

# Enhancing Minority Participation in Clinical Trials: Strategies & Resources

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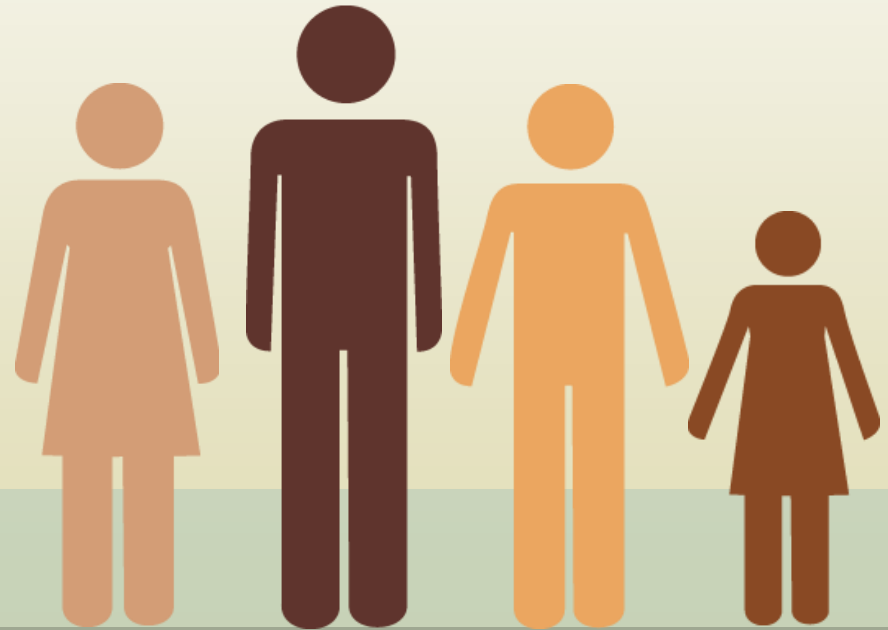
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*Schools of Nursing, Medicine*

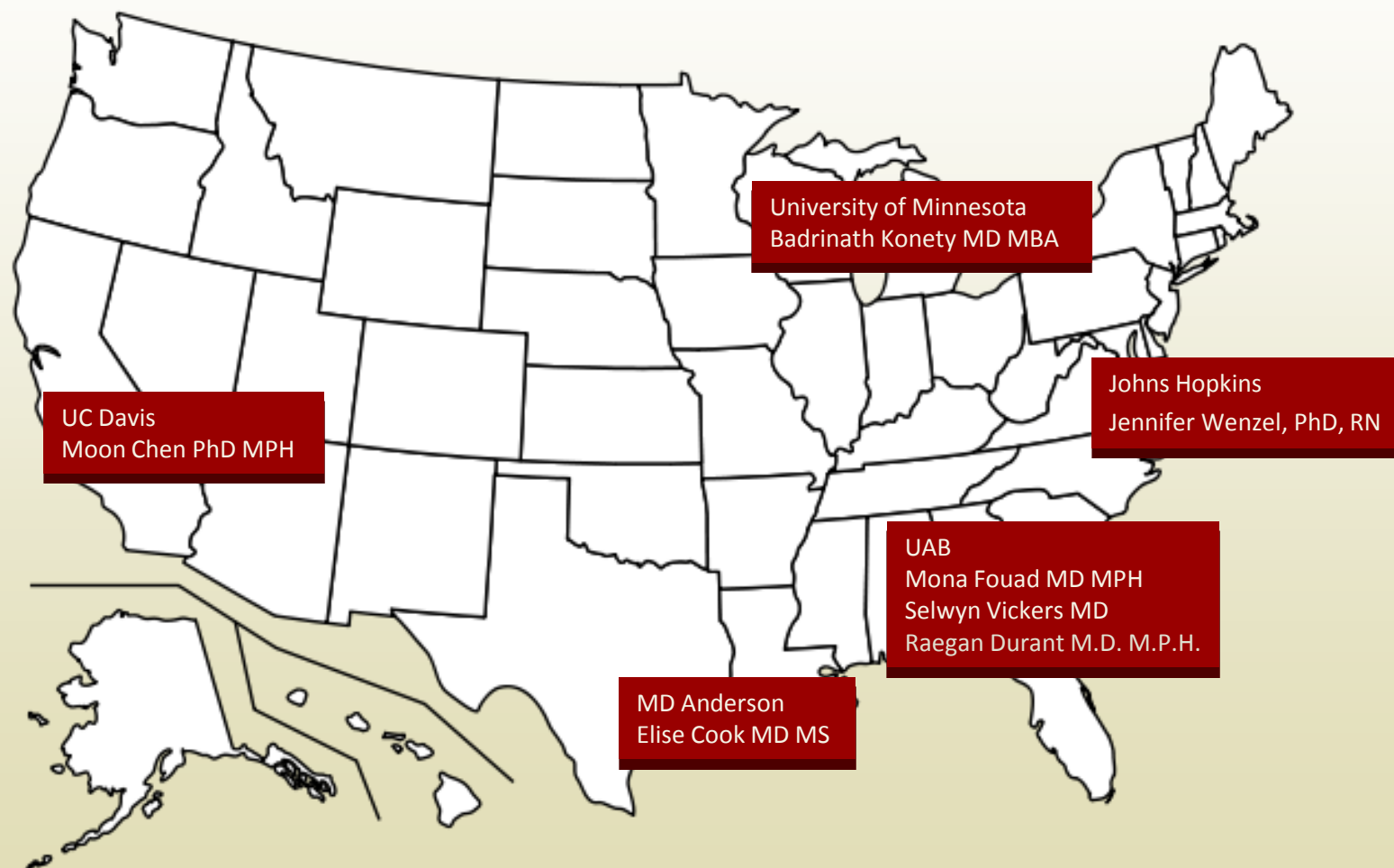
*Johns Hopkins University; Baltimore, MD*

