

# Improving Cultural Inclusivity in Clinical Trials: Implementation of The EDICT Project Recommendations

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# Objectives

- Increase knowledge of disparities in underserved groups participation in clinical trial research
- Explore the EDICT history
- Provide examples on how to use the EDICT recommendations to improve participation disparities

# Why Is This Topic Important?

- Can disparities in clinical trial representation lead to physical harm?
  - Yes. Studies that don't include certain groups are not easily generalizable to those populations leading to risk.
- There is also a moral hazard in addition to a physical one.
  - Disparities are indicative of deeper latent racisms in health care that can lead and often do lead to physical harm.

# Perils and Beauty of Clinical Trial Research

Irene Teo, M.S.  
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University of Houston  
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# Clinical Trial Research

- Research is used to advance medical treatments
- Clinical trials are conducted to explore the safety and efficacy of new prevention, diagnostic and treatment methods for disease

# Beauty of Clinical Trial Research

- Education
- Prevention and management
- Outcomes
- Advanced treatment
- Access to healthcare

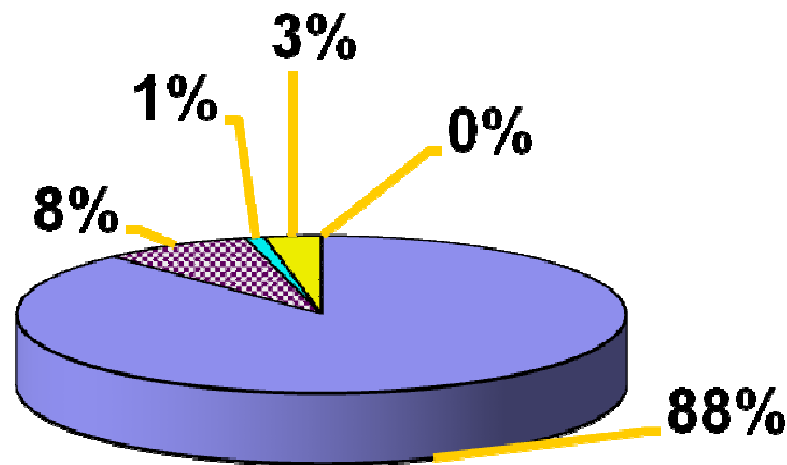
The National Cancer Institute (NCI) is the largest sponsor of cancer clinical trials in the U.S., with approximately 800 ongoing trials at 3,000 sites. Over 30,000 patients are enrolled in cancer clinical trials annually. From 1998-2001, total enrollment in NCI-sponsored treatment trials increased 22%. 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\*

(n=263,704)\*



■ White ■ Black ■ Hispanic ■ Asian ■ Am. Ind.

\* 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.

# Barriers to Participation

- Participants

- Cultural mistrust
- Cultural and language barriers
- Perceived harm
- Cost
- Transportation
- Family issues
- Lack of education about clinical trials

- Researchers

- Increased study cost
- Increased study length
- Cultural and language barriers
- Lack of cultural awareness
- Lack of incentives

