Eliminating Disparities in Clinical Trials (EDICT) Project

CTAC Meeting

COL. (Ret.) James E. Williams, Jr., MS, SPHR
Chair, Intercultural Cancer Council
Chair, Pennsylvania Prostate Cancer Coalition

The EDICT Project…

- Brings together representative stakeholders from the **public**, **private**, and **non-profit sectors** to develop policy recommendations to comprehensively address disparities in clinical trials participation.

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The EDICT Project…

- Emphasizes a **systems approach** to identifying both the
  - root causes of disparities and
  - critical policy makers and stakeholders who can address them.

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The EDICT Project…

- Communicates policy recommendations to the widest possible audience using a **pro-active dissemination model.**

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Overview of EDICT Health Policy Research

- **Year 1:** Research policy issues, identify stakeholders, partners, interview experts.
- **Year 2:** Conduct a National Policy Development Roundtable, define policy areas, develop national volunteer teams to further develop policy.
- **Years 3&4:** Conduct internal and external policy review and refinement. Launch policies and conduct dissemination activities involving education and advocacy.

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The EDICT Project: A Roadmap of Progress

Phases I and II

I POLICY *RESEARCH* and *STAKEHOLDER IDENTIFICATION*
(Public, Private and Non-Profit Sectors)

Sept. 2005 – August 2006

PROBLEM:

Dangerous disparities in clinical trials in the United States.

ACTION:

Creation of EDICT (Eliminating Disparities in Clinical Trials)

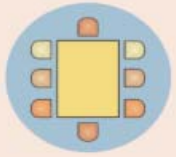
II POLICY *DEVELOPMENT*

Sept. 2006

National Policy Development Roundtable

(Public, Private, Non-Profit Representatives)

Opportunity Team (OT) Policy Areas Developed



Oct. – Dec. 2006

Methodology for Policy Development

Opportunity Teams

OTs Develop Policy Recommendations

Jan.– April 2007

Team Virtual Meetings

May 2007

Houston Team Meeting

"BackPack" and "CLAS-ACT" Roll-out (Complimentary Projects)

August 2007

Complete Draft Policies

Phases III and IV

III POLICY *REVIEW*

IV NATIONAL POLICY *DISSEMINATION* and *IMPLEMENTATION*

Sept. 2007

Policy "Soft Launch" – Houston
(Review by Core Leadership, ICC)

Oct. – Dec. 2007

Internal Stakeholder Policy Review

WAVE ONE

Jan. – Feb. 2008

External Stakeholder Policy Review

WAVE TWO

March 2008

Final Policy Recommendations

March 2008 – April 2008

National Policy Launch

"National Policy Launch"
(Presentation at ICC Biennial Symposium)

Press Conference & Capitol Hill Briefing

April 2008 >>>>>>>> Onward

ACTION

- Policy Education and Dissemination Continues
- Assessing Impact
- Tracking Progress

ACTION

New Policy Development and Advancement (Ongoing) > > > > > > > > > > >

Who Is Underrepresented?

- Underserved
- Racial/Ethnic
- Adolescents
- Women
- Rural
- Uninsured
- Elderly
- Special Health Needs, i.e., disabled, chronic illness, etc.

The Multiplier Effect

M^2

M^3

… M^x

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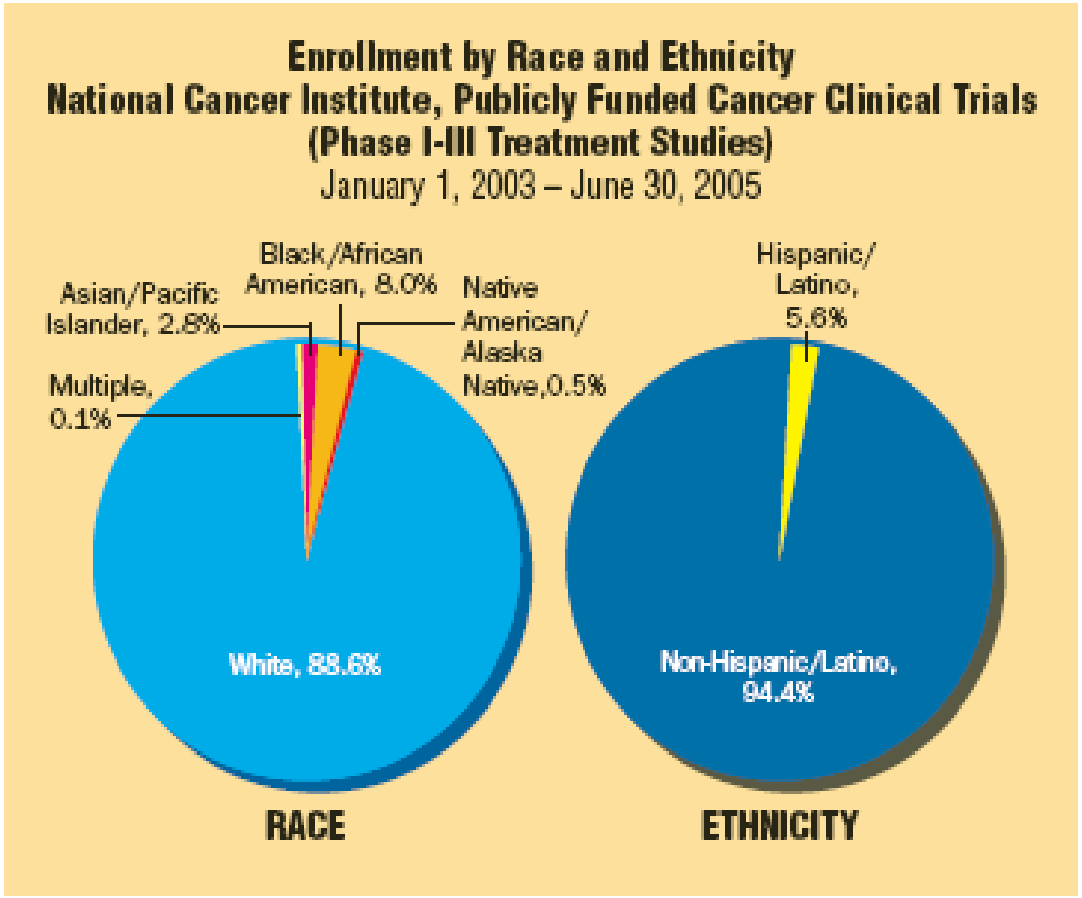
- The Coalition of Cancer Cooperative Groups evaluated accrual to NCI publicly funded treatment trials from January 2003 through June 2005. The data presented in the figures below show accrual rates by racial and ethnic status:



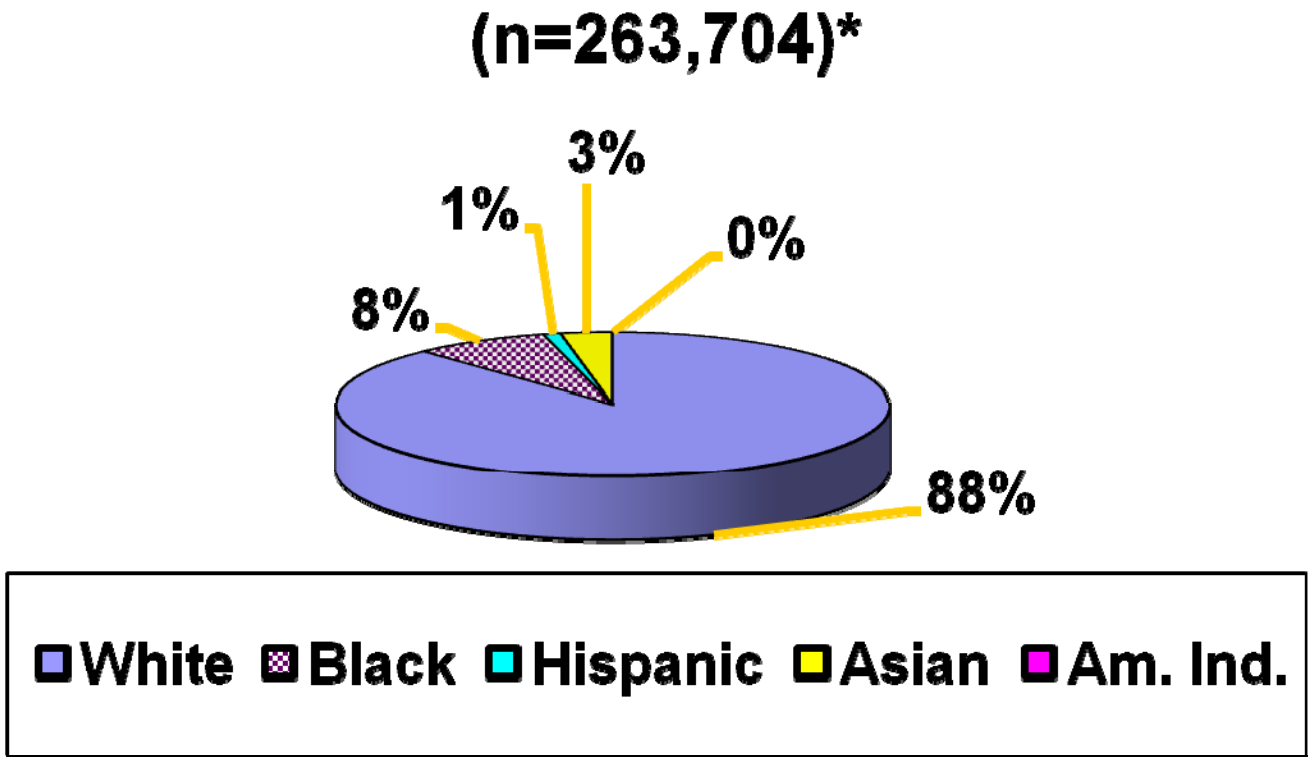
Source: Baseline Study of Patient Accrual Onto Publicly Sponsored Trials," Coalition of Cancer Cooperative Groups for the Global Access Project, National Patient Advocate Foundation, April 2006.

The National Cancer Institute (NCI) is the largest sponsor of cancer clinical trials in the U.S., with approximately 800 ongoing trials at 3,000 sites. Over 30,000 patients are enrolled in cancer clinical trials annually.

From 1998-2001, total enrollment in NCI-sponsored treatment trials increased 22%. However, the number of minority participants during that period remained stable, causing a decrease in the overall percentage of minorities in trials. 4,10

4. Christian, M.C. and E.L. Trimble, *Increasing participation of physicians and patients from underrepresented racial and ethnic groups in National Cancer Institute-sponsored clinical trials.* Cancer Epidemiology Biomarkers and Prevention, 2003. 12(3): p. 277s-283s.
10. Goldman, D.P., et al., *Incremental treatment costs in National Cancer Institute-sponsored clinical trials.* Journal of the American Medical Association, 2003. 289(22): p. 2970-2977.

Clinical Trials Participants by Race for NDAs 1995-1999*



* From medical reviewers comments. Excludes 229,643 patients where race/ethnicity was not described

Source: Evelyn et al; JNMA, vol. 93, no. 12, December, 2001.

