The EDICT Project:
Policy Recommendations to Eliminate Disparities in Clinical Trials
It has been known for decades that members of certain populations are medically underserved due to many factors, such as age, gender, race, ethnicity, language, and geographic location. These populations also remain “underrepresented” in our nation’s clinical trials, often resulting in clinical research that does not assess how treatments may affect members of specific populations differently.

Addressing any national health concern requires a systematic approach, one that provides assistance not only directly to individuals, but also promotes change at community, organizational, local, state, and national levels.

This strategy underlies the Eliminating Disparities in Clinical Trials (EDICT) Project. Representatives from the public, private and non-profit sectors have collaborated to propose thoughtful and viable policy solutions to the problem of under-representation of certain populations in clinical trials. The EDICT recommendations are designed not only to address the diverse aspects of this problem, but are also specific to the groups and organizations responsible for affecting change.

The goal of this document is to enhance your understanding of the problem of underrepresentation in clinical trials and to help each of us understand our roles in providing a solution.

Sincerely,

Armin D. Weinberg, PhD
Principal Investigator, EDICT Project
Director, Chronic Disease Prevention and Control Research Center
Professor of Medicine
Baylor College of Medicine
Houston, Texas
Introduction

The EDICT (Eliminating Disparities in Clinical Trials) Project developed this booklet to provide an overview of the issues related to “underrepresentation” in clinical trials conducted in the United States. Our ultimate goal is to identify specific policy recommendations that address these disparities and serve as a resource for the broad spectrum of policy makers and those interested in policies affecting clinical trials such as:

- Local, state, and federal governments
- Not-for-profit agencies and foundations
- Pharmaceutical and biotechnology companies
- Medical journals
- Educational and professional organizations
- Employee benefits and insurance trade groups

What is EDICT?

The EDICT (Eliminating Disparities in Clinical Trials) Project was developed to design practical and realizable policy solutions to disparities in participation in clinical trials. The Chronic Disease Prevention and Control Research Center at Baylor College of Medicine is home to this Project, a collaborative endeavor of over 300 individuals nationwide, including medical researchers, healthcare professionals, patient advocates, public health officials and pharmaceutical company representatives who worked together to develop the EDICT policy recommendations.

Specifically, 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.
- Emphasizes a systems approach to identifying both the root causes of disparities and the critical policy makers who could address them.
- Communicates policy recommendations to the widest possible audience using a creative and proactive dissemination model.

This booklet is designed in four sections as listed below:

- SECTION 1 – Background on Issues Related to Disparities in Clinical Trials – page 4
- SECTION 2 – EDICT Policy Development Process – page 8
- SECTION 3 – EDICT Policy Recommendations – page 10
- SECTION 4 – EDICT Complementary Projects, Collaborations and Resources – page 22

“Scientifically, it makes no sense to develop new treatments among populations of patients who are different from those who will be using them.”

Endocrine Society White Paper, December, 2007
SECTION 1
Background on Issues Related to Disparities in Clinical Trials

Why Is It Important to Have Representation of All Populations in Clinical Trials?

Clinical trials are a critical resource for the discovery of new life-saving drugs and for developing better prevention, diagnostic and treatment methods for disease. Many of today’s most effective prevention and treatment modalities are based upon previous clinical trial results. People with low income, the elderly, racial/ethnic minorities, women and those who live in rural areas represent the smallest percentage of clinical trial participants. Unfortunately, these same populations also bear a disproportionate burden of disease.

Without adequate representation of these populations in clinical trials, researchers cannot learn about potential differences among groups and ensure the generalizability of results to the entire U.S. population.

For clinical trials to be useful to all populations, individuals from all backgrounds, racial/ethnic groups, ages and locations need to participate.

Who Is Underrepresented in Clinical Trials?

The following populations are underrepresented in U.S. clinical trials:

- **Elderly**: While nearly two-thirds of cancer patients are age 65 or older, this age group accounts for less than one-third of clinical trial enrollees.

- **Racial/Ethnic groups**: African Americans, Asian/Pacific Islanders, Hispanic/Latinos and Native Americans collectively represented less than 10% of participants in clinical trials testing cancer drugs in 1995-1999, according to an FDA review.