# Who Is Underrepresented?

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

The Multiplier Effect

$M^2$

$M^3$

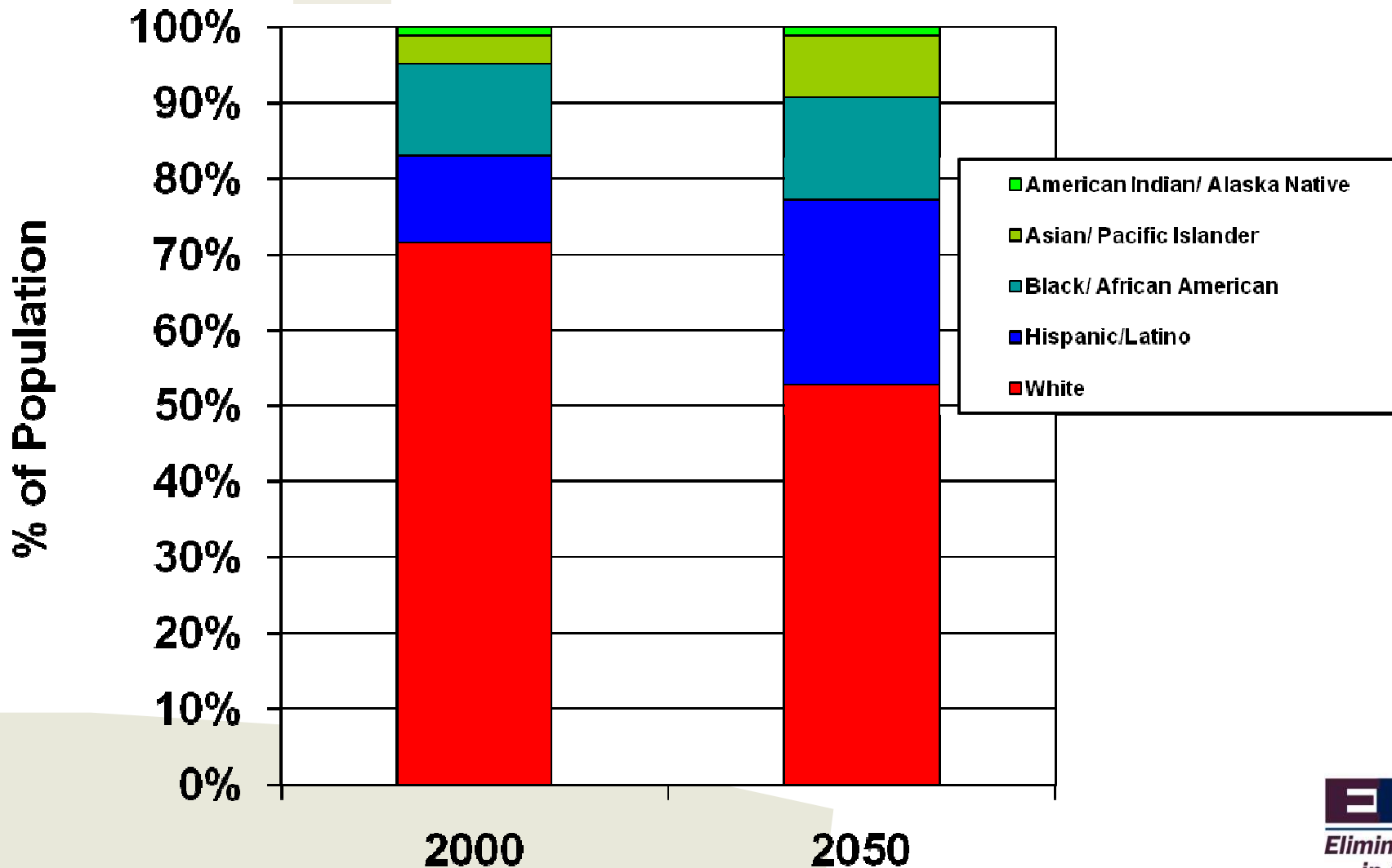
...  $M^x$

# How this Disparity came to Pass

- Exploitation of certain minority groups goes hand-in-hand with safety concerns
  - Nazi medical experiments
  - Jewish Chronic Disease Hospital Case
  - Willowbrook State School
  - Syphilis Study at Tuskegee
  - Sterilization of Puerto Rican Women