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Patient Barriers to Clinical Trial Participation

- Mistrust
- Lack of awareness
- Lack of invitation
- Cultural barriers
- Study design eligibility criteria
- Cost / lack of insurance
- Language / linguistic differences
- Low literacy
- Practical obstacles

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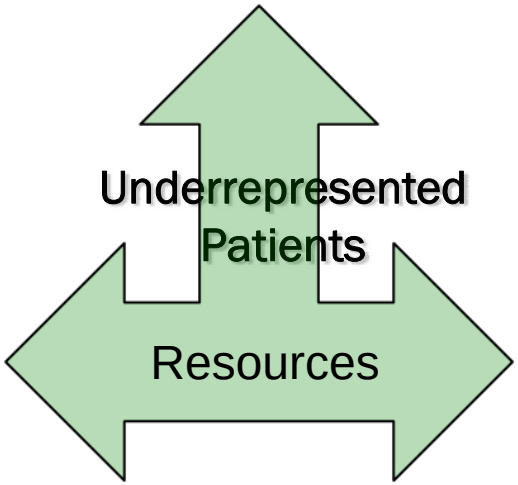
The Four R's



- **Recruitment** - In addition to issues of active recruitment, this "R" also includes issues of access.
- **Retention** - Keeping participants satisfied and "on protocol."
- **Return** - Giving back to our participant populations.
- **Resources**

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Opportunity Teams

OT1 **Allocation** of Research Funding Proportionate to Case Fatality

OT2 **Insurance** - Assuring Healthcare Coverage in Clinical Trials

OT3 **Professional Education** and Training

OT4 **Public and Patient Education** and Training

OT5 **Community** Input, Involvement & Relationships

OT6 **Clinical Trials Navigation**

OT7 **Pharmaceutical/Industry Partnerships**

OT8 **Publication**-Related Policies

OT9 **Regulatory** Oversight and Enforcement

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Credo

The following beliefs guide our work together:

- *All individuals will have the opportunity and necessary support to participate voluntarily in clinical trials for which they are eligible.*
- *Participants and researchers will understand and promote the benefits of diversity in clinical trials.*
- *Results from clinical research will benefit the participants' communities and society at large.*

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EDICT Policy Formulation Process - with Public, Private, Non-Profit Sectors

- Medical, policy, and legal literature
- Identification and interview of key experts, stakeholders, partners
- National Policy Roundtable – formulate policy areas through “Whole-Scale Change Process®”
- Teams of volunteers refine policy and implementation plans in facilitated meetings for 9 months

POLICY PROCESS QUESTIONS:

(Methodology for Opportunity Teams)

1. What is the problem? How does it manifest itself?
2. What would success look like?
3. Whose behavior needs to change to order to achieve the goal? (Audience)
4. Who has the ability to change the behavior of the target audience? (Policy Maker)
5. What policy is recommended to achieve the behavior change in the target audience? (ignoring perceived limitations)
6. What is the feasibility of this policy?
7. What is the underlying thinking on why this policy will be effective?

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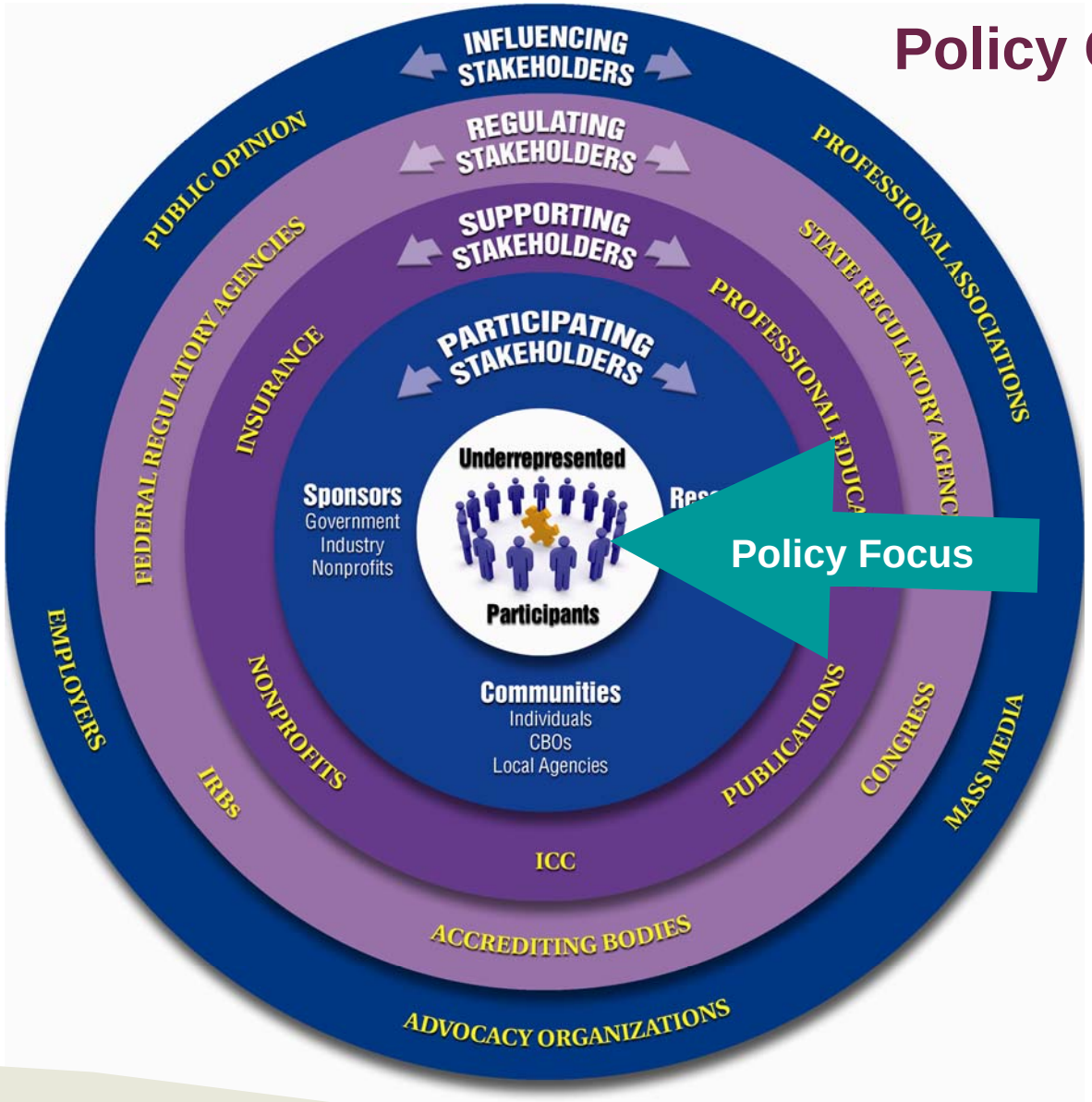
Policy Context



