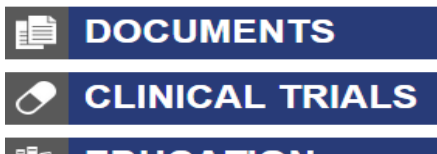


Recruitment/ Retention for Underrepresented Minorities/Ethnicities Advisory Working Group

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Advisory Working Group Members

- Maggie Baker
- Claire Binley
- Devin Brown
- Dorothy Edwards
- Dawn Kleindorfer
 - (Co-Chair)
- Patricia Tanzi
- Salina Waddy
- Olajide Williams
- Michael Parides
- Jose Romano
- Bernadette Boden-Albala (Chair)



Working Group's Mission

- Provide resources and guidance ensuring that StrokeNet trials **describe/implement plans** to **support** and **optimize** the recruitment and retention of underrepresented groups, e.g., racial-ethnic minorities and women.

Support:

- Evaluate if investigators have access to these populations
- To monitor recruitment of trials as they move forward to “catch” any recruitment problems as they arise

Optimize:

- Provide tools needed to bring in target populations
- Ensure that trial design, site selection, statistical analysis plans are inclusive of racial-ethnic minorities and women

Support: Minority Recruitment and Retention

- **1. Site selection guidance**
 - Help investigators identify and obtain access to the populations (information to make reasonable decisions)
 - Guidance on site selection criteria
- **2. Creating/evaluating minority recruitment/retention plans**
 - A. Trial mechanics
 - How your study design might influence recruitment and retention
 - B. Researcher Narrative
 - C. Statistical plan

Minority Recruitment and Retention Plans

A. Trial mechanics

1. Trial's eligibility criteria

- Do the criteria systematically exclude a specific group of people?

2. Patient population demographics

- Vulnerable populations, age, sex, race, ethnicity

3. Type of recruitment sites

4. Each site's resources

- CTSA, community outreach etc.

5. Enrollment

- Setting, enrollment hours, language translation services

6. Retention

- Compensation, length of follow-up

Minority Recruitment and Retention Plans

B. Researcher Narrative

1. Reflect recruitment and retention experience
 - Best practices
 - Barriers
2. Based on past experience, what would you do differently?

- **“Approach:** Provide an assessment of the outreach and recruitment needs that are unique to the center as well as to the geographical area
- **Local needs:** Coordination with others for recruitment and retention of subjects for particular research protocols and clinical trials, with a special emphasis on underserved/underrepresented populations. *An outreach plan should address the needs identified, including both strengths and barriers (e.g., parking/transportation).*
- **Recruitment methods:** 1) Descriptions of seminar or lecture series, or workshops; 2) Outreach to specific communities to publicize research; 3) collaboration with other organizations such as state and local agencies, community/service groups, hospitals, religious organizations, business groups, local medical societies, etc.; and 4) Descriptions of materials (e.g., videos and printed matter)
- **Cultural sensitivity:** information should be structured so that it can effectively reach diverse populations, including non-English-speaking people.”

Minority Recruitment and Retention Plans

C. Statistical Analysis

The screenshot shows the NIH Office of Extramural Research website. The main navigation bar includes links for HOME, ABOUT GRANTS, FUNDING, FORMS & DEADLINES, GRANTS POLICY (highlighted), eRA, NEWS & EVENTS, and ABOUT OER. Below this is a blue banner for "Grants & Funding". On the left, a sidebar lists various policy areas under "Grants Policy". The main content area features the "NIH Guideline on The Inclusion of Women and Minorities as Subjects in Clinical Research - Updated August 1, 2000". It includes a link to the October 2001 Amended Guidelines and a note about additional information. The introduction states that in March 1994, NIH issued a policy on the inclusion of women and minorities as subjects in clinical research. It also mentions that NIH experience has indicated that inclusion has been accomplished, but that results of planned analyses of NIH defined Phase III clinical trials need to be more consistently reported. A reference is provided: "Inclusion of Women and Minorities in Clinical Trials and the NIH Revitalization Act of 1993 - The Perspective of NIH Clinical Trialists." Freedman, et.al. Controlled Clinical Trials, 16:277 (1995).