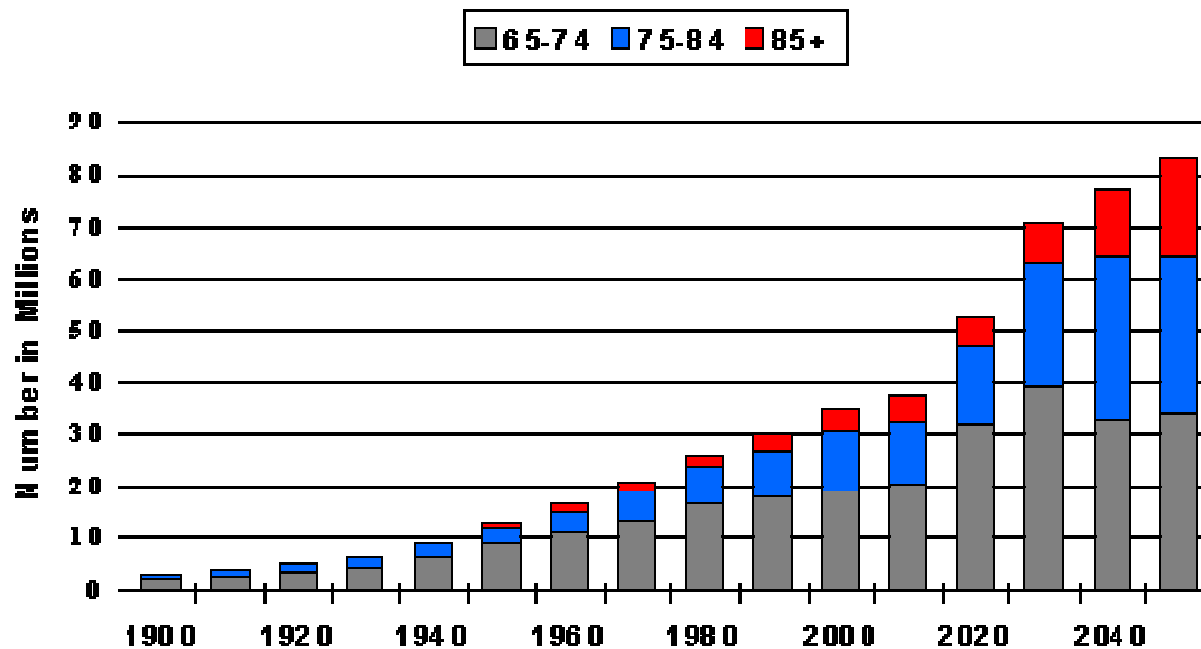
# Population Shifts

Percent of Population by Race and Hispanic Origin, 2000 vs. 2050

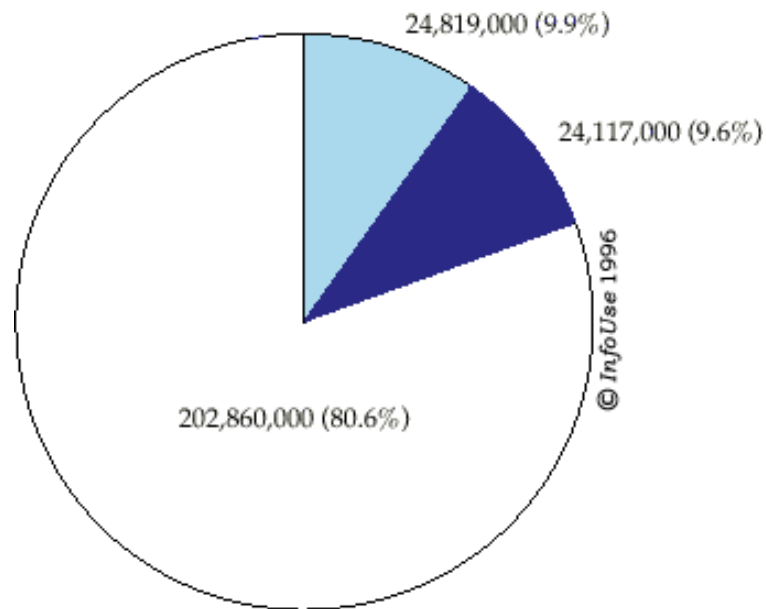





# The Elderly

## Growth of U.S. Older Adult Population



# The Physical Disabled



-  with a disability, not severe
-  with a severe disability
-  with no disability

# Does Ethics Require Diversity in Clinical Trials?

- Fair Participant Selection:
  - Moral principles of justice require that there be fair participant selection
  - This is to ensure that all groups have a fair shot at any benefits that may accrue,
  - And so as not to overburden one group with the risks of research.

# NIH Guidelines



- NIH policy for the inclusion of women and minorities as subjects in clinical research
  - Less than 1/3 elderly
  - Less than 10 % ethnic minority
  - Less than 10% women
  - Less than 10% adolescents

# Who funds clinical trials...

- 20 % - Public (Federal Sources)
- 5 % - Non-profit/Foundations
- 75 % - Private (Industry)

# History and Application of EDICT

Gina Evans Hudnall, Ph.D.

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# Eliminating Disparities in Clinical Trials (EDICT) Project

Putting safety concerns in the context of policy change aimed at eliminating disparities in clinical trials.



