes that are culturally and linguistically appropriate to identify, prevent, and resolve conflicts or complaints.

15. Communicate the organization's progress in implementing and sustaining CLAS to all stakeholders, constituents, and the general public.

Why is application of the CLAS standards important for research?

- The CLAS standards provide a systematic way to integrate culturally competent care into research
- Adoption of the CLAS standards makes it possible to:

Obtain true informed consent

Establish an intimate relationship between researcher and participant

Allow for better treatment adherence and outcomes

[Source: http://www.empactconsortium.com/wp-content/uploads/2012/05/CLAS_Standards.pdf](http://www.empactconsortium.com/wp-content/uploads/2012/05/CLAS_Standards.pdf)

Questions to Consider

- What role does cultural congruence play in the development of a researcher-participant relationship?
- What value does language interpretation add to the understanding of study protocols for non-English speaking patients?
- What implications can the lack of adequate language services have on a participant's willingness to consider enrolling in a study?

Source: http://www.empactconsortium.com/wp-content/uploads/2012/05/CLAS_Standards.pdf

How well does your current research recruitment and retention efforts adhere to CLAS standards?

- Take the CLAS self-assessment quiz to identify gaps in your service/research and ways to improve your cultural competence in research.
- Link to quiz: http://www.culturecareconnection.org/navigating/assessment.html

Recruiting/retaining minority populations as participants in research

- Recruit and train bilingual/bicultural staff in cultural competency
- Assess staff on their skills and comfort level of cultural terms/references
- Provide appropriate compensation for research participants
- Translate necessary research materials/tools

  (consent forms, surveys, protocols)
  - Take into account the literacy rate of your target population reading level
    - SMOG Tool http://www.wordscount.info/wc/jsp/clear/analyze_smog.jsp
- Engage the community in your research through community-based participatory research (CBPR)
  - Engage bilingual/bicultural staff in development and testing of research materials/tools
  - Increases validity of materials, tools, and research for minority populations

Recruiting/retaining minority populations as community advisors/researchers

- Ensure participants understand their roles
  - provide community bidirectional training to understand research and community feedback
- Encourage bidirectional exchange of knowledge
- Provide appropriate compensation
- Provide accessible in-language research materials
- Provide evaluation mechanisms for community to respond to concerns and incorporate feedback

Source: Chang Weir, R, Diep, T, Liu, J, Lui, B, Song, H, Tseng, W, Kurtovich, E, Ivey, S. Engaging Community Members in a Chinese Diabetes Care Intervention at a Community Health Center..

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Guidelines for compensating community/patient participants in research

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Community consultants/advisors :

- Compensated at a professional level; this validates the value of their expertise and contribution to the research. CAG members are compensated at $25/hr for meeting attendance and special consultations.
- Invited to attend local conferences and trainings, at no cost.
- Asked to attend and present at national conferences
- Asked to contribute/participate in authorship of articles/presentations, and are noted as authors when appropriate.

Research Participants:

- Research participants are usually given gift cards in lieu of cash payments for participating in research
- All participant incentives are vetted by community IRB
- Amounts of incentives are usually not enough to make them ineligible for other benefits.
- Participation or refusal to participate in research does not affect their healthcare received at the HC, either positively or negatively.

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Summary

- Successful application of the CLAS standards in your research protocol has evidence of:
  - Culturally and linguistically appropriate services being integrated into each step of the research process
  - Engagement in community capacity development
  - Programs that are community driven and have real world validity and community applicability
  - Trust and communication between researcher and the targeted population

Source: http://www.empactconsortium.com/wp-content/uploads/2012/05/CLAS_Standards.pdf

Resources

- The Office of Minority Health. http://minorityhealth.hhs.gov/templates/browse.aspx?lvl=2&lvlID=11
- National Standards for Culturally and Linguistically Appropriate Services in Health Care: Executive Summary. U.S. Department of Health and Human Services, OPHS, Office of Minority Health. (2001) http://minorityhealth.hhs.gov/assets/pdf/checked/executive.pdf
- Betancourt JR, Green AR, Carrillo JE. (2002) Cultural Competence in Health Care: Emerging Frameworks and Practical Approaches. The Commonwealth Fund. www.cmwf.org.
- Vigil A, Hotrum K, Rodriguez D, Sutin J, Armitage K. Culturally and Linguistically Appropriate Services (CLAS) Toolkit. Department of Health, New Mexico. http://nmdohcc.org/files/DR-CLAS%20instrument%20final%208-18-09.pdf

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Where can you find more information about the *National CLAS Standards?*

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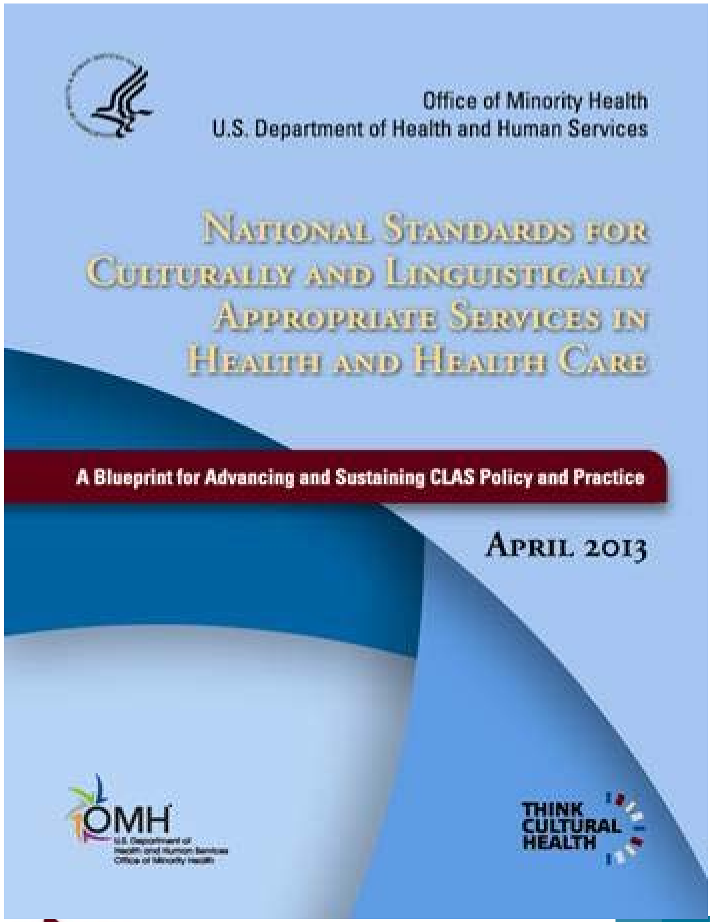
National CLAS Standards: A Blueprint for Advancing and Sustaining CLAS Policy and Practice