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NIH Guideline on The Inclusion of Women and Minorities as Subjects in Clinical Research - Updated August 1, 2000

Please see October 2001 Amended Guidelines at
http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm

NOTE: Additional information concerning the NIH Policy on Inclusion of Women and Minorities as Subjects in Clinical Research is available at http://grants.nih.gov/grants/funding/women_min/women_min.htm.

INTRODUCTION

In March, 1994, NIH issued a policy on the inclusion of women and minorities as subjects in clinical research (<http://grants.nih.gov/grants/guide/notice-files/not94-100.html>).

NIH experience has indicated that inclusion has been accomplished, but that results of planned analyses of NIH defined Phase III clinical trials need to be more consistently reported. This document updates and provides further guidance on planning, conducting, and reporting the analysis of sex/gender and/or race/ethnicity differences in the intervention effect in NIH Phase III clinical trials (see Definitions, Section V-A below).

The following reference published since the 1994 Guidelines provides additional background information.
"Inclusion of Women and Minorities in Clinical Trials and the NIH Revitalization Act of 1993 - The Perspective of NIH Clinical Trialists." Freedman, et.al. Controlled Clinical Trials, 16:277 (1995).

Women, minorities and their subpopulations must be included in numbers adequate for valid analysis of differences in intervention effect.

Valid analysis – unbiased assessment yielding correct estimate of differences between the groups

Optimize: Minority Recruitment and Retention efforts



NIMICT

NATIONAL INITIATIVE FOR
MINORITY INVOLVEMENT IN
NEUROLOGICAL CLINICAL TRIALS

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**Tools to Increase Minority
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Optimize: Minority Recruitment and Retention efforts

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Examining Barriers and Practices to Recruitment and Retention in Stroke Clinical Trials

Bernadette Boden-Albala, DrPH; Heather Carman, MPH; Lauren Southwick, BA;
Nina S. Parikh, PhD, MPH; Eric Roberts, MPH; Salina Waddy, MD; Dorothy Edwards, PhD

Background and Purpose—The National Institutes of Health policy calls for the inclusion of under-represented groups, such as women and minorities, in clinical research. Poor minority recruitment and retention in stroke clinical trials remain a significant challenge limiting safety and efficacy in a general population. Previous research examines participant barriers to clinical trial involvement, but little is known about the investigator perspective. This study addresses this gap and examines researcher-reported barriers and best practices of minority involvement in stroke clinical trials.

Methods—Quantitative and qualitative methods, including surveys, focus groups, and key informant interviews were used.

Results—In a survey of 93 prominent stroke researchers, 43 (51.2%; 70% response rate) respondents reported proactively setting recruitment goals for minority inclusion, 29 respondents (36.3%) reported requiring cultural competency staff training, and 44 respondents (51.2%) reported using community consultation about trial design. Focus groups and key informant interviews highlighted structural and institutional challenges to recruitment of minorities, including mistrust of the research/medical enterprise, poor communication, and lack of understanding of clinical trials. Researcher-identified best practices included using standardized project management procedures and protocols (eg, realistic budgeting to support challenges in recruitment, such as travel/parking reimbursement for participants), research staff cultural competency and communication training, and developing and fostering community partnerships that guide the research process.

Conclusions—This study's formative evaluation contributes a new dimension to the literature as it highlights researcher-

[Full text](#)

Recommendations for the NIH StrokeNet Clinical Study Concept Synopsis

Briefly describe the proposed trial design:

Patient selection criteria, including window of treatment:

- Inclusion/Exclusion Criteria

Describe Recruitment and Retention plans

1). Site selection criteria

2). Considerations for underserved populations (i.e., women and racial-ethnic minorities)

Please provide an estimate of your study sample size to assist with the feasibility assessment.

Proposed number of subjects to be enrolled: _____

Describe the statistical basis for the proposed sample size calculation:

Describe the statistical basis for inclusion of underserved populations

Paradigm Shift in Clinical Trial Proposal and Planning

- Nothing can be accomplished in isolation
- Stakeholder engagement
 - NIH
 - Reviewers
 - Principal Investigators
 - Research community
 - Training session at ISC?



Recruitment and Retention for Underrepresented Minorities and Ethnicities Advisory Working Group

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