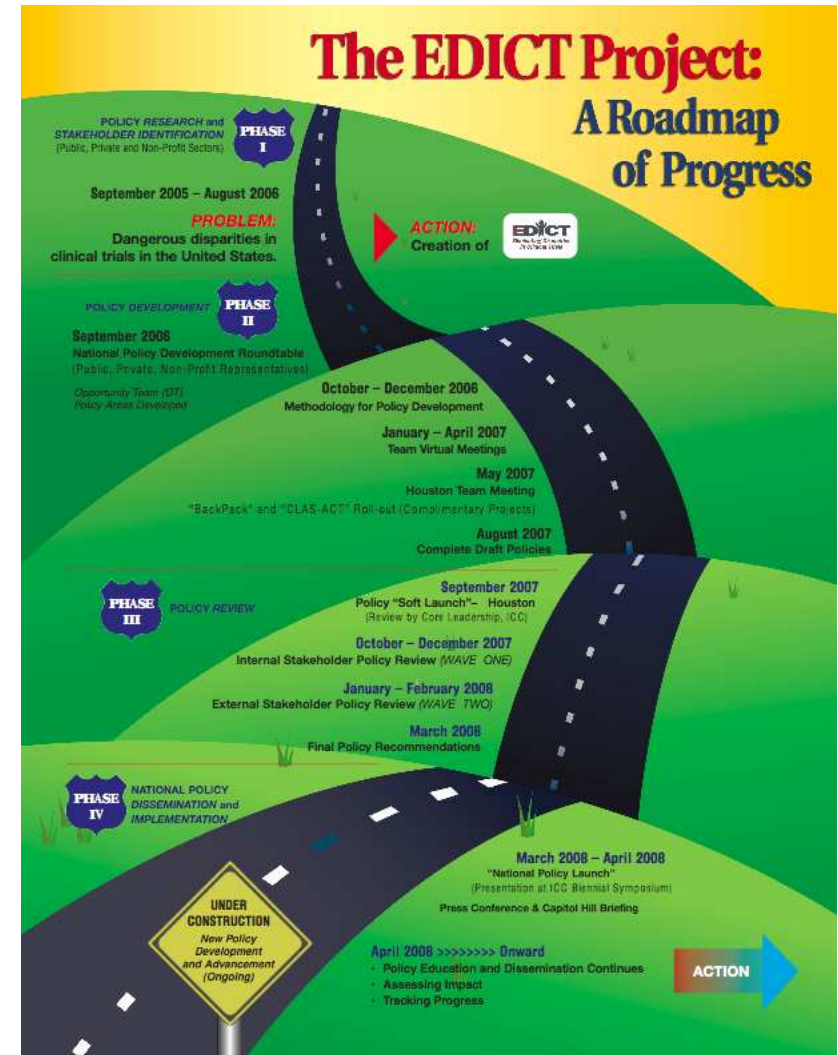
# Credo

The following beliefs guide our work together:

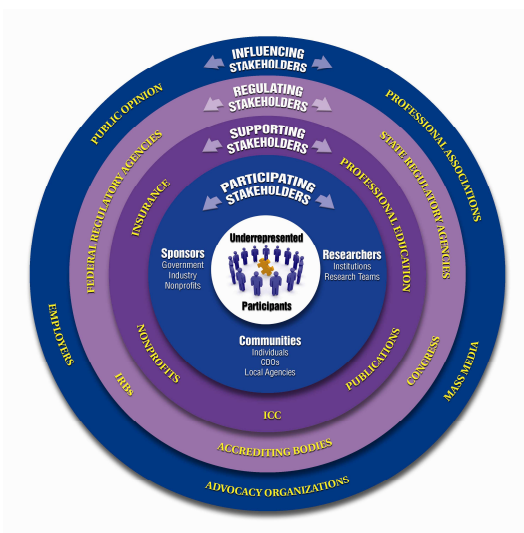
- **All individuals will have the opportunity and necessary support to participate voluntarily in clinical trials for which they are eligible.**
- **Participants and researchers will understand and promote the benefits of diversity in clinical trials.**
- **Results from clinical research will benefit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