- **Women**: Eight of the ten drugs eliminated from the market in the last decade of the 20th century were removed because of unexpected side-effects that affected women more than men.

- **Children**: A study of thirty-one U.S. pediatric hospitals found that 79% of all patients were given at least one medication that had not been approved for children and was tested only on adults.

- **Adolescents**: Only 10% of 15-to-19 year old cancer patients enter into trials, while 60% under age 15 take part.

- **Low income**: Regardless of race or ethnicity, low socio-economic status has a negative impact on clinical research participation.

- **Those who live in rural areas**: Among patients enrolled in National Cancer Institute (NCI) sponsored trials, investigators found that suburban areas had the highest participation.

- **Others**: Additional populations who are underrepresented in clinical trials include those with special health needs (disabled, chronic illness, co-morbidities) and the uninsured.

The Coalition of Cancer Cooperative Groups evaluated enrollment to NCI treatment trials from January 2003 through June 2005. The data presented below shows accrual rates by racial and ethnic status:

![Enrollment by Race and Ethnicity](image)

**Participant Barriers to Clinical Trials Participation**

Many studies have tried to determine the reason for underrepresentation of certain populations in clinical trials and have identified multiple barriers to participation. The following barriers may work independently or in tandem to keep underrepresented populations from having opportunities to participate in clinical trials:

- **Mistrust**: The historical mistreatment faced by groups such as African-Americans and Puerto Ricans has resulted in mistrust of research and the medical system, and ultimately, underrepresentation.\(^{17,18}\)

- **Lack of awareness**: A national survey of cancer patients found that 85% of respondents were unaware that participating in a clinical trial was an option for them.\(^{19}\)

- **Cultural barriers**: Certain cultures’ non-Western views of health and disease may make clinical trials a less desirable option.\(^{20}\)

- **Language/Linguistic differences**: Many U.S. clinical trials require English proficiency for potential participants, automatically excluding those who do not speak the language.\(^{21}\)

- **Low literacy**: The complexity of consent forms and other clinical trials materials may also be a barrier to those individuals with low literacy.\(^{22}\)

*(Continued on page 6)*
Socio-economic obstacles: Underrepresented populations are more likely to encounter social and economic barriers to participating in clinical trials. Unreliable transportation and living in remote areas may prevent many otherwise eligible patients from participating in clinical trials. Some low income groups have decreased participation due to competing issues such as unpaid work leave and lack of childcare.  

Cost/Lack of insurance: Costs associated with clinical trials are often a concern for potential participants. A study of NCI-sponsored cancer treatment trials found that uninsured patients represented only 5.4% of all clinical trial participants. Even when participants have insurance coverage, many cannot participate due to high out of pocket expenses not covered by their benefit plan.  

Study design eligibility criteria: Traditional clinical trial eligibility criteria typically limits participation of patients suffering from more than one health condition, which in turn often excludes the elderly, members of racial/ethnic groups, and patients with lower socio-economic status.

Physician/Investigator Barriers to Referring Participants to Clinical Trials

Participants are also often excluded from clinical trials due to characteristics, preferences, and circumstances of the physicians who conduct or refer patients to clinical trials.

- Lack of minority investigators: 2004 data show that only 12% of all U.S. physicians are African American, Hispanic/Latino, Asian, or Native American. Yet, these minority groups make up more than 30% of the U.S. population. Minority patients often choose physicians of their own background, but minority physicians are underrepresented as investigators for clinical trials in the United States. Physicians with access to minority patients could be an important source of racial and ethnic minority trial participants.

- Lack of physician referral: Although physician referral is one of the most effective means of recruiting patients to clinical trials, some physicians may be reluctant to refer because they perceive an excessive administrative or financial burden to their practice. Physicians may also hesitate to inform patients of trials based on their own attitudes and beliefs about trials and their assumptions about patient eligibility to enroll according to factors such as age, other existing conditions, cost, or ability to adhere to study protocol.

- Lack of physician awareness: Primary care and specialty physicians who are not affiliated with research institutions may be less aware of patient eligibility for clinical trials. Lack of awareness is one of the most common reasons physicians fail to refer patients to trials.
Policy Efforts to Date that Address Clinical Trials Disparities

It is important to acknowledge that there have been both national and state level initiatives in the past two decades designed to address disparities in clinical trial participation.