# EMPACT

Enhancing  
Minority  
Participation  
in Clinical Trials



# EMPACT Sites & Principal Investigators



# Rationale for Minority Recruitment Focus

## Methodological

- Increase generalizability of study results to traditionally underrepresented populations
- Generation of new hypotheses regarding racial differences in cancer prevention, diagnosis, or treatment

## Ethical

- Equal sharing of risks and benefits of trial participation
- Access to potentially life-saving or life-prolonging, cutting-edge therapies

# EMPaCT Needs Assessment

## Qualitative Needs Assessment



**Outstanding minority recruitment needs**  
**Barriers/facilitators**  
**Best practices**



## Quantitative Needs Assessment



**Minority recruitment trends**



**Action: Create a menu of adaptable options  
for optimization of minority recruitment and  
retention**



**Dissemination of options to improve minority  
recruitment by EMPaCT sites to other cancer  
centers and institutions**

Durant et al. *Cancer*. 2014;120: 1097-0142; Hawk et al. *Cancer*. 2014;120: 1097-0142.

# EMPaCT Web Portal Resources

**Web portal** designed to:

- a) include web-based training modules customized for investigators, research staff, referring physicians, and patient navigators**
- b) provide resources for recruitment and retention**
- c) serve as communications and information hub, in order to address identified barriers to recruitment and retention of minorities into therapeutic cancer clinical trials**

# www.empactconsortium.net

## EMPACT

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## Increasing Awareness of Opportunities for Trial Participation

An EMPACT training course.  
[Start this Training Course](#)



**Our Goal**  
The mission of EMPACT is to increase recruitment and retention of racial/ethnic minority populations in clinical trials with the ultimate goal of reducing cancer-related health disparities.

### FEATURED TRAINING COURSE



#### Successful Models for Minority Recruitment

Based on Dr. Jean Ford's  
model.

### FEATURED COURSE MATERIAL



#### Defining and Identifying Cultural Factors Affecting Recruitment

### FEATURED NEWS



#### Enrollment in Clinical Trials Improves Survival

## EMPACT

# Web Portal Courses

- **Successful Models for Minority Recruitment**
- **Increasing Awareness of Opportunities for Trial Participation Among Minority Participants**
- **Assessing Effectiveness of Minority Recruitment Efforts**
- **Cultural Competency**



AUDIENCE: PATIENT NAVIGATORS, PRINCIPAL INVESTIGATORS, REFERRING CLINICIANS, RESEARCH STAFF

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# Patient Navigation

**Goal:** Implement and evaluate a **Patient Navigation Program** designed to increase recruitment and retention of minority patients into therapeutic cancer clinical trials

## Patient Navigators

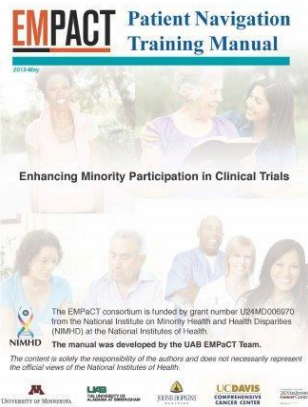
- Provide clinic-based information about trials to minority patients
- Support minority patients enrolled in clinical trials
  - Logistical barriers
    - Utilizing resources available within cancer centers
    - Referral to existing community resources
  - Cultural considerations
  - Emotional support