# 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

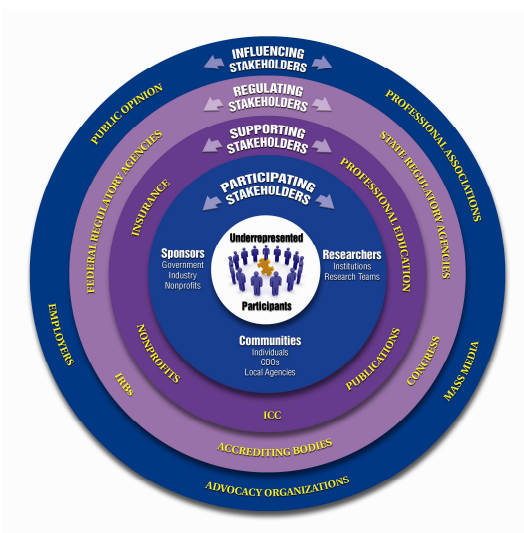


## Places Policy Change Can Make a Difference



- 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.

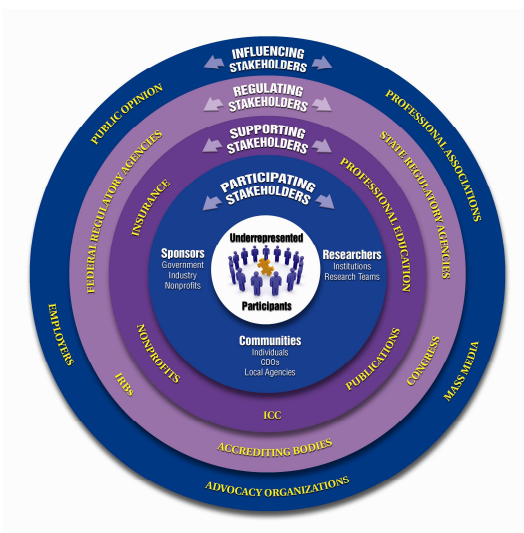
## Places Policy Change Can Make a Difference



- 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.