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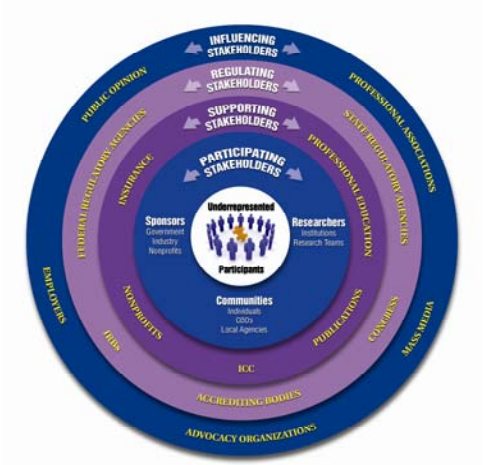
Places Policy Change Can Make a Difference



- Seek regulatory changes that improve the way research trials are designed and conducted.
- Reinvigorating federal policies and regulation related to disparities in clinical trials.
- Increase collaboration between the government and industry sectors in designing and conducting research studies.

EDICT Policy Context Model

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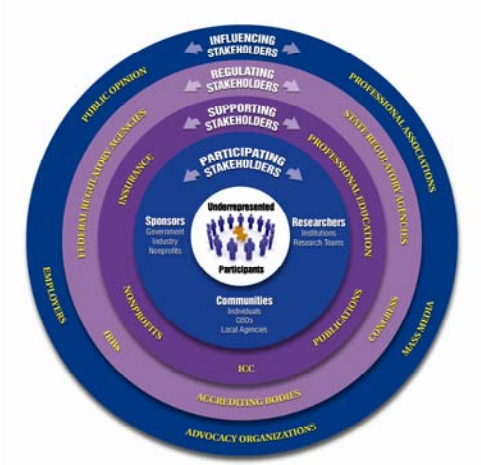
Places Policy Change Can Make a Difference



- Implement new policies so that peer-reviewed medical/science journals address representation of trial subjects in clinical studies.
- Invest in specialized training for Institutional Review Boards and health professionals.
- Reallocate research funding to avoid duplication and address disparities.

EDICT Policy Context Model

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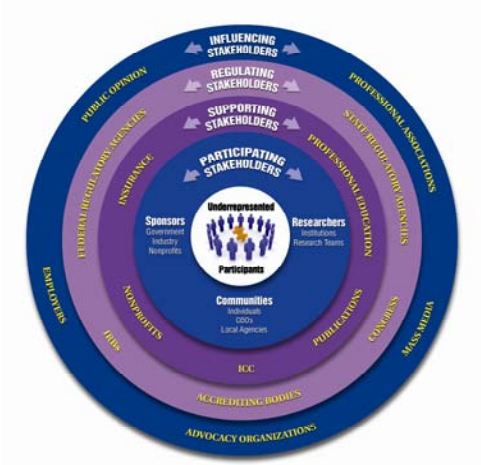
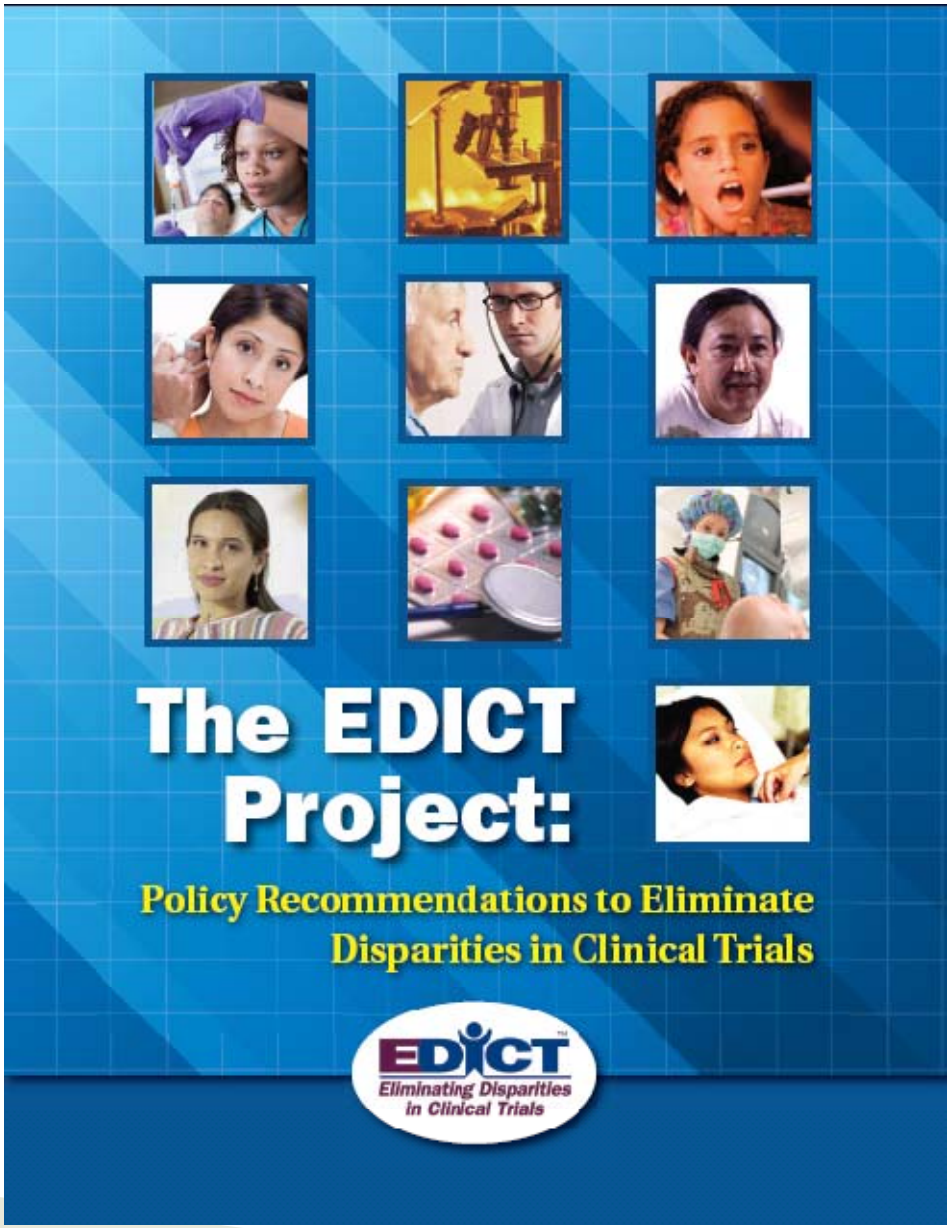
Places Policy Change Can Make a Difference