Office of Minority Health
U.S. Department of Health and Human Services

National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care

A Blueprint for Advancing and Sustaining CLAS Policy and Practice

April 2013

OMH

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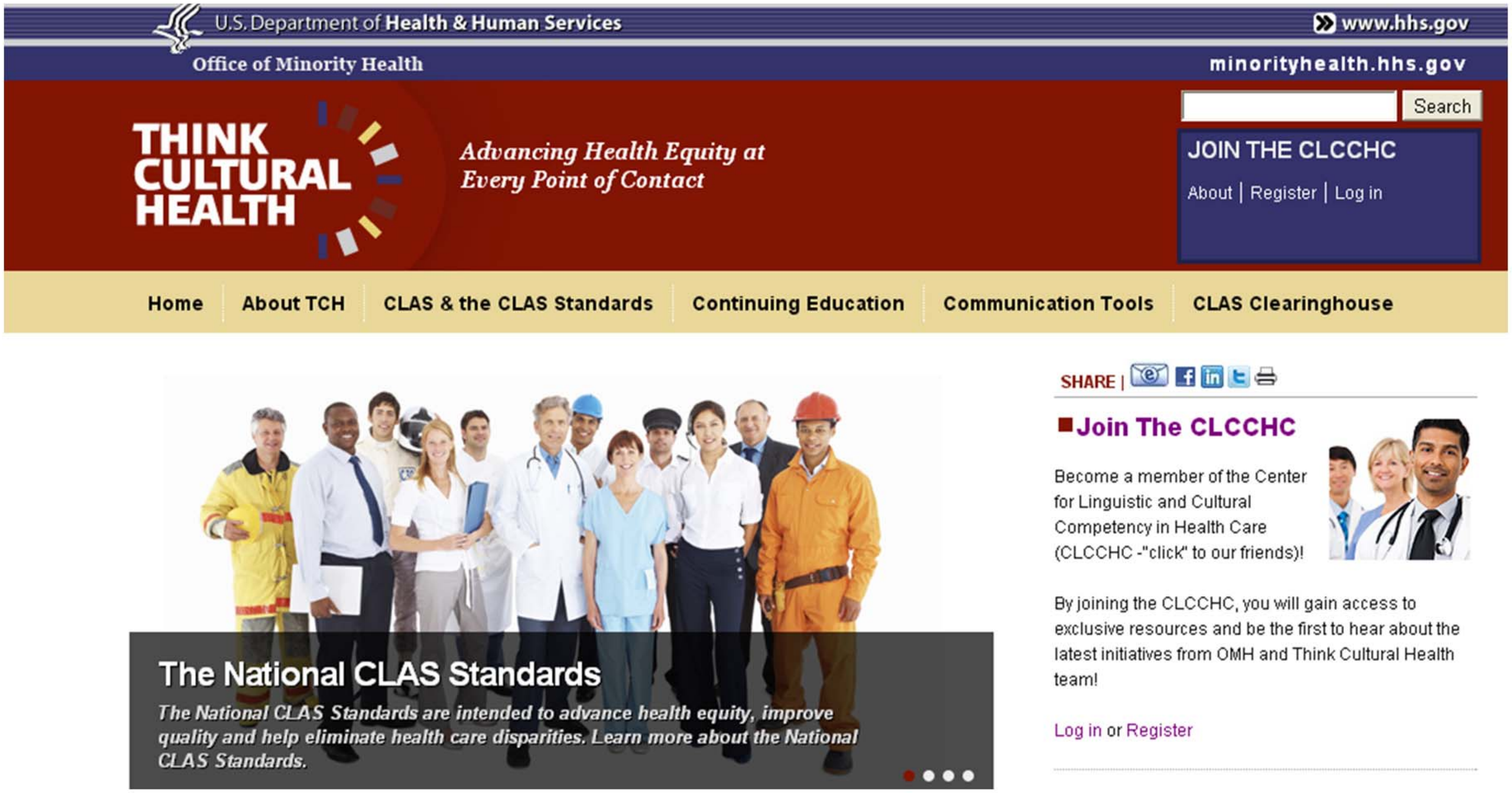

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The National CLAS Standards

The National CLAS Standards are intended to advance health equity, improve quality and help eliminate health care disparities. Learn more about the National CLAS Standards.

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By joining the CLCCHC, you will gain access to exclusive resources and be the first to hear about the latest initiatives from OMH and Think Cultural Health team!

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Homework

- Complete your free Human Subjects Protection Training
  - https://phrp.nihtraining.com/users/register.php
- Human Subjects Protection Worksheet Exercise
  - Think about your proposed PCORI research project and address human subjects requirements

QUESTIONS AND DISCUSSION