NATIONAL INITIATIVES:

• National Institutes of Health (NIH): The NIH Revitalization Act of 1993 requires applicants for federal research funding to provide a strategy for inclusion of women and people of diverse racial and ethnic origin into clinical trials.34 However, more than a decade later, women and minorities continue to be underrepresented at varying levels in clinical trials.23,35 The Act does not address the appropriate representation of other identified underrepresented groups.

• Food and Drug Administration (FDA): The FDA oversees the research conducted to bring all new drugs to the market. The FDA Modernization Act of 1997 provides guidance on standardization of data collection of racial/ethnic groups in clinical trials, but does not address appropriate racial and ethnic inclusion.36 Compliance with this guideline has been optional and relatively low.28 In addition, it does not provide guidance on other underrepresented groups.

• Centers for Medicare and Medicaid Services (CMS): In 2000, CMS authorized payment of routine care costs for Medicare beneficiaries who are participants in clinical trials.37 Yet, the elderly remain among the most under-represented populations in clinical trials today.38

STATE INITIATIVES:

• States: As of 2007, only 20 states in the U.S. required reimbursement of routine medical costs for clinical trial participants by legislative mandates or agreements with large health insurers.39 Many private health insurers are exempt from these mandates.40
SECTION 2
EDICT Policy Development Process

A Framework for EDICT Policy - the Four Rs

The EDICT Project has identified four important issues to consider when developing policy recommendations for clinical trials. Disparities in clinical trials cannot be eliminated without addressing how Recruitment, Retention, Return, and Resources contribute to underrepresentation. The EDICT Project considered many questions in developing policy recommendations for reducing disparities in clinical trials including:

- **Recruitment:** As the first step to participation, what are barriers to recruitment of underrepresented populations and how can healthcare policy be shaped to eliminate these barriers? What are strategies to recruit a more diverse participant population?

- **Retention:** How can clinical trials be designed to address the obstacles that lead to high drop-out rates of underrepresented populations?

- **Return:** Many participants experience limited or no benefit from their participation. What is the benefit for participants and their communities upon conclusion of the trial? What level of responsibility, if any, do researchers and sponsors owe individuals whose participation allowed for the private, intellectual, and societal benefits that are reaped from clinical trials?

- **Resources:** What resources would facilitate greater participation of underrepresented populations? How can the need for these resources be incorporated into planning for clinical trials?

EDICT Policy Development Process

Building upon the Four Rs (Recruitment, Retention, Return, and Resources) and existing policy initiatives, the EDICT Policy Development Process evolved as a systematic approach to resolving challenges and enhancing the benefits of clinical trials participation. This included:

- Assessing policy issues related to clinical trials disparities
- Identifying key experts, stakeholders, and partners
- Convening a National Policy Development Roundtable of stakeholders
- Creation of nine specialized policy teams to develop policy proposals
- Successive internal/external review of proposed policies
- An open public comment period
- Dissemination of policy recommendations through education, communication, and stakeholder engagement
EDICT Policy Context Model of Stakeholders

Based on its Policy Development Process, the EDICT Team created the EDICT Policy Context Model of Stakeholders, shown below. Given the complexity of policy context relating to disparities in clinical trials, the following model was developed to capture the key features of the systems approach.

As the diagram indicates, assisting the underrepresented is at the core of the EDICT Project. Each concentric circle represents a level of stakeholders who must be engaged and involved to promote parity in clinical trials.
SECTION 3
EDICT Policy Recommendations

The next section contains nine areas of policy recommendations. Brief background statements are presented followed by a summary of the policies. More specific details related to each policy, including detailed rationale, background information, and references can be found at the EDICT website: www.bcm.edu/edict.

The various policy recommendations are intentionally designed to target different kinds and phases of clinical trials. The EDICT Project incorporated this understanding into their recommendations.