# Patient Navigator Training

**Patient Navigator & Supervisor training includes:**

- Didactic content with introduction of the EMPACT Patient Navigation Manual
- Role play to simulate patient-navigator interactions
- Videotaped interviews with clinical investigators
- Discussion panel of navigators
- Small group discussions



# Patient Navigation Training Manual

## Clinical Trials

- Participation
- Barriers
- Process
- Types
- Phases
- Protocols
- Randomization
- Advancing Care
- Participant Protection (IRB, DSMB, Informed Consent, HIPAA)

## Patient Navigation

- Enhancing Minority Participation in Clinical Trials
- Intervention Levels
- Integration in Cancer Clinics and Clinical Trials
- Resources for Patients
- Record Keeping and Data Tracking

## Skills

- Effective Communication
- Setting Boundaries
- Coordination of Care

# Training Content

## Phase 1: Pre-training assignments

**Review of EMPaCT:**

**Patient Navigation Manual sections:**

- 1) The Clinical Trial Process
- 2) Patient Navigation
- 3) Barriers to Participation among Racial and Ethnic Minorities

**Manual of Operations and Procedures**

- 1) Protocol for Referral to Patient Navigators
- 2) Initiation of Navigator-Patient Relationship
- 3) Continuing Education
- 4) Integration of Patient Navigation Program into Cancer Center

**Discussions with existing navigation supervisory staff who are familiar with EMPaCT.**

## Phase 2: Video Conference Training

**Topics [didactic & interactive formats]:**

- Role of Navigator
- Compassion Fatigue
- Problem Solving
- Communication Skills
- Review and Feedback

### Patient Navigation

### Manual of Operations and Procedures

July 2014

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**EMPaCT**

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**EMPaCT**

# Views from the Field

I will have to say, we haven't had good training for, for our investigators at any level, not just minority recruitment. It's sort of been a little bit by osmosis



**Cancer Center Leader**

... I don't specifically recall training per se. I don't know how to talk to somebody or if things like that I don't think we've ever really-- I don't remember participating in stuff like that



**Referring Clinician**

The biggest problem that I've seen here.... there are so many portals that people come through. And so it's very difficult to identify sometimes all the different areas where there may be people eligible for your study



**Principal Investigator**

There may have been a piece in my original training for this job five years ago. But again...focus was never recruiting



**Research Staff**



# EMPACT

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**“YOUR OPPORTUNITY TO  
MAKE A DIFFERENCE”:**

**A Model of Cancer Clinical Trial  
Decision-Making**



# Background



- Racial & ethnic minorities in the U.S. experience **higher cancer incidence & mortality**
- 3-5% of adult cancer patient participate in clinical trials; fewer than 10% are racial & ethnic minorities
- African American men & women only **60% as likely as Whites to enroll** in a therapeutic trial; men are least likely
- Research focus has been on barriers & facilitators

# Patient Perspectives

*The overriding influence, I think, didn't come from a medical practitioner. It came from my wife who was saying, no, no, no."*



**Decliner**

*Black people, black men of my age cannot forget the Tuskegee experiment either... I do understand having somewhat of a scientific background, the need for research... So there is a profound need for us, let me include myself, to step up to the plate to give the scientists information about new initiatives, new drugs, new medicines, and so forth...*



**Decliner**

*I think when they have trials like that, that should be offered before you go through your other stuff. You know, that would be your opportunity to make a difference. But they wait until you go through all this stuff, and then offer you a trial."*