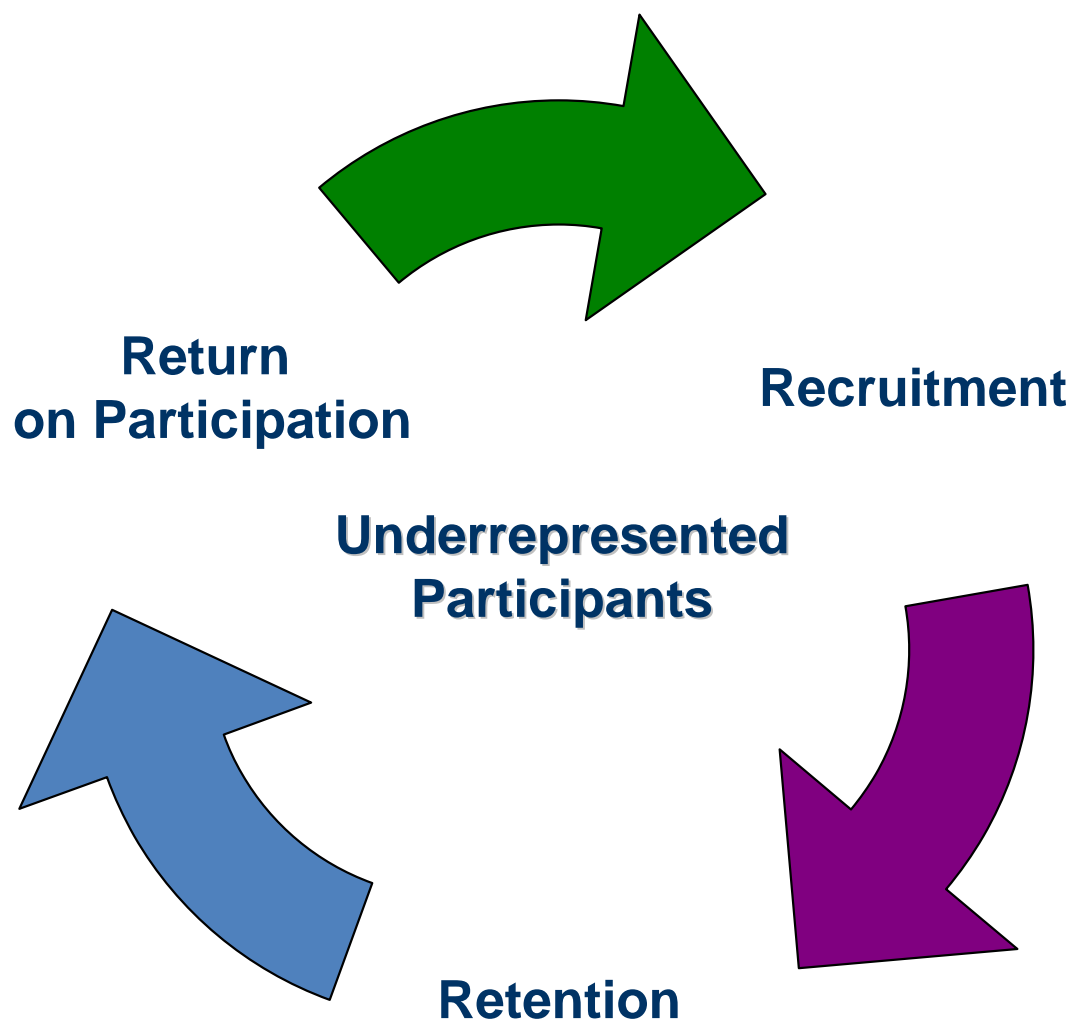
## EDICT Policy Context Model

## 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.

# Practical Tools & Techniques



- **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**

● The Three R's Plus One

# Practical Tools & Techniques

- Recruitment
  - Incentives
    - Must be careful not to coerce.
    - Therapeutic misconception must not be fostered.
    - Though targeted advertising is essential, it must be accurate, non-coercive, and approved by IRB.
  - Proven strategies
    - Behavioral interventions clinical trials

# Application



- Recruitment and Retention procedures:
  - Incorporate participant family and friends
  - Hiring of multicultural and bilingual research staff
  - Use of translators and interpreters
  - Provide study incentives that may be more beneficial to underserved minorities
  - Provide additional needed resources

# Practical Tools & Techniques

- Retention
  - Key to equitable participation.
  - Burdens and barriers are often hidden at trial inception.
  - Allows for better safety monitoring.
  - Groups that drop out at higher rates end up with worse outcomes, higher burdens, and fewer benefits.

# Application

- Data Collection Methods:
  - Have flexible hours for data collection
  - Provide flexible methods of data collection
    - Home visits
    - child care
    - Transportation
  - Use of community and health educators for data collection

# Practical Tools & Techniques

- Return
  - Continued benefits to research populations are both ethically sound and professionally wise.
- Why?
  - Fairness
  - Incentive for community to participate subsequently
  - Builds relationship with community.

# Practical Tools & Techniques

- Return, cont.
  - How?
    - For how long is continued benefit appropriate?
    - Will participants have continued access to approved treatments? Results?
    - How do we show appropriate reciprocity without being coercive or fostering a “gift response”?

# Application



- Return to community:
  - Share study results with community leaders
  - Sustain healthcare efforts
    - future screenings
  - Turn results into future programs

# Application of the EDICT recommendation

Elizabeth Ross, B.S.

Doctoral student

University of Houston

# Chart a Course Together Through Policy

Training

CLAS  
standards

Advocacy

# Cultural Competency Training

Provide cultural competency and clinical trials disparities training to researchers and staff

# Staff must be trained to....



- Respect culturally based values, beliefs, and behaviors
- Understand how culture influences behaviors and choices to participate in clinical trial research
- Recruit in areas where there are a large population of underserved
- Practice an ongoing commitment to appropriate practices and policies for diverse populations throughout the entire process.