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

THE CHALLENGE:

• The NIH Revitalization Act of 1993 mandates appropriate inclusion of women and racial/ethnic minorities in clinical trials, but applies only to federally funded research, lacks direct instruction as to what an appropriate plan for inclusion should look like, and does not require appropriate inclusion of other underrepresented populations. Thus, the Act has not translated into measurable improvement in including underrepresented populations in clinical trials.23, 35

• The FDA Modernization Act of 1997 provides guidelines on the standardization of data collection of racial and ethnic minorities participating in clinical trials without requiring appropriate racial and ethnic inclusion. Compliance with this guidance has been optional and relatively low.28 In addition, it does not address other identified underrepresented groups.

• The National Standards on Culturally and Linguistically Appropriate Services (CLAS), developed in 2000 by the Department of Health and Human Services (DHHS) Office of Minority Health (OMH) to promote culturally competent health services, are currently not addressed consistently or systematically, if at all, in clinical trials.41
RECOMMENDATIONS:

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

**National Institutes of Health (NIH) should:**

✔ Provide more direct instruction on appropriate inclusion plans for all underrepresented populations in clinical trial protocols.

✔ Provide substantial incentives for implementing appropriate inclusion plans.

**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.

**Federally and privately funded sponsors of clinical trials should:**

✔ Adopt the DHHS OMH National Standards on Culturally and Linguistically Appropriate Services (CLAS).
II. Collaboration with the Pharmaceutical Industry

THE CHALLENGE:

• Clinical trials supported by the pharmaceutical industry, representing over 75% of all trials,\textsuperscript{42} are not subject to the NIH Revitalization Act that mandates inclusion of certain underrepresented populations such as women and racial/ethnic minorities in clinical trials.\textsuperscript{34} Thus, many clinical trials sponsored by the pharmaceutical industry do not have appropriate representation of underrepresented populations.

• Current investigators generally lack strong community relationships needed to recruit members of underrepresented populations.

• Some patients may be discouraged from participating in clinical trials due to the dearth of minority investigators conducting clinical trials, an important source of racial and ethnic minority trial volunteers.

• Potential participants may not feel the possible benefits to their community justify participating in clinical trials.\textsuperscript{43}

RECOMMENDATIONS:

Because clinical trials with diverse representation assure better scientific evidence:

The Pharmaceutical Industry should:

✓ Require investigators to have the subject population include members of underrepresented communities that appropriately correspond to the proportions such communities comprise in the targeted population.

✓ Select and develop investigators with the capability of achieving appropriate diversity of inclusion based on the population served.

✓ Require that clinical trial plans take into account how the affected communities will receive information and other benefits as a result of the trial.
III. Fostering Community Involvement in Clinical Trials

THE CHALLENGE:

• Communities are generally not involved in prioritizing the concerns or the design of clinical trials, as they are engaged by researchers only after research funding has been secured.44

• When communities do participate in clinical trials, little or no communication of study results and the implications for their specific communities is received.45

• Communities indicate a lack of trust in the medical system that could be rectified through involvement in research planning and implementation.46

• Communities indicate a lack of awareness of clinical trials.47

RECOMMENDATIONS:

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

Public and private sponsors of clinical trials should:

✔ Require demonstration in the protocol 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.

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.
IV. Role of Biomedical Publications in Setting Standards for Inclusion in Clinical Trials

THE CHALLENGE:

• Discussion of diversity, inclusion, and representation in clinical trials is often missing from published studies.

• Journal editors and publication editors must be informed of the rationale for eliminating disparities in clinical trials on the grounds of scientific rigor, social justice, and business interests.

• The two chief editorial organizations for biomedical publications, the International Committee of Medical Journal Editors (ICMJE) and the World Association of Medical Editors (WAME), who set standards for appropriate publication policies, do not address disparities in clinical trials.

• The CONSORT (Consolidated Standards for Reporting Clinical Trials) Statement, a checklist developed by investigators and editors of the CONSORT Group to provide an evidence-based, minimum set of standards for authors to improve the reporting of randomized controlled trials, does not address disparities in clinical trials.

RECOMMENDATIONS:

Because publications provide a forum for enhanced awareness, discussion and analysis of disparities in clinical trials:

The International Committee of Medical Journal Editors and the World Association of Medical Editors should:

✔ Adopt standards that require authors to include in their manuscripts an analysis of how the subject population’s demographics correspond to those of the population that bears the disease burden.