**Acceptor**

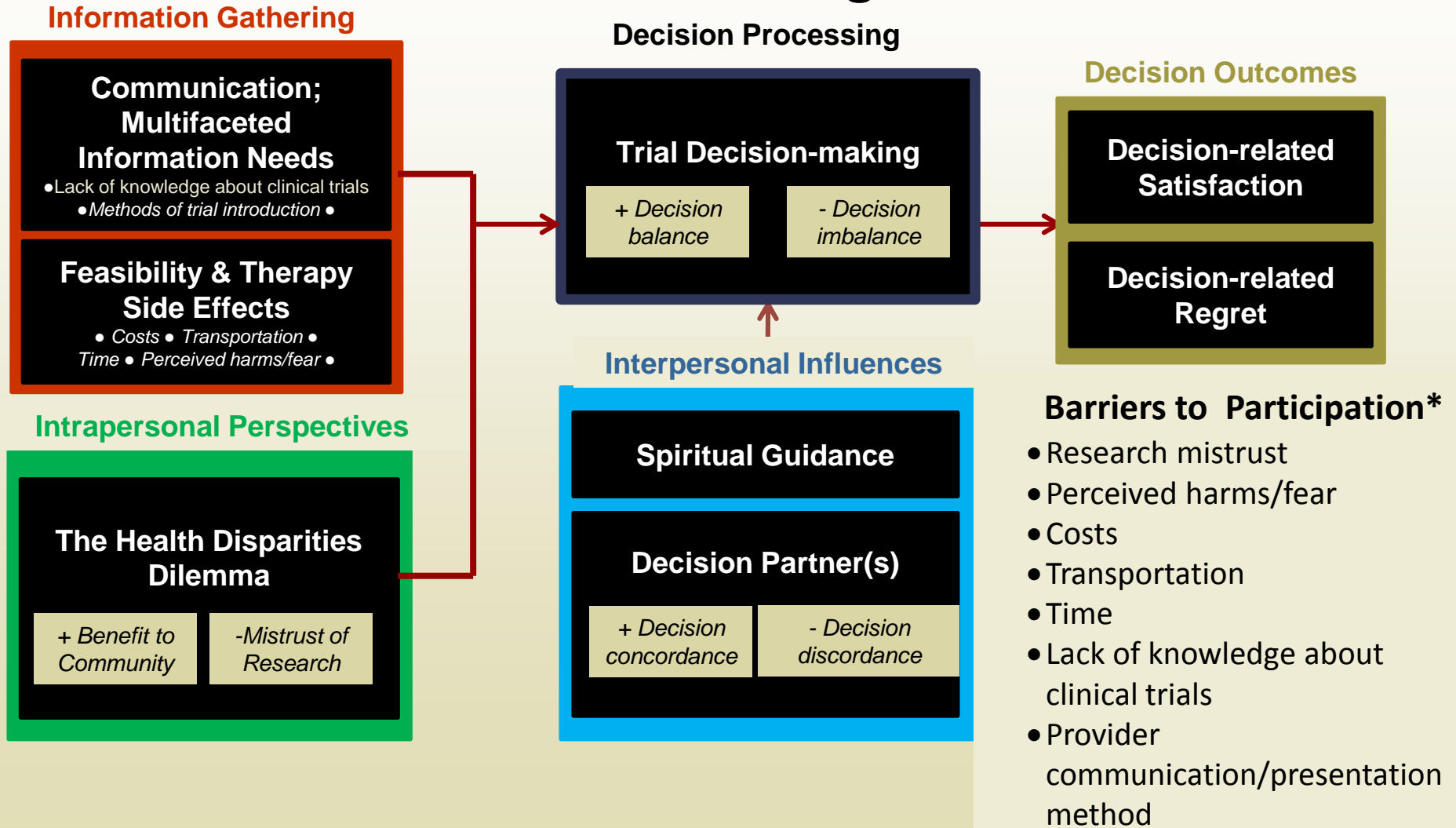
*I think I would have liked to have been better informed....I maybe would have said, 'dang, if I'm going to be that sick I mean, oh, well maybe I should have done the clinical trial.' Maybe I would have been able to help the next person or even myself...*



**Decliner**

# A Model of Cancer Clinical Trial Decision-Making

Wenzel et al., 2015



\*Ford et al., 2008



# Preparation for Decision-making Tool

## Decision Processing

Rating: Not at all (1) A little (2) Somewhat (3) Quite a bit (4) A great deal (5)

Did the Clinical Trial navigation. . .

1. Help you recognize that a decision needs to be made?
2. Prepare you to make a better decision?
3. Help you think about the pros and cons of clinical trial enrollment?
4. Help you think about which pros and cons are most important?
5. Help you know that the decision depends on what matters most to you?
6. Help you organize your own thoughts about the decision?
7. Help you think about how involved you want to be in this decision?
8. Help you identify questions you want to ask your provider or research staff?
9. Prepare you to talk to your provider/research staff about what matters most to you?
10. Prepare you for a follow-up visit with your provider or research staff?

*Preparation for Decision Making Scale (Graham, O'Connor 1996, revised 2005;  
Wenzel et al. revised 2015 with permission of authors) University of Ottawa.*

# On behalf of the EMPaCT Consortium: Thank You!

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