



## Introduction

If clinical trials are to be useful to all groups, people from all backgrounds, races, ages and locations need to participate. Disparities in clinical trials result in deficient information and inadequate understanding of whether and how drugs affect various groups differently.

In addition to bearing a disproportionate burden of disease, certain groups are underrepresented among clinical trial participants. Examples include people who are of low income, elderly, racial/ethnic minorities, women, and residents of rural areas. Without adequate representation of these groups in clinical trials, researchers cannot learn about potential differences between groups and ensure the generalization of results to the entire US population.<sup>1-6</sup>

Eliminating disparities in clinical trials is therefore important to reducing health disparities in general by providing better scientific information, using resources more efficiently, and increasing treatment effectiveness of new drugs.<sup>7,8</sup>

Traditional scientific and academic channels of communication alone are probably not adequate to address disparities in clinical trials. It often takes longer than 17 years for patients to benefit from as little as 14% of original research.<sup>9</sup> Therefore, it is also necessary to reduce the time lag between research on improving recruitment of underrepresented groups

to clinical trials and the implementation of lessons learned from that research.

## EDICT<sup>10</sup>

Eliminating Disparities in Clinical Trials (EDICT) is a four-year project (2005-2009) of the Chronic Disease Prevention and Control Research Center (CDRC) at Baylor College of Medicine and the Intercultural Cancer Council (ICC).<sup>11,12</sup> The EDICT Project was designed to develop practical and realizable policy solutions to the problem of clinical trial disparities, through which change can occur at the federal, state, and institutional levels as well as in the public, private, and non-profit sectors. The project has two arms – policy research and field research – which provide both a theoretical and practical basis for policy recommendations.

## The BackPack Project<sup>13</sup>

There have been a variety of excellent efforts to assess and document best and promising practices related to reducing disparities across an array of health and medical areas.<sup>14-22</sup> However, these resources are frequently focused only on a single disease or problem area. They are often known and accessible only to specialists or those who are already familiar with the field. Furthermore, successful activities are usually reported only at professional conferences or in scientific journals. These are not easily accessible or useful to the professional and community based practitioners

actively engaged in clinical trials recruitment “on the ground” in traditional clinical venues.

Therefore, building on the successful approach of the EDICT Project, the

CDRC initiated the Backpack Project in 2007 with initial funding from the Department of Health and Human Services (DHHS) Office of Minority Health (OMH).

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**The goals of the EDICT Backpack Project are:**

- To identify and compile policies, best or promising practices, programs, projects, and other resources that have been demonstrated to help eliminate disparities in the recruitment and retention of underrepresented groups in clinical trials; and
- To make these resources available to researchers, advocates, policy makers, and healthcare providers who are actively involved in various levels of conducting clinical trials.

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**BackPack contents include the following definitions and examples:**

**Policy**

- Adopted action plan
- Formal guideline, principle, or mandate.

**Practice**

- Translation of a policy into action.
- Institutional requirement that all new employees attend a training program on cultural competence.

**Program**

- A system of projects or services designed to meet a public need
- A set of practices designed to implement a policy.
- Classes or a course of study for staff to ensure culturally and linguistically appropriate patient care.

**Resources**

- Articles
- Brochures
- CDs or DVDs
- Training materials
- Videotapes

## TIMELINE OF EDICT BACKPACK ACTIVITIES

BackPack Project Staff have worked closely with the OMH and BackPack Advisory Group since April 2007. The timeline of EDICT BackPack Project Activities is as follows:

### *April – June, 2007*

Project Staff invited selected individuals to serve on the BackPack Advisory Group. In addition to the first Advisory Committee meeting in Houston, May 7, the group participated in several WebEx conference calls.

### *June – September, 2007*

Project Staff developed a work plan with methods and a timeline. A subgroup was formed to develop evidence based eligibility criteria for best or promising practices to be considered for inclusion in the BackPack. Project Staff engaged in regular conference calls to discuss eligibility criteria with OMH and Advisory Group members. A database was created of key non-profit, public and private organizations, agencies, and other entities.

### *September, 2007*

The Advisory Committee met in Houston on September 18, during the EDICT fall conference.

### *October – December, 2007*

Small group meetings were held to discuss the:

- Refinement of eligibility criteria and the
- Nominations database, in which additions continue to be made.

### *January – March 2008*

In February 2008, BackPack Project staff invited more than 600 people to

nominate best policies, programs, practices, and/or other resources that help reduce disparities in clinical trials participation. The invitations were sent in three waves, including approximately:

- 120 individuals identified as knowledgeable about clinical trials in the private (pharmaceutical industry), public (government), and non-profit (national organizations) sectors;
- 100 members of the ICC; and
- 400 participants in previous EDICT meetings and work groups.

Respondents replied via the BackPack Nominations Website<sup>23</sup> and e-mail. Using the following criteria, nominations were reviewed by Project Staff and volunteer experts for evidence that the policies, practices, programs, or other resources have:

- demonstrated one or more positive outcomes regarding increased recruitment and retention of diverse populations in clinical trials;
- published or disseminated results to the public in some way; and
- manuals, guides, tools, strategies, training materials, etc., that are available to the public

If the nominations have met these criteria, they are included in the EDICT BackPack.

### *April, 2008*

The EDICT BackPack was announced nationally in Washington, D.C., at a press conference and at the 11<sup>th</sup> Biennial Symposium on Minorities, the Medically Underserved & Cancer.

**FOR MORE INFORMATION:**

Examples of BackPack policies, practices, programs, and other resources can be found at the BackPack Website (<http://www.bcm.edu/edict/backpack>).

Project staff are always looking for more nominations to include in the BackPack. If you know of good examples, please complete the online nomination form at:

<http://ww.bcm.edu/edict/backpack/nominations>

For more information about the EDICT BackPack Project, contact:

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