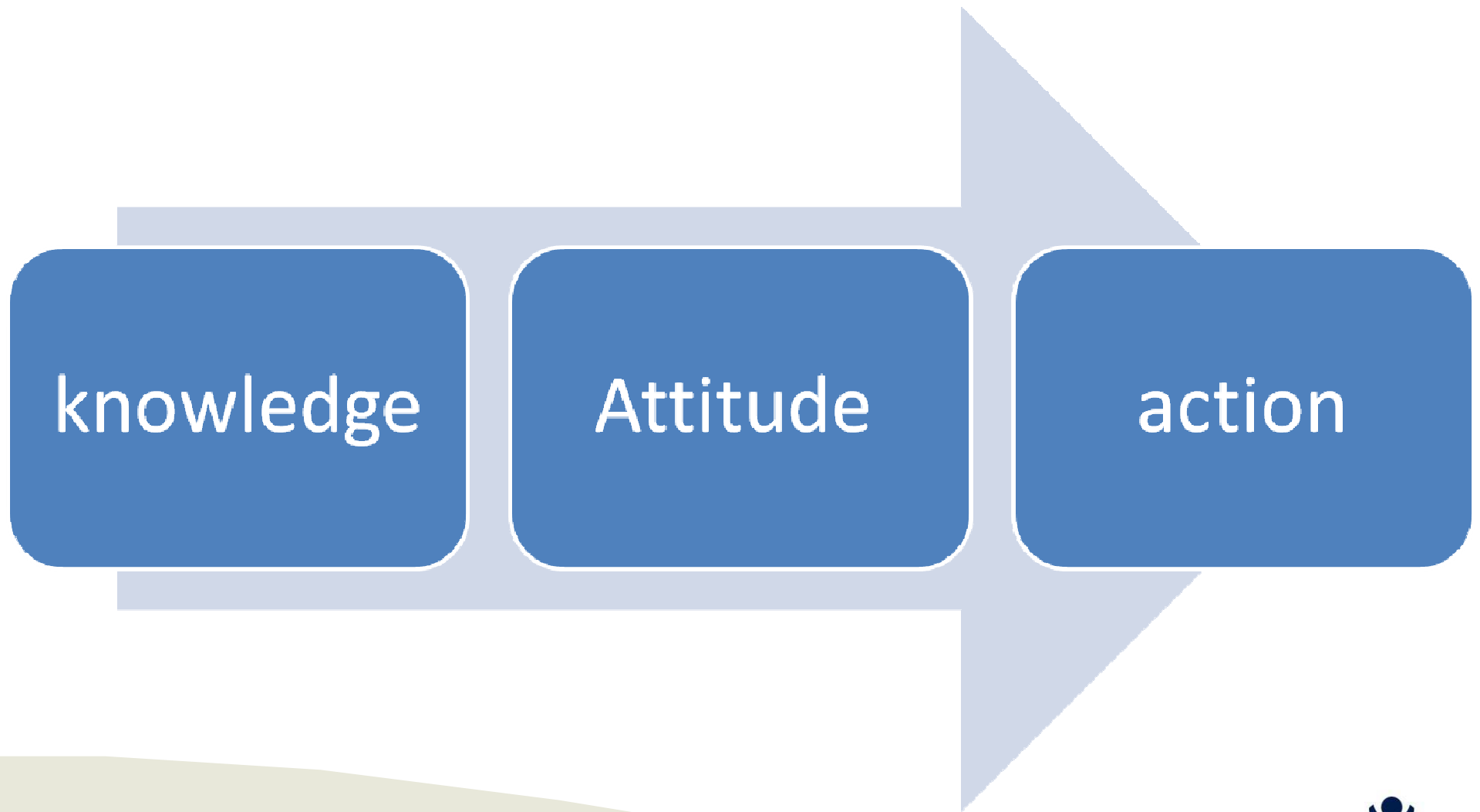
# Train the Trainers

- Minority and non-minority principal investigators should also receive cultural competency training
  - Increase mentorship and recruitment of minority investigators
- Build networks to keep investigators informed of available clinical trial
- Understand the importance of hiring staff from vulnerable populations

# Train the Trainers to...

- Need to form partnerships with community members, potential participants, and other community based investigators
  - Knowledgeable about community, increase trust, credibility and referrals
- Involve community leaders and intended participants in the design, and recruitment and retention efforts
- Use culturally appropriate intervention materials
  - Choose assessment instruments that included minorities in the development and validation process