The Consolidated Standards for Reporting Clinical Trials group should:

✔ Adopt standards for the CONSORT Statement checklist for authors to include in their manuscripts an analysis of how the subject population’s demographics correspond to those of the population that bears the disease burden.
Part 1. Professional Education – Researchers and Healthcare Professionals

THE CHALLENGE:

• Institutional clinical research training required of federally funded researchers lacks sufficient training regarding disparities in clinical trials.

• Education for health professionals, including allied health, nursing and medicine, as well as continuing education for health professionals, does not provide sufficient information on clinical research in general, culturally and linguistically appropriate care, or the specific manifestations of disparities in clinical trials.

RECOMMENDATIONS:

Because enhancing education of research investigators and all health professionals is essential for eliminating disparities in clinical trials:

Institutions that mandate clinical research training should:

✔ Include modules addressing the existence of disparities and providing practical strategies for ameliorating them.

Accrediting organizations for undergraduate, graduate, and continuing education of health professionals should:

✔ Require education addressing basic principles of clinical research, culturally and linguistically appropriate care, and disparities in clinical trials.

Providers of continuing education for health professionals should:

✔ Incorporate into their education programs basic principles of clinical research, culturally and linguistically appropriate care, and disparities in clinical trials.
Part 2. Professional Education – Members of Institutional Review Boards (IRBs)

THE CHALLENGE:

• Although it is the responsibility of Institutional Review Boards (IRBs) to review and approve all research protocols before clinical trials begin, IRB members often lack training to recognize disparities in protocols and the scientific and ethical implications of these disparities.

RECOMMENDATIONS:

Because education of IRBs is crucial to eliminating disparities in clinical trials:

The Association for the Accreditation of Human Research Protection Programs (AAHRPP) should:

✔ Ensure that Institutional Review Boards (IRBs) receive training in health care disparities in general and disparities in clinical trials specifically.

The Office of Human Research Protections (OHRP) in the Department of Health and Human Services (HHS) should:

✔ Issue policy guidance materials designed to enhance IRBs’ knowledge of the inclusion of underrepresented populations in clinical trials.
VI. Reallocate Research Funding to Avoid Duplication and Address Disparities

THE CHALLENGE:

• Approximately 75% of funding for clinical trials in the U.S. comes from corporate sponsors, 20% from federal funds, and 5% from non-profit organizations. Economic considerations dictate funding decisions in the private sector; political considerations dictate funding policy in the public sector.

• There is a significant duplication of effort in clinical trials funded by the federal government and private industry sponsors, resulting in insufficient attention and resources for trials addressing diseases such as liver and kidney cancers, where there are significant disparities in outcomes and high fatality rates. This approach to resource allocation leaves many populations underrepresented in clinical trials.

• There is no defined, formal way of making allocation decisions for funding clinical trials in the public, private, or non-profit sectors.

• On the state level, priorities for research/clinical trials funding are often addressed in individual state health plans. Few states, however, have addressed disparities in clinical trials when allocating state resources.

RECOMMENDATIONS:

Because identifying and eliminating duplicative funding is integral to eliminating disparities in clinical trials:

Congress should:

✓ Ensure that federal research funding complements private sector funding, and gives priority to diseases with the greatest disparities and the highest case fatality rates.

✓ Request that the Institute of Medicine conduct a study to investigate duplication of clinical trials funding among public, private, and nonprofit sectors, and recommend strategies for eliminating duplication and promoting coordination.

Because state health plans’ attention to disparities in clinical trials is crucial to their elimination:

State, municipal, and federal policymakers should:

✓ Work with states as they implement state health plans in order to increase participation of underrepresented populations in clinical trials.
VII. Enhancing Public Education about Clinical Trials in Communities

THE CHALLENGE:

- Mistrust and lack of awareness are significant barriers to clinical trial participation among underrepresented populations, yet efforts to enhance patient and public information on clinical trials are infrequent, inconsistent, and seldom follow recommended culturally and linguistically appropriate guidelines.  

- Low literacy presents a barrier to potential clinical trials participants as the complexity of educational materials, consent and other medical information forms often exceeds the reading skills of many individuals.

- Local community members are rarely consulted by clinical trials teams to provide advice on culturally and linguistically appropriate recruitment methods and educational materials.