- Foster community involvement in clinical trials.
- Enhance public education about clinical trials.
- Implement participant navigation as a critical element of the clinical trials process.
- Assure insurance coverage of the costs associated with clinical trials.

EDICT Policy Context Model

EDICT
Eliminating Disparities in Clinical Trials



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I. Reinvigorating Regulation & Policy Related to Disparities in Clinical Trials

Because strengthening and enforcing existing regulations and policies is crucial to eliminating disparities in clinical trials…:

The National Institutes of Health (NIH) should:

- Provide more direct instruction on appropriate inclusion plans for all under-represented populations in clinical trial protocols.
- Provide substantial incentives for implementing appropriate inclusion plans.

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I. Reinvigorating Regulation & Policy Related to Disparities in Clinical Trials

The Food and Drug Administration (FDA) should:

- Strengthen its policy to require appropriate inclusion of underrepresented populations in all clinical trials.
- Implement penalties for non-compliance with inclusion policies in clinical trials.
- Implement incentives for appropriate inclusion of all underrepresented populations in clinical trials.

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I. Reinvigorating Regulation & Policy Related to Disparities in Clinical Trials

Federally and privately funded sponsors of clinical trials should:

- Adopt the DHHS Office of Minority Health (OMH) National Standards on Culturally and Linguistically Appropriate Services (CLAS).

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III. Fostering Community Involvement in Clinical Trials

Because increasing community participation is crucial to eliminating disparities an clinical trials:

Public and private sponsors of clinical trials should:

- Require demonstration in protocols of methods and measures to ensure meaningful community participation throughout the clinical trial process.
- Require a detailed plan to build community capacity for understanding and supporting clinical research.

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III. Fostering Community Involvement in Clinical Trials

Because increasing community participation is crucial to eliminating disparities in clinical trials:

Community groups should:

- Develop plans to actively disseminate information on clinical trials to community members.
- Develop ongoing relationships with individual investigators and research institutions to promote meaningful dialogue that ensures community involvement.

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VII. Enhancing Public Education about Clinical Trials in Communities

Because enhancing patient and public understanding of clinical trials is integral to eliminating disparities:

Public and private sponsors of clinical trials should:

- Require the development and implementation of culturally appropriate recruitment and retention plans with an additional focus on community education in appropriate languages for non-English and limited-English speaking populations and appropriate reading levels for all populations.
- Require that all local clinical trial teams convene a community "recruitment and retention" committee to advise on such plans as part of the IRB review.

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VIII. Navigation and Support of Individuals in Clinical Trials

Because navigating the various elements of a clinical trial is a significant barrier to participation by underrepresented populations:

Institutions and providers of continuing education should:

- Provide basic training in Clinical Trials Navigation.

Institutions and sponsors of clinical trials should:

- Ensure that entities conducting clinical trials have the capacity to deliver Clinical Trials Navigation services and encourage research protocols that include specific Clinical Trials Navigation plans.