# Translation



# Cultural Competency as an Action

- **Applying Principles of Cultural Competency to Research on Lesbian Health**
  - Improved recruitment among lesbian women
  - Recruited participants from lesbian organizations
  - Hired lesbians as staff workers
  - Greater retention for follow up breast cancer screening appointments
  - Greater generalizability of results
  - Better data for community, clinical and policy change

Disparities in breast cancer care

# EDICT CLAS-ACT

## ❖ National Standards for Culturally and Linguistically Appropriate Services

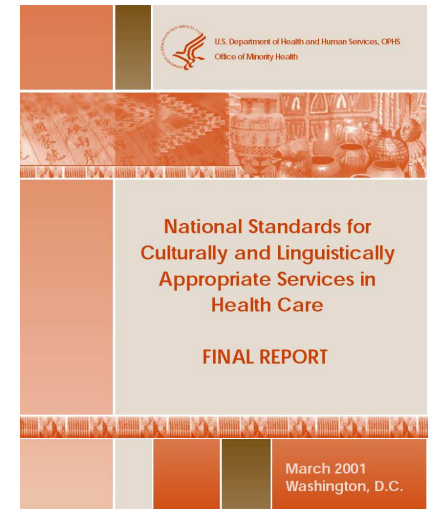
### ..... and Clinical Trials – “CLAS-ACT”

## ❖ CLAS mandates are current Federal requirements for all recipients of Federal funds.

- CLAS guidelines are activities recommended by OMH for adoption as mandates by Federal, State, and National accrediting agencies.
- CLAS recommendations are suggested by OMH for voluntary adoption by health care organizations.

## ❖ Identification of existing evidence-based and promising practices to support those addressing the elimination of disparities in clinical trials.

- Government, Private, Non-profits
- Exemplar sites
- Review process



# Mandatory Standards

- **Standard 4**  
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**  
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**  
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).
- **Standard 7**  
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.

<http://www.bcm.edu/edict>

# Practicing the CLAS Standards

Have all researchers, staff and policy makers formally:

- **Acknowledge their commitment to CLAS standards in their written policies and research guidelines.**
- **Incorporate CLAS standards into their formal professional training, whether for certification or as continuing education.**

# Practicing CLAS Standards

- **Distribute the CLAS standards to all researchers and staff engaged in clinical research under their auspices.**
- **Strive for adherence to the CLAS Standards related to language access services (Standards 4, 5, 6, and 7), diversity of staffing (Standard 2), and maintaining a current demographic, cultural, and epidemiological profile of the community for purposes of recruiting and retaining representative participants in clinical trials**

# Resource Utilization and Diabetes Self-Care

- Researchers and training staff were trained according to the CLAS Standards
- Certified Spanish translators were available for Spanish speaking individuals
- Research materials were translated into Spanish
- Study materials were provided at the appropriate reading level for participants
- Font size was increased to accommodate older study participants

# Resource Utilization and Diabetes Self-Care

- Over a 97% retention rate
- Participants have been willing to participate in other ancillary studies
- Openly discussed health care barriers and status
- Greater investment in study

# Advocacy




- State, municipal, and federal policymakers work with states as they implement state health plans to increase accrual and retention in clinical research of racial and ethnic minorities, socially and economically disadvantaged populations, and others who bear the greatest disease burden.

# Advocacy

- Researcher incentives for conducting of clinical trial research in community health settings
- Medicaid reimbursement for chronic disease prevention and/or management care for clinical trial recipients
- A percentage of patients of all clinical trials include racial and ethnic minorities, socially and economically disadvantaged populations regardless of funding source

# Stroke Management in Acute Care

- Public hospital acute care recruitment site
  - Greater reach for underserved and chronically ill stroke patients
  - Provided self-management services to those who would otherwise not receive them
  - Improved service utilization
  - Working to implement self-management education into acute care treatment model
  - Working with organizations to implement reimbursement for promotoras and self-management education
- 

# Addressing Health Disparities

- The movement toward integrating these recommendations can lead to a improved treatment and health status among vulnerable populations.

# Conclusion

Correct yourself first,  
then you may correct others.

Before you ask another person to change, make  
some changes in yourself.

Too often we ask of others more than we  
demand of ourselves.

[Bava Metzia 107b]

# Special Thanks...



<http://www.bcm.edu/edict>