RECOMMENDATIONS:

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.
VIII. Navigation and Support of Individuals in Clinical Trials

THE CHALLENGE:

• Patient navigators help to eliminate the barriers related to access, diagnosis, and treatment within the complex and fragmented healthcare system by providing personalized education, direction and support to patients and their families.52

• There is an increasing necessity for navigation of the special needs of participants in clinical trials. “Clinical Trials Navigation” is a relatively new concept whose services represent a crucial liaison between investigators, subjects and communities.

• Clinical Trials Navigators may be healthcare professionals, social workers, cancer survivors or other lay persons from the community. Because of the diverse background of those entering this work, there is a need to institute basic training to establish the core knowledge and skills they need.

• Elevating Clinical Trials Navigation to a standard of practice for institutions conducting clinical trials, including dedicating funds to deliver these services, would incorporate this approach as a routine part of clinical trials design and protocols.

RECOMMENDATIONS:

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.
Part 1. Assuring Insurance Coverage for Costs Associated with Clinical Trials – Private Insurance

THE CHALLENGE:

• Insured patients may not elect to enroll in clinical trials when they learn their health plans do not cover the full cost of clinical trials.

• Although insurance companies cite cost as a concern for lack of clinical trial coverage, numerous studies have shown that the cost for a patient to take part in a cancer clinical trial is not necessarily more expensive than standard care.53,54

• Most employer insurance plans are exempt from state coverage mandates to cover clinical trials under federal benefits laws.

• Both employer benefits staff and employees may lack knowledge of clinical trials and their coverage.

RECOMMENDATIONS:

Because lack of private insurance coverage is a significant barrier for underrepresented populations to participate in clinical trials:

Business groups and associations should:

✓ Request that employer members provide coverage for clinical trials.

Employers should:

✓ Ensure that coverage is accessible and usable by the employee.

Employee benefit or insurance trade groups should:

✓ Request their members educate benefit managers on clinical trials coverage.
Part 2. Assuring Insurance Coverage for Costs Associated with Clinical Trials – Medicare, Medicaid, and SCHIP Coverage

THE CHALLENGE:

- In 2000, the Center for Medicare and Medicaid Services (CMS) authorized coverage of standard costs associated with clinical trials participation for Medicare beneficiaries, but did not require covered protocols to include underrepresented populations.37

- Medicaid does not have universal standards for covering clinical trial participation, although several states document the provision of this coverage under their Medicaid program.39

- The State Children's Health Insurance Program (SCHIP) coverage of clinical trials varies by state and no comprehensive data exists on overall coverage.

- Neither states that mandate insurance coverage of clinical trials nor CMS provides education regarding this benefit.

RECOMMENDATIONS:

Because limitations of public insurance coverage are a significant barrier for underrepresented populations:

Congress should:

- Expressly authorize CMS to adopt policies linking Medicare coverage of costs associated with clinical trials to sponsors' and research teams' certification that protocols contain specific plans and demonstrated capacity to ensure appropriate inclusion and representation of populations underrepresented in clinical trials.

Centers for Medicare and Medicaid Services (CMS) should:

- Develop a reporting mechanism to gather and disseminate information on existing state coverage for clinical trials in Medicaid and SCHIP.

- Encourage Medicaid and SCHIP programs to adopt Medicare standards on clinical trials coverage, and gather and disseminate that information.

- Ensure that Medicare beneficiaries have education and information about clinical trials coverage.

States mandating clinical trials coverage should:

- Mandate that insurers educate policyholders of coverage status for clinical trials.

For more information on the EDICT Project and its policy recommendations, please visit our project website: www.bcm.edu/edict.
EDICT Complementary Projects:

Following the early success of the EDICT Project, the Department of Health and Human Services (HHS) Office of Minority Health (OMH), Office on Women's Health (OWH) and NIH National Center for Minority Health and Health Disparities have supported two additional projects for use by researchers, pharmaceutical companies and non-profit organizations.55

- **EDICT CLAS-ACT** (Culturally and Linguistically Appropriate Services And Clinical Trials): The CLAS-ACT Project is designed to help researchers and organizations self-assess how well they incorporate the HHS National Standards on Culturally and Linguistically Appropriate Services in designing new clinical trials and recruiting minority patients. The EDICT CLAS-ACT Self-Study Handbook, the Individual and Institutional Research Self Studies, and additional CLAS resources are available on the CLAS-ACT website: [www.bcm.edu/edict/clas-act](http://www.bcm.edu/edict/clas-act).