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http://www.bcm.edu/edict

EDICT Dissemination - Policy Launch
April 2008

National Press Conference– April 1, 2008 - story featured by ABC news, NPR, US News & World Report, Fox Business, Centerwatch Clinical Trials Today, AARP

Capitol Hill Briefing – April 1, 2008 - initial follow ups with staff of Senators Kennedy, Hutchison, Murkowski

National Launch of the EDICT recommendations at the Intercultural Cancer Council Biennial Symposium – April 3, 2008 – 1,000 attendees from public, private, non-profit sectors, community advocacy organizations

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EDICT Dissemination
Meetings to Share Recommendations

Research Institutes – targeting top 100 public, private and non-profit research institutes

Non- profit – sponsors of clinical research (American Heart Association, American Cancer Society, American Lung Association, American Diabetes Association, Komen for the Cure, Lance Armstrong Foundation)

Federal Agencies – Such as CMS, NIH, FDA, Office of Civil Rights, DHHS Office of Human Research Protections (OHRP)

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EDICT Dissemination
Meetings to Share Recommendations

- Medical Journal Leadership
- Legislative contacts
- Special Supplement to the Journal of Cancer Education
- Expanded EDICT Website and Reading Room Publications
- News Media coverage

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EDICT Dissemination Collaborations

National Medical Association – Project IMPACT, targeting African American physicians

Society of Clinical Research Associates (SoCRA) – Disparities-specific articles with CEUs

ENACCT (Education Network to Advance Cancer Clinical Trials) **–** conferences and community related policies

AAMC (American Association of Medical Colleges) – Professional education on clinical research and disparities

C-Change – support of EDICT policies with members

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EDICT – Regional Dialogue Meetings
October 2008-June 2009

Eight City Sites Will Have:

- **Community meeting** - with community representatives and stakeholders about EDICT issues and policies
- **Roundtable meetings** related to identified disparities issues

Five of these Sites Will Also Have:

- **Focus Groups** -Clinical Trials Navigation

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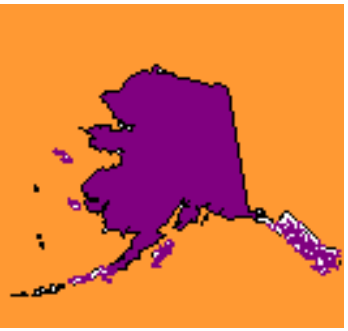
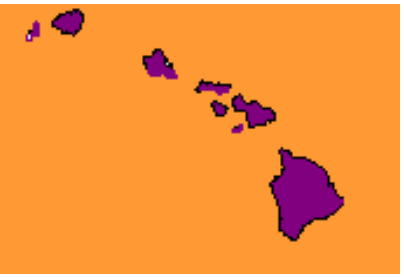
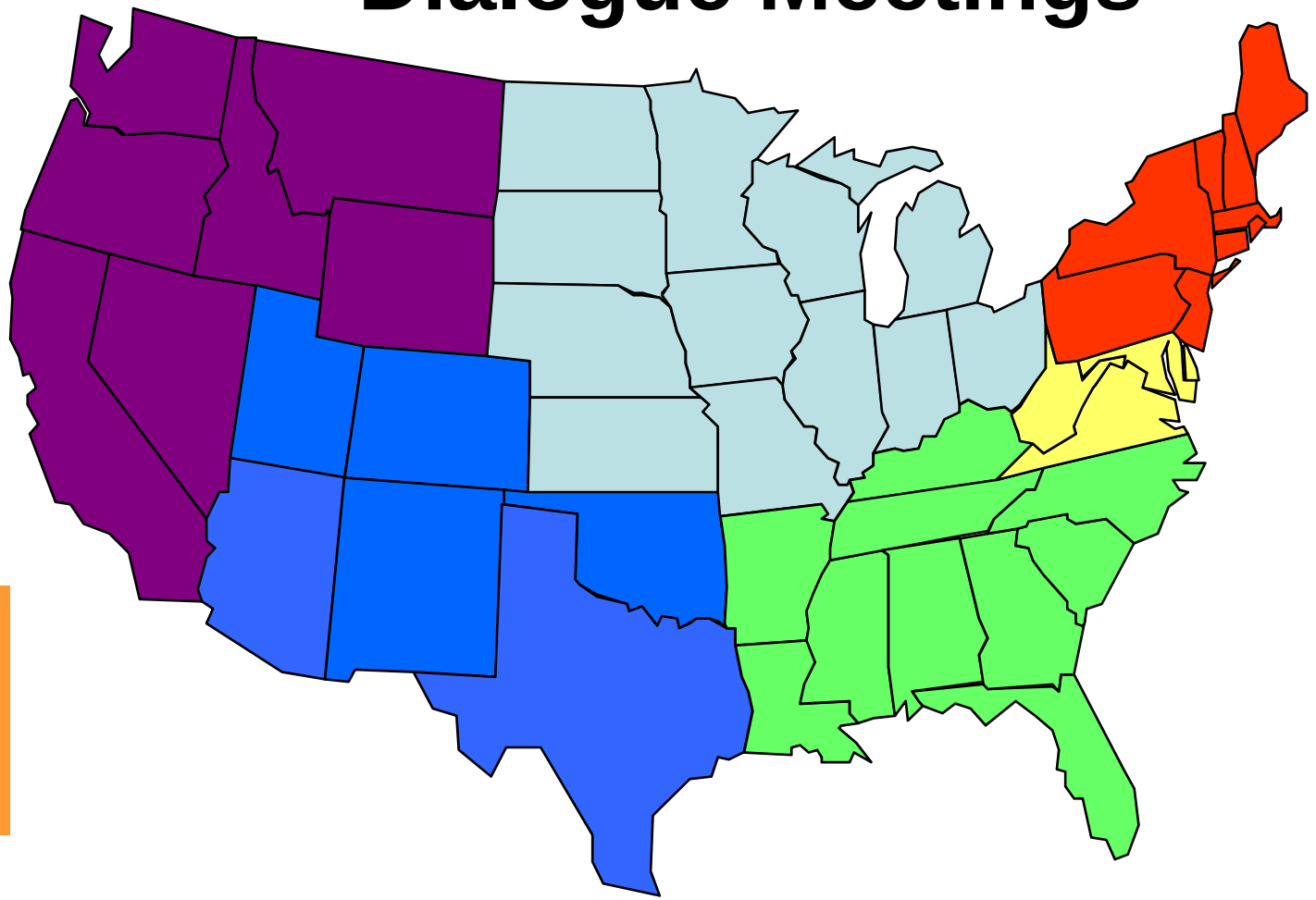
EDICT Regional Dialogue Meetings







EDICT – Regional Dialogue Meetings
Roundtable Meeting Topics
October 2008- June 2009

New York City - October 20, 2008

1. Clinical Trials Navigation (2 meetings)

2. African Americans and Clinical Trials Participation

Tampa

1. Elderly in Trials

2. Literacy/Cultural Competency Issues in Clinical Trials

Cincinnati

1. Role of Community Heath Professionals in Clinical Trials

2. National Medical Association's Project IMPACT

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Clinical Trial Navigator

Promotoras de Salud

Community Health Worker-CHW

Nurse Navigator

Patient Advocate

Healthcare Professionals

Patient Navigator

Social Worker

EDICT – Regional Dialogue Meetings
Primary and Secondary Focus Areas
October 2008- June 2009

Tucson

1. American Indians and Clinical Trials
2. Insurance Issues Related to Clinical Trials

San Francisco

1. Health Professionals Training Regarding Disparities in Clinical Trials
2. Asian Americans and Clinical Trials Participation

Charleston, WVa

1. Appalachian Communities and Clinical Trials
2. Rural Communities and Clinical Trials

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EDICT – Regional Dialogue Meetings
Primary and Secondary Focus Areas
October 2008- June 2009

San Juan

1. Hispanic/Latino Populations and Clinical Trials
2. Pharmaceutical Industry Perspective

Honolulu

1. Asian/Pacific Islander Populations and Clinical Trials
2. Issues Related to Cancer Clinical Trials for Asian/Pacific Islander Communities

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EDICT Dissemination Complementary Projects

- EDICT BackPack Project
- EDICT CLAS-ACT Project
- EDICT BackPack and CLAS-ACT Training Workshops
- EDICT Fellowships – training the next generation of researchers
- National Recognition Program

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EDICT BackPack Project

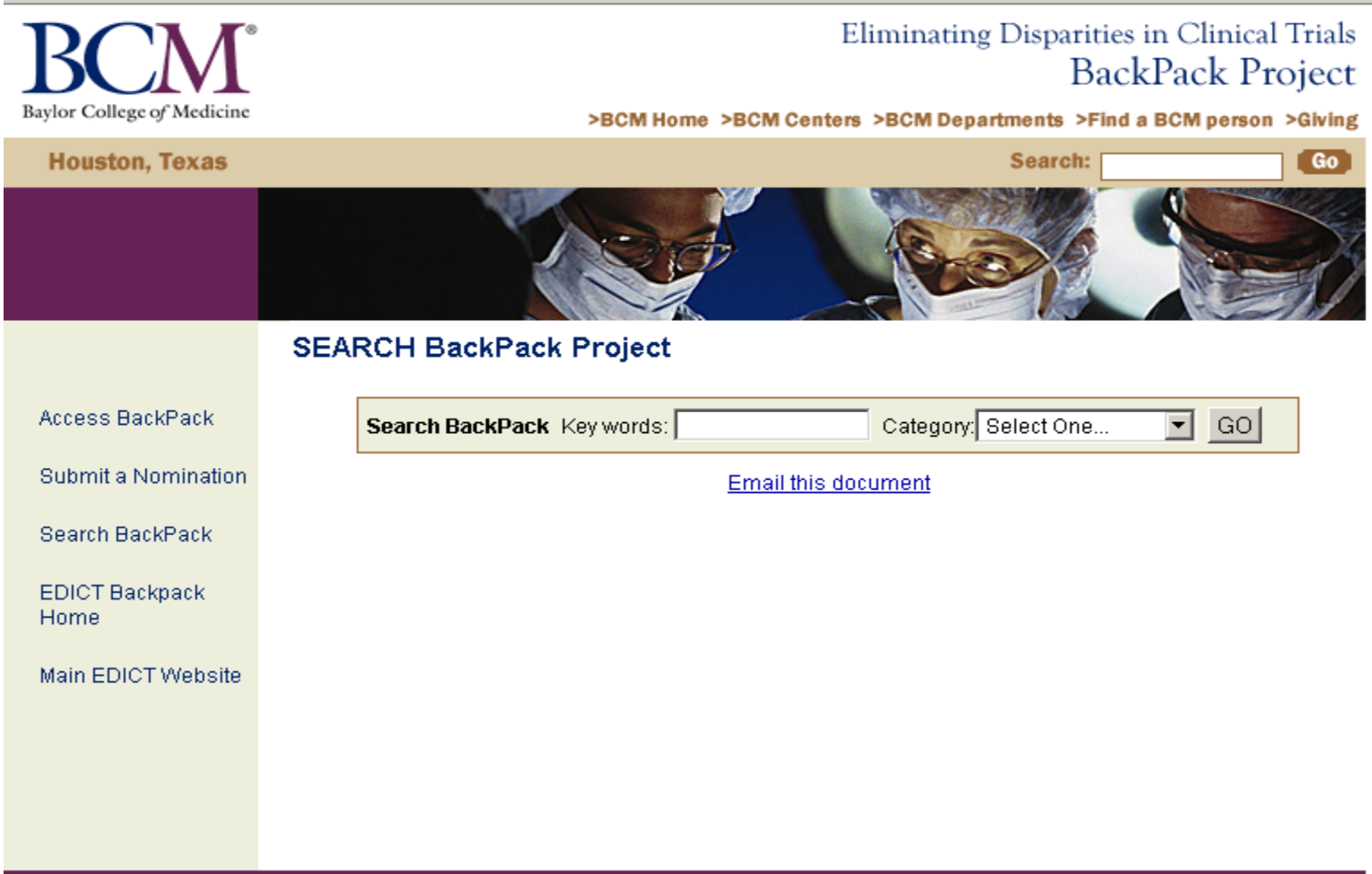
- **Best and promising practices related to reducing health disparities are often:**
  - focused only on a single disease or problem area.
  - known only to specialists or those who are already familiar with the field.
  - reported only at professional conferences or in scientific journals.
  - not easily accessible or useful to community based practitioners actively engaged in clinical trials recruitment “on the ground” in traditional clinical venues.

EDICT BackPack Project

Goals:

- To identify policies, projects, programs, promising practices, and other resources that have been demonstrated to help eliminate disparities in recruitment and retention of underrepresented groups in clinical trials.
- To make these materials and resources available to researchers, advocates, policy makers, and healthcare providers.

Search BackPack

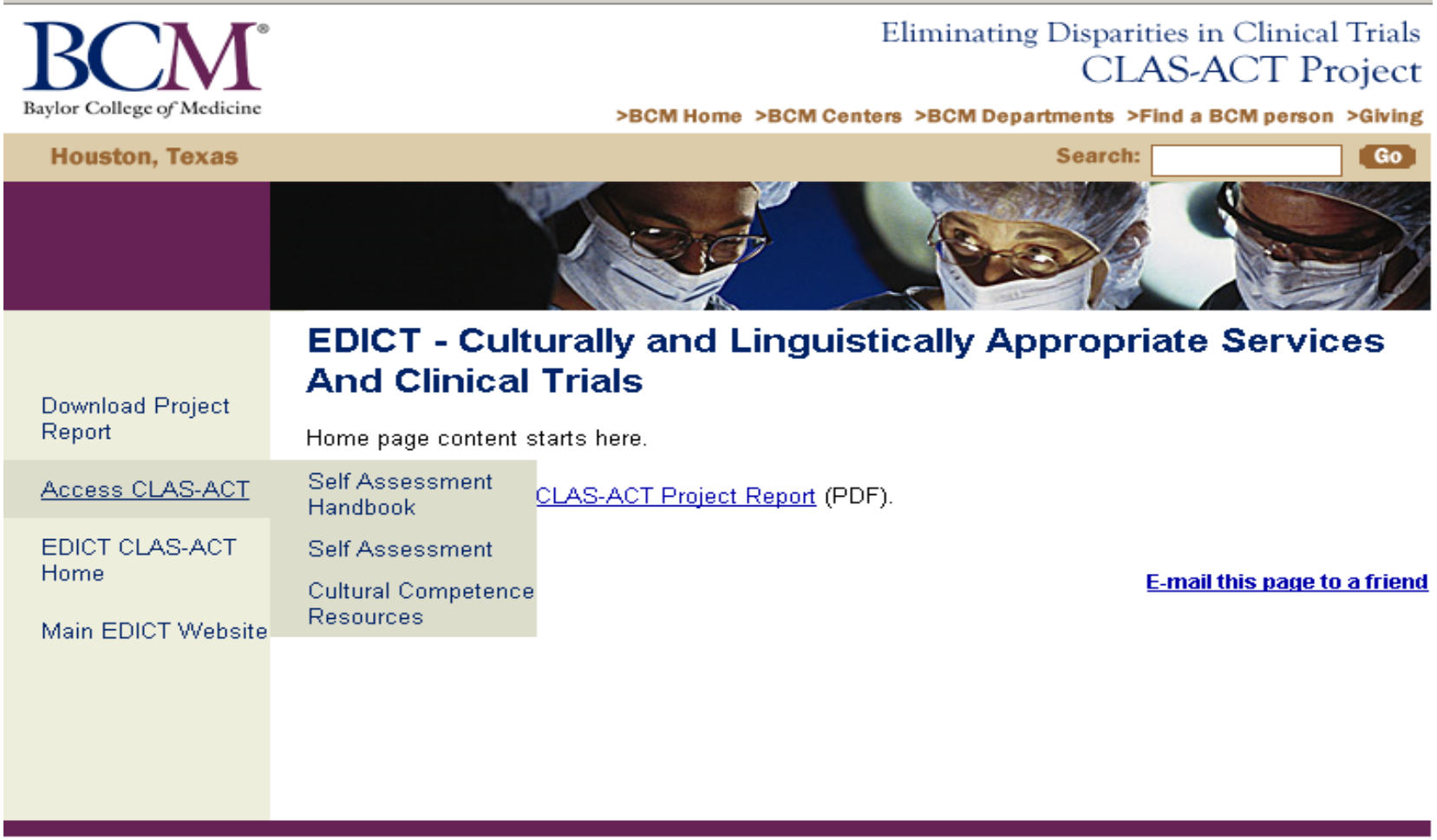


CLAS-ACT Project

- National Standards for Culturally and Linguistically Appropriate Services (CLAS)
- Developed by the DHHS Office of Minority Health (OMH) in 2000
- As a result of OMH involvement in the EDICT Project, OMH funded the CDRC to study how to apply CLAS standards to eliminating disparities in clinical trials.

→ **CLAS "And Clinical Trials" (CLAS-ACT).**

Access CLAS-ACT



BackPack and CLAS-ACT

at Baylor College of Medicine

The EDICT BackPack and CLAS-ACT Projects are funded under Cooperative Agreement Number MPCMP051006-03 from the U.S. Department of Health and Human Services Office of Minority Health to the Baylor College of Medicine Chronic Disease Prevention and Control Research Center. The Office of Minority Health acknowledges the NIH National Center for Minority Health and Health Disparities for its financial contribution to this effort, and also to HHS Office on Women's Health for its support.

In Summary, Why Is This Important?

- **Science Case** - enhance research quality
- **Business Case** - facilitate return on investment
- **Social Justice Case -** distribute the fruits of biomedical research justly

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