- **EDICT BackPack**: BackPack identifies, compiles, and makes available projects, programs, best or promising practices, policies, and other resources that have demonstrated to help eliminate disparities in the recruitment and retention of underrepresented groups in clinical trials. For additional information, or to contribute a best practice, visit the BackPack website at: [www.bcm.edu/edict/backpack](http://www.bcm.edu/edict/backpack).

Other Complementary Projects:

- **EDICT Recognition Program**: This program is designed to recognize institutions, organizations, corporations, and agencies (public, private, and non-profit groups) that consistently demonstrate policies, programs, and commitment to systematically include underrepresented populations in clinical trials. For more information, visit [www.bcm.edu/edict](http://www.bcm.edu/edict).

- **EDICT Fellowships**: These fellowships provide an opportunity for post-doctoral students to gain experience in health policy related to clinical research and disparities. For more information on the fellowships, visit [www.bcm.edu/edict](http://www.bcm.edu/edict).
EDICT Collaborations:

The EDICT Project continues to identify opportunities to address disparities in clinical trials by building partnerships and relationships with a variety of national organizations. These partnerships are designed to promote education and awareness to reduce disparities in clinical trials.

Examples of EDICT collaborations include:

- **National Medical Association (NMA)** – EDICT works with NMA’s Project IMPACT to increase awareness among African American physicians of opportunities to participate in clinical research.

- **Education Network to Advance Cancer Clinical Trials (ENACCT)** – EDICT has partnered with ENACCT and the Community-Campus Partnerships for Health to sponsor an invitational conference series, “Communities as Partners in Changing Clinical Trials: Changing Research, Practice, and Policy.”

- **Society of Clinical Research Associates (SoCRA) Partnership** – EDICT collaborates with SoCRA to educate clinical research professionals about disparities in clinical trials.

If your organization would like to collaborate with the EDICT Project, please contact: edict@bcm.edu.

EDICT Resources:

The EDICT Website, at [www.bcm.edu/edict](http://www.bcm.edu/edict) serves as a central repository, giving public access to Project information, resources, and policy recommendations.

- **EDICT Reading Room** – EDICT has created a virtual library, to compile and share short informational writings about the various aspects of clinical trial disparities and strategies to overcome them.

- **Online Resource Center** – This online resource compiles links to governmental, private sector, and non-profit resources on clinical trial disparities and the associated issues. Resources include webcasts of prior EDICT events.

- **EDICT Network** – While engaging in the EDICT process, policy makers and healthcare professionals have coalesced as a network of individuals that focus on changing policies and procedures relating to eliminating disparities in clinical trials.

To Participate in the EDICT Process:

To join the EDICT mailing list, for new policies and resources, or to assist with EDICT policy education and dissemination in your area, please visit the EDICT homepage at [www.bcm.edu/edict](http://www.bcm.edu/edict).
References


EDICT Credo:

The following beliefs guide our work together:

• Everyone should have the opportunity and necessary support to participate voluntarily in clinical trials for which they are eligible.

• Participants and researchers should understand the benefits of diversity in clinical trials.

• Results from clinical research should benefit the participants’ communities and society at large.

Baylor College of Medicine

Faculty and staff of the Chronic Disease Prevention and Control Research Center at Baylor College of Medicine have over 25 years experience developing and applying proven bio-behavioral research models among culturally diverse, at-risk populations.

www.bcm.edu/edict

Intercultural Cancer Council (ICC)

ICC is a national coalition of experts, advocates and organizations. The ICC promotes policies, programs, partnerships, and research to eliminate the unequal burden of cancer among racial and ethnic minorities and medically underserved populations in the United States and its associated territories.

The ICC has presented the “Biennial Symposium on Minorities, the Medically Underserved & Cancer” since 1987.

www.iccnetwork.org
The EDICT Project is conducted by the Chronic Disease Prevention and Control Research Center at Baylor College of Medicine in collaboration with the Intercultural Cancer Council (ICC).

The EDICT Project is funded by an unrestricted educational grant from Genentech